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42

Parts 430 to 481

Revised as of October 1, 2010

Public Health

Containing a codification of documents of general applicability and future effect

As of October 1, 2010

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To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 430.0 *refers to title 42, part 430, section 0.*

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Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
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Title 42 through Title 50.....as of October 1

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RAYMOND A. MOSLEY,
Director,
Office of the Federal Register.
October 1, 2010.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of five volumes. The parts in these volumes are arranged in the following order: Parts 1–399, parts 400–413, parts 414–429, parts 430 to 481, and part 482 to end. The first volume (parts 1–399) contains current regulations issued under chapter I—Public Health Service (HHS). The second, third, and fourth volumes (parts 400–413, parts 414–429, and parts 430 to 481) include regulations issued under chapter IV—Centers for Medicare & Medicaid Services (HHS) and the fifth volume (part 482 to end) contains the remaining regulations in chapter IV and the regulations issued under chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 2010.

The OMB control numbers for the Centers for Medicare & Medicaid Services appear in § 400.310 of chapter IV. For the convenience of the user, subpart C consisting of §§ 400.300–400.310 is reprinted in the Finding Aids section of the third, fourth and fifth volumes.

For this volume, Jonn V. Lilyea was Chief Editor. The Code of Federal Regulations publication program is under the direction of Michael L. White, assisted by Ann Worley.

Title 42—Public Health

(This book contains parts 430 to 481)

Part

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CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 66 FR 39452, July 31, 2001; 67 FR 36540, May 24, 2002; and 69 FR 18803, Apr. 9, 2004.

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SUBCHAPTER C—MEDICAL ASSISTANCE PROGRAMS

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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

SOURCE: 53 FR 36571, Sept. 21, 1988, unless otherwise noted.

Subpart A—Introduction; General Provisions

§ 430.0 Program description.

Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services.

§ 430.1 Scope of subchapter C.

The regulations in subchapter C set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP). Each part (or subpart of section) in the subchapter describes the specific statutory basis for the regulation. However, where the basis is the Secretary's general authority to issue regulations for any program under the Act (section 1102 of the Act), or his general authority to prescribe State plan requirements needed for proper and efficient administration of the

plan (section 1902(a)(4)), those statutory provisions are simply cited without further description.

§ 430.2 Other applicable Federal regulations.

Other regulations applicable to State Medicaid programs include the following:

(a) 5 CFR part 900, subpart F, Administration of the Standards for a Merit System of Personnel Administration.

(b) The following HHS Regulations in 45 CFR subtitle A:

Part 16—Procedures of the Departmental Appeals Board.

Part 74—Administration of Grants.

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of Title VI of the Civil Rights Act of 1964.

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80.

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance.

Part 95—General Administration—grant programs (public assistance and medical assistance).

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.3 Appeals under Medicaid.

Three distinct types of disputes may arise under Medicaid.

(a) *Compliance with Federal requirements.* Disputes that pertain to whether a State's plan or proposed plan amendments, or its practice under the plan meet or continue to meet Federal requirements are subject to the hearing provisions of subpart D of this part.

(b) *FFP in Medicaid expenditures.* Disputes that pertain to disallowances of FFP in Medicaid expenditures (mandatory grants) are heard by the Departmental Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16.

(c) *Discretionary grants disputes.* Disputes pertaining to discretionary grants, such as grants for special demonstration projects under sections 1110 and 1115 of the Act, which may be awarded to a Medicaid agency, are also heard by the Board. 45 CFR part 16, appendix A, lists all the types of disputes that the Board hears.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.5 Definitions.

As used in this subchapter, unless the context indicates otherwise—

Contractor means any entity that contracts with the State agency, under the State plan, in return for a payment, to process claims, to provide or pay for medical services, or to enhance the State agency's capability for effective administration of the program.

Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.

[67 FR 41094, June 14, 2002]

Subpart B—State Plans

§ 430.10 The State plan.

The State plan is a comprehensive written statement submitted by the agency describing the nature and scope of its Medicaid program and giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances of the Department. The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

§ 430.12 Submittal of State plans and plan amendments.

(a) *Format.* A State plan for Medicaid consists of preprinted material that covers the basic requirements, and individualized content that reflects the characteristics of the particular State's program.

(b) *Governor's review*—(1) *Basic rules.* Except as provided in paragraph (b)(2) of this section—

(i) The Medicaid agency must submit the State plan and State plan amendments to the State Governor or his designee for review and comment before submitting them to the CMS regional office.

(ii) The plan must provide that the Governor will be given a specific period

of time to review State plan amendments, long-range program planning projections, and other periodic reports on the Medicaid program, excluding periodic statistical, budget and fiscal reports.

(iii) Any comments from the Governor must be submitted to CMS with the plan or plan amendment.

(2) *Exceptions.* (i) Submission is not required if the Governor's designee is the head of the Medicaid agency.

(ii) Governor's review is not required for preprinted plan amendments that are developed by CMS if they provide absolutely no options for the State.

(c) *Plan amendments.* (1) The plan must provide that it will be amended whenever necessary to reflect—

(i) Changes in Federal law, regulations, policy interpretations, or court decisions; or

(ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program. For changes related to advance directive requirements, amendments must be submitted as soon as possible, but no later than 60 days from the effective date of the change to State law concerning advance directives.

(2) Prompt submittal of amendments is necessary—

(i) So that CMS can determine whether the plan continues to meet the requirements for approval; and

(ii) To ensure the availability of FFP in accordance with § 430.20.

[53 FR 36571, Sept. 21, 1988, as amended at 60 FR 33293, June 27, 1995]

§ 430.14 Review of State plan material.

CMS regional staff reviews State plans and plan amendments, discusses any issues with the Medicaid agency, and consults with central office staff on questions regarding application of Federal policy.

§ 430.15 Basis and authority for action on State plan material.

(a) *Basis for action.* (1) Determinations as to whether State plans (including plan amendments and administrative practice under the plans) originally meet or continue to meet the requirements for approval are based on relevant Federal statutes and regulations.

(2) Guidelines are furnished to assist in the interpretation of the regulations.

(b) *Approval authority.* The Regional Administrator exercises delegated authority to approve the State plan and plan amendments on the basis of policy statements and precedents previously approved by the Administrator.

(c) *Disapproval authority.* (1) The Administrator retains authority for determining that proposed plan material is not approvable or that previously approved material no longer meets the requirements for approval.

(2) The Administrator does not make a final determination of disapproval without first consulting the Secretary.

§ 430.16 Timing and notice of action on State plan material.

(a) *Timing.* (1) A State plan or plan amendment will be considered approved unless CMS, within 90 days after receipt of the plan or plan amendment in the regional office, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of any additional information it needs in order to make a final determination.

(2) If CMS requests additional information, the 90-day period for CMS action on the plan or plan amendment begins on the day it receives that information.

(b) *Notice of final determination.* (1) The Regional Administrator or the Administrator notifies the Medicaid agency of the approval of a State plan or plan amendment.

(2) Only the Administrator gives notice of disapproval of a State plan or plan amendment.

§ 430.18 Administrative review of action on State plan material.

(a) *Request for reconsideration.* Any State dissatisfied with the Administrator's action on plan material under § 430.15 may, within 60 days after receipt of the notice provided under § 430.16(b), request that the Administrator reconsider the issue of whether the plan or plan amendment conforms to the requirements for approval.

(b) *Notice and timing of hearing.* (1) Within 30 days after receipt of the request, the Administrator notifies the

State of the time and place of the hearing.

(2) The hearing takes place not less than 30 days nor more than 60 days after the date of the notice, unless the State and the Administrator agree in writing on an earlier or later date.

(c) *Hearing procedures.* The hearing procedures are set forth in subpart D of this part.

(d) *Decision.* A decision affirming, modifying, or reversing the Administrator's original determination is made in accordance with § 430.102.

(e) *Effect of hearing decision.* (1) Denial of Federal funds, if required by the Administrator's original determination, will not be delayed pending a hearing decision.

(2) However, if the Administrator determines that his or her original decision was incorrect, CMS pays the State a lump sum equal to any funds incorrectly denied.

§ 430.20 Effective dates of State plans and plan amendments.

For purposes of FFP, the following rules apply:

(a) *New plans.* The effective date of a new plan—

(1) May not be earlier than the first day of the quarter in which an approvable plan is submitted to the regional office; and

(2) With respect to expenditures for medical assistance, may not be earlier than the first day on which the plan is in operation on a statewide basis.

(b) *Plan amendment.* (1) For a plan amendment that provides additional services to individuals eligible under the approved plan, increases the payment amounts for services already included in the plan, or makes additional groups eligible for services provided under the approved plan, the effective date is determined in accordance with paragraph (a) of this section.

(2) For a plan amendment that changes the State's payment method and standards, the rules of § 447.256 of this chapter apply.

(3) For other plan amendments, the effective date may be a date requested by the State if CMS approves it.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.25 Waivers of State plan requirements.

(a) *Scope of section.* This section describes the purpose and effect of waivers, identifies the requirements that may be waived and the other regulations that apply to waivers, and sets forth the procedures that CMS follows in reviewing and taking action on waiver requests.

(b) *Purpose of waivers.* Waivers are intended to provide the flexibility needed to enable States to try new or different approaches to the efficient and cost-effective delivery of health care services, or to adapt their programs to the special needs of particular areas or groups of recipients. Waivers allow exceptions to State plan requirements and permit a State to implement innovative programs or activities on a time-limited basis, and subject to specific safeguards for the protection of recipients and the program. Detailed rules for waivers are set forth in subpart B of part 431, subpart A of part 440, and subpart G of part 441 of this chapter.

(c) *Effect of waivers.* (1) Waivers under section 1915(b) allow a State to take the following actions:

(i) Implement a primary care case-management system or a specialty physician system.

(ii) Designate a locality to act as central broker in assisting Medicaid recipients to choose among competing health care plans.

(iii) Share with recipients (through provision of additional services) cost-savings made possible through the recipients' use of more cost-effective medical care.

(iv) Limit recipients' choice of providers (except in emergency situations and with respect to family planning services) to providers that fully meet reimbursement, quality, and utilization standards, which are established under the State plan and are consistent with access, quality, and efficient and economical furnishing of care.

(2) A waiver under section 1915(c) of the Act allows a State to include as ''medical assistance'' under its plan home and community based services furnished to recipients who would otherwise need inpatient care that is furnished in a hospital, SNF, ICF, or ICF/

MR, and is reimbursable under the State plan.

(3) A waiver under section 1916 (a)(3) or (b)(3) of the Act allows a State to impose a deduction, cost-sharing or similar charge of up to twice the ''nominal charge'' established under the plan for outpatient services, if—

(i) The outpatient services are received in a hospital emergency room but are not emergency services; and

(ii) The State has shown that Medicaid recipients have actually available and accessible to them alternative services of nonemergency outpatient services.

(d) *Requirements that are waived.* In order to permit the activities described in paragraph (c) of this section, one or more of the title XIX requirements must be waived, in whole or in part.

(1) Under section 1915(b) of the Act, and subject to certain limitations, any of the State plan requirements of section 1902 of the Act may be waived to achieve one of the purposes specified in that section.

(2) Under section 1915(c) of the Act, the following requirements may be waived:

(i) Statewideness—section 1902(a)(1).

(ii) Comparability of services—section 1902(a)(10)(B).

(iii) Income and resource rules—section 1902(a)(10)(C)(i)(III).

(3) Under section 1916 of the Act, paragraphs (a)(3) and (b)(3) require that any cost-sharing imposed on recipients be nominal in amount, and provide an exception for nonemergency services furnished in a hospital emergency room if the conditions of paragraph (c)(3) of this section are met.

(e) *Submittal of waiver request.* The State Governor, the head of the Medicaid agency, or an authorized designee may submit the waiver request.

(f) *Review of waiver requests.* (1) This paragraph applies to initial waiver requests and to requests for renewal or amendment of a previously approved waiver.

(2) CMS regional and central office staff review waiver requests and submit a recommendation to the Administrator, who—

(i) Has the authority to approve or deny waiver requests; and

(ii) Does not deny a request without first consulting the Secretary.

(3) A waiver request is considered approved unless, within 90 days after the request is received by CMS, the Administrator denies the request, or the Administrator or the Regional Administrator sends the State a written request for additional information necessary to reach a final decision. If additional information is requested, a new 90-day period begins on the day the response to the additional information request is received by the addressee.

(g) *Basis for approval*—(1) *Waivers under section 1915 (b) and (c).* The Administrator approves waiver requests if the State's proposed program or activity meets the requirements of the Act and the regulations at § 431.55 or subpart G of part 441 of this chapter.

(2) *Waivers under section 1916.* The Administrator approves a waiver under section 1916 of the Act if the State shows, to CMS's satisfaction, that the Medicaid recipients have available and accessible to them sources, other than a hospital emergency room, where they can obtain necessary nonemergency outpatient services.

(h) *Effective date and duration of waivers*—(1) *Effective date.* Waivers receive a prospective effective date determined, with State input, by the Administrator. The effective date is specified in the letter of approval to the State.

(2) *Duration of waivers*—(i) *Home and community-based services under section 1915(c).* The initial waiver is for a period of three years and may be renewed thereafter for periods of five years.

(ii) *Waivers under sections 1915(b) and 1916.* The initial waiver is for a period of two years and may be renewed for additional periods of up to two years as determined by the Administrator.

(3) *Renewal of waivers.* (i) A renewal request must be submitted at least 90 days (but not more than 120 days) before a currently approved waiver expires, to provide adequate time for CMS review.

(ii) If a renewal request for a section 1915(c) waiver proposes a change in services provided, eligible population, service area, or statutory sections

waived, the Administrator may consider it a new waiver, and approve it for a period of three years.

[56 FR 8846, Mar. 1, 1991]

Subpart C—Grants; Reviews and Audits; Withholding for Failure To Comply; Deferral and Disallowance of Claims; Reduction of Federal Medicaid Payments

§ 430.30 Grants procedures.

(a) *General provisions.* (1) Once CMS has approved a State plan, it makes quarterly grant awards to the State to cover the Federal share of expenditures for services, training, and administration.

(2) The amount of the quarterly grant is determined on the basis of information submitted by the State agency (in quarterly estimate and quarterly expenditure reports) and other pertinent documents.

(b) *Quarterly estimates.* The Medicaid agency must submit Form CMS–25 (Medicaid Program Budget Report; Quarterly Distribution of Funding Requirements) to the central office (with a copy to the regional office) 45 days before the beginning of each quarter.

(c) *Expenditure reports.* (1) The State must submit Form CMS–64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) to the central office (with a copy to the regional office) not later than 30 days after the end of each quarter.

(2) This report is the State's accounting of actual recorded expenditures. The disposition of Federal funds may not be reported on the basis of estimates.

(d) *Grant award*—(1) *Computation by CMS.* Regional office staff analyzes the State's estimates and sends a recommendation to the central office. Central office staff considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant.

(2) *Content of award.* The grant award computation form shows the estimate of expenditures for the ensuring quarter, and the amounts by which that estimate is increased or decreased because of an underestimate or overestimate for prior quarters, or for any of the following reasons:

(i) Penalty reductions imposed by law.

(ii) Accounting adjustments.

(iii) Deferrals or disallowances.

(iv) Interest assessments.

(v) Mandated adjustments such as those required by section 1914 of the Act.

(3) *Effect of award.* The grant award authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements.

(4) *Drawing procedure.* The draw is through a commercial bank and the Federal Reserve system against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee. (The letter of credit payment system was established in accordance with Treasury Department regulations—Circular No. 1075.)

(e) *General administrative requirements.* With the following exceptions, the provisions of 45 CFR part 74, which establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

45 CFR part 74
Subpart G—Matching and Cost Sharing
Subpart I—Financial Report Requirements

§ 430.32 Program reviews.

(a) *Review of State and local administration.* In order to determine whether the State is complying with the Federal requirements and the provisions of its plan, CMS reviews State and local administration through analysis of the State's policies and procedures, on-site review of selected aspects of agency operation, and examination of samples of individual case records.

(b) *Quality control program.* The State itself is required to carry out a continuing quality control program as set forth in part 431, subpart P, of this chapter.

(c) *Action on review findings.* If Federal or State reviews reveal serious problems with respect to compliance with any Federal requirement, the State must correct its practice accordingly.

§ 430.33 Audits.

(a) *Purpose.* The Department's Office of Inspector General (OIG) periodically audits State operations in order to determine whether—

(1) The program is being operated in a cost-efficient manner; and

(2) Funds are being properly expended for the purposes for which they were appropriated under Federal and State law and regulations.

(b) *Reports.* (1) The OIG releases audit reports simultaneously to State officials and the Department's program officials.

(2) The reports set forth OIG opinion and recommendations regarding the practices it reviewed, and the allowability of the costs it audited.

(3) Cognizant officials of the Department make final determinations on all audit findings.

(c) *Action on audit exceptions*—(1) *Concurrence or clearance.* The State agency has the opportunity of concurring in the exceptions or submitting additional facts that support clearance of the exceptions.

(2) *Appeal.* Any exceptions that are not disposed of under paragraph (c)(1) of this section are included in a disallowance letter that constitutes the Department's final decision unless the State requests reconsideration by the Appeals Board. (Specific rules are set forth in § 430.42.)

(3) *Adjustment.* If the decision by the Board requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8846, Mar. 1, 1991]

§ 430.35 Withholding of payment for failure to comply with Federal requirements.

(a) *Basis for withholding.* CMS withholds payments to the State, in whole or in part, only if, after giving the agency reasonable notice and opportunity for a hearing in accordance with subpart D of this part, the Administrator finds—

(1) That the plan no longer complies with the provisions of section 1902 of the Act; or

(2) That in the administration of the plan there is failure to comply substantially with any of those provisions.

(Hearings under subpart D are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These may be continued even if a date and place have been set for the hearing.)

(b) *Noncompliance of the plan.* A question of noncompliance of a State plan may arise from an unapprovable change in the approved State plan or the failure of the State to change its approved plan to conform to a new Federal requirement for approval of State plans.

(c) *Noncompliance in practice.* A question of noncompliance in practice may arise from the State's failure to actually comply with a Federal requirement, regardless of whether the plan itself complies with that requirement.

(d) *Notice and implementation of withholding.* If the Administrator makes a finding of noncompliance under paragraph (a) of this section, the following rules apply:

(1) The Administrator notifies the State:

(i) That no further payments will be made to the State (or that payments will be made only for those portions or aspects of the program that are not affected by the noncompliance); and

(ii) That the total or partial withholding will continue until the Administrator is satisfied that the State's plan and practice are, and will continue to be, in compliance with Federal requirements.

(2) CMS withholds payments, in whole or in part, until the Administrator is satisfied regarding the State's compliance.

§ 430.38 Judicial review.

(a) *Right to judicial review.* Any State dissatisfied with the Administrator's final determination on approvability of plan material (§ 430.18) or compliance with Federal requirements (§ 430.35) has a right to judicial review.

(b) *Petition for review.* (1) The State must file a petition for review with the U.S. Court of Appeals for the circuit in which the State is located, within 60

days after it is notified of the determination.

(2) The clerk of the court will file a copy of the petition with the Administrator and the Administrator will file in the court the record of the proceedings on which the determination was based.

(c) *Court action.* (1) The court is bound by the Administrator's findings of fact if they are supported by substantial evidence.

(2) The court has jurisdiction to affirm the Administrator's decision, to set it aside in whole or in part, or, for good cause, to remand the case for additional evidence.

(d) *Response to remand.* (1) If the court remands the case, the Administrator may make new or modified findings of fact and may modify his or her previous determination.

(2) The Administrator will certify to the court the transcript and record of the further proceedings.

(e) *Review by the Supreme Court.* The judgment of the appeals court is subject to review by the U.S. Supreme Court upon certiorari or certification, as provided in 28 U.S.C. 1254.

§ 430.40 Deferral of claims for FFP.

(a) *Requirements for deferral.* Payment of a claim or any portion of a claim for FFP is deferred only if—

(1) The Regional Administrator or the Administrator questions its allowability and needs additional information in order to resolve the question; and

(2) CMS takes action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with CMS instructions) that includes that claim.

(b) *Notice of deferral and State's responsibility.* (1) Within 15 days of the action described in paragraph (a)(2) of this section, the Regional Administrator sends the State a written notice of deferral that—

(i) Identifies the type and amount of the deferred claim and specifies the reason for deferral; and

(ii) Requests the State to make available all the documents and materials the regional office then believes are necessary to determine the allowability of the claim.

(2) It is the responsibility of the State to establish the allowability of a deferred claim.

(c) *Handling of documents and materials.* (1) Within 60 days (or within 120 days if the State requests an extension) after receipt of the notice of deferral, the State must make available to the regional office, in readily reviewable form, all requested documents and materials except any that it identifies as not being available.

(2) Regional office staff usually initiates review within 30 days after receipt of the documents and materials.

(3) If the Regional Administrator finds that the materials are not in readily reviewable form or that additional information is needed, he or she promptly notifies the State that it has 15 days to submit the readily reviewable or additional materials.

(4) If the State does not provide the necessary materials within 15 days, the Regional Administrator disallows the claim.

(5) The Regional Administrator has 90 days, after all documentation is available in readily reviewable form, to determine the allowability of the claim.

(6) If the Regional Administrator cannot complete review of the material within 90 days, CMS pays the claim, subject to a later determination of allowability.

(d) *Effect of decision to pay a deferred claim.* Payment of a deferred claim under paragraph (c)(6) of this section does not preclude a subsequent disallowance based on the results of an audit or financial review. (If there is a subsequent disallowance, the State may request reconsideration as provided in paragraph (e)(2) of this section.)

(e) *Notice and effect of decision on allowability.* (1) The Regional Administrator or the Administrator gives the State written notice of his or her decision to pay or disallow a deferred claim.

(2) If the decision is to disallow, the notice informs the State of its right to reconsideration in accordance with 45 CFR part 16.

§ 430.42 Disallowance of claims for FFP.

(a) *Notice of disallowance and of right to reconsideration.* When the Regional Administrator or the Administrator determines that a claim or portion of claim is not allowable, he or she promptly sends the State a disallowance letter that includes the following, as appropriate:

(1) The date or dates on which the State's claim for FFP was made.

(2) The time period during which the expenditures in question were made or claimed to have been made.

(3) The date and amount of any payment or notice of deferral.

(4) A statement of the amount of FFP claimed, allowed, and disallowed and the manner in which these amounts were computed.

(5) Findings of fact on which the disallowance determination is based or a reference to other documents previously furnished to the State or included with the notice (such as a report of a financial review or audit) which contain the findings of fact on which the disallowance determination is based.

(6) Pertinent citations to the law, regulations, guides and instructions supporting the action taken.

(7) A request that the State make appropriate adjustment in a subsequent expenditure report.

(8) Notice of the State's right to request reconsideration of the disallowance and the time allowed to make the request.

(9) A statement indicating that the disallowance letter is the Department's final decision unless the State requests reconsideration under paragraph (b)(2) of this section.

(b) *Reconsideration of FFP disallowance.* (1) The Departmental Appeals Board reviews disallowances of FFP under title XIX.

(2) A State that wishes to request reconsideration must submit the request to the Chair, Departmental Appeals Board, within 30 days after receipt of the disallowance letter, and include—

(i) A copy of the disallowance letter;

(ii) A statement of the amount in dispute; and

(iii) A brief statement of why the disallowance is wrong.

(c) *Reconsideration procedures.* The reconsideration procedures are those set forth in 45 CFR part 16 for Medicaid and for many other programs administered by the Department.

(d) *Implementation of decisions.* If the reconsideration decision requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8846, Mar. 1, 1991]

§ 430.45 Reduction of Federal Medicaid payments.

(a) *Methods of reduction.* CMS may reduce Medicaid payments to a State as required under the Act by reducing—

(1) The Federal Medical Assistance Percentage;

(2) The amount of State expenditures subject to FFP;

(3) The rates of FFP; or

(4) The amount otherwise payable to the State.

(b) *Right to reconsideration.* A state that receives written final notice of a reduction under paragraph (a) of this section has a right to reconsideration. The provisions of § 430.42 (b) and (c) apply.

(c) *Other applicable rules.* Other rules regarding reduction of Medicaid payments are set forth in parts 433 and 447 of this chapter.

§ 430.48 Repayment of Federal funds by installments.

(a) *Basic conditions.* When Federal payments have been made for claims that are later found to be unallowable, the State may repay the Federal Funds by installments if the following conditions are met:

(1) The amount to be repaid exceeds 2½ percent of the estimated or actual annual State share for the Medicaid program; and

(2) The State has given the Regional Administrator written notice, before total repayment was due, of its intent to repay by installments.

(b) *Annual State share determination.* CMS determines whether the amount to be repaid exceeds 2½ percent of the annual State share as follows:

(1) If the Medicaid program is ongoing, CMS uses the annual *estimated*

State share of Medicaid expenditures. This is the sum of the estimated State shares for four consecutive quarters, beginning with the quarter in which the first installment is to be paid, as shown on the State's latest CMS–25 form.

(2) If the Medicaid program has been terminated by Federal law or by the State, CMS uses the *actual* State share. The actual State share is that shown on the State's Statement of Expenditures reports for the last four quarters before the program was terminated.

(c) *Repayment amounts, schedules, and procedures*—(1) *Repayment amount.* The repayment amount may not include any amount previously approved for installment repayment.

(2) *Repayment schedule.* The number of quarters allowed for repayment is determined on the basis of the ratio of the repayment amount to the annual State share of Medicaid expenditures. The higher the ratio of the total repayment amount is to the annual State share, the greater the number of quarters allowed, as follows:

Total repayment amount as percentage of State share of annual expenditures for Medicaid	Number of quarters to make repayment
2.5 pct. or less	1
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12

(3) *Quarterly repayment amounts.* The quarterly repayment amounts for each of the quarters in the repayment schedule may not be less than the following percentages of the estimated State share of the annual expenditures for Medicaid:

For each of the following quarters	Repayment installment may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 to 12	17.5

(4) *Extended schedule.* The repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100% of the estimated State share of annual expenditures. In these circumstances, paragraph (c)(2) of this section is followed for repayment of the amount equal to 100 percent of the annual State share. The remaining amount of the repayment is in quarterly amounts equal to not less than 17.5 percent of the estimated State share of annual expenditures.

(5) *Repayment process.* Repayment is accomplished through adjustment in the quarterly grants over the period covered by the repayment schedule.

If the State chooses to repay amounts representing higher percentages during the early quarters, any corresponding reduction in required minimum percentages is applied first to the last scheduled payment, then to the next to the last payment, and so forth as neccessary.

(6) *Offsetting of retroactive claims.* The amount of a retroactive claim to be paid a State will be offset against any amounts to be, or already being, repaid by the State in installments. Under this provision, the State may choose to:

(i) Suspend payments until the retroactive claim due the State has, in fact, been offset; or

(ii) Continue payments until the reduced amount of its debt (remaining after the offset), has been paid in full.

This second option would result in a shorter payment period.

A retroactive claim for the purpose of this regulation is a claim applicable to any period ending 12 months or more before the beginning of the quarter in which CMS would pay that claim.

Subpart D—Hearings on Conformity of State Medicaid Plans and Practice to Federal Requirements

§ 430.60 Scope.

(a) This subpart sets forth the rules for hearings to States that appeal a decision to disapprove State plan material (under § 430.18) or to withhold Federal funds (under § 430.35), because the

State plan or State practice in the Medicaid program is not in compliance with Federal requirements.

(b) Nothing in this subpart is intended to preclude or limit negotiations between CMS and the State, whether before, during, or after the hearing to resolve the issues that are, or otherwise would be, considered at the hearing. Such negotiations and resolution of issues are not part of the hearing, and are not governed by the rules in this subpart except as expressly provided.

§ 430.62 Records to be public.

All pleadings, correspondence, exhibits, transcripts of testimony, exceptions, briefs, decisions, and other documents filed in the docket in any proceeding may be inspected and copied in the office of the CMS Docket Clerk. Inquiries may be made to the Docket Clerk, Hearing Staff, Bureau of Eligibility, Reimbursment and Coverage, 300 East High Rise, 6325 Security Boulevard, Baltimore, Maryland, 21207. Telephone: (301) 594–8261.

§ 430.63 Filing and service of papers.

(a) *Filing.* All papers in the proceedings are filed with the CMS Docket Clerk, in an original and two copies. Originals only of exhibits and transcripts of testimony need be filed.

(b) *Service.* All papers in the proceedings are served on all parties by personal delivery or by mail. Service on the party's designated attorney is considered service upon the party.

§ 430.64 Suspension of rules.

Upon notice to all parties, the Administrator or the presiding officer may modify or waive any rule in this subpart upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

§ 430.66 Designation of presiding officer for hearing.

(a) The presiding officer at a hearing is the Administrator or his designee.

(b) The designation of the presiding officer is in writing. A copy of the designation is served on all parties.

§ 430.70 Notice of hearing or opportunity for hearing.

The Administrator mails the State a notice of hearing or opportunity for hearing that—

(a) Specifies the time and place for the hearing;

(b) Specifies the issues that will be considered;

(c) Identifies the presiding officer; and

(d) Is published in the FEDERAL REGISTER.

§ 430.72 Time and place of hearing.

(a) *Time.* The hearing is scheduled not less than 30 nor more than 60 days after the date of notice to the State. The scheduled date may be changed by written agreement between CMS and the State.

(b) *Place.* The hearing is conducted in the city in which the CMS regional office is located or in another place fixed by the presiding officer in light of the circumstances of the case, with due regard for the convenience and necessity of the parties or their representatives.

§ 430.74 Issues at hearing.

The list of issues specified in the notice of hearing may be augmented or reduced as provided in this section.

(a) *Additional issues.* (1) Before a hearing under § 430.35, the Administrator may send written notice to the State listing additional issues to be considered at the hearing. That notice is published in the FEDERAL REGISTER.

(2) If the notice of additional issues is furnished to the State less than 20 days before the scheduled hearing date, postponement is granted if requested by the State or any other party. The new date may be 20 days after the date of the notice, or a later date agreed to by the presiding officer.

(b) *New or modified issues.* If, as a result of negotiations between CMS and the State, the submittal of plan amendment, a change in the State program, or other actions by the State, any issue is resolved in whole or in part, but new or modified issues are presented, as specified by the presiding officer, the hearing proceeds on the new or modified issues.

(c) *Issues removed from consideration*—(1) *Basis for removal.* If at any time before, during, or after the hearing, the presiding officer finds that the State has come into compliance with Federal requirements on any issue or part of an issue, he or she removes the appropriate issue or part of an issue from consideration. If all issues are removed, the hearing is terminated.

(2) *Notice to parties.* Before removing any issue or part of an issue from consideration, the presiding officer provides all parties other than CMS and the State with—

(i) A statement of the intent to remove and the reasons for removal; and

(ii) A copy of the proposed State plan provision on which CMS and the State have agreed.

(3) *Opportunity for written comment.* The notified parties have 15 days to submit, for consideration by the presiding officer, and for the record, their views as to, or any information bearing upon, the merits of the proposed plan provision and the merits of the reasons for removing the issue from consideration.

(d) *Remaining issues.* The issues considered at the hearing are limited to those issues of which the State is notified as provided in §430.70 and paragraph (a) of this section, and new or modified issues described in paragraph (b) of this section. They do not include issues or parts of issues removed in accordance with paragraph (c) of this section.

§ 430.76 Parties to the hearing.

(a) *CMS and the State.* CMS and the State are parties to the hearing.

(b) *Other individuals*—(1) *Basis for participation.* Other individuals or groups may be recognized as parties if the issues to be considered at the hearing have caused them injury and their interest is within the zone of interests to be protected by the governing Federal statute.

(2) *Petition for participation.* Any individual or group wishing to participate as a party must, within 15 days after notice of hearing is published in the FEDERAL REGISTER, file with the CMS Docket Clerk, a petition that concisely states—

(i) Petitioner's interest in the proceeding;

(ii) Who will appear for petitioner;

(iii) The issues on which petitioner wishes to participate; and

(iv) Whether petitioner intends to present witnesses.

The petitioner must also serve a copy of the petition on each party of record at that time.

(3) *Comments on petition.* Any party may, within 5 days of receipt of the copy of the petition, file comments on it.

(4) *Action on petition.* (i) The presiding officer promptly determines whether each petitioner has the requisite interest in the proceedings and approves or denies participation accordingly.

(ii) If petitions are made by more than one individual or group with common interests, the presiding officer may—

(A) Request all those petitioners to designate a single representative; or

(B) Recognize one or more of those petitioners to represent all of them.

(iii) The presiding officer gives each petitioner written notice of the decision and, if the decision is to deny, briefly states the grounds for denial.

(c) *Amicus curiae (friend of the court)*—(1) *Petition for participation.* Any person or organization that wishes to participate as amicus curiae must, before the hearing begins, file with the CMS Docket Clerk, a petition that concisely states—

(i) The petitioners' interest in the hearing;

(ii) Who will represent the petitioner; and

(iii) The issues on which the petitioner intends to present argument.

(2) *Action on amicus curiae petition.* The presiding officer may grant the petition if he or she finds that the petitioner has a legitimate interest in the proceedings, that such participation will not unduly delay the outcome and may contribute materially to the proper disposition of the issues.

(3) *Nature of amicus participation.* An amicus curiae is not a party to the hearing but may participate by—

(i) Submitting a written statement of position to the presiding officer before the beginning of the hearing;

(ii) Presenting a brief oral statement at the hearing, at the point in the proceedings specified by the presiding officer; and

(iii) Submitting a brief or written statement when the parties submit briefs.

The amicus curiae must serve copies of any briefs or written statements on all parties.

§ 430.80 Authority of the presiding officer.

(a) The presiding officer has the duty to conduct a fair hearing, to avoid delay, maintain order, and make a record of the proceedings. He or she has the authority necessary to accomplish those ends, including but not limited to authority to take the following actions:

(1) Change the date, time, and place of the hearing after due notice to the parties. This includes authority to postpone or adjourn the hearing in whole or in part. In a hearing on disapproval of a State plan, or State plan amendments, changes in the date of the hearing are subject to the time limits imposed by section 1116(a)(2) of the Act.

(2) Hold conferences to settle or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the issues.

(3) Regulate participation of parties and amici curiae and require parties and amici curiae to state their position with respect to the various issues in the proceeding.

(4) Administer oaths and affirmations.

(5) Rule on motions and other procedural items, including issuance of protective orders or other relief to a party against whom discovery is sought.

(6) Regulate the course of the hearing and conduct of counsel.

(7) Examine witnesses.

(8) Receive, rule on, exclude or limit evidence or discovery.

(9) Fix the time for filing motions, petitions, briefs, or other items.

(10) If the presiding officer is the Administrator, make a final decision.

(11) If the presiding officer is a designee of the Administrator, certify the entire record including recommended findings and proposed decision to the Administrator.

(12) Take any action authorized by the rules in this subpart or in conformance with the provisions of 5 U.S.C. 551 through 559.

(b) The presiding officer does not have authority to compel by subpoena the production of witnesses, papers, or other evidence.

(c) If the presiding officer is a designee of the Administrator, his or her authority pertains to the issues of compliance by a State with Federal requirements, and does not extend to the question of whether, in case of any noncompliance, Federal payments will be denied in respect to the entire State plan or only for certain categories under, or parts of, the State plan affected by the noncompliance.

§ 430.83 Rights of parties.

All parties may:

(a) Appear by counsel or other authorized representative, in all hearing proceedings.

(b) Participate in any prehearing conference held by the presiding officer.

(c) Agree to stipulations as to facts which will be made a part of the record.

(d) Make opening statements at the hearing.

(e) Present relevant evidence on the issues at the hearing.

(f) Present witnesses who then must be available for cross-examination by all other parties.

(g) Present oral arguments at the hearing.

(h) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

§ 430.86 Discovery.

CMS and any party named in the notice issued under § 430.70 has the right to conduct discovery (including depositions) against opposing parties. Rules 26–37 of the Federal Rules of Civil Procedures apply to such proceedings; there will be no fixed rule on priority of discovery. Upon written motion, the presiding officer promptly rules upon any objection to discovery action initiated under this section. The presiding officer also has the power to grant a

protective order or relief to any party against whom discovery is sought and to restrict or control discovery so as to prevent undue delay in the conduct of the hearing. Upon the failure of any party to make discovery, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by Rule 37 of the Federal Rules of Civil Procedure.

§ 430.88 Evidence.

(a) *Evidentiary purpose.* The hearing is directed to receiving factual evidence and expert opinion testimony related to the issues involved in the proceeding. Argument is not received in evidence. It must be presented in statements, memoranda, or briefs, as determined by the presiding officer. Brief opening statements, concerning the party's position and what he or she intends to prove, may be made at hearings.

(b) *Testimony.* Testimony is given orally under oath or affirmation by witnesses at the hearing. Witnesses are available at the hearing for cross-examination by all parties.

(c) *Stipulations and exhibits.* Two or more parties may agree to stipulations of fact. Those stipulations, and any exhibit proposed by any party, are exchanged before the hearing if the presiding officer so requires.

(d) *Rules of evidence.* (1) Technical rules of evidence do not apply to hearings conducted under this subpart. However, rules or principles designed to ensure production of the most credible evidence available and to subject testimony to test by cross-examination are applied by the presiding officer when reasonably necessary.

(2) A witness may be cross-examined on any matter material to the proceeding without regard to the scope of his or her direct examination.

(3) The presiding officer may exclude irrelevant, immaterial, or unduly repetitious evidence.

(4) All documents and other evidence offered or taken for the record are open to examination by the parties and an opportunity is given to refute facts and arguments advanced on either side of the issues.

§ 430.90 Exclusion from hearing for misconduct.

The presiding officer may immediately exclude from the hearing any person who—

(a) Uses disrespectful, disorderly, or contumacious language or engages in contemptuous behavior;

(b) Refuses to comply with directions; or

(c) Uses dilatory tactics.

§ 430.92 Unsponsored written material.

Letters expressing views or urging action and other unsponsored written material regarding matters in issue in a hearing are placed in the correspondence section of the docket of the proceeding. These data are not considered part of the evidence or record in the hearing.

§ 430.94 Official transcript.

(a) *Filing.* The official transcripts of testimony, together with any stipulations, briefs, or memoranda of law, are filed with CMS.

(b) *Availability of transcripts.* CMS designates an official reporter for each hearing. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not in excess of the maximum rates fixed by the contract between CMS and the reporter.

(c) *Correction of transcript.* Upon notice to all parties, the presiding officer may authorize corrections that affect substantive matters in the transcript.

§ 430.96 Record for decision.

The transcript of testimony, exhibits, and all papers and requests filed in the proceedings, except the correspondence section of the docket, including rulings and any recommended or initial decision constitute the exclusive record for decision.

§ 430.100 Posthearing briefs.

The presiding officer fixes the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law. The presiding officer may also permit reply briefs.

§ 430.102 Decisions following hearing.

(a) *Administrator presides.* If the presiding officer is the Administrator, he or she issues the hearing decision within 60 days after expiration of the period for submission of posthearing briefs.

(b) *Administrator's designee presides.* If the presiding officer is other than the Administrator, the procedure is as follows:

(1) Upon expiration of the period allowed for submission of posthearing briefs, the presiding officer certifies the entire record, including his or her recommended findings and proposed decision, to the Administrator. The Administrator serves a copy of the recommended findings and proposed decision upon all parties and amici, if any.

(2) Any party may, within 20 days, file with the Administrator exceptions to the recommended findings and proposed decision and a supporting brief or statement.

(3) The Administrator reviews the recommended decision and, within 60 days of its issuance, issues his or her own decision.

(c) *Effect of Administrator's decision.* The decision of the Administrator under this section is the final decision of the Secretary and constitutes ''final agency action'' within the meaning of 5 U.S.C. 704 and a ''final determination'' within the meaning of section 1116(a)(3) of the Act and § 430.38. The Administrator's decision is promptly served on all parties and amici.

§ 430.104 Decisions that affect FFP.

(a) *Scope of decisions.* If the Administrator concludes that withholding of FFP is necessary because a State is out of compliance with Federal requirements, in accordance with § 430.35, the decision also specifies—

(1) Whether no further payments will be made to the State or whether payments will be limited to parts of the program not affected by the noncompliance; and

(2) The effective date of the decision to withhold.

(b) *Consultation.* The Administrator may ask the parties for recommendations or briefs or may hold conferences of the parties on the question of further payments to the State.

(c) *Effective date of decision.* The effective date of a decision to withhold Federal funds will not be earlier than the date of the Administrator's decision and will not be later than the first day of the next calendar quarter. The provisions of this section may not be waived under § 430.64.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

Sec.

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

SOURCE: 43 FR 45188, Sept. 29, 1978, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part appear at 75 FR 48852, Aug. 11, 2010.

§431.1 Purpose.

This part establishes State plan requirements for the designation, organization, and general administrative activities of a State agency responsible for operating the State Medicaid program, directly or through supervision of local administering agencies.

Subpart A—Single State Agency

§431.10 Single State agency.

(a) *Basis and purpose.* This section implements section 1902(a)(5) of the Act, which provides for designation of a single State agency for the Medicaid program.

(b) *Designation and certification.* A State plan must—

(1) Specify a single State agency established or designated to administer or supervise the administration of the plan; and

(2) Include a certification by the State Attorney General, citing the legal authority for the single State agency to—

(i) Administer or supervise the administration of the plan; and

(ii) Make rules and regulations that it follows in administering the plan or that are binding upon local agencies that administer the plan.

(c) *Determination of eligibility.* (1) The plan must specify whether the agency that determines eligibility for families and for individuals under 21 is—

(i) The Medicaid agency; or

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia), or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands.

(2) The plan must specify whether the agency that determines eligibility for the aged, blind, or disabled is—

(i) The Medicaid agency;

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia) or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands; or

(iii) The Federal agency administering the supplemental security income program under title XVI (SSI). In this case, the plan must also specify whether the Medicaid agency or the title IV-A agency determines eligibility for any groups whose eligibility is not determined by the Federal agency.

(d) *Agreement with Federal or State agencies.* The plan must provide for written agreements between the Medicaid agency and the Federal or other State agencies that determine eligibility for Medicaid, stating the relationships and respective responsibilities of the agencies.

(e) *Authority of the single State agency.* In order for an agency to qualify as the Medicaid agency—

(1) The agency must not delegate, to other than its own officials, authority to—

(i) Exercise administrative discretion in the administration or supervision of the plan, or

(ii) Issue policies, rules, and regulations on program matters.

(2) The authority of the agency must not be impaired if any of its rules, regulations, or decisions are subject to review, clearance, or similar action by other offices or agencies of the State.

(3) If other State or local agencies or offices perform services for the Medicaid agency, they must not have the authority to change or disapprove any administrative decision of that agency, or otherwise substitute their judgment for that of the Medicaid agency with respect to the application of policies, rules, and regulations issued by the Medicaid agency.

[44 FR 17930, Mar. 23, 1979]

§ 431.11 Organization for administration.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the general organization and staffing requirements for the Medicaid agency and the State plan.

(b) *Medical assistance unit.* A State plan must provide for a medical assistance unit within the Medicaid agency, staffed with a program director and other appropriate personnel who participate in the development, analysis, and evaluation of the Medicaid program.

(c) *Description of organization.* (1) The plan must include—

(i) A description of the organization and functions of the Medicaid agency and an organization chart;

(ii) A description of the organization and functions of the medical assistance unit and an organization chart; and

(iii) A description of the kinds and number of professional medical personnel and supporting staff used in the administration of the plan and their responsibilities.

(d) *Eligibility determined by other agencies.* If eligibility is determined by State agencies other than the Medicaid agency or by local agencies under the supervision of other State agencies, the plan must include a description of the staff designated by those other agencies and the functions they perform in carrying out their responsibility.

[44 FR 17931, Mar. 23, 1979]

§ 431.12 Medical care advisory committee.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for establishment of a committee to advise the Medicaid agency about health and medical care services.

(b) *State plan requirement.* A State plan must provide for a medical care advisory committee meeting the requirements of this section to advise the Medicaid agency director about health and medical care services.

(c) *Appointment of members.* The agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

(d) *Committee membership.* The committee must include—

(1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care;

(2) Members of consumers' groups, including Medicaid recipients, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and

(3) The director of the public welfare department or the public health department, whichever does not head the Medicaid agency.

(e) *Committee participation.* The committee must have opportunity for participation in policy development and program administration, including furthering the participation of recipient members in the agency program.

(f) *Committee staff assistance and financial help.* The agency must provide the committee with—

(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and

(2) Financial arrangements, if necessary, to make possible the participation of recipient members.

(g) *Federal financial participation.* FFP is available at 50 percent in expenditures for the committee's activities.

§431.15 Methods of administration.

A State plan must provide for methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the plan.

(Sec. 1902(a)(4) of the Act)

[44 FR 17931, Mar. 23, 1979]

§431.16 Reports.

A State plan must provide that the Medicaid agency will—

(a) Submit all reports required by the Secretary;

(b) Follow the Secretary's instructions with regard to the form and content of those reports; and

(c) Comply with any provisions that the Secretary finds necessary to verify and assure the correctness of the reports.

[44 FR 17931, Mar. 23, 1979]

§431.17 Maintenance of records.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the kinds of records a Medicaid agency must maintain, the retention period, and the conditions under which microfilm copies may be substituted for original records.

(b) *Content of records.* A State plan must provide that the Medicaid agency will maintain or supervise the maintenance of the records necessary for the proper and efficient operation of the plan. The records must include—

(1) Individual records on each applicant and recipient that contain information on—

(i) Date of application;

(ii) Date of and basis for disposition;

(iii) Facts essential to determination of initial and continuing eligibility;

(iv) Provision of medical assistance;

(v) Basis for discontinuing assistance;

(vi) The disposition of income and eligibility verification information received under §§435.940 through 435.960 of this subchapter; and

(2) Statistical, fiscal, and other records necessary for reporting and accountability as required by the Secretary.

(c) *Retention of records.* The plan must provide that the records required under paragraph (b) of this section will be retained for the periods required by the Secretary.

(d) *Conditions for optional use of microfilm copies.* The agency may substitute certified microfilm copies for the originals of substantiating documents required for Federal audit and review, if the conditions in paragraphs (d)(1) through (4) of this section are met.

(1) The agency must make a study of its record storage and must show that the use of microfilm is efficient and economical.

(2) The microfilm system must not hinder the agency's supervision and control of the Medicaid program.

(3) The microfilm system must—

(i) Enable the State to audit the propriety of expenditures for which FFP is claimed; and

(ii) Enable the HHS Audit Agency and CMS to properly discharge their respective responsibilities for reviewing the manner in which the Medicaid program is being administered.

(4) The agency must obtain approval from the CMS regional office indicating—

(i) The system meets the conditions of paragraphs (d)(2) and (3) of this section; and

(ii) The microfilming procedures are reliable and are supported by an adequate retrieval system.

[44 FR 17931, Mar. 23, 1979, as amended at 51 FR 7210, Feb. 28, 1986]

§431.18 Availability of agency program manuals.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for facilitating access to Medicaid rules and policies by individuals outside the State Medicaid agency.

(b) *State plan requirements.* A State plan must provide that the Medicaid agency meets the requirements of paragraphs (c) through (g) of this section.

(c) *Availability in agency offices.* (1) The agency must maintain, in all its offices, copies of its current rules and

policies that affect the public, including those that govern eligibility, provision of medical assistance, covered services, and recipient rights and responsibilities.

(2) These documents must be available upon request for review, study, and reproduction by individuals during regular working hours of the agency.

(d) *Availability through other entities.* The agency must provide copies of its current rules and policies to—

(1) Public and university libraries;

(2) The local or district offices of the Bureau of Indian Affairs;

(3) Welfare and legal services offices; and

(4) Other entities that—

(i) Request the material in order to make it accessible to the public;

(ii) Are centrally located and accessible to a substantial number of the recipient population they serve; and

(iii) Agree to accept responsibility for filing all amendments or changes forwarded by the agency.

(e) *Availability in relation to fair hearings.* The agency must make available to an applicant or recipient, or his representative, a copy of the specific policy materials necessary—

(1) To determine whether to request a fair hearing; or

(2) To prepare for a fair hearing.

(f) *Availability for other purposes.* The agency must establish rules for making program policy materials available to individuals who request them for other purposes.

(g) *Charges for reproduction.* The agency must make copies of its program policy materials available without charge or at a charge related to the cost of reproduction.

[44 FR 17931, Mar. 23, 1979]

§ 431.20 Advance directives.

(a) *Basis and purpose.* This section, based on section 1902(a) (57) and (58) of the Act, prescribes State plan requirements for the development and distribution of a written description of State law concerning advance directives.

(b) A State Plan must provide that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the State law (whether statutory or as recognized by the courts of the State) concerning advance directives, as defined in § 489.100 of this chapter, to be distributed by Medicaid providers and health maintenance organizations (as specified in section 1903(m)(1)(A) of the Act) in accordance with the requirements under part 489, subpart I of this chapter. Revisions to the written descriptions as a result of changes in State law must be incorporated in such descriptions and distributed as soon as possible, but no later than 60 days from the effective date of the change in State law, to Medicaid providers and health maintenance organizations.

[57 FR 8202, Mar. 6, 1992, as amended at 60 FR 33293, June 27, 1995]

Subpart B—General Administrative Requirements

SOURCE: 56 FR 8847, Mar. 1, 1991, unless otherwise noted.

§ 431.40 Basis and scope.

(a) This subpart sets forth State plan requirements and exceptions that pertain to the following administrative requirements and provisions of the Act:

(1) Statewideness—section 1902(a)(1);

(2) Proper and efficient administration—section 1902(a)(4);

(3) Comparability of services—section 1902(a)(10) (B)–(E);

(4) Payment for services furnished outside the State—section 1902(a)(16);

(5) Free choice of providers—section 1902(a)(23);

(6) Special waiver provisions applicable to American Samoa and the Northern Mariana Islands—section 1902(j); and

(7) Exceptions to, and waiver of, State plan requirements—sections 1915 (a)–(c) and 1916 (a)(3) and (b)(3).

(b) Other applicable regulations include the following:

(1) Section 430.25 Waivers of State plan requirements.

(2) Section 440.250 Limits on comparability of services.

§ 431.50 Statewide operation.

(a) *Statutory basis.* Section 1902(a)(1) of the Act requires a State plan to be

in effect throughout the State, and section 1915 permits certain exceptions.

(b) *State plan requirements.* A State plan must provide that the following requirements are met:

(1) The plan will be in operation statewide through a system of local offices, under equitable standards for assistance and administration that are mandatory throughout the State.

(2) If administered by political subdivisions of the State, the plan will be mandatory on those subdivisions.

(3) The agency will ensure that the plan is continuously in operation in all local offices or agencies through—

(i) Methods for informing staff of State policies, standards, procedures, and instructions;

(ii) Systematic planned examination and evaluation of operations in local offices by regularly assigned State staff who make regular visits; and

(iii) Reports, controls, or other methods.

(c) *Exceptions.* (1) ''Statewide operation'' does not mean, for example, that every source of service must furnish the service State-wide. The requirement does not preclude the agency from contracting with a comprehensive health care organization (such as an HMO or a rural health clinic) that serves a specific area of the State, to furnish services to Medicaid recipients who live in that area and chose to receive services from that HMO or rural health clinic. Recipients who live in other parts of the State may receive their services from other sources.

(2) Other allowable exceptions and waivers are set forth in §§431.54 and 431.55.

[56 FR 8847, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§431.51 Free choice of providers.

(a) *Statutory basis.* This section is based on sections 1902(a)(23), 1902(e)(2), and 1915(a) and (b) and 1932(a)(3) of the Act.

(1) Section 1902(a)(23) of the Act provides that recipients may obtain services from any qualified Medicaid provider that undertakes to provide the services to them.

(2) Section 1915(a) of the Act provides that a State shall not be found out of compliance with section 1902(a)(23) solely because it imposes certain specified allowable restrictions on freedom of choice.

(3) Section 1915(b) of the Act authorizes waiver of the section 1902(a)(23) freedom of choice of providers requirement in certain specified circumstances, but not with respect to providers of family planning services.

(4) Section 1902(a)(23) of the Act provides that a recipient enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

(b) *State plan requirements.* A State plan, except the plan for Puerto Rico, the Virgin Islands, or Guam, must provide as follows:

(1) Except as provided under paragraph (c) of this section and part 438 of this chapter, a recipient may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is—

(i) Qualified to furnish the services; and

(ii) Willing to furnish them to that particular recipient.

This includes an organization that furnishes, or arranges for the furnishing of, Medicaid services on a prepayment basis.

(2) A recipient enrolled in a primary care case-management system, a Medicaid MCO, or other similar entity will not be restricted in freedom of choice of providers of family planning services.

(c) *Exceptions.* Paragraph (b) of this section does not prohibit the agency from—

(1) Establishing the fees it will pay providers for Medicaid services;

(2) Setting reasonable standards relating to the qualifications of providers; or

(3) Subject to paragraph (b)(2) of this section, restricting recipients' free choice of providers in accordance with one or more of the exceptions set forth in § 431.54, or under a waiver as provided in § 431.55; or

(4) Limiting the providers who are available to furnish targeted case management services defined in § 440.169 of this chapter to target groups that consist solely of individuals with developmental disabilities or with chronic mental illness. This limitation may only be permitted so that the providers of case management services for eligible individuals with developmental disabilities or with chronic mental illness are capable of ensuring that those individuals receive needed services.

(d) *Certification requirement*—(1) *Content of certification.* If a State implements a project under one of the exceptions allowed under § 431.54 (d), (e) or (f), it must certify to CMS that the statutory safeguards and requirements for an exception under section 1915(a) of the Act are met.

(2) *Timing of certification.* (i) For an exception under § 431.54(d), the State may not institute the project until after it has submitted the certification and CMS has made the findings required under the Act, and so notified the State.

(ii) For exceptions under § 431.54 (e) or (f), the State must submit the certificate by the end of the quarter in which it implements the project.

[56 FR 8847, Mar. 1, 1991, as amended at 67 FR 41094, June 14, 2002; 72 FR 68091, Dec. 4, 2007]

§ 431.52 Payments for services furnished out of State.

(a) *Statutory basis.* Section 1902(a)(16) of the Act authorizes the Secretary to prescribe State plan requirements for furnishing Medicaid to State residents who are absent from the State.

(b) *Payment for services.* A State plan must provide that the State will pay for services furnished in another State to the same extent that it would pay for services furnished within its boundaries if the services are furnished to a recipient who is a resident of the State, and any of the following conditions is met:

(1) Medical services are needed because of a medical emergency;

(2) Medical services are needed and the recipient's health would be endangered if he were required to travel to his State of residence;

(3) The State determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State;

(4) It is general practice for recipients in a particular locality to use medical resources in another State.

(c) *Cooperation among States.* The plan must provide that the State will establish procedures to facilitate the furnishing of medical services to individuals who are present in the State and are eligible for Medicaid under another State's plan.

§ 431.53 Assurance of transportation.

A State plan must—

(a) Specify that the Medicaid agency will ensure necessary transportation for recipients to and from providers; and

(b) Describe the methods that the agency will use to meet this requirement.

[74 FR 31195, June 30, 2009]

§ 431.54 Exceptions to certain State plan requirements.

(a) *Statutory basis*—(1) Section 1915(a) of the Act provides that a State shall not be deemed to be out of compliance with the requirements of sections 1902(a)(1), (10), or (23) of the Act solely because it has elected any of the exceptions set forth in paragraphs (b) and (d) through (f) of this section.

(2) Section 1915(g) of the Act provides that a State may provide, as medical assistance, targeted case management services under the plan without regard to the requirements of sections 1902(a)(1) and 1902(a)(10)(B) of the Act.

(b) *Additional services under a prepayment system.* If the Medicaid agency contracts on a prepayment basis with an organization that provides services additional to those offered under the State plan, the agency may restrict the provision of the additional services to

recipients who live in the area served by the organization and wish to obtain services from it.

(c) [Reserved]

(d) *Special procedures for purchase of medical devices and laboratory and X-ray tests.* The Medicaid agency may establish special procedures for the purchase of medical devices or laboratory and X-ray tests (as defined in §440.30 of this chapter) through a competitive bidding process or otherwise, if the State assures, in the certification required under §431.51(d), and CMS finds, as follows:

(1) Adequate services or devices are available to recipients under the special procedures.

(2) Laboratory services are furnished through laboratories that meet the following requirements:

(i) They are independent laboratories, or inpatient or outpatient hospital laboratories that provide services for individuals who are not hospital patients, or physician laboratories that process at least 100 specimens for other physicians during any calendar year.

(ii) They meet the requirements of subpart M of part 405 or part 482 of this chapter.

(iii) Laboratories that require an interstate license under 42 CFR part 74 are licensed by CMS or receive an exemption from the licensing requirement by the College of American Pathologists. (Hospital and physician laboratories may participate in competitive bidding only with regard to services to non-hospital patients and other physicians' patients, respectively.)

(3) Any laboratory from which a State purchases services under this section has no more than 75 percent of its charges based on services to Medicare beneficiaries and Medicaid recipients.

(e) *Lock-in of recipients who over-utilize Medicaid services.* If a Medicaid agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services from designated providers only. The agency may impose these restrictions only if the following conditions are met:

(1) The agency gives the recipient notice and opportunity for a hearing (in accordance with procedures established by the agency) before imposing the restrictions.

(2) The agency ensures that the recipient has reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality.

(3) The restrictions do not apply to emergency services furnished to the recipient.

(f) *Lock-out of providers.* If a Medicaid agency finds that a Medicaid provider has abused the Medicaid program, the agency may restrict the provider, through suspension or otherwise, from participating in the program for a reasonable period of time.

Before imposing any restriction, the agency must meet the following conditions:

(1) Give the provider notice and opportunity for a hearing, in accordance with procedures established by the agency.

(2) Find that in a significant number or proportion of cases, the provider has:

(i) Furnished Medicaid services at a frequency or amount not medically necessary, as determined in accordance with utilization guidelines established by the agency; or

(ii) Furnished Medicaid services of a quality that does not meet professionally recognized standards of health care.

(3) Notify CMS and the general public of the restriction and its duration.

(4) Ensure that the restrictions do not result in denying recipients reasonable access (taking into account geographic location: and reasonable travel time) to Medicaid services of adequate quality, including emergency services.

(g) *Targeted case management services.* The requirements of §431.50(b) relating to the statewide operation of a State plan and §440.240 of this chapter related to comparability of services do not apply with respect to targeted case management services defined in §440.169 of this chapter.

[56 FR 8847, Mar. 1, 1991, as amended at 72 FR 68091, Dec. 4, 2007]

§ 431.55 Waiver of other Medicaid requirements.

(a) *Statutory basis.* Section 1915(b) of the Act authorizes the Secretary to waive most requirements of section 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (f) and (h) prescribe how such waivers are to be approved, continued, monitored, and terminated. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 1915(b)(1) waiver on the State's provision for exclusion of certain entities from participation.

(b) *General requirements.* (1) General requirements for submittal of waiver requests, and the procedures that CMS follows for review and action on those requests are set forth in § 430.25 of this chapter.

(2) In applying for a waiver to implement an approvable project under paragraph (c), (d), (e), or (f) of this section, a Medicaid agency must document in the waiver request and maintain data regarding:

(i) The cost-effectiveness of the project;

(ii) The effect of the project on the accessibility and quality of services;

(iii) The anticipated impact of the project on the State's Medicaid program and;

(iv) Assurances that the restrictions on free choice of providers do not apply to family planning services.

(3) No waiver under this section may be granted for a period longer than 2 years, unless the agency requests a continuation of the waiver.

(4) CMS monitors the implementation of waivers granted under this section to ensure that requirements for such waivers are being met.

(i) If monitoring demonstrates that the agency is not in compliance with the requirements for a waiver under this section, CMS gives the agency notice and opportunity for a hearing.

(ii) If, after a hearing, CMS finds an agency to be out of compliance with the requirements of a waiver, CMS terminates the waiver and gives the agency a specified date by which it must demonstrate that it meets the applicable requirements of section 1902 of the Act.

(5) The requirements of section 1902(s) of the Act, with regard to adjustments in payments for inpatient hospital services furnished to infants who have not attained age 1 and to children who have not attained age 6 and who receive these services in disproportionate share hospitals, may not be waived under a section 1915(b) waiver.

(c) *Case-management system.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to implement a primary care case-management system or specialty physician services system.

(i) Under a primary care case-management system the agency assures that a specific person or persons or agency will be responsible for locating, coordinating, and monitoring all primary care or primary care and other medical care and rehabilitative services on behalf of a recipient. The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

(ii) A specialty physician services system allows States to restrict recipients of specialty services to designated providers of such services, even in the absence of a primary care case-management system.

(2) A waiver under this paragraph (c) may not be approved unless the State's request assures that the restrictions—

(i) Do not apply in emergency situations; and

(ii) Do not substantially impair access to medically necessary services of adequate quality.

(d) *Locality as central broker.* Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to allow a locality to act as a central broker to assist recipients in selecting among competing health care plans. States must ensure that access to medically necessary services of adequate quality is not substantially impaired.

(1) A locality is any defined jurisdiction, e.g., district, town, city, borough, county, parish, or State.

(2) A locality may use any agency or agent, public or private, profit or nonprofit, to act on its behalf in carrying out its central broker function.

(e) *Sharing of cost savings.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to share with recipients the cost savings resulting from the recipients' use of more cost-effective medical care.

(2) Sharing is through the provision of additional services, including—

(i) Services furnished by a plan selected by the recipient; and

(ii) Services expressly offered by the State as an inducement for recipients to participate in a primary care case-management system, a competing health care plan or other system that furnishes health care services in a more cost-effective manner.

(f) *Restriction of freedom of choice*—(1) Waiver of appropriate requirements of section 1902 of the Act may be authorized for States to restrict recipients to obtaining services from (or through) qualified providers or practitioners that meet, accept, and comply with the State reimbursement, quality and utilization standards specified in the State's waiver request.

(2) An agency may qualify for a waiver under this paragraph (f) only if its applicable State standards are consistent with access, quality and efficient and economic provision of covered care and services and the restrictions it imposes—

(i) Do not apply to recipients residing at a long-term care facility when a restriction is imposed unless the State arranges for reasonable and adequate recipient transfer.

(ii) Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services; and

(iii) Do not apply in emergency circumstances.

(3) Demonstrated effectiveness and efficiency refers to reducing costs or slowing the rate of cost increase and maximizing outputs or outcomes per unit of cost.

(4) The agency must make payments to providers furnishing services under a freedom of choice waiver under this paragraph (f) in accordance with the timely claims payment standards specified in § 447.45 of this chapter for health care practitioners participating in the Medicaid program.

(g) [Reserved]

(h) *Waivers approved under section 1915(b)(1) of the Act*—(1) *Basic rules.* (i) An agency must submit, as part of it's waiver request, assurance that the entities described in paragraph (h)(2) of this section will be excluded from participation under an approved waiver.

(ii) FFP is available in payments to an entity that furnishes services under a section 1915(b)(1) waiver only if the agency excludes from participation any entity described in paragraph (h)(2) of this section.

(2) Entities that must be excluded. The agency must exclude an entity that meets any of the following conditions:

(i) Could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(ii) Has a substantial contractual relationship (direct or indirect) with an individual convicted of certain crimes, as described in section 1128(b)(8)(B) of the Act.

(iii) Employs or contracts directly or indirectly with one of the following:

(A) Any individual or entity that, under section 1128 or section 1128A of the Act, is precluded from furnishing health care, utilization review, medical social services, or administrative services.

(B) Any entity described in paragraph (h)(2)(i) of this section.

(3) Definitions. As used in this section, substantial contractual relationship means any contractual relationship that provides for one or more of the following services:

(i) The administration, management, or provision of medical services.

(ii) The establishment of policies, or the provision of operational support, for the administration, management, or provision of medical services.

[56 FR 8847, Mar. 1, 1991, as amended at 59 FR 4599, Feb. 1, 1994; 59 FR 36084, July 15, 1994; 67 FR 41094, June 14, 2002]

§ 431.56 Special waiver provisions applicable to American Samoa and the Northern Mariana Islands.

(a) *Statutory basis.* Section 1902(j) of the Act provides for waiver of all but three of the title XIX requirements, in the case of American Samoa and the Northern Mariana Islands.

(b) *Waiver provisions.* American Samoa or the Northern Mariana Islands may request, and CMS may approve, a waiver of any of the title XIX requirements except the following:

(1) The Federal medical assistance percentage specified in section 1903 of the Act and § 433.10(b) of this chapter.

(2) The limit imposed by section 1108(c) of the Act on the amount of Federal funds payable to American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition for Medicaid assistance.

(3) The requirement that payment be made only with respect to expenditure made by American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition of medical assistance.

§ 431.57 Waiver of cost-sharing requirements.

(a) Sections 1916(a)(3) and 1916(b)(3) of the Act specify the circumstances under which the Secretary is authorized to waive the requirement that cost-sharing amounts be nominal.

(b) For nonemergency services furnished in a hospital emergency room, the Secretary may by waiver permit a State to impose a copayment of up to double the ''nominal'' copayment amounts determined under § 447.54(a)(3) of this subchapter.

(c) Nonemergency services are services that do not meet the definition of emergency services at § 447.53(b)(4) of this subchapter.

(d) In order for a waiver to be approved under this section, the State must establish to the satisfaction of CMS that alternative sources of nonemergency, outpatient services are available and accessible to recipients.

(e) Although, in accordance with § 431.55(b)(3) of this part, a waiver will generally be granted for a 2-year duration, CMS will reevaluate waivers approved under this section if the State increases the nominal copayment amounts in effect when the waiver was approved.

(f) A waiver approved under this section cannot apply to services furnished before the waiver was granted.

[59 FR 4600, Feb. 1, 1994]

Subpart C—Administrative Requirements: Provider Relations

§ 431.105 Consultation to medical facilities.

(a) *Basis and purpose.* This section implements section 1902(a)(24) of the Act, which requires that the State plan provide for consultative services by State agencies to certain institutions furnishing Medicaid services.

(b) *State plan requirements.* A State plan must provide that health agencies and other appropriate State agencies furnish consultative services to hospitals, nursing homes, home health agencies, clinics, and laboratories in order to assist these facilities to—

(1) Qualify for payments under the maternal and child health and crippled children's program (title V of the Act), Medicaid or Medicare;

(2) Establish and maintain fiscal records necessary for the proper and efficient administration of the Act; and

(3) Provide information needed to determine payments due under the Act for services furnished to recipients.

(c) *State plan option: Consultation to other facilities.* The plan may provide that health agencies and other appropriate State agencies furnish consultation to other types of facilities if those facilities are specified in the plan and provide medical care to individuals receiving services under the programs specified in paragraph (b) of this section.

§ 431.107 Required provider agreement.

(a) *Basis and purpose.* This section sets forth State plan requirements, based on sections 1902(a)(4), 1902(a)(27), 1902(a)(57), and 1902(a)(58) of the Act, that relate to the keeping of records and the furnishing of information by all providers of services (including individual practitioners and groups of practitioners).

(b) *Agreements.* A State plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to:

(1) Keep any records necessary to disclose the extent of services the provider furnishes to recipients;

(2) On request, furnish to the Medicaid agency, the Secretary, or the State Medicaid fraud control unit (if such a unit has been approved by the Secretary under §455.300 of this chapter), any information maintained under paragraph (b)(1) of this section and any information regarding payments claimed by the provider for furnishing services under the plan;

(3) Comply with the disclosure requirements specified in part 455, subpart B of this chapter; and

(4) Comply with the advance directives requirements for hospitals, nursing facilities, providers of home health care and personal care services, hospices, and HMOs specified in part 489, subpart I, and §417.436(d) of this chapter.

(5)(i) Furnish to the State agency its National Provider Identifier (NPI) (if eligible for an NPI); and

(ii) Include its NPI on all claims submitted under the Medicaid program.

[44 FR 41644, July 17, 1979, as amended at 57 FR 8202, Mar. 6, 1992; 75 FR 24449, May 5, 2010]

§431.108 Effective date of provider agreements.

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to Medicaid provider agreements with entities that, as a basis for participation in Medicaid—

(i) Are subject to survey and certification by CMS or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has CMS approval at the time of accreditation survey and accreditation decision.

(2) *Exception.* A Medicaid provider agreement with a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) *All requirements are met on the date of survey.* The agreement is effective on the date the onsite survey (including the Life Safety Code survey if applicable) is completed, if on that date the provider meets—

(1) All applicable Federal requirements as set forth in this chapter; and

(2) Any other requirements imposed by the State for participation in the Medicaid program. (If the provider has a time-limited agreement, the new agreement is effective on the day following expiration of the current agreement.)

(c) *All requirements are not met on the date of survey.* If on the date the survey is completed the provider fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1) An NF provider agreement is effective on the date on which—

(i) The NF is found to be in substantial compliance as defined in §488.301 of this chapter; and

(ii) CMS or the State survey agency receives from the NF, if applicable, an approvable waiver request.

(2) For an agreement with any other provider, the effective date is the earlier of the following:

(i) The date on which the provider meets all requirements.

(ii) The date on which a provider is found to meet all conditions of participation but has lower level deficiencies, and CMS or the State survey agency receives from the provider an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date of the agreement, regardless of when CMS approves the plan of correction or waiver request, or both.)

(d) *Accredited provider requests participation in the Medicaid program*—(1) *General rule.* If a provider is currently accredited by a national accrediting organization whose program had CMS approval at the time of accreditation survey and accreditation decision, and on the basis of accreditation, CMS has deemed the provider to meet Federal

requirements, the effective date depends on whether the provider is subject to requirements in addition to those included in the accrediting organization's approved program.

(i) *Provider subject to additional requirements.* For a provider that is subject to additional requirements, Federal or State, or both, the effective date is the date on which the provider meets all requirements, including the additional requirements.

(ii) *Provider not subject to additional requirements.* For a provider that is not subject to additional requirements, the effective date is the date of the provider's initial request for participation if on that date the provider met all Federal requirements.

(2) *Special rule: Retroactive effective date.* If the provider meets the requirements of paragraphs (d)(1) and (d)(1)(i) or (d)(1)(ii) of this section, the effective date may be retroactive for up to one year, to encompass dates on which the provider furnished, to a Medicaid recipient, covered services for which it has not been paid.

[62 FR 43935, Aug. 18, 1997]

§ 431.110 Participation by Indian Health Service facilities.

(a) *Basis.* This section is based on section 1902(a)(4) of the Act, proper and efficient administration; 1902(a)(23), free choice of provider; and 1911, reimbursement of Indian Health Service facilities.

(b) *State plan requirements.* A State plan must provide that an Indian Health Service facility meeting State requirements for Medicaid participation must be accepted as a Medicaid provider on the same basis as any other qualified provider. However, when State licensure is normally required, the facility need not obtain a license but must meet all applicable standards for licensure. In determining whether a facility meets these standards, a Medicaid agency or State licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 431.115 Disclosure of survey information and provider or contractor evaluation.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(36) of the Act, which requires a State plan to provide that the State survey agency will make publicly available the findings from surveys of health care facilities, laboratories, agencies, clinics, or organizations; and

(2) Section 1106(d) of the Act, which places certain restrictions on the Medicaid agency's disclosure of contractor and provider evaluations.

(b) *Definition of State survey agency.* The State survey agency referred to in this section means the agency specified under section 1902(a)(9) of the Act as responsible for establishing and maintaining health standards for private or public institutions in which Medicaid recipients may receive services.

(c) *State plan requirements.* A State plan must provide that the requirements of this section and § 488.325 of this chapter are met.

(d) *Disclosure procedure.* The Medicaid agency must have a procedure for disclosing pertinent findings obtained from surveys made by the State survey agency to determine if a health care facility, laboratory, agency, clinic or health care organization meets the requirements for participation in the Medicaid program.

(e) *Documents subject to disclosure.* Documents subject to disclosure include—

(1) Survey reports, except for Joint Commission on the Accreditation of Hospitals reports prohibited from disclosure under § 422.426(b)(2) of this chapter;

(2) Official notifications of findings based on survey reports:

(3) Pertinent parts of written documents furnished by the health care provider to the survey agency that relate to the reports and findings; and

(4) Ownership and contract information as specified in § 455.104 of this subchapter.

(f) *Availability for inspection and copy of statements listing deficiencies.* The disclosure procedure must provide that the State survey agency will—

(1) Make statements of deficiencies based on the survey reports available for inspection and copying in both the public assistance office and the Social Security Administration district office serving the area where the provider is located; and

(2) Submit to the Regional Medicaid Director, through the Medicaid agency, a plan for making those findings available in other public assistance offices in standard metropolitan statistical areas where this information would be helpful to persons likely to use the health care provider's services.

(g) *When documents must be made available.* The disclosure procedure must provide that the State survey agency will—

(1) Retain in the survey agency office and make available upon request survey reports and current and accurate ownership information; and

(2) Make available survey reports, findings, and deficiency statements immediately upon determining that a health care provider is eligible to begin or continue participation in the Medicaid program, or within 90 days after completion of the survey, whichever occurs first.

(h) *Evaluation reports on providers and contractors.* (1) If the Secretary sends the following reports to the Medicaid agency, the agency must meet the requirements of paragraphs (h) (2) and (3) of this section in releasing them:

(i) Individual contractor performance reviews and other formal performance evaluations of carriers, intermediaries, and State agencies, including the reports of followup reviews;

(ii) Comparative performance evaluations of those contractors, including comparisons of either overall performance or of any particular aspect of contractor operations; and

(iii) Program validation survey reports and other formal performance evaluations of providers, including the reports of followup reviews.

(2) The agency must not make the reports public until—

(i) The contractor or provider has had a reasonable opportunity, not to exceed 30 days, to comment on them; and

(ii) Those comments have been incorporated in the report.

(3) The agency must ensure that the reports contain no identification of individual patients, individual health care practitioners or other individuals.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 41644, July 17, 1979; 59 FR 56232, Nov. 10, 1994]

§431.120 State requirements with respect to nursing facilities.

(a) *State plan requirements.* A State plan must—

(1) Provide that the requirements of subpart D of part 483 of this chapter are met; and

(2) Specify the procedures and rules that the State follows in carrying out the specified requirements, including review and approval of State-operated programs.

(3) To an NF or ICF/MR that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) *Basis and scope of requirements.* The requirements set forth in part 483 of this chapter pertain to the following aspects of nursing facility services and are required by the indicated sections of the Act.

(1) Nurse aide training and competency programs, and evaluation of nurse aide competency (1919(e)(1) of the Act).

(2) Nurse aide registry (1919(e)(2) of the Act).

[56 FR 48918, Sept. 26, 1991, as amended at 62 FR 43935, Aug. 18, 1997]

Subpart D—Appeals Process for NFs and ICFs/MR

SOURCE: 44 FR 9753, Feb. 15, 1979, unless otherwise noted.

§431.151 Scope and applicability.

(a) *General rules.* This subpart sets forth the appeals procedures that a State must make available as follows:

(1) To a nursing facility (NF) that is dissatisfied with a State's finding of noncompliance that has resulted in one of the following adverse actions:

(i) Denial or termination of its provider agreement.

(ii) Imposition of a civil money penalty or other alternative remedy.

(2) To an intermediate care facility for the mentally retarded (ICF/MR) that is dissatisfied with a State's finding of noncompliance that has resulted in the denial, termination, or nonrenewal of its provider agreement.

(3) To an NF or ICF/MR that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) *Special rules.* This subpart also sets forth the special rules that apply in particular circumstances, the limitations on the grounds for appeal, and the scope of review during a hearing.

[61 FR 32348, June 24, 1996, as amended at 62 FR 43935, Aug. 18, 1997]

§ 431.152 State plan requirements.

The State plan must provide for appeals procedures that, as a minimum, satisfy the requirements of §§ 431.153 and 431.154.

[59 FR 56232, Nov. 10, 1994, as amended at 61 FR 32348, June 24, 1996]

§ 431.153 Evidentiary hearing.

(a) *Right to hearing.* Except as provided in paragraph (b) of this section, and subject to the provisions of paragraphs (c) through (j) of this section, the State must give the facility a full evidentiary hearing for any of the actions specified in § 431.151.

(b) *Limit on grounds for appeal.* The following are not subject to appeal:

(1) The choice of sanction or remedy.

(2) The State monitoring remedy.

(3) [Reserved]

(4) The level of noncompliance found by a State except when a favorable final administrative review decision would affect the range of civil money penalty amounts the State could collect.

(5) A State survey agency's decision as to when to conduct an initial survey of a prospective provider.

(c) *Notice of deficiencies and impending remedies.* The State must give the facility a written notice that includes:

(1) The basis for the decision; and

(2) A statement of the deficiencies on which the decision was based.

(d) *Request for hearing.* The facility or its legal representative or other authorized official must file written request for hearing within 60 days of receipt of the notice of adverse action.

(e) *Special rules: Denial, termination or nonrenewal of provider agreement*—(1) *Appeal by an ICF/MR.* If an ICF/MR requests a hearing on denial, termination, or nonrenewal of its provider agreement—

(i) The evidentiary hearing must be completed either before, or within 120 days after, the effective date of the adverse action; and

(ii) If the hearing is made available only after the effective date of the action, the State must, before that date, offer the ICF/MR an informal reconsideration that meets the requirements of § 431.154.

(2) *Appeal by an NF.* If an NF requests a hearing on the denial or termination of its provider agreement, the request does not delay the adverse action and the hearing need not be completed before the effective date of the action.

(f) *Special rules: Imposition of remedies.* If a State imposes a civil money penalty or other remedies on an NF, the following rules apply:

(1) *Basic rule.* Except as provided in paragraph (f)(2) of this section (and notwithstanding any provision of State law), the State must impose all remedies timely on the NF, even if the NF requests a hearing.

(2) *Exception.* The State may not collect a civil money penalty until after the 60-day period for request of hearing has elapsed or, if the NF requests a hearing, until issuance of a final administrative decision that supports imposition of the penalty.

(g) *Special rules: Dually participating facilities.* If an NF is also participating or seeking to participate in Medicare as an SNF, and the basis for the State's denial or termination of participation in Medicaid is also a basis for denial or termination of participation in Medicare, the State must advise the facility that—

(1) The appeals procedures specified for Medicare facilities in part 498 of this chapter apply; and

(2) A final decision entered under the Medicare appeals procedures is binding for both programs.

(h) *Special rules: Adverse action by CMS.* If CMS finds that an NF is not in

substantial compliance and either terminates the NF's Medicaid provider agreement or imposes alternative remedies on the NF (because CMS's findings and proposed remedies prevail over those of the State in accordance with §488.452 of this chapter), the NF is entitled only to the appeals procedures set forth in part 498 of this chapter, instead of the procedures specified in this subpart.

(i) *Required elements of hearing.* The hearing must include at least the following:

(1) Opportunity for the facility—

(i) To appear before an impartial decision-maker to refute the finding of noncompliance on which the adverse action was based;

(ii) To be represented by counsel or other representative; and

(iii) To be heard directly or through its representative, to call witnesses, and to present documentary evidence.

(2) A written decision by the impartial decision-maker, setting forth the reasons for the decision and the evidence on which the decision is based.

(j) *Limits on scope of review: Civil money penalty cases.* In civil money penalty cases—

(1) The State's finding as to a NF's level of noncompliance must be upheld unless it is clearly erroneous; and

(2) The scope of review is as set forth in §488.438(e) of this chapter.

[61 FR 32348, June 24, 1996, as amended at 62 FR 43935, Aug. 18, 1997; 64 FR 39937, July 23, 1999]

§431.154 Informal reconsideration for ICFs/MR.

The informal reconsideration must, at a minimum, include—

(a) Written notice to the facility of the denial, termination or nonrenewal and the findings upon which it was based;

(b) A reasonable opportunity for the facility to refute those findings in writing, and

(c) A written affirmation or reversal of the denial, termination, or nonrenewal.

[44 FR 9753, Feb. 15, 1979, as amended at 59 FR 56233, Nov. 10, 1994; 61 FR 32349, June 24, 1996]

Subpart E—Fair Hearings for Applicants and Recipients

SOURCE: 44 FR 17932, Mar. 29, 1979, unless otherwise noted.

GENERAL PROVISIONS

§431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for a hearing if the State agency or PAHP takes action, as stated in this subpart, to suspend, terminate, or reduce services, or an MCO or PIHP takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the preadmission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

[67 FR 41094, June 14, 2002]

§431.201 Definitions.

For purposes of this subpart:

Action means a termination, suspension, or reduction of Medicaid eligibility or covered services. It also means determinations by skilled nursing facilities and nursing facilities to transfer or discharge residents and adverse determinations made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

Adverse determination means a determination made in accordance with sections 1919(b)(3)(F) or 1919(e)(7)(B) of the Act that the individual does not require the level of services provided by a nursing facility or that the individual does or does not require specialized services.

Date of action means the intended date on which a termination, suspension, reduction, transfer or discharge

becomes effective. It also means the date of the determination made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

De novo hearing means a hearing that starts over from the beginning.

Evidentiary hearing means a hearing conducted so that evidence may be presented.

Notice means a written statement that meets the requirements of § 431.210.

Request for a hearing means a clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority.

Service authorization request means a managed care enrollee's request for the provision of a service.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 67 FR 41095, June 14, 2002]

§ 431.202 State plan requirements.

A State plan must provide that the requirements of §§ 431.205 through 431.246 of this subpart are met.

§ 431.205 Provision of hearing system.

(a) The Medicaid agency must be responsible for maintaining a hearing system that meets the requirements of this subpart.

(b) The State's hearing system must provide for—

(1) A hearing before the agency; or

(2) An evidentiary hearing at the local level, with a right of appeal to a State agency hearing.

(c) The agency may offer local hearings in some political subdivisions and not in others.

(d) The hearing system must meet the due process standards set forth in *Goldberg v. Kelly*, 397 U.S. 254 (1970), and any additional standards specified in this subpart.

§ 431.206 Informing applicants and recipients.

(a) The agency must issue and publicize its hearing procedures.

(b) The agency must, at the time specified in paragraph (c) of this section, inform every applicant or recipient in writing—

(1) Of his right to a hearing;

(2) Of the method by which he may obtain a hearing; and

(3) That he may represent himself or use legal counsel, a relative, a friend, or other spokesman.

(c) The agency must provide the information required in paragraph (b) of this section—(1) At the time that the individual applies for Medicaid;

(2) At the time of any action affecting his or her claim;

(3) At the time a skilled nursing facility or a nursing facility notifies a resident in accordance with § 483.12 of this chapter that he or she is to be transferred or discharged; and

(4) At the time an individual receives an adverse determination by the State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

NOTICE

§ 431.210 Content of notice.

A notice required under § 431.206 (c)(2), (c)(3), or (c)(4) of this subpart must contain—

(a) A statement of what action the State, skilled nursing facility, or nursing facility intends to take;

(b) The reasons for the intended action;

(c) The specific regulations that support, or the change in Federal or State law that requires, the action;

(d) An explanation of—

(1) The individual's right to request an evidentiary hearing if one is available, or a State agency hearing; or

(2) In cases of an action based on a change in law, the circumstances under which a hearing will be granted; and

(e) An explanation of the circumstances under which Medicaid is continued if a hearing is requested.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992]

§ 431.211 Advance notice.

The State or local agency must mail a notice at least 10 days before the date

of action, except as permitted under §§431.213 and 431.214 of this subpart.

§431.213 Exceptions from advance notice.

The agency may mail a notice not later than the date of action if—

(a) The agency has factual information confirming the death of a recipient;

(b) The agency receives a clear written statement signed by a recipient that—

(1) He no longer wishes services; or

(2) Gives information that requires termination or reduction of services and indicates that he understands that this must be the result of supplying that information;

(c) The recipient has been admitted to an institution where he is ineligible under the plan for further services;

(d) The recipient's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address (See §431.231 (d) of this subpart for procedure if the recipient's whereabouts become known);

(e) The agency establishes the fact that the recipient has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth;

(f) A change in the level of medical care is prescribed by the recipient's physician;

(g) The notice involves an adverse determination made with regard to the preadmission screening requirements of section 1919(e)(7) of the Act; or

(h) The date of action will occur in less than 10 days, in accordance with §483.12(a)(5)(ii), which provides exceptions to the 30 days notice requirements of §483.12(a)(5)(i).

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§431.214 Notice in cases of probable fraud.

The agency may shorten the period of advance notice to 5 days before the date of action if—

(a) The agency has facts indicating that action should be taken because of probable fraud by the recipient; and

(b) The facts have been verified, if possible, through secondary sources.

RIGHT TO HEARING

§431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

(1) Any applicant who requests it because his claim for services is denied or is not acted upon with reasonable promptness.

(2) Any recipient who requests it because he or she believes the agency has taken an action erroneously.

(3) Any resident who requests it because he or she believes a skilled nursing facility or nursing facility has erroneously determined that he or she must be transferred or discharged.

(4) Any individual who requests it because he or she believes the State has made an erroneous determination with regard to the preadmission and annual resident review requirements of section 1919(e)(7) of the Act.

(5) Any MCO or PIHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

(6) Any PAHP enrollee who has an action as stated in this subpart.

(7) Any enrollee who is entitled to a hearing under subpart B of part 438 of this chapter.

(b) The agency need not grant a hearing if the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all recipients.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§431.221 Request for hearing.

(a) The agency may require that a request for a hearing be in writing.

(b) The agency may not limit or interfere with the applicant's or recipient's freedom to make a request for a hearing.

(c) The agency may assist the applicant or recipient in submitting and processing his request.

(d) The agency must allow the applicant or recipient a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearings.

§431.222 Group hearings.

The agency—

(a) May respond to a series of individual requests for hearing by conducting a single group hearing;

(b) May consolidate hearings only in cases in which the sole issue involved is one of Federal or State law or policy;

(c) Must follow the policies of this subpart and its own policies governing hearings in all group hearings; and

(d) Must permit each person to present his own case or be represented by his authorized representative.

§ 431.223 Denial or dismissal of request for a hearing.

The agency may deny or dismiss a request for a hearing if—

(a) The applicant or recipient withdraws the request in writing; or

(b) The applicant or recipient fails to appear at a scheduled hearing without good cause.

PROCEDURES

§ 431.230 Maintaining services.

(a) If the agency mails the 10-day or 5-day notice as required under § 431.211 or § 431.214 of this subpart, and the recipient requests a hearing before the date of action, the agency may not terminate or reduce services until a decision is rendered after the hearing unless—

(1) It is determined at the hearing that the sole issue is one of Federal or State law or policy; and

(2) The agency promptly informs the recipient in writing that services are to be terminated or reduced pending the hearing decision.

(b) If the agency's action is sustained by the hearing decision, the agency may institute recovery procedures against the applicant or recipient to recoup the cost of any services furnished the recipient, to the extent they were furnished solely by reason of this section.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980]

§ 431.231 Reinstatement of services.

(a) The agency may reinstate services if a recipient requests a hearing not more than 10 days after the date of action.

(b) The reinstated services must continue until a hearing decision unless, at the hearing, it is determined that the sole issue is one of Federal or State law or policy.

(c) The agency must reinstate and continue services until a decision is rendered after a hearing if—

(1) Action is taken without the advance notice required under § 431.211 or § 431.214 of this subpart;

(2) The recipient requests a hearing within 10 days of the mailing of the notice of action; and

(3) The agency determines that the action resulted from other than the application of Federal or State law or policy.

(d) If a recipient's whereabouts are unknown, as indicated by the return of unforwardable agency mail directed to him, any discontinued services must be reinstated if his whereabouts become known during the time he is eligible for services.

§ 431.232 Adverse decision of local evidentiary hearing.

If the decision of a local evidentiary hearing is adverse to the applicant or recipient, the agency must—

(a) Inform the applicant or recipient of the decision;

(b) Inform the applicant or recipient that he has the right to appeal the decision to the State agency, in writing, within 15 days of the mailing of the notice of the adverse decision;

(c) Inform the applicant or recipient of his right to request that his appeal be a *de novo* hearing; and

(d) Discontinue services after the adverse decision.

§ 431.233 State agency hearing after adverse decision of local evidentiary hearing.

(a) Unless the applicant or recipient specifically requests a *de novo* hearing, the State agency hearing may consist of a review by the agency hearing officer of the record of the local evidentiary hearing to determine whether the decision of the local hearing officer was supported by substantial evidence in the record.

(b) A person who participates in the local decision being appealed may not participate in the State agency hearing decision.

§ 431.240 Conducting the hearing.

(a) All hearings must be conducted—

(1) At a reasonable time, date, and place;

(2) Only after adequate written notice of the hearing; and

(3) By one or more impartial officials or other individuals who have not been directly involved in the initial determination of the action in question.

(b) If the hearing involves medical issues such as those concerning a diagnosis, an examining physician's report, or a medical review team's decision, and if the hearing officer considers it necessary to have a medical assessment other than that of the individual involved in making the original decision, such a medical assessment must be obtained at agency expense and made part of the record.

§ 431.241 Matters to be considered at the hearing.

The hearing must cover—

(a) Agency action or failure to act with reasonable promptness on a claim for services, including both initial and subsequent decisions regarding eligibility;

(b) Agency decisions regarding changes in the type or amount of services;

(c) A decision by a skilled nursing facility or nursing facility to transfer or discharge a resident; and

(d) A State determination with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

[57 FR 56505, Nov. 30, 1992]

§ 431.242 Procedural rights of the applicant or recipient.

The applicant or recipient, or his representative, must be given an opportunity to—

(a) Examine at a reasonable time before the date of the hearing and during the hearing:

(1) The content of the applicant's or recipient's case file; and

(2) All documents and records to be used by the State or local agency or the skilled nursing facility or nursing facility at the hearing;

(b) Bring witnesses;

(c) Establish all pertinent facts and circumstances;

(d) Present an argument without undue interference; and

(e) Question or refute any testimony or evidence, including opportunity to confront and cross-examine adverse witnesses.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56506, Nov. 30, 1992]

§ 431.243 Parties in cases involving an eligibility determination.

If the hearing involves an issue of eligibility and the Medicaid agency is not responsible for eligibility determinations, the agency that is responsible for determining eligibility must participate in the hearing.

§ 431.244 Hearing decisions.

(a) Hearing recommendations or decisions must be based exclusively on evidence introduced at the hearing.

(b) The record must consist only of—

(1) The transcript or recording of testimony and exhibits, or an official report containing the substance of what happened at the hearing;

(2) All papers and requests filed in the proceeding; and

(3) The recommendation or decision of the hearing officer.

(c) The applicant or recipient must have access to the record at a convenient place and time.

(d) In any evidentiary hearing, the decision must be a written one that—

(1) Summarizes the facts; and

(2) Identifies the regulations supporting the decision.

(e) In a *de novo* hearing, the decision must—

(1) Specify the reasons for the decision; and

(2) Identify the supporting evidence and regulations.

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing; or

(ii) If permitted by the State, the date the enrollee filed for direct access to a State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO or PIHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PIHP—

(i) Meets the criteria for expedited resolution as set forth in §438.410(a) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) If the State agency permits direct access to a State fair hearing, as expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, directly from an MCO or PIHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in §438.410(a) of this chapter.

(g) The public must have access to all agency hearing decisions, subject to the requirements of subpart F of this part for safeguarding of information.

[44 FR 17932, Mar. 29, 1979, as amended at 67 FR 41095, June 14, 2002]

§ 431.245 Notifying the applicant or recipient of a State agency decision.

The agency must notify the applicant or recipient in writing of—

(a) The decision; and

(b) His right to request a State agency hearing or seek judicial review, to the extent that either is available to him.

§ 431.246 Corrective action.

The agency must promptly make corrective payments, retroactive to the date an incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility if—

(a) The hearing decision is favorable to the applicant or recipient; or

(b) The agency decides in the applicant's or recipient's favor before the hearing.

[57 FR 56506, Nov. 30, 1992]

FEDERAL FINANCIAL PARTICIPATION

§ 431.250 Federal financial participation.

FFP is available in expenditures for—

(a) Payments for services continued pending a hearing decision;

(b) Payments made—

(1) To carry out hearing decisions; and

(2) For services provided within the scope of the Federal Medicaid program and made under a court order.

(c) Payments made to take corrective action prior to a hearing;

(d) Payments made to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order;

(e) Retroactive payments under paragraphs (b), (c), and (d) of this section in accordance with applicable Federal policies on corrective payments; and

(f) Administrative costs incurred by the agency for—

(1) Transportation for the applicant or recipient, his representative, and witnesses to and from the hearing;

(2) Meeting other expenses of the applicant or recipient in connection with the hearing;

(3) Carrying out the hearing procedures, including expenses of obtaining the additional medical assessment specified in §431.240 of this subpart; and

(4) Hearing procedures for Medicaid and non-Medicaid individuals appealing transfers, discharges and determinations of preadmission screening and annual resident reviews under part 483, subparts C and E of this chapter.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980; 57 FR 56506, Nov. 30, 1992]

Subpart F—Safeguarding Information on Applicants and Recipients

SOURCE: 44 FR 17934, Mar. 29, 1979, unless otherwise noted.

§ 431.300 Basis and purpose.

(a) Section 1902(a)(7) of the Act requires that a State plan must provide

safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. This subpart specifies State plan requirements, the types of information to be safeguarded, the conditions for release of safeguarded information, and restrictions on the distribution of other information.

(b) Section 1137 of the Act, which requires agencies to exchange information in order to verify the income and eligibility of applicants and recipients (see § 435.940ff), requires State agencies to have adequate safeguards to assure that—

(1) Information exchanged by the State agencies is made available only to the extent necessary to assist in the valid administrative needs of the program receiving the information, and information received under section 6103(l) of the Internal Revenue Code of 1954 is exchanged only with agencies authorized to receive that information under that section of the Code; and

(2) The information is adequately stored and processed so that it is protected against unauthorized disclosure for other purposes.

[51 FR 7210, Feb. 28, 1986]

§ 431.301 State plan requirements.

A State plan must provide, under a State statute that imposes legal sanctions, safeguards meeting the requirements of this subpart that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan.

§ 431.302 Purposes directly related to State plan administration.

Purposes directly related to plan administration include—

(a) Establishing eligibility;

(b) Determining the amount of medical assistance;

(c) Providing services for recipients; and

(d) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the plan.

§ 431.303 State authority for safeguarding information.

The Medicaid agency must have authority to implement and enforce the provisions specified in this subpart for safeguarding information about applicants and recipients.

§ 431.304 Publicizing safeguarding requirements.

(a) The agency must publicize provisions governing the confidential nature of information about applicants and recipients, including the legal sanctions imposed for improper disclosure and use.

(b) The agency must provide copies of these provisions to applicants and recipients and to other persons and agencies to whom information is disclosed.

§ 431.305 Types of information to be safeguarded.

(a) The agency must have criteria that govern the types of information about applicants and recipients that are safeguarded.

(b) This information must include at least—

(1) Names and addresses;

(2) Medical services provided;

(3) Social and economic conditions or circumstances;

(4) Agency evaluation of personal information;

(5) Medical data, including diagnosis and past history of disease or disability; and

(6) Any information received for verifying income eligibility and amount of medical assistance payments (see § 435.940ff). Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data.

(7) Any information received in connection with the identification of legally liable third party resources under § 433.138 of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.306 Release of information.

(a) The agency must have criteria specifying the conditions for release and use of information about applicants and recipients.

(b) Access to information concerning applicants or recipients must be restricted to persons or agency representatives who are subject to standards of confidentiality that are comparable to those of the agency.

(c) The agency must not publish names of applicants or recipients.

(d) The agency must obtain permission from a family or individual, whenever possible, before responding to a request for information from an outside source, unless the information is to be used to verify income, eligibility and the amount of medical assistance payment under section 1137 of this Act and §§ 435.940 through 435.965 of this chapter.

If, because of an emergency situation, time does not permit obtaining consent before release, the agency must notify the family or individual immediately after supplying the information.

(e) The agency's policies must apply to all requests for information from outside sources, including governmental bodies, the courts, or law enforcement officials.

(f) If a court issues a subpoena for a case record or for any agency representative to testify concerning an applicant or recipient, the agency must inform the court of the applicable statutory provisions, policies, and regulations restricting disclosure of information.

(g) Before requesting information from, or releasing information to, other agencies to verify income, eligibility and the amount of assistance under §§ 435.940 through 435.965 of this chapter, the agency must execute data exchange agreements with those agencies, as specified in § 435.945(f).

(h) Before requesting information from, or releasing information to, other agencies to identify legally liable third party resources under § 433.138(d) of this chapter, the agency must execute data exchanges agreements, as specified in § 433.138(h)(2) of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.307 Distribution of information materials.

(a) All materials distributed to applicants, recipients, or medical providers must—

(1) Directly relate to the administration of the Medicaid program;

(2) Have no political implications except to the extent required to implement the National Voter Registration Act of 1993 (NVRA) Pub. L. 103–931; for States that are exempt from the requirements of NVRA, voter registration may be a voluntary activity so long as the provisions of section 7(a)(5) of NVRA are observed;

(3) Contain the names only of individuals directly connected with the administration of the plan; and

(4) Identify those individuals only in their official capacity with the State or local agency.

(b) The agency must not distribute materials such as ''holiday'' greetings, general public announcements, partisan voting information and alien registration notices.

(c) The agency may distribute materials directly related to the health and welfare of applicants and recipients, such as announcements of free medical examinations, availability of surplus food, and consumer protection information.

(d) Under NVRA, the agency must distribute voter information and registration materials as specified in NVRA.

[44 FR 17934, Mar. 29, 1979, as amended at 61 FR 58143, Nov. 13, 1996]

Subparts G–L [Reserved]

Subpart M—Relations With Other Agencies

§ 431.610 Relations with standard-setting and survey agencies.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in Medicaid; and

(2) Section 1902(a)(33) of the Act, concerning the designation of the State licensing agency to be responsible for determining whether institutions and agencies meet requirements for participation in the State's Medicaid program.

(3) Section 1919(g)(1)(A) of the Act, concerning responsibilities of the State for certifying the compliance of non-State operated NFs with requirements of participation in the State's Medicaid program.

(b) *Designated agency responsible for health standards.* A State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to Medicaid recipients, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in Medicare (see 42 CFR 405.1902). The requirement for establishing and maintaining standards does not apply with respect to religious nonmedical institutions as defined in §440.170(b) of this chapter.

(c) *Designated agency responsible for standards other than health standards.* The plan must designate the Medicaid agency or other appropriate State authority or authorities to be responsible for establishing and maintaining standards, other than those relating to health, for private or public institutions that provide services to Medicaid recipients.

(d) *Description and retention of standards.* (1) The plan must describe the standards established under paragraphs (b) and (c) of this section.

(2) The plan must provide that the Medicaid agency keeps these standards on file and makes them available to the Administrator upon request.

(e) *Designation of survey agency.* The plan must provide that—

(1) The agency designated in paragraph (b) of this section, or another State agency responsible for licensing health institutions in the State, determines for the Medicaid agency whether institutions and agencies meet the requirements for participation in the Medicaid program; and

(2) The agency staff making the determination under paragraph (e)(1) of this section is the same staff responsible for making similar determinations for institutions or agencies participating under Medicare; and

(3) The agency designated in paragraph (e)(1) of this section makes recommendations regarding the effective dates of provider agreements, as determined under §431.108.

(f) *Written agreement required.* The plan must provide for a written agreement (or formal written intra-agency arrangement) between the Medicaid agency and the survey agency designated under paragraph (e) of this section, covering the activities of the survey agency in carrying out its responsibilities. The agreement must specify that—

(1) Federal requirements and the forms, methods and procedures that the Administrator designates will be used to determine provider eligibility and certification under Medicaid;

(2) Inspectors surveying the premises of a provider will—

(i) Complete inspection reports;

(ii) Note on completed reports whether or not each requirement for which an inspection is made is satisfied; and

(iii) Document deficiencies in reports;

(3) The survey agency will keep on file all information and reports used in determining whether participating facilities meet Federal requirements; and

(4) The survey agency will make the information and reports required under paragraph (f)(3) of this section readily accessible to HHS and the Medicaid agency as necessary—

(i) For meeting other requirements under the plan; and

(ii) For purposes consistent with the Medicaid agency's effective administration of the program.

(g) *Responsibilities of survey agency.* The plan must provide that, in certifying NFs and ICFs/MR, the survey agency designated under paragraph (e) of this section will—

(1) Review and evaluate medical and independent professional review team reports obtained under part 456 of this subchapter as they relate to health and safety requirements;

(2) Have qualified personnel perform on-site inspections periodically as appropriate based on the timeframes in the correction plan and—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For non-State operated NFs, within the timeframes specified in § 488.308 of this chapter.

(3) Have qualified personnel perform on-site inspections—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For intermediate care facilities with deficiencies as described in §§ 442.112 and 442.113 of this subchapter, within 6 months after initial correction plan approval and every 6 months thereafter as required under those sections.

(h) *FFP for survey responsibilities.* (1) FFP is available in expenditures that the survey agency makes to carry out its survey and certification responsibilities under the agreement specified in paragraph (f) of this section.

(2) FFP is not available in any expenditures that the survey agency makes that are attributable to the State's overall responsibilities under State law and regulations for establishing and maintaining standards.

[43 FR 45188, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 53 FR 20494, June 3, 1988; 57 FR 43923, Sept. 23, 1992; 59 FR 56233, Nov. 10, 1994; 62 FR 43936, Aug. 18, 1997; 64 FR 67052, Nov. 30, 1999]

§ 431.615 Relations with State health and vocational rehabilitation agencies and title V grantees.

(a) *Basis and purpose.* This section implements section 1902(a)(11) and (22)(C) of the Act, by setting forth State plan requirements for arrangements and agreements between the Medicaid agency and—

(1) State health agencies;

(2) State vocational rehabilitation agencies; and

(3) Grantees under title V of the Act, Maternal and Child Health and Crippled Children's Services.

(b) *Definitions.* For purposes of this section—

''Title V grantee'' means the agency, institution, or organization receiving Federal payments for part or all of the cost of any service program or project authorized by title V of the Act, including—

(1) Maternal and child health services;

(2) Crippled children's services;

(3) Maternal and infant care projects;

(4) Children and youth projects; and

(5) Projects for the dental health of children.

(c) *State plan requirements.* A state plan must—

(1) Describe cooperative arrangements with the State agencies that administer, or supervise the administration of, health services and vocational rehabilitation services designed to make maximum use of these services;

(2) Provide for arrangements with title V grantees, under which the Medicaid agency will utilize the grantee to furnish services that are included in the State plan;

(3) Provide that all arrangements under this section meet the requirements of paragraph (d) of this section; and

(4) Provide, if requested by the title V grantee in accordance with the arrangements made under this section, that the Medicaid agency reimburse the grantee or the provider for the cost of services furnished recipients by or through the grantee.

(d) *Content of arrangements.* The arrangements referred to in paragraph (c) must specify, as appropriate—

(1) The mutual objectives and responsibilities or each party to the arrangement;

(2) The services each party offers and in what circumstances;

(3) The cooperative and collaborative relationships at the State level;

(4) The kinds of services to be provided by local agencies; and

(5) Methods for—

(i) Early identification of individuals under 21 in need of medical or remedial services;

(ii) Reciprocal referrals;

(iii) Coordinating plans for health services provided or arranged for recipients;

(iv) Payment or reimbursement;

(v) Exchange of reports of services furnished to recipients;

(vi) Periodic review and joint planning for changes in the agreements;

(vii) Continuous liaison between the parties, including designation of State and local liaison staff; and

(viii) Joint evaluation of policies that affect the cooperative work of the parties.

(e) *Federal financial participation.* FFP is available in expenditures for Medicaid services provided to recipients through an arrangement under this section.

§431.620 Agreement with State mental health authority or mental institutions.

(a) *Basis and purpose.* This section implements section 1902(a)(20)(A) of the Act, for States offering Medicaid services in institutions for mental diseases for recipients aged 65 or older, by specifying the terms of the agreement those States must have with other State authorities and institutions. (See part 441, subpart C of this chapter for regulations implementing section 1902(a)(20) (B) and (C).)

(b) *Definition.* For purposes of this section, an ''institution for mental diseases'' means an institution primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases. This includes medical attention, nursing care, and related services.

(c) *State plan requirement.* A State plan that includes Medicaid for persons aged 65 or older in institutions for mental diseases must provide that the Medicaid agency has in effect a written agreement with—

(1) The State authority or authorities concerned with mental diseases; and

(2) Any institution for mental diseases that is not under the jurisdiction of those State authorities, and that provides services under Medicaid to recipients aged 65 or older.

(d) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the authority or institution, including arrangements for—

(1) Joint planning between the parties to the agreement;

(2) Development of alternative methods of care;

(3) Immediate readmission to an institution when needed by a recipient who is in alternative care;

(4) Access by the agency to the institution, the recipient, and the recipient's records when necessary to carry out the agency's responsibilities;

(5) Recording, reporting, and exchanging medical and social information about recipients; and

(6) Other procedures needed to carry out the agreement.

[44 FR 17935, Mar. 23, 1979]

§431.621 State requirements with respect to nursing facilities.

(a) *Basis and purpose.* This section implements sections 1919(b)(3)(F) and 1919(e)(7) of the Act by specifying the terms of the agreement the State must have with the State mental health and mental retardation authorities concerning the operation of the State's preadmission screening and annual resident review (PASARR) program.

(b) *State plan requirement.* The State plan must provide that the Medicaid agency has in effect a written agreement with the State mental health and mental retardation authorities that meets the requirements specified in paragraph (c) of this section.

(c) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the State mental health and mental retardation authorities, including arrangements for—(1) Joint planning between the parties to the agreement;

(2) Access by the agency to the State mental health and mental retardation authorities' records when necessary to carry out the agency's responsibilities;

(3) Recording, reporting, and exchanging medical and social information about individuals subject to PASARR;

(4) Ensuring that preadmission screenings and annual resident reviews are performed timely in accordance with §§483.112(c) and 483.114(c) of this part;

(5) Ensuring that, if the State mental health and mental retardation authorities delegate their respective responsibilities, these delegations comply with §483.106(e) of this part;

(6) Ensuring that PASARR determinations made by the State mental

health and mental retardation authorities are not countermanded by the State Medicaid agency, except through the appeals process, but that the State mental health and mental retardation authorities do not use criteria which are inconsistent with those adopted by the State Medicaid agency under its approved State plan;

(7) Designating the independent person or entity who performs the PASARR evaluations for individuals with MI; and

(8) Ensuring that all requirements of §§ 483.100 through 483.136 are met.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 431.625 Coordination of Medicaid with Medicare part B.

(a) *Basis and purpose.* (1) Section 1843(a) of the Act requires the Secretary to have entered into an agreement with any State that requested that agreement before January 1, 1970, or during calendar year 1981, under which the State could enroll certain Medicare-eligible recipients under Medicare Part B and agree to pay their premiums.

(2) Section 1902(a)(10) of the Act (in clause (II) following subparagraph (D)), allows the State to pay the premium, deductibles, cost sharing, and other charges for recipients enrolled under Medicare Part B without obligating itself to provide the range of Part B benefits to other recipients; and

(3) Section 1903 (a)(1) and (b) of the Act authorizes FFP for State payment of Medicare Part B premiums for certain recipients.

(4) This section—

(i) Specifies the exception, relating to Part B coverage, from the requirement to provide comparable services to all recipients; and

(ii) Prescribes FFP rules concerning State payment for Medicare premiums and for services that could have been covered under Medicare.

(5) Section 1902(a)(15) of the Act requires that if a State chooses to pay only a portion of deductibles, cost sharing or other charges for recipients enrolled under Medicare Part B, the portion that is to be paid by a Medicaid recipient must be reasonably related to the recipient's income and resources.

(b) *Exception from obligation to provide comparable services; State plan requirement.* (1) The State's payment of premiums, deductibles, cost sharing, or similar charges under Part B does not obligate it to provide the full range of Part B services to recipients not covered by Medicare.

(2) The State plan must specify this exception if it applies.

(c) *Effect of payment of premiums on State liability for cost sharing.* (1) State payment of Part B premiums on behalf of a Medicaid recipient does not obligate it to pay on the recipient's behalf the Part B deductible and coinsurance amounts for those Medicare Part B services not covered in the Medicaid State plan.

(2) If a State pays on a recipient's behalf any portion of the deductible or cost sharing amounts under Medicare Part B, the portion paid by a State must be reasonably related to the recipient's income and resources.

(d) *Federal financial participation: Medicare Part B premiums*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, FFP is not available in State expenditures for Medicare Part B premiums for Medicaid recipients unless the recipients receive money payments under title I, IV-A, X, XIV, XVI (AABD or SSI) of the Act, or State supplements as permitted under section 1616(a) of the Act, or as required by section 212 of Pub. L. 93–66.

(2) *Exception.* FFP is available in expenditures for Medicare Part B premiums for the following groups:

(i) AFDC families required to be covered under §§ 435.112 and 436.116 of this subchapter, those eligible for continued Medicaid coverage despite increased income from employment;

(ii) Recipients required to be covered under §§ 435.114, 435.134, and 436.112 of this subchapter, those eligible for continued Medicaid coverage despite increased income from monthly insurance benefits under title II of the Act;

(iii) Recipients required to be covered under § 435.135 of this subchapter, those eligible for continued Medicaid coverage despite increased income from cost-of-living increases under title II of the Act;

(iv) Recipients of foster care maintenance payments or adoption assistance

payments who, under Part E of title IV of the Act are considered as receiving AFDC;

(v) Individuals required to be covered under §435.120 of this chapter, that is, blind or disabled individuals who, under section 1619(b) of the Act, are considered to be receiving SSI;

(vi) Individuals who, in accordance with §§435.115 and 436.114 of this chapter are, for purposes of Medicaid eligibility, considered to be receiving AFDC. These are participants in a work supplementation program, or individuals denied AFDC because the payment would be less than $10;

(vii) Certain recipients of Veterans Administration pensions during the limited time they are, under section 310(b) of Pub. L. 96–272, considered as receiving SSI, mandatory State supplements, or AFDC;

(viii) Disabled children living at home to whom the State provides Medicaid under section 1902(e)(3) of the Act;

(ix) Individuals who become ineligible for AFDC because of the collection or increased collection of child or spousal support, but, in accordance with section 406(h) of the Act, remain eligible for Medicaid for four more months; and

(x) Individuals who become ineligible for AFDC because they are no longer eligible for the disregard of earnings of $30 or of $30 plus one-third of the remainder, but, in accordance with section 402(a)(37) of the Act, are considered as receiving AFDC for a period of 9 to 15 months.

(3) No FFP is available in State Medicaid expenditures that could have been paid for under Medicare Part B but were not because the person was not enrolled in Part B. This limit applies to all recipients eligible for enrollment under Part B, whether individually or through an agreement under section 1843(a) of the Act. However, FFP is available in expenditures required by §§435.914 and 436.901 of this subchapter for retroactive coverage of recipients.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 17935, Mar. 23, 1979; 52 FR 47933, Dec. 17, 1987; 53 FR 657, Jan. 11, 1988]

§431.630 Coordination of Medicaid with QIOs.

(a) The State plan may provide for the review of Medicaid services through a contract with a QIO designated under Part 462 of this chapter. Medicaid requirements for medical and utilization review are deemed to be met for those services or providers subject to review under the contract.

(b) The State plan must provide that the contract with the QIO—

(1) Meets the requirements of §434.6(a) of this part;

(2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the QIO;

(3) Identifies the services and providers subject to QIO review;

(4) Ensures that the review activities performed by the QIO are not inconsistent with QIO review activities of Medicare services and includes a description of whether and to what extent QIO determinations will be considered conclusive for Medicaid payment purposes.

[50 FR 15327, Apr. 17, 1985]

§431.635 Coordination of Medicaid with Special Supplemental Food Program for Women, Infants, and Children (WIC).

(a) *Basis.* This section implements sections 1902(a)(11)(C) and 1902(a) (53) of the Act, which provide for coordination of Medicaid with the Special Supplemental Food Program for Women, Infants, and Children (WIC) under section 17 of the Child Nutrition Act of 1966.

(b) *Definitions.* As used in this section, the terms *breastfeeding women, postpartum women,* and *pregnant women* mean women as defined in section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786(b)).

(c) *State plan requirements.* A State Plan must provide for—

(1) Coordinating operation of the Medicaid program with the State's operation of the Special Supplemental Food Program for Women, Infants, and Children;

(2) Providing timely written notice of the availability of WIC benefits to all individuals in the State who are determined to be eligible (including presumptively eligible) for Medicaid and who are:

(i) Pregnant women;

(ii) Postpartum women;

(iii) Breastfeeding women; and

(iv) Children under the age of 5.

(3) Referring individuals described under paragraphs (c)(2) (i) through (iv) of this section to the local agency responsible for administering the WIC program.

(d) *Notification requirements.* (1) The agency must give the written notice required under paragraph (c) of this section as soon as the agency identifies the individual (e.g., at the time of an eligibility determination for Medicaid) or immediately thereafter (e.g., at the time of notice of eligibility).

(2) The agency, no less frequently than annually, must also provide written notice of the availability of WIC benefits, including the location and telephone number of the local WIC agency or instructions for obtaining further information about the WIC program, to all Medicaid recipients (including those found to be presumptively eligible) who are under age 5 or who are women who might be pregnant, postpartum, or breastfeeding as described in paragraphs (c)(2) (i) through (iv) of this section.

(3) The agency must effectively inform those individuals who are blind or deaf or who cannot read or understand the English language.

[57 FR 28103, June 24, 1992]

§ 431.636 Coordination of Medicaid with the Children's Health Insurance Program (CHIP).

(a) *Statutory basis.* This section implements—

(1) Section 2102(b)(3)(B) of the Act, which provides that children who apply for coverage under a separate child health plan under title XXI, but are found to be eligible for medical assistance under the State Medicaid plan, must be enrolled in the State Medicaid plan; and

(2) Section 2102(c)(2) of the Act, which requires coordination between a State child health program and other public health insurance programs.

(b) *Obligations of State Medicaid Agency.* The State Medicaid agency must adopt procedures to facilitate the Medicaid application process for, and the enrollment of children for whom the Medicaid application and enrollment process has been initiated in accordance with § 457.350(f) of this chapter. The procedures must ensure that—

(1) The applicant is not required to provide information or documentation that has been provided to the State agency responsible for determining eligibility under a separate child health program under title XXI and forwarded by such agency to the Medicaid agency on behalf of the child in accordance with § 457.350(f) of this chapter;

(2) Eligibility is determined in a timely manner in accordance with § 435.911 of this chapter;

(3) The Medicaid agency promptly notifies the State agency responsible for determining eligibility under a separate child health program when a child who was screened as potentially eligible for Medicaid is determined ineligible or eligible for Medicaid; and

(4) The Medicaid agency adopts a process that facilitates enrollment in a State child health program when a child is determined ineligible for Medicaid at initial application or redetermination.

[66 FR 2666, Jan. 11, 2001, as amended at 75 FR 48847, Aug. 11, 2010]

Subpart N—State Programs for Licensing Nursing Home Administrators

§ 431.700 Basis and purpose.

This subpart implements sections 1903(a)(29) and 1908 of the Act which require that the State plan include a State program for licensing nursing home administrators.

§ 431.701 Definitions.

Unless otherwise indicated, the following definitions apply for purposes of this subpart:

Agency means the State agency responsible for licensing individual practitioners under the State's healing arts licensing act.

Board means an appointed State board established to carry out a State program for licensing administrators of nursing homes, in a State that does not have a healing arts licensing act or an agency as defined in this section.

Licensed means certified by a State agency or board as meeting all of the requirements for a licensed nursing home administrator specified in this subpart.

Nursing home means any institution, facility, or distinct part of a hospital that is licensed or formally recognized as meeting nursing home standards established under State law, or that is determined under §431.704 to be included under the requirements of this subpart. The term does not include—

(a) A religious nonmedical institution as defined in §440.170(b) of this chapter; or

(b) A distinct part of a hospital, if the hospital meets the definition in §440.10 or §440.140 of this subchapter, and the distinct part is not licensed separately or formally approved as a nursing home by the State even though it is designated or certified as a skilled nursing facility.

Nursing home administrator means any person who is in charge of the general administration of a nursing home whether or not the person—

(a) Has an ownership interest in the home; or

(b) Shares his functions and duties with one or more other persons.

[43 FR 45188, Sept. 29, 1978, as amended at 64 FR 67052, Nov. 30, 1999]

§431.702 State plan requirement.

A State plan must provide that the State has a program for licensing administrators of nursing homes that meets the requirements of §§431.703 through 431.713 of this subpart.

§431.703 Licensing requirement.

The State licensing program must provide that only nursing homes supervised by an administrator licensed in accordance with the requirements of this subpart may operate in the State.

§431.704 Nursing homes designated by other terms.

If a State licensing law does not use the term ''nursing home,'' the CMS Administrator will determine the term or terms equivalent to ''nursing home'' for purposes of applying the requirements of this subpart. To obtain this determination, the Medicaid agency must submit to the Regional Medicaid Director copies of current State laws that define institutional health care facilities for licensing purposes.

§431.705 Licensing authority.

(a) The State licensing program must provide for licensing of nursing home administrators by—

(1) The agency designated under the healing arts act of the State; or

(2) A State licensing board.

(b) The State agency or board must perform the functions and duties specified in §§431.707 through 431.713 and the board must meet the membership requirements specified in §431.706 of this subpart.

§431.706 Composition of licensing board.

(a) The board must be composed of persons representing professions and institutions concerned with the care and treatment of chronically ill or infirm elderly patients. However—

(1) A majority of the board members may not be representative of a single profession or category of institution; and

(2) Members not representative of institutions may not have a direct financial interest in any nursing home.

(b) For purposes of this section, nursing home administrators are considered representatives of institutions.

§431.707 Standards.

(a) The agency or board must develop, impose, and enforce standards that must be met by individuals in order to be licensed as a nursing home administrator.

(b) The standards must be designed to insure that nursing home administrators are—

(1) Of good character;

(2) Otherwise suitable; and

(3) Qualified to serve because of training or experience in institutional administration.

§431.708 Procedures for applying standards.

The agency or board must develop and apply appropriate procedures and techniques, including examinations and investigations, for determining if a person meets the licensing standards.

§ 431.709 Issuance and revocation of license.

Except as provided in § 431.714 of this subpart, the agency or board must—

(a) Issue licenses to persons who meet the agency's or board's standards; and

(b) Revoke or suspend a license if the agency or board determines that the person holding the license substantially fails to meet the standards.

§ 431.710 Provisional licenses.

To fill a position of nursing home administrator that unexpectedly becomes vacant, the agency or board may issue one provisional license, for a single period not to exceed 6 months. The license may be issued to a person who does not meet all of the licensing requirements established under § 431.707 but who—

(a) Is of good character and otherwise suitable; and

(b) Meets any other standards established for provisional licensure by the agency or board.

§ 431.711 Compliance with standards.

The agency or board must establish and carry out procedures to insure that licensed administrators comply with the standards in this subpart when they serve as nursing home administrators.

§ 431.712 Failure to comply with standards.

The agency or board must investigate and act on all complaints it receives of violations of standards.

§ 431.713 Continuing study and investigation.

The agency or board must conduct a continuing study of nursing homes and administrators within the State to improve—

(a) Licensing standards; and

(b) The procedures and methods for enforcing the standards.

§ 431.714 Waivers.

The agency or board may waive any standards developed under § 431.707 of this subpart for any person who has served in the capacity of a nursing home administrator during all of the 3 calendar years immediately preceding the calendar year in which the State first meets the requirements in this subpart.

§ 431.715 Federal financial participation.

No FFP is available in expenditures by the licensing board for establishing and maintaining standards for the licensing of nursing home administrators.

Subpart O [Reserved]

Subpart P—Quality Control

GENERAL PROVISIONS

SOURCE: Sections 431.800 through 431.808 appear at 55 FR 22166, May 31, 1990, unless otherwise noted.

§ 431.800 Scope of subpart.

This subpart—

(a) Establishes State plan requirements for a Medicaid eligibility quality control (MEQC) program designed to reduce erroneous expenditures by monitoring eligibility determinations and a claims processing assessment system that monitors claims processing operations.

(b) Establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous Medicaid payments due to eligibility and recipient liability errors as detected through the MEQC program.

§ 431.802 Basis.

This subpart implements the following sections of the Act, which establish requirements for State plans and for payment of Federal financial participation (FFP) to States:

1902(a)(4) Administrative methods for proper and efficient operation of the State plan.

1903(u) Limitation of FFP for erroneous medical assistance expenditures.

§ 431.804 Definitions.

As used in this subpart—

Active case means an individual or family determined to be currently authorized as eligible for Medicaid by the agency.

Administrative period means the period of time recognized by the MEQC program for State agencies to reflect

changes in case circumstances, i.e., a change in a common program area, during which no case error based on the circumstance change would be cited. This period consists of the review month and the month prior to the review month.

Claims processing error means FFP has been claimed for a Medicaid payment that was made—

(1) For a service not authorized under the State plan;

(2) To a provider not certified for participation in the Medicaid program;

(3) For a service already paid for by Medicaid; or

(4) In an amount above the allowable reimbursement level for that service.

Eligibility error means that Medicaid coverage has been authorized or payment has been made for a recipient or family under review who—

(1) Was ineligible when authorized or when he received services; or

(2) Was eligible for Medicaid but was ineligible for certain services he received; or

(3) Had not met recipient liability requirements when authorized eligible for Medicaid; that is, he had not incurred medical expenses equal to the amount of his excess income over the State's financial eligibility level or he had incurred medical expenses that exceeded the amount of excess income over the State's financial eligibility level, or was making an incorrect amount of payment toward the cost of services.

Negative case action means an action that was taken to deny or otherwise dispose of a Medicaid application without a determination of eligibility (for instance, because the application was withdrawn or abandoned) or an action to deny, suspend, or terminate an individual or family.

State agency means either the State Medicaid agency or a State agency that is responsible for determining eligibility for Medicaid.

§431.806 State plan requirements.

(a) *MEQC program.* A State plan must provide for operating a Medicaid eligibility quality control program that meets the requirements of §§431.810 through 431.822 of this subpart.

(b) *Use of PERM data.* A State plan must provide for operating a Medicaid eligibility quality control program that is in accordance with §431.978 through §431.988 of this part to meet the requirements of §431.810 through §431.822 of this subpart when a State is in their PERM year.

(c) *Claims processing assessment system.* Except in a State that has an approved Medicaid Management Information System (MMIS) under subpart C of part 433 of this subchapter, a State plan must provide for operating a Medicaid quality control claims processing assessment system that meets the requirements of §§431.830 through 431.836 of this subpart.

[55 FR 22166, May 31, 1990, as amended at 75 FR 48847, Aug. 11, 2010]

§431.808 Protection of recipient rights.

Any individual performing activities under the MEQC program or the claims processing assessment system specified in this subpart must do so in a manner that is consistent with the provisions of §§435.902 and 436.901 of this subchapter concerning the rights of recipients.

MEDICAID ELIGIBILITY QUALITY CONTROL (MEQC) PROGRAM

SOURCE: Sections 431.810 through 431.822 appear at 55 FR 22167, May 31, 1990, unless otherwise noted.

§431.810 Basic elements of the Medicaid eligibility quality control (MEQC) program.

(a) *General requirements.* The agency must operate the MEQC program in accordance with this section and §§431.812 through 431.822 and other instructions established by CMS.

(b) *Review requirements.* The agency must conduct MEQC reviews in accordance with the requirements specified in §431.812 and other instructions established by CMS.

(c) *Sampling requirements.* The agency must conduct MEQC sampling in accordance with the requirements specified in §431.814 and other instructions established by CMS.

§ 431.812 Review procedures.

(a) *Active case reviews.* (1) Except as provided in paragraph (a)(2) of this section, the agency must review all active cases selected from the State agency's lists of cases authorized eligible for the review month, to determine if the cases were eligible for services during all or part of the month under review, and, if appropriate, whether the proper amount of recipient liability was computed.

(2) The agency is not required to conduct reviews of the following cases:

(i) Supplemental Security Income (SSI) recipient cases in States with contracts under section 1634 of the Act for determining Medicaid eligibility.

(ii) Foster care and adoption assistance cases under title IV-E of the Act found eligible for Medicaid.

(iii) Cases under programs that are 100 percent federally funded.

(b) *Negative case reviews.* Except as provided in paragraph (c) of this section, or unless a State is utilizing an approved sampling plan to conduct negative case action reviews under § 431.978(a) and § 431.980(b), the agency must review those negative cases selected from the State agency's list of cases that are denied, suspended, or terminated in the review month to determine if the reason for the denial, suspension, or termination was correct and if requirements for timely notice of negative action were met. A State's negative case sample size is determined on the basis of the number of negative case actions in the universe.

(iv) Individuals whose eligibility was determined under a State's option under section 1902(e)(13) of the Act.

(c) *Alternate systems of negative case reviews*—(1) *Basic provision.* A State may be exempt from the negative case review requirements specified in paragraphs (b) and (e)(2) of this section and in § 431.814(d) upon CMS's approval of a plan for the use of a superior system.

(2) *Submittal of plan for alternate system.* An agency must submit its plan for the use of a superior system to CMS for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit it. The agency must receive approval for a plan before it can be implemented.

(3) *Requirement for alternate system.* To be approved, the State's plan must—

(i) Clearly define the purpose of the system and demonstrate how the system is superior to the current negative case review requirements.

(ii) Contain a methodology for identifying significant problem areas that could result in erroneous denials, suspensions, and terminations of applicants and recipients. Problem areas selected for review must contain at least as many applicants and recipients as were included in the negative case sample size previously required for the State.

(iii) Provide a detailed methodology describing how the extent of the problem area will be measured through sampling and review procedures, the findings expected from the review, and planned corrective actions to resolve the problem.

(iv) Include documentation supporting the use of the system methodology. Documentation must include the timeframes under which the system will be operated.

(v) Provide a superior means of monitoring denials, terminations, and suspensions than that required under paragraph (b) of this section.

(vi) Provide a statistically valid error rate that can be projected to the universe that is being studied.

(d) *Reviews for erroneous payments.* The agency must review all claims for services furnished during the review month and paid within 4 months of the review month to all members of each active case related in the sample to identify erroneous payments resulting from—

(1) Ineligibility for Medicaid;

(2) Ineligibility for certain Medicaid services; and

(3) Recipient understated or overstated liability.

(e) *Reviews for verification of eligibility status.* The agency must collect and verify all information necessary to determine the eligibility status of each individual included in an active case selected in the sample as of the review month and whether Medicaid payments were for services which the individual was eligible to receive.

The agency must apply the administrative period described in §431.804 when considering the case circumstances and the case correctness. In order to verify eligibility information, the agency must—

(1) Examine and analyze each case record for all cases under review to establish what information is available for use in determining eligibility in the review month;

(2) Conduct field investigations including in-person recipient interviews for each case in the active case sample, and conduct in-person interviews only when the correctness of the agency action cannot be determined by review of the case record with recipients for cases in the negative case action sample (unless this is otherwise addressed in a superior system provided for in paragraph (c)(1) of this section);

(3) Verify all appropriate elements of eligibility for active cases through at least one primary source of evidence or two secondary sources of evidence as defined by CMS by documentation or by collateral contacts as required, or both, and fully record the information on the appropriate forms;

(4) Determine the basis on which eligibility was established and the eligibility status of the active case and each case member;

(5) Collect copies of State paid claims or recipient profiles for services delivered during the review month and, if indicated, any months prior to the review month in the agency's selected spenddown period, for all members of the active case under review;

(6) Associate dollar values with eligibility status for each active case under review; and

(7) Complete the payment, case, and review information for all individuals in the active case under review on the appropriate forms.

(f) *Substitution of PERM data.*

(1) A State in its Payment Error Rate Measurement (PERM) year may elect to substitute the random sample of selected cases, eligibility review findings, and payment review findings obtained through PERM reviews conducted in accordance with §431.978 through §431.988 of this part for data required in this section, if the only exclusions are those set forth in §431.978(d)(1) of this part.

(2) PERM cases cited as undetermined may be dropped when calculating MEQC error rates if reasons for drops are acceptable reasons listed in the State Medicaid Manual.

[55 FR 22167, May 31, 1990, as amended at 72 FR 50513, Aug. 31, 2007; 75 FR 48847, Aug. 11, 2010]

§431.814 Sampling plan and procedures.

(a) *Plan approval.* The agency must submit a basic MEQC sampling plan (or revisions to a current plan) that meets the requirements of this section to the appropriate CMS regional office for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit the entire plan. Universe estimates and sampling intervals are required 2 weeks before the first monthly sample selection for each review period. The agency must receive approval for a plan before it can be implemented.

(b) *Plan requirements.* The agency must have an approved sampling plan in effect for the full 6-month sampling period that includes the following:

(1) The population to be sampled;

(2) The list(s) from which the sample is selected and the following characteristics of the list(s):

(i) Sources;

(ii) All types of cases in the selection lists;

(iii) Accuracy and completeness of sample lists in reference to the population(s) of interest;

(iv) Whether or not the selection list was constructed by combining more than one list;

(v) The form of the selection list (whether the list or part of the list is automated);

(vi) Frequency and length of delays in updating the selection lists or their sources;

(vii) Number of items on the lists and proportion of listed-in-error items:

(viii) Methods of deleting unwanted items from the selection lists; and

(ix) Structure of the selection lists.

(3) The sample size, including the minimum number of reviews to be

completed and the expected number of cases to be selected. Minimum sample sizes are based on the State's relative level of Medicaid annual expenditures for services for active cases, and on the total number of negative case actions in the universe for negative cases. When the sample is substratified, there can be no fewer than 75 cases in each substratum, except as provided in paragraph (c) of this section or as provided in an exception documented in an approved sampling plan which contains a statement accepting the precision and reliability of the reduced sample.

(4) The sample selection procedure. Systematic random sampling is recommended. Alternative procedures must provide a representative sample, conform to principles of probability sampling, and yield estimates with the same or better precision than achieved in systematic random sampling.

(5) Procedures used to identify amounts paid for services received in the review month.

(6) Specification as to whether the agency chooses to—

(i) Use billed amounts to offset recipient liability toward cost of care (No indication will be interpreted to mean that the agency will use paid claims); and

(ii) Use denied claims to offset recipient liability toward cost of care in the payment review. (No indication will be interpreted to mean denied claims will not be used.)

(7) Indication of whether the agency opts to drop or complete cases selected more than once in a sample period. (No indication will be interpreted to mean that the agency will complete cases selected more than once.)

(c) *Eligibility universe—active cases.* The MEQC universe for active cases must be divided into two strata, the Aid to Families with Dependent Children (AFDC) stratum and the Medical Assistance Only (MAO) stratum.

(1) All States must use the AFDC quality control sample for the AFDC stratum.

(2) States must include in the MAO stratum all cases certified as eligible for Medicaid that are not in the AFDC stratum, excluding individuals specified in paragraph (c)(4) of this section.

(3) States that do not have an agreement with the Social Security Administration under section 1634 of the Act and do not have more restrictive eligibility criteria under section 1902(f) of the Act but require a separate Medicaid application for recipients of SSI and determine Medicaid eligibility using SSI criteria must divide the MAO stratum into two substrata: MAO cases and SSI cash cases for the first review period beginning after July 1, 1990 and for review periods thereafter. The SSI substratum sample size must be 75 cases or one-half of the total MAO sample, whichever is smaller. The non-SSI MAO substratum sample will be the remainder of the MAO stratum cases.

States may be exempt from this requirement when implementing an approved sampling option that does not accommodate this stratification method.

(4) States must exclude from the MEQC universe all of the following:

(i) SSI beneficiaries whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act.

(ii) Individuals in foster care or receiving adoption assistance whose eligibility is determined under Title IV–E of the Act.

(iii) Individuals receiving Medicaid under programs that are 100 percent Federally-funded.

(iv) Individuals whose eligibility was determined under a State's option for Express Lane Eligibility under section 1902(e)(13) of the Act.

(d) *Eligibility universe—negative cases.* Unless the agency has an approved superior system under § 431.812(c) that provides otherwise, the universe for negative Medicaid eligibility cases must consist of all denied applications, suspensions, and terminations occurring during the review month except transfers between counties without any break in eligibility, cases in which eligibility is exclusively determined by SSA under a section 1634 contract, cases determined eligible for foster care and adoption assistance under title IV-E of the Act, and cases under programs that are 100 percent federally funded.

(e) *Sampling procedures.* The agency must document all sampling procedures used by the State agency, including 98 percent accuracy of program identifier codes used in the sampling frame to separate listed-in-error cases from those in the population of interest, must make them available for review by CMS, and must be able to demonstrate the integrity of its sampling procedures in accordance with this section.

(f) *Sampling periods.* The agency must use 6-month sampling periods, from April through September and from October through March.

(g) *Statistical samples.* The agency must select statistically valid samples of both active and negative case actions.

(h) *Sample selection lists.* The agency must submit to CMS monthly a list of cases selected in the sample to be reviewed, after the State's sample selection and before commencing MEQC reviews on the cases in the sample.

(i) *Universe estimates and sampling intervals.* The agency must submit detailed universe estimates and sampling intervals to CMS for approval at least 2 weeks before the first sample selection of the review period if the estimates differ from the previous period. The sampling intervals must be used continuously throughout the sampling period unless otherwise specified in an approved sampling plan. Final universe counts based on the actual sampling universe must be determined and reported to CMS for each stratum/substratum designated in the sampling plan.

The agency also must submit universe counts for cases eligible for foster care and adoption assistance under title IV-E of the Act, and, for States with an agreement under section 1634 of the Act, for cases found eligible by the Social Security Administration.

(j) *Sample size and methodology options.* The agency may select a sample size in accordance with the minimum established under paragraph (b)(3) of this section or use one of the methodologies specified in paragraph (j)(1) or (2) of this section.

(1) *Increase in size.* The agency may, at its option, increase its sample size for a sampling period above the federally prescribed minimum sample size provided for under paragraph (b)(3) of this section, and receive FFP for any increased administrative costs the agency incurs by exercising this option.

(2) *Retrospective sampling.* The agency may, at its option, implement retrospective sampling in which cases are stratified by dollar value of claims paid. If the agency selects retrospective sampling, it must—

(i) Draw an initial case sample size each month that is no less than 5 times the required sample size. The sample will be selected from the universe of cases that were certified eligible in the fourth month prior to the month of case selection;

(ii) Identify claims paid for services furnished to all individuals during the review month (and, if indicated, any months prior to the review month in the agency's selected spenddown period) for these cases;

(iii) Stratify the cases by dollar value of the claims into three strata; and

(iv) Select a second statistically valid sample within each group subject to the sample size requirements specified in paragraph (b)(3) or (j)(1) of this section.

[55 FR 22166, May 31, 1990, as amended at 75 FR 48847, Aug. 11, 2010]

§431.816 Case review completion deadlines and submittal of reports.

(a) The agency must complete case reviews and submit reports of findings to CMS as specified in paragraph (b) of this section in the form and at the time specified by CMS.

(b) In addition to the reporting requirements specified in §431.814 relating to sampling, the agency must complete case reviews and submit reports of findings to CMS in accordance with paragraphs (b)(1) through (6) of this section for review periods beginning after July 1, 1990. The agency must not combine or otherwise integrate case findings from the MAO and AFDC strata to meet the case percentage deadlines as specified in paragraphs (b)(1) through (6) of this section.

(1) *Active case eligibility reviews—MAO stratum.* (i) The agency must complete case eligibility reviews and report the

findings electronically through the system prescribed by CMS for 90 percent of all active MAO cases within 105 days of the end of the review month for which those cases were reviewed, within 125 days for 95 percent of all active MAO cases, and within 150 days for 100 percent of all MAO active cases.

(ii) The agency must submit a report on cases selected for the review month.

(2) *Active case eligibility reviews—AFDC stratum.* (i) The agency must complete case eligibility reviews for AFDC ineligible and overpaid error cases caused by ineligible individuals and report the findings electronically through the system prescribed by CMS within 105 days of the end of the review month for which those cases were reviewed for 90 percent of the total reviews; within 125 days of the end of the review month for which those cases were reviewed for 95 percent of the total reviews; and within 150 days of the end of the review month for which those cases were reviewed for 100 percent of the total reviews.

(ii) The agency must report findings electronically through the system prescribed by CMS for 100 percent of the State agency-reported eligible individuals within 30 days after the final timeframe required by the AFDC program as specified in program regulations at 45 CFR 205.40(b)(2)(ii).

(3) *Negative case eligibility reviews.* The agency must submit a monthly progress report on negative case reviews completed during the month unless the agency has an approved superior system in effect. The agency must submit a report on its findings by June 30 of each year for the previous April-September sampling period and by December 31, for the October-March sampling period.

(4) *Payment reviews.* (i) The agency must submit payment review findings electronically through the system prescribed by CMS.

(ii) The agency must complete payment review findings for 100 percent of the active case reviews in its sample and report the findings within 60 days after the first day of the month in which the claims collection process begins. The agency must wait 5 months after the end of each review month before associating the amount of claims paid for each case for services furnished during the review month unless retrospective sampling is elected.

(iii) The agency must make any necessary corrections to claims payments during the month the claim is paid and the following month. CMS will take necessary action to reject any State adjustment adversely affecting the error rate, for example, by not paying claims on error cases.

(5) *Summary of reviews and findings.* The agency must submit summary reports of the findings for all active cases in the 6-month sample by July 31 of each year for the previous April-September sampling period and by January 31 for the October-March sampling period. These summary reports must include findings changed in the Federal re-review process.

(6) *Other data and reports.* The agency must report other requested data and reports in a manner prescribed by CMS.

§ 431.818 Access to records: MEQC program.

(a) The agency, upon written request, must mail to the HHS staff all records, including complete local agency eligibility case files or legible copies and all other documents pertaining to its MEQC reviews to which the State has access, including information available under part 435, subpart I, of this chapter.

(b) The agency must mail requested records within 10 working days of receipt of a request, unless the State has an alternate method of submitting these records that is approved by CMS or has received, on an as-needed basis, approval from CMS to extend this timeframe by 3 additional working days to allow for exceptional circumstances.

§ 431.820 Corrective action under the MEQC program.

The agency must—

(a) Take action to correct any active or negative case action errors found in the sample cases;

(b) Take administrative action to prevent or reduce the incidence of those errors; and

(c) By September 15 each year, submit to CMS a report on its error rate analysis and a corrective action plan

based on that analysis. The agency must submit revisions to the plan within 60 days of identification of additional error-prone areas, other significant changes in the error rate (that is, changes that the State experiences that increase or decrease its error rate and necessitate immediate corrective action or discontinuance of corrective actions that effectively control the cause of the error rate change), or changes in planned corrective action.

§431.822 Resolution of differences in State and Federal case eligibility or payment findings.

(a) When a difference exists between State and Federal case eligibility or payment findings, the Regional Office will notify the agency by a difference letter.

(b) The agency must return the difference letter to the Regional Office within 28 calendar days of the date of the letter indicating either agreement with the Federal finding or reasons for disagreement and if the agency desires a conference to resolve the difference. This period may be shortened if the Regional Office finds that it is necessary to do so in order to meet a case completion deadline, and the State still has a reasonable period of time in which to respond to the letter. If the agency fails to submit the difference letter indicating its agreement or disagreement with the Federal findings within the 28 calendar days (or the shorter period designated as described above), the Federal findings will be sustained.

(c) If the Regional Office disagrees with the agency's response, a difference conference will be scheduled within 20 days of the request of the agency. If a difference cannot be resolved, the State may request a direct presentation of its position to the Regional Administrator. The Regional Administrator has final authority for resolving the difference.

MEDICAID QUALITY CONTROL (MQC) CLAIMS PROCESSING ASSESSMENT SYSTEM

SOURCE: Sections 431.830 through 431.836 appear at 55 FR 22170, May 31, 1990, unless otherwise noted.

§431.830 Basic elements of the Medicaid quality control (MQC) claims processing assessment system.

An agency must—

(a) Operate the MQC claims processing assessment system in accordance with the policies, sampling methodology, review procedures, reporting forms, requirements, and other instructions established by CMS.

(b) Identify deficiencies in the claims processing operations.

(c) Measure cost of deficiencies;

(d) Provide data to determine appropriate corrective action;

(e) Provide an assessment of the State's claims processing or that of its fiscal agent;

(f) Provide for a claim-by-claim review where justifiable by data; and

(g) Produce an audit trail that can be reviewed by CMS or an outside auditor.

§431.832 Reporting requirements for claims processing assessment systems.

(a) The agency must submit reports and data specified in paragraph (b) of this section to CMS, in the form and at the time specified by CMS.

(b) Except when CMS authorizes less stringent reporting, States must submit:

(1) A monthly report on claims processing reviews sampled and or claims processing reviews completed during the month;

(2) A summary report on findings for all reviews in the 6-month sample to be submitted by the end of the 3rd month following the scheduled completion of reviews for that 6 month period; and

(3) Other data and reports as required by CMS.

§431.834 Access to records: Claims processing assessment systems.

The agency, upon written request, must provide HHS staff with access to all records pertaining to its MQC claims processing assessment system reviews to which the State has access, including information available under part 435, subpart J, of this chapter.

§431.836 Corrective action under the MQC claims processing assessment system.

The agency must—

(a) Take action to correct those errors identified through the claims processing assessment system review and, if cost effective, to recover those funds erroneously spent;

(b) Take administrative action to prevent and reduce the incidence of those errors; and

(c) By August 31 of each year, submit to CMS a report of its error analysis and a corrective action plan on the reviews conducted since the cut-off-date of the previous corrective action plan.

FEDERAL FINANCIAL PARTICIPATION

§§ 431.861–431.864 [Reserved]

§ 431.865 Disallowance of Federal financial participation for erroneous State payments (for annual assessment periods ending after July 1, 1990).

(a) *Purpose and applicability*—

(1) *Purpose.* This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical assistance payments due to eligibility and beneficiary liability errors, as detected through the Medicaid eligibility quality control (MEQC) program required under § 431.806 in effect on and after July 1, 1990.

(2) *Applicability*. This section applies to all States except Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa beginning July 1, 1990.

(b) *Definitions.* For purposes of this section—

Administrator means the Administrator, Centers for Medicare & Medicaid Services or his or her designee.

Annual assessment period means the 12-month period October 1 through September 30 and includes two 6-month sample periods (October-March and April-September).

Beneficiary liability means—

(1) The amount of excess income that must be offset with incurred medical expenses to gain eligibility; or

(2) The amount of payment a recipient must make toward the cost of services.

Erroneous payments means the Medicaid payment that was made for an individual or family under review who—

(1) Was ineligible for the review month or, if full month coverage is not provided, at the time services were received;

(2) Was ineligible to receive a service provided during the review month; or

(3) Had not properly met enrollee liability requirements prior to receiving Medicaid services.

(4) The term does not include payments made for care and services covered under the State plan and furnished to children during a presumptive eligibility period as described in § 435.1102 of this chapter.

National mean error rate means the payment weighted average of the eligibility payment error rates for all States.

National standard means a 3-percent eligibility payment error rate.

State payment error rate means the ratio of erroneous payments for medical assistance to total expenditures for medical assistance (less payments to Supplemental Security Income beneficiaries in section 1634 contract States and payments for children eligible for foster care and adoption assistance under title IV-E of the Act) for cases under review under the MEQC system for each assessment period.

Technical error means an error in an eligibility condition that, if corrected, would not result in a difference in the amount of medical assistance paid. These errors include work incentive program requirements, assignment of social security numbers, the requirement for a separate Medicaid application, monthly reporting requirements, assignment of rights to third party benefits, and failure to apply for benefits for which the family or individual is not eligible. Errors other than those listed in this definition, identified by CMS in subsequent instructions, or approved by CMS are not technical errors.

(c) *Setting of State's payment error rate.* (1) Each State must, for each annual assessment period, have a payment error rate no greater than 3 percent or be subject to a disallowance of FFP.

(2) A payment error rate for each State is determined by CMS for each annual assessment period by computing the statistical estimate of the

ratio of erroneous payments for medical assistance made on behalf of individuals or cases in the sample for services received during the review month to total expenditures for medical assistance for that State made on behalf of individuals or cases in the sample for services received during the review month. This ratio incorporates the findings of a federally re-reviewed subsample of the State's review findings and is projected to the universe of total medical assistance payments for calculating the amount of disallowance under paragraph (d)6) of this section.

(3) The State's payment error rate does not include payments made on behalf of individuals whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act or children found eligible for foster care and adoption assistance under title IV-E of the Act.

(4) The amount of erroneous payments is determined as follows:

(i) For ineligible cases resulting from excess resources, the amount of error is the lesser of—

(A) The amount of the payment made on behalf of the family or individual for the review month; or

(B) The difference between the actual amount of countable resources of the family or individual for the review month and the State's applicable resources standard.

(ii) For ineligible cases resulting from other than excess resources, the amount of error is the total amount of medical assistance payments made for the individual or family under review for the review month.

(iii) For erroneous payments resulting from failure to properly meet beneficiary liability, the amount of error is the lesser of—

(A) The amount of payments made on behalf of the family or individual for the review month; or

(B) The difference between the correct amount of beneficiary liability and the amount of beneficiary liability met by the individual or family for the review month.

(iv) The amount of payments made for services provided during the review month for which the individual or family was not eligible.

(5) In determining the amount of erroneous payments, errors caused by technical errors are not included.

(6) If a State fails to cooperate in completing a valid MEQC sample or individual reviews in a timely and appropriate fashion as required, CMS will establish the State's payment error rate based on either—

(i) A special sample or audit;

(ii) The Federal subsample; or

(iii) Other arrangements as the Administrator may prescribe.

(7) When it is necessary for CMS to exercise the authority in paragraph (c)(6) of this section, the amount that would otherwise be payable to the State under title XIX of the Act is reduced by the full costs incurred by CMS in making these determinations. CMS may make these determinations either directly or under contractual or other arrangements.

(d) *Computation of anticipated error rate.* (1) Before the beginning of each quarter, CMS will project the anticipated medical assistance payment error rate for each State for that quarter. The anticipated error rate is the lower of the weighted average error rate of the two most recent 6-month review periods or the error rate of the most recent 6-month review period. In either case, cases in the review periods must have been completed by the State and CMS. If a State fails to provide CMS with information needed to project anticipated excess erroneous expenditures, CMS will assign the State an error rate as prescribed in paragraph (c)(6) of this section.

(2) If the State believes that the anticipated error rate established in accordance with paragraph (d)(1) of this section is based on erroneous data, the State may submit evidence that demonstrates the data were erroneous. If the State satisfactorily demonstrates that CMS's data were erroneous, the State's anticipated error rate will be adjusted accordingly. Submittal of evidence is subject to the following conditions:

(i) The State must inform CMS of its intent to submit evidence at least 70 days prior to the beginning of the quarter.

(ii) The State may request copies of data that CMS used to compute its anticipated error rate within 7 days of receiving notification of its projected error rate.

(iii) The State has up to 40 days before the quarter begins to present the evidence.

(iv) The evidence is restricted to documentation of suspected CMS data entry errors, processing errors, and resolutions of Federal subsample difference cases subsequent to calculation of the error rate projection as contained in the original notice to the State.

(v) The State may not submit other evidence, such as that consisting of revisions to State errors as a result of changes to the original State review findings submitted to CMS.

(vi) The State may not submit evidence challenging the error rate computational methodology.

(3) Based on the anticipated error rate established in paragraph (d)(1) or (d)(2) of this section, CMS reduces its estimate of the State's requirements for FFP for medical assistance for the quarter by the percentage by which the anticipated payment error rate exceeds the 3-percent national standard. This reduction is applied against CMS's total estimate of FFP for medical assistance expenditures (less payments to Supplemental Security Income beneficiaries in 1634 contract States and payments to children found eligible for foster care and adoption assistance under title IV-E of the Act) prior to any other required reductions. The reduction is noted on the State's grant award for the quarter and does not constitute a disallowance, and, therefore, is not appealable.

(4) After the end of each quarter, an adjustment to the reduction will be made based on the State's actual expenditures.

(5) After the actual payment error rate has been established for each annual assessment period, CMS will compute the actual amount of the disallowance and adjust the FFP payable to each State based on the difference between the amounts previously withheld for each of the quarters during the appropriate assessment period and the amount that should have been withheld based on the State's actual final error rate. If CMS determines that the amount withheld for the period exceeds the amount of the actual disallowance, the excess amount withheld will be returned to the States through the normal grant awards process within 30 days of the date the actual disallowance is calculated.

(6) CMS will compute the amount to be withheld or disallowed as follows:

(i) Subtract the 3-percent national standard from the State's anticipated or actual payment error rate percentage.

(ii) If the difference is greater than zero, the Federal medical assistance funds for the period, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, are multiplied by that percentage. This product is the amount of the disallowance or withholding.

(7) A State's payment error rate for an annual assessment period is the weighted average of the payment error rates in the two 6-month review periods comprising the annual assessment period.

(8) The weights are established as the percent of the total annual payments, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, that occur in each of the 6-month periods.

(e) *Notice to States and showing of good faith.* (1) When the actual payment error rate data are finalized for each annual assessment period ending after July 1, 1990, CMS will establish each State's error rate and the amount of any disallowance. States that have error rates above the national standard will be notified by letter of their error rates and the amount of the disallowance.

(i) The State has 65 days from the date of receipt of this notification to show that this disallowance should not

be made because it failed to meet the national standard despite a good faith effort to do so.

(ii) If CMS is satisfied that the State did not meet the national standard despite a good faith effort, CMS may reduce the funds being disallowed in whole or in part as it finds appropriate under the circumstances shown by the State.

(iii) A finding that a State did not meet the national standard despite a good faith effort will be limited to extraordinary circumstances.

(iv) The burden of establishing that a good faith effort was made rests entirely with the State.

(2) Some examples of circumstances under which CMS may find that a State did not meet the national standard despite a good faith effort are—

(i) Disasters such as fire, flood, or civil disorders that—

(A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration; or

(B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes;

(iii) Sudden and unanticipated workload changes that result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6-month period;

(iv) State actions resulting from incorrect written policy interpretations to the State by a Federal official reasonably assumed to be in a position to provide that interpretation; and

(v) The State has taken the action it believed was needed to meet the national standard, but the national standard was not met. CMS will consider request for a waiver under this criterion only if a State has achieved an error rate for the sample period that (after reducing the error rate by taking into account the cases determined by CMS to be in error as a result of conditions listed in paragraphs (e)(2) (i) through (iv) of this section) is less than its error rate for the preceding sample year and does not exceed the national mean error rate for the sample period under review (unless that national mean error rate is at or below the 3-percent national standard). If the agency has met this error reduction requirement or had error rates of 3 percent or below for the prior two review periods, and its error rate for the review period under consideration is less than one-third above the national standard, CMS will evaluate a request for a good faith waiver based on the following factors:

(A) The State has fully met the performance standards in the operation of a quality control system in accordance with Federal regulations and CMS guidelines (e.g., adherence to Federal case completion timeliness requirements and verification standards).

(B) The State has achieved substantial performance in the formulation of error reduction initiatives based on the following processes:

(*1*) Performance of an accurate and thorough statistical and program analysis for error reduction which utilized quality control and other data:

(*2*) The translation of such analysis into specific and appropriate error reduction practices for major error elements; and

(*3*) The use of monitoring systems to verify that the error reduction initiatives were implemented at the local office level.

(C) The State has achieved substantial performance in the operation of the following systems supported by evidence of the timely utilization of their outputs in the determination of case eligibility:

(*1*) The operation of the Income and Eligibility Verification System in accordance with the requirements of parts 431 and 435 of this chapter, and

(*2*) The operation of systems that interface with Social Security data and, where State laws do not restrict agency access, records from agencies responsible for motor vehicles, vital statistics, and State or local income and property taxes (where these taxes exist).

(D) The State has achieved substantial performance in the use of the following accountability mechanisms to ensure that agency staff adhere to

error reduction initiatives. The following are minimum requirements:

(*1*) Accuracy of eligibility and liability determinations and timely processing of case actions are used as quantitative measures of employee performance and reflected in performance standards and appraisal forms:

(*2*) Selective second-party case reviews are conducted. The second-party review results are periodically reported to higher level management, as well as supervisors and workers and are used in performance standards and appraisal forms; and

(*3*) Regular operational reviews of local offices are performed by the State to evaluate the offices' effectiveness in meeting error reduction goals with periodic monitoring to ensure that review recommendations have been implemented.

(vi) A State that meets the performance standards specified in paragraphs (e)(2)(v) (A) through (D) of this section will be considered for a full or partial waiver of its disallowance amount. The State must submit only specific documentation that verifies that the necessary actions were accomplished. For example, a State could submit worker performance standards reflecting timeliness and case accuracy as quantitative measures of performance.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources is not a basis for finding that a State failed to meet the national standard despite a good faith effort.

(f) *Disallowance subject to appeal.* (1) If a State does not agree with a disallowance imposed under paragraph (e) of this section, it may appeal to the Departmental Appeals Board within 30 days from the date of the final disallowance notice from CMS. The regular procedures for an appeal of a disallowance will apply, including review by the Appeals Board under 45 CFR part 16.

(2) This appeal provision, as it applies to MEQC disallowances, is not applicable to the Administrator's decision on a State's waiver request provided for under paragraph (e) of this section.

[55 FR 22171, May 31, 1990, as amended at 61 FR 38398, July 24, 1996; 66 FR 2666, Jan. 11, 2001]

Subpart Q—Requirements for Estimating Improper Payments in Medicaid and CHIP

SOURCE: 71 FR 51081, Aug. 28, 2006, unless otherwise noted.

§ 431.950 Purpose.

This subpart requires States and providers to submit information necessary to enable the Secretary to produce national improper payment estimates for Medicaid and the Children's Health Insurance Program (CHIP).

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48847, Aug. 11, 2010]

§ 431.954 Basis and scope.

(a) *Basis.* The statutory bases for this subpart are as follows:

(1) Sections 1102, 1902(a)(6), and 2107(b)(1) of the Act, which contain the Secretary's general rulemaking authority and obligate States to provide information, as the Secretary may require, to monitor program performance.

(2) The Improper Payments Information Act of 2002 (Pub. L. 107–300), which requires Federal agencies to review and identify annually those programs and activities that may be susceptible to significant erroneous payments, estimate the amount of improper payments, report such estimates to the Congress, and submit a report on actions the agency is taking to reduce erroneous payments.

(3) Section 1902(a)(27)(B) of the Act requires States to require providers to agree to furnish the State Medicaid agencies and the Secretary with information regarding payments claimed by Medicaid providers for furnishing Medicaid services.

(4) Section 601 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3) which requires that the new PERM regulations include the following: Clearly defined criteria for errors for both States and providers; Clearly defined processes for appealing error determinations; clearly defined responsibilities and deadlines for States in implementing any corrective action plans; requirements for State

verification of an applicant's self-declaration or self-certification of eligibility for, and correct amount of, medical assistance under Medicaid or child health assistance under CHIP; and State-specific sample sizes for application of the PERM requirements.

(b) *Scope.* (1) This subpart requires States under the statutory provisions cited in paragraph (a) of this section to submit information as set forth in §431.970 for, among other purposes, estimating improper payments in the fee-for-service (FFS) and managed care components of the Medicaid and CHIP programs and to determine whether eligibility was correctly determined. This subpart also requires providers to submit to the Secretary any medical records and other information necessary to disclose the extent of services provided to individuals receiving assistance, and to furnish information regarding any payments claimed by the provider for furnishing such services, as requested by the Secretary.

(2) All information must be furnished in accordance with section 1902(a)(7)(A) of the Act, regarding confidentiality.

(3) This subpart does not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands or American Samoa.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48847, Aug. 11, 2010]

§431.958 Definitions and use of terms.

Active case means a case containing information on a beneficiary who is enrolled in the Medicaid or CHIP program in the month that eligibility is reviewed.

Active fraud investigation means a beneficiary or a provider has been referred to the State Medicaid Fraud Control Unit or similar Federal or State investigative entity including a Federal oversight agency and the unit is currently actively pursuing an investigation to determine whether the beneficiary or the provider committed health care fraud. This definition applies to both the claims and eligibility review for PERM.

Adjudication date means either the date on which money was obligated to pay a claim or the date the decision was made to deny a claim.

Agency means, for purposes of the PERM eligibility reviews under this part, the entity that performs the Medicaid and CHIP eligibility reviews under PERM and excludes the State Medicaid or CHIP agency as defined in the regulation.

Annual sample size means the number of fee-for-service claims, managed care payments, or eligibility cases necessary to meet precision requirements in a given PERM cycle.

Application means an application form for Medicaid or CHIP benefits deemed complete by the State, with respect to which such State approved or denied eligibility.

Beneficiary means an applicant for, or recipient of, Medicaid or CHIP program benefits.

Case means an individual beneficiary or family enrolled in Medicaid or CHIP or who has been denied enrollment or has been terminated from Medicaid or CHIP. The case as a sampling unit only applies to the eligibility component.

Case error rate means an error rate that reflects the number of cases in error in the eligibility sample for the active cases plus the number of cases in error in the eligibility sample for the negative cases expressed as a percentage of the total number of cases examined in the sample.

Case record means either a hardcopy or electronic file that contains information on a beneficiary regarding program eligibility.

Children's Health Insurance Program (CHIP) means the program authorized and funded under Title XXI of the Act.

Eligibility means meeting the State's categorical and financial criteria for receipt of benefits under the Medicaid or CHIP programs.

Improper payment means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and includes any payment to an ineligible recipient, any duplicate payment, any payment for services not received, any payment incorrectly denied, and any payment that does not account for credits or applicable discounts.

Last action means the most recent date on which the State agency took action to grant, deny, or terminate program benefits based on the State agency's eligibility determination; and is the point in time for the PERM eligibility reviews unless the last action occurred outside of 12 months prior to the sample month.

Medicaid means the joint Federal and State program, authorized and funded under Title XIX of the Act, that provides medical care to people with low incomes and limited resources.

Negative case means a case containing information on a beneficiary who applied for benefits and was denied or whose program benefits were terminated, based on the State agency's eligibility determination or on a completed redetermination.

Payment means any payment to a provider, insurer, or managed care organization for a Medicaid or CHIP beneficiary for which there is Medicaid or CHIP Federal financial participation. It may also mean a direct payment to a Medicaid or CHIP beneficiary in limited circumstances permitted by CMS regulation or policy.

Payment error rate means an annual estimate of improper payments made under Medicaid and CHIP equal to the sum of the overpayments and underpayments in the sample, that is, the absolute value of such payments, expressed as a percentage of total payments made in the sample.

Payment review means the process by which payments for services are associated with cases reviewed for eligibility. Payments are collected for services received in the review month or in the sample month, depending on the case reviewed.

PERM means the Payment Error Rate Measurement process to measure improper payment in Medicaid and CHIP.

Provider means any qualified provider recognized under Medicaid and CHIP statute and regulations.

Provider error includes, but is not limited to, medical review errors as described in § 431.960(c) of this subpart, as determined in accordance with documented State or Federal policies or both.

Review cycle means the complete timeframe to complete the improper payments measurement including the fiscal year being measured; generally this timeframe begins in October of the fiscal year reviewed and ends in August of the following fiscal year.

Review month means the month in which eligibility is reviewed and is usually when the State took its last action to grant or redetermine eligibility. If the State's last action was taken beyond 12 months prior to the sample month, the review month shall be the sample month.

Review year means the Federal fiscal year being analyzed for errors by Federal contractors or the State.

Sample month means the month the State selects a case from the sample for an eligibility review.

State agency means the State agency that is responsible for determining program eligibility for Medicaid and CHIP, as applicable, based on applications and redeterminations.

State error includes, but is not limited to, data processing errors and eligibility errors as described in § 431.960(b) and (d) of this subpart, as determined in accordance with documented State or Federal policies or both.

States means the 50 States and the District of Columbia.

Undetermined means a beneficiary case subject to a Medicaid or CHIP eligibility determination under this regulation about which a definitive determination of eligibility could not be made.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48847, Aug. 11, 2010]

§ 431.960 Types of payment errors.

(a) *General rule.* State or provider errors identified for the Medicaid and CHIP improper payments measurement under the Improper Payments Information Act of 2002 must affect payment under applicable Federal policy or State policy or both.

(b) *Data processing errors.*

(1) A data processing error is an error resulting in an overpayment or underpayment that is determined from a review of the claim and other information available in the State's Medicaid

Management Information System, related systems, or outside sources of provider verification.

(2) The difference in payment between what the State paid (as adjusted within improper payment measurement guidelines) and what the State should have paid, in accordance with the State's documented policies, is the dollar measure of the payment error.

(3) Data processing errors include, but are not limited to the following:

(i) Payment for duplicate items.

(ii) Payment for non-covered services.

(iii) Payment for fee-for-service claims for managed care services.

(iv) Payment for services that should have been paid by a third party but were inappropriately paid by Medicaid or CHIP.

(v) Pricing errors.

(vi) Logic edit errors.

(vii) Data entry errors.

(viii) Managed care rate cell errors.

(ix) Managed care payment errors.

(c) *Medical review errors.* (1) A medical review error is an error resulting in an overpayment or underpayment that is determined from a review of the provider's medical record or other documentation supporting the service(s) claimed, Code of Federal Regulations that are applicable to conditions of payment, the State's written policies, and a comparison between the documentation and written policies and the information presented on the claim.

(2) The difference in payment between what the State paid (as adjusted within improper payment measurement guidelines) and what the State should have paid, in accordance with 42 CFR 440 to 484.55 of the Code of Federal Regulations that are applicable to conditions of payment and the State's documented policies, is the dollar measure of the payment error.

(3) Medical review errors include, but are not limited to the following:

(i) Lack of documentation.

(ii) Insufficient documentation.

(iii) Procedure coding errors.

(iv) Diagnosis coding errors.

(v) Unbundling.

(vi) Number of unit errors.

(vii) Medically unnecessary services.

(viii) Policy violations.

(ix) Administrative errors.

(d) *Eligibility errors.*

(1) An eligibility error includes, but is not limited to, errors determined by applying Federal rules and the State's documented policies and procedures, resulting from services being provided to an individual who meets at least one of the following provisions:

(i) Was ineligible when authorized as eligible or when he or she received services.

(ii) Was eligible for the program but was ineligible for certain services he or she received.

(iii) Lacked or had insufficient documentation in his or her case record, in accordance with the State's documented policies and procedures, to make a definitive review decision of eligibility or ineligibility.

(iv) Overpaid the assigned liability due to the individual's liability being understated.

(v) Underpaid toward assigned liability due to the individual's liability being overstated.

(vi) Was ineligible for managed care but enrolled in managed care.

(vii) Was eligible for managed care but improperly enrolled in the incorrect managed care plan.

(2) The dollars paid in error due to the eligibility error is the measure of the payment error.

(3) A State eligibility error does not result from the State's verification of an applicant's self-declaration or self-certification of eligibility for, and the correct amount of, medical assistance or child health assistance, if the State process for verifying an applicant's self-declaration or self-certification satisfies the requirements in Federal law, guidance, or if applicable, Secretary approval.

(4) Negative case errors are errors, based on the State's documented policies and procedures, resulting from either of the following:

(i) Applications for Medicaid or CHIP that are improperly denied by the State.

(ii) Existing cases that are improperly terminated from Medicaid or CHIP by the State.

(5) No payment errors are associated with negative cases.

(e) *Errors for purposes of determining the national error rates.* The Medicaid

and CHIP national error rates include but are not limited to the errors described in paragraphs (b) through (d) of this section, with the exception of negative case errors described in paragraph (d)(4) of this section.

(f) *Errors for purposes of determining the State error rates.* The Medicaid and CHIP State error rates include but are not limited to, the errors described in paragraphs (b) through (d)(1)(vii) of this section, with the exception of negative case errors as described in paragraph (d)(4) of this section.

(g) *Error codes.* CMS may define different types of errors within the above categories for analysis and reporting purposes. Only dollars in error will factor into a State's PERM error rate.

[75 FR 48848, Aug. 11, 2010]

§ 431.970 Information submission requirements.

(a) States must submit information to the Secretary for, among other purposes, estimating improper payments in Medicaid and CHIP, that include but are not limited to—

(1) Adjudicated fee-for-service (FFS) or managed care claims information or both, on a quarterly basis, from the review year;

(2) Upon request from CMS, provider contact information that has been verified by the State as current;

(3) All medical and other related policies in effect and any quarterly policy updates;

(4) Current managed care contracts, rate information, and any quarterly updates applicable to the review year for CHIP and, as requested, for Medicaid;

(5) Data processing systems manuals;

(6) Repricing information for claims that are determined during the review to have been improperly paid;

(7) Information on claims that were selected as part of the sample, but changed in substance after selection, for example, successful provider appeals;

(8) Adjustments made within 60 days of the adjudication dates for the original claims or line items with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items;

(9) For the eligibility improper payment measurement, information as set forth in § 431.978 through § 431.988;

(10) A corrective action plan for purposes of reducing erroneous payments in FFS, managed care, and eligibility; and

(11) Other information that the Secretary determines is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and CHIP.

(b) Providers must submit information to the Secretary for, among other purposes estimating improper payments in Medicaid and CHIP, which include but are not limited to, Medicaid and CHIP beneficiary medical records within 75 calendar days of the date the request is made by CMS. If CMS determines that the documentation is insufficient, providers must respond to the request for additional documentation within 14 calendar days of the date the request is made by CMS.

[71 FR 51081, Aug. 28, 2006, as amended at 72 FR 50513, Aug. 31, 2007; 75 FR 48848, Aug. 11, 2010]

§ 431.972 Claims sampling procedures.

(a) *Claims universe.*

(1) The PERM claims universe includes payments that were originally paid (paid claims) and for which payment was requested but denied (denied claims) during the FFY, and for which there is FFP (or would have been if the claim had not been denied) through Title XIX (Medicaid) or Title XXI (CHIP).

(2) The State must establish controls to ensure FFS and managed care universes are accurate and complete, including comparing the FFS and managed care universes to the Form CMS–64 and Form CMS–21 as appropriate.

(b) *Sample size.* CMS estimates a State's annual sample size for claims review at the beginning of the PERM cycle.

(1) *Precision and confidence levels.* The annual sample size should be estimated to achieve a State-level error rate within a 3 percent precision level at 95 percent confidence interval for the claims component of the PERM program, unless the precision requirement is waived by CMS on its own initiative.

(2) *Base year sample size.* The annual sample size in a State's first PERM cycle (the ''base year'') is—

(i) Five hundred fee-for-service claims and 250 managed care payments drawn from the claims universe; or

(ii) If the claims universe of fee-for-service claims or managed care capitation payments from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(3) *Subsequent year sample size.* In PERM cycles following the base year:

(i) CMS considers the error rate from the State's previous PERM cycle to determine the State's annual sample size for the current PERM cycle.

(ii) The maximum sample size is 1,000 fee-for-service or managed care payments, respectively.

(iii) If a State measured in the FY 2007 or FY 2008 cycle elects to reject its State-specific CHIP PERM rate determined during those cycles, information from those cycles will not be used to calculate its annual sample size in subsequent PERM cycles and the State's annual sample size in its base year is 500 fee-for-service and 250 managed care payments.

[75 FR 48849, Aug. 11, 2010]

§431.974 Basic elements of Medicaid and CHIP eligibility reviews.

(a) *General requirements.* (1) States selected in any given year for Medicaid and CHIP improper payments measurement under the Improper Payments Information Act of 2002 must conduct reviews of a statistically valid random sample of beneficiary cases for such programs to determine if improper payments were made based on errors in the State agency's eligibility determinations.

(2) The agency and personnel responsible for the development, direction, implementation, and evaluation of the eligibility reviews and associated activities, including calculation of the error rates under this section, must be functionally and physically separate from the State agencies and personnel that are responsible for Medicaid and CHIP policy and operations, including eligibility determinations.

(3) Any individual performing activities under this section must do so in a manner that is consistent with the provisions of §435.901, concerning the rights of recipients.

(b) *Sampling requirements.* The State must have in effect a CMS-approved sampling plan for the review year in accordance with the requirements specified in §431.978.

(c) *Review requirements.* The State must conduct eligibility reviews in accordance with the requirements specified in §431.980.

§431.978 Eligibility sampling plan and procedures.

(a) *Plan approval.* For each review year, the agency must—

(1) Submit its Medicaid or CHIP sampling plan (or revisions to a current plan) for both active and negative cases to CMS for approval by the August 1 before the review year; and

(2) Have its sampling plan approved by CMS before the plan is implemented.

(b) *Maintain current plan.* The agency must do both of the following:

(1) Keep its plan current, for example, by making adjustments to the plan when necessary due to fluctuations in the universe.

(2) Review its plan each review year. If it is determined that the approved plan is—

(i) Unchanged from the previous review year, the agency must notify CMS that it is using the plan from the previous review year; or

(ii) Changed from the previous review year, the agency must submit a revised plan for CMS approval.

(c) *Sample size.*

(1) *Precision and confidence levels.* Annual sample size for eligibility reviews should be estimated to achieve within a 3 percent precision level at 95 percent confidence interval for the eligibility component of the program.

(2) *Base year sample size.* Annual sample size for each State's base year of PERM is—

(i) Five hundred four active cases and 204 negative cases drawn from the active and negative universes; or

(ii) If the active case universe or negative case universe of Medicaid or

CHIP beneficiaries from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(3) *Subsequent year sample size.* In PERM cycles following the base year the annual sample size may increase or decrease based on the State's prior results of the previous cycle PERM error rate information. The State may provide information to CMS in the eligibility sampling plan due to CMS by the August 1 prior to the start of the review year to support the calculation of a reduced annual sample size for the next PERM cycle.

(i) CMS considers the error rate from the State's previous PERM cycle to determine the State's annual sample size for the current PERM cycle.

(ii) The maximum sample size is 1,000 for the active cases and negative cases, respectively.

(iii) If the active case universe or negative case universe of Medicaid or CHIP beneficiaries from which the annual sample is drawn is less than 10,000, the State may request to reduce its sample size by the finite population correction factor for the relevant PERM cycle.

(iv) If a State measured in the FY 2007 or FY 2008 cycle elects to reject its PERM CHIP rate as determined during those cycles, information from those cycles is not used to calculate the State's sample size in subsequent PERM cycles and the State's sample size in its base year is 504 active cases and 204 negative cases.

(d) *Sample selection.* The sample must be stratified in accordance with § 431.978(d)(3). Cases must be selected each month throughout the fiscal year under review. Each month throughout the year and before commencing the eligibility reviews, States must submit to CMS a monthly sample selection list that identifies the cases selected in that month.

(1) *Eligibility universe-active cases*—(i) *Medicaid.* (A) The Medicaid active universe consists of all active Medicaid cases funded through Title XIX for the sample month.

(B) The following types of cases are excluded from the Medicaid active universe:

(*1*) Cases for which the Social Security Administration, under section 1634 of the Act agreement with a State, determines Medicaid eligibility for Supplemental Security Income recipients.

(*2*) All foster care and adoption assistance cases under Title IV–E of the Act are excluded from the universe in all States.

(*3*) Cases under active fraud investigation.

(*4*) Cases in which eligibility was determined under section 1902(e)(13) of the Act for States' Express Lane Eligibility option.

(C) If the State cannot identify cases that meet the exclusion criteria specified in paragraph (d)(1)(i)(B) of this section before sample selection, the State must drop these cases from review if they are selected in the sample and are later determined to meet the exclusion criteria specified in paragraph (d)(1)(i)(B) of this section.

(ii) *CHIP.* (A) The CHIP active universe consists of all active case CHIP and Title XXI Medicaid expansion cases that are funded through Title XXI for the sample month.

(B) The following types of cases are excluded from the CHIP active universe:

(*1*) Cases under active fraud investigation.

(*2*) Cases in which eligibility was determined under section 2107(e)(1) of the Act for States' Express Lane Eligibility option.

(C) If the State cannot identify cases that meet the exclusion criteria specified in paragraph (d)(1)(ii)(B) of this section before sample selection, the State must drop these cases from review if it is later determined that the cases meet the exclusion criteria specified in paragraph (d)(1)(ii)(B) of this section.

(2) *Eligibility universe—negative cases.* The Medicaid and CHIP negative universe consists of all negative cases for the sample month. The negative case universe is not stratified.

(3) *Stratifying the universe.* States have the option to stratify the active case universe.

(i) Each month, the State may stratify the Medicaid and CHIP active case universe into three strata:

(A) Program applications completed by the beneficiaries in which the State took action in the sample month to approve such beneficiaries for Medicaid or CHIP based on the eligibility determination.

(B) Redeterminations of eligibility in which the State took action in the sample month to approve the beneficiaries for Medicaid or CHIP based on information obtained through a completed redetermination.

(C) All other cases.

(ii) States that do not stratify the universe will sample from the entire active case universe each month.

(4) *Sample selection.* Each month, an equal number of cases are selected for review from one of the following:

(i) Each stratum as described in paragraph (d)(3)(i) of this section.

(ii) The entire active case universe if opting not to stratify cases under paragraph (d)(2)(ii) of this section.

(iii) Otherwise provided for in the State's sampling plan approved by CMS.

[71 FR 51081, Aug. 28, 2006, as amended at 72 FR 50513, Aug. 31, 2007; 75 FR 48849, Aug. 11, 2010]

§431.980 Eligibility review procedures.

(a) *Active case reviews.* The agency must verify eligibility for all selected active cases for Medicaid and CHIP for the review month for compliance with the State's eligibility criteria.

(b) *Negative case reviews.* The agency must review all selected negative cases for Medicaid and CHIP for the review month to determine whether the cases were properly denied or terminated.

(c) *Payment review.* The agency must identify all Medicaid and CHIP payments made for services furnished, either in the first 30 days of eligibility or in the review month for applications under §431.978(d)(3)(i) and redeterminations under §431.978(d)(3)(ii) in accordance to State policy or from the sample month for all other cases under §431.978(d)(3)(iii), to identify erroneous payments resulting from ineligibility for services or for the program.

(d) *Eligibility review decision*—(1) *Active cases—Medicaid.* Unless the State has selected to substitute MEQC data for PERM data under paragraph (f) of this section, the agency must complete all of the following:

(i) Review the cases specified at §§431.978(d)(3)(i)(A) and 431.978(d)(3)(i)(B) of this subpart in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the review month and identify payments made on behalf of such beneficiary or family for services received in the first 30 days of eligibility.

(ii) For cases specified in §431.978(d)(3)(i)(C) of this subpart, review the last action as follows:

(A) If the last action was not more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the last action and identify payments made on behalf of such beneficiary or family in the first 30 days of eligibility.

(B) If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the sample month and identify payments made on behalf of the beneficiary or family for services received in the sample month.

(iii) For cases in States that do not stratify the universe, as specified in §431.978(d)(3)(ii) of this subpart, review the last action as follows:

(A) If the last action was no more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria and documented policies and procedures as of the last action and identify payments made on behalf of such beneficiary or family for services received in the sample month.

(B) If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria, and documented policies and procedures, as of the sample month and identify payments made on behalf of the beneficiary or family for services received in the sample month.

(C) Cases that are not stratified must have the last action identified as either

falling under the criteria of § 431.978(d)(3)(i)(A) or § 431.978(d)(3)(i)(B) of this subpart after the sample is selected.

(iv) Examine the evidence in the case file that supports categorical and financial eligibility for the category of coverage in which the case is assigned, and independently verify information that is missing, outdated (older than 12 months) and likely to change, or otherwise as needed, to verify eligibility.

(v) For managed care cases, also verify residency and eligibility for and actual enrollment in the managed care plan during the month under review.

(vi) Elements of eligibility in which State policy allows for self-declaration or self-certification are considered to be verified with a self-declaration or self-certification statement. The self-declaration or self-certification must be—

(A) Present in the record;

(B) Not outdated (more than 12 months old);

(C) Originating from the last case action that was not more than 12 months prior to the sample month;

(D) In a valid, State-approved format; and

(E) Consistent with other facts in the case record.

(vii) If a self-declaration or self-certification statement does not meet the provisions of paragraphs (e)(1)(vi)(A) through (D) of this section, eligibility may be verified through a new self-declaration or self-certification statement or other third party sources.

(A) If eligibility or ineligibility cannot be verified, cite a case as undetermined.

(ix) As a result of paragraphs (e)(1)(i) through (e)(1)(vii) of this section—

(A) Cite the case as eligible or ineligible based on the review findings and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month, or sample month, as appropriate; or

(B) Cite the case as undetermined if after due diligence an eligibility determination could not be made and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month or sample month, as appropriate.

(2) *Active cases—CHIP.* In addition to the procedures for active cases as set forth in paragraphs (e)(1)(i) through (e)(1)(vii) of this section, the agency must verify that the case is not eligible for Medicaid by determining that the child has income above the Medicaid levels in accordance with the requirements in § 457.350 of this chapter. Upon verification, the agency must—

(e) *Negative cases—Medicaid and CHIP.* The agency must—

(1) Identify the reason the State agency determined ineligibility;

(2) Examine the evidence in the case file to determine whether the State agency's denial or termination was correct or whether there is any reason the case should have been denied or terminated; and

(i) Record the State agency's finding as correct if the case record review substantiates that the individual was not eligible; or

(ii) Record the case as an error if there is no valid reason for the denial or termination.

(f) *Substitution of MEQC data.* (1) A State in their PERM year may elect to substitute the random sample of selected cases, eligibility review findings, and payment review findings, as qualified by paragraphs (d)(2) and (d)(3) of this section, which are obtained through MEQC reviews conducted in accordance with section 1903(u) of the Act for data required in this section, as long as the State MEQC reviews meet the requirements of the MEQC Sampling Plan and Procedures at § 431.814 of this part, and if the only exclusions are those set forth in section 1902(e)(13) of the Act, § 431.814(c)(4), and § 431.978(d)(1) of this part.

(2) MEQC samples must also meet PERM confidence and precision requirements.

(3) MEQC cases that are dropped due to the acceptable reasons listed in the State Medicaid Manual are included in the PERM error rate calculation.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48850, Aug. 11, 2010]

§431.988 Eligibility case review completion deadlines and submittal of reports.

(a)(1) States must complete and report to CMS the findings, including total number of cases in the eligibility universe, the error causes for all case reviews listed on the monthly sample selection lists, including cases dropped from review due to active fraud investigations, and cases for which eligibility could not be determined.

(2) States must submit a summary report of the active case eligibility and payment review findings to CMS by July 1 following the review year.

(b) The agency must report by July 1 following the review year, information as follows:

(1) Case and payment error data for active cases.

(2) Case error data for negative cases.

(3) Identify the last action on a case, either application or redetermination for States that do not stratify the eligibility sample in accordance with §431.978(d)(3)(i) of this subpart.

(4) The number and amounts of undetermined cases in the sample and the total amount of payments from all undetermined cases.

(5) The number of cases dropped from review due to active fraud investigations.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48851, Aug. 11, 2010]

§431.992 Corrective action plan.

(a) The State agency must develop a separate corrective action plan for Medicaid and CHIP, which is not required to be approved by CMS, designed to reduce improper payments in each program based on its analysis of the error causes in the FFS, managed care, and eligibility components.

(b) In developing a corrective action plan, the State must take the following actions:

(1) *Data analysis.* States must conduct data analysis such as reviewing clusters of errors, general error causes, characteristics, and frequency of errors that are associated with improper payments.

(2) *Program analysis.* States must review the findings of the data analysis to determine the specific programmatic causes to which errors are attributed (for example, provider lack of understanding of the requirement to provide documentation) and to identify root error causes.

(3) *Corrective action planning.* States must determine the corrective actions to be implemented that address the root error causes.

(4) *Implementation and monitoring.*

(i) States must develop an implementation schedule for each corrective action initiative and implement those actions in accordance with the schedule.

(ii) The implementation schedule must identify all of the following:

(A) Major tasks.

(B) Key personnel responsible for each activity.

(C) A timeline for each action including target implementation dates, milestones, and monitoring.

(5) *Evaluation.* States must evaluate the effectiveness of the corrective action by assessing all of the following:

(i) Improvements in operations.

(ii) Efficiencies.

(iii) Number of errors.

(iv) Improper payments.

(c) The State agency must submit to CMS and implement the corrective action plan for the fiscal year it was reviewed no later than 90 calendar days after the date on which the State's Medicaid or CHIP error rates are posted on the CMS contractor's Web site.

(d) The State must submit to CMS a new corrective action plan for each subsequent error rate measurement that contains an update on the status of a previous corrective action plan. Items to address in the new corrective action plan include, but are not limited to the following:

(1) Effectiveness of implemented corrective actions, as assessed using objective data sources.

(2) Discontinued or ineffective actions, actions not implemented, and those actions, if any, that were substituted for such discontinued, ineffective, or abandoned actions.

(3) Findings on short-term corrective actions.

(4) The status of the long-term corrective actions.

[75 FR 48851, Aug. 11, 2010]

§ 431.998 Difference resolution and appeal process.

(a) The State may file, in writing, a request with the Federal contractor to resolve differences in the Federal contractor's findings based on medical or data processing reviews on FFS and managed care claims in Medicaid or CHIP within 20 business days after the disposition report of claims review findings is posted on the contractor's Web site. The State must complete all of the following:

(1) Have a factual basis for filing the difference.

(2) Provide the Federal contractor with valid evidence directly related to the error finding to support the State's position that the claim was properly paid.

(b) For a claim in which the State and the Federal contractor cannot resolve the difference in findings, the State may appeal to CMS for final resolution, filing the appeal within 10 business days from the date the contractor's finding as a result of the difference resolution is posted on the contractor's Web site. There is no minimum dollar threshold required to appeal a difference in findings.

(c) For eligibility error determinations made by the agency with personnel functionally and physically separate from the State Medicaid and CHIP agencies with personnel that are responsible for Medicaid and CHIP policy and operations, the State may appeal error determinations by filing an appeal request.

(1) *Filing an appeal request.* The State may—

(i) File its appeal request with the appropriate State agency or entity; or

(ii) If no appeals process is in place at the State level, differences in findings—

(A) Must be documented in writing and submitted directly to the agency responsible for the PERM eligibility review for its consideration;

(B) May be resolved through document exchange facilitated by CMS, whereby CMS will act as intermediary by receiving the written documentation supporting the State's appeal from the State agency and submitting that documentation to the agency responsible for the PERM eligibility review; or

(C) Any unresolved differences may be addressed by CMS between the final month of payment data submission and error rate calculation.

(2) *After the filing of an appeals request.* (i) Any changes in error findings must be reported to CMS by the deadline for submitting final eligibility review findings.

(ii) Any appeals of determinations based on interpretations of Federal policy may be referred to CMS.

(iii) CMS's eligibility error resolution decision is final.

(iv) If CMS's or the State-level appeal board's decision causes an erroneous payment finding to be made, if the final adjudicated claim is actually a payment error in accordance with documented State policies and procedures, any resulting recoveries are governed by § 431.1002 of this subchapter.

(d) All differences, including those pending in CMS for final decision that are not resolved in time to be included in the error rate calculation, will be considered as errors for meeting the reporting requirements of the IPIA. Upon State request, CMS will calculate a subsequent State-specific error rate that reflects any reversed disposition of the unresolved claims.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48851, Aug. 11, 2010]

§ 431.1002 Recoveries.

(a) *Medicaid.* States must return to CMS the Federal share of overpayments based on medical and processing errors in accordance with section 1903(d)(2) of the Act and related regulations at part 433, subpart F of this chapter. Payments based on erroneous Medicaid eligibility determinations are addressed under section 1903(u) of the Act and related regulations at part 431, subpart P of this chapter.

(b) *CHIP.* Quarterly Federal payments to the States under Title XXI of the Act must be reduced in accordance with section 2105(e) of the Act and related regulations at part 457, subpart B of this chapter.

PART 432—STATE PERSONNEL ADMINISTRATION

Subpart A—General Provisions

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

SOURCE: 43 FR 45199, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§432.1 Basis and purpose.

This part prescribes regulations to implement section 1902(a)(4) of the Act, which relates to a merit system of State personnel administration and training and use of subprofessional staff and volunteers in State Medicaid programs, and section 1903(a), rates of FFP for Medicaid staffing and training costs. It also prescribes regulations, based on the general administrative authority in section 1902(a)(4), for State training programs for all staff.

§432.2 Definitions.

As used in this part—

Community service aides means subprofessional staff, employed in a variety of positions, whose duties are an integral part of the agency's responsibility for planning, administration, and for delivery of health services.

Directly supporting staff means secretarial, stenographic, and copying personnel and file and records clerks who provide clerical services that directly support the responsibilities of skilled professional medical personnel, who are directly supervised by the skilled professional medical personnel, and who are in an employer-employee relationship with the Medicaid agency.

Fringe benefits means the employer's share of premiums for workmen's compensation, employees' retirement, unemployment compensation, health insurance, and similar expenses.

Full-time training means training that requires employees to be relieved of all responsibility for performance of current agency work to participate in a training program.

Part-time training means training that allows employees to continue full-time in their agency jobs or requires only partial reduction of work activities to participate in the training activity.

Skilled professional medical personnel means physicians, dentists, nurses, and other specialized personnel who have professional education and training in the field of medical care or appropriate medical practice and who are in an employer-employee relationship with the Medicaid agency. It does not include other nonmedical health professionals such as public administrators, medical analysts, lobbyists, senior managers or administrators of public assistance programs or the Medicaid program.

Staff of other public agencies means skilled professional medical personnel and directly supporting staff who are employed in State or local agencies other than the Medicaid agency who perform duties that directly relate to the administration of the Medicaid program.

Subprofessional staff means persons performing tasks that demand little or no formal education; a high school diploma; or less than 4 years of college.

Supporting staff means secretarial, stenographic, clerical, and other subprofessional staff whose activities are directly necessary to the carrying out of the functions which are the responsibility of skilled professional medical personnel, as defined in this section.

Training program means a program of educational activities based on the agency's training needs and aimed at insuring that agency staff acquire the knowledge and skills necessary to perform their jobs.

Volunteer means a person who contributes personal service to the community through the agency's program but is not a replacement or substitute for paid staff.

[43 FR 45199, Sept. 29, 1978, as amended at 50 FR 46663, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 432.10 Standards of personnel administration.

(a) *State plan requirement.* A State plan must provide that the requirements of paragraphs (c) through (h) of this section are met.

(b) *Terms.* In this section, ''standards'' refer to those specified in paragraph (c) of this section.

(c) *Methods of personnel administration.* Methods of personnel administration must be established and maintained, in the Medicaid agency and in local agencies administering the propgram, in conformity with:

(1) [Reserved]

(2) 5 CFR part 900, subpart F, Administration of the Standards for Merit System of Personnel Administration.

(d) *Compliance of local jurisdictions.* The Medicaid agency must have in effect methods to assure compliance with the standards by local jurisdictions included in the plan.

(e) *Review and adequacy of State laws, regulations, and policies.* The agency must—

(1) Assure that the U.S. Civil Service Commission has determined the adequacy of current State laws, regulations, and policy statements that effect methods of personnel administration in conformity with the standards, and

(2) Submit any changes in them to the Commission for review.

(f) *Statements of acceptance by local agencies.* If the Medicaid agency changes from a State-administered to a State-supervised, locally administered program, it must obtain statements of acceptance of the standards from the local agencies.

(g) *Affirmative action plan.* The Medicaid agency must have in effect an affirmative action plan for equal employment opportunity, that includes specific action steps and timetables to assure that opportunity, and meets all other requirements of 45 CFR 70.4.[1]

(h) *Submittal of requested materials.* The Medicaid agency must submit to HHS, upon request, copies of the affirmative action plan and of the State and local materials that assure compliance with the standards.

[43 FR 45199, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

Subpart B—Training Programs; Subprofessional and Volunteer Programs

§ 432.30 Training programs: General requirements.

(a) A State plan must provide for a program of training for Medicaid agency personnel. (See also §§ 432.31 and 432.32 for training programs for subprofessional staff and for volunteers.)

(b) The program must—

(1) Include initial inservice training for newly appointed staff, and continuing training opportunities to improve the operation of the program;

(2) Be related to job duties performed or to be performed by the persons trained; and

(3) Be consistent with the program objectives of the agency.

§ 432.31 Training and use of subprofessional staff.

(a) *State plan requirement.* A State plan must provide for the training and effective use of subprofessional staff as community service aides, in accordance with the requirements of this section.

(b) *Recruitment and selection.* The Medicaid agency must have methods of recruitment and selection that afford opportunity for full-time or part-time employment of persons of low income, including:

(1) Young, middle-aged, and older persons;

(2) Physically and mentally disabled; and

(3) Recipients.

(c) *Merit system.* Subprofessional positions must be subject to merit system

[1] Editorial Note: The regulations formerly contained in 45 CFR 70.4 were revised and reissued by the Office of Personnel Management at 5 CFR Part 900, (Subpart F).

requirements except where special exemption is approved on the basis of a State alternative plan for employment of disadvantaged persons.

(d) *Staffing plan.* The agency staffing plan must include the kinds of jobs that subprofessional staff can perform.

(e) *Career service.* The agency must have a career service program that allows persons:

(1) To enter employment at the subprofessional level; and

(2) To progress to positions of increasing responsibility and reward:

(i) In accordance with their abilities; and

(ii) Through work experience and preservice and in-service training.

(f) *Training, supervision and supportive services.* The agency must have an organized training program, supervision, and supportive services for subprofessional staff.

(g) *Progressive expansion.* The agency must provide for annual increase in the number of subprofessional staff until:

(1) An appropriate ratio of subprofessional and professional staff has been achieved; and

(2) There is maximum use of subprofessional staff as community aides in the operation of the program.

§ 432.32 Training and use of volunteers.

(a) *State plan requirement.* A State plan must provide for the training and use of non-paid or partially paid volunteers in accordance with the requirements of this section.

(b) *Functions of volunteers.* The Medicaid agency must make use of volunteers in:

(1) Providing services to applicants and recipients; and

(2) Assisting any advisory committees established by the agency.

As used in this paragraph, ''partially paid volunteers'' means volunteers who are reimbursed only for actual expenses incurred in giving service, without regard to the value of the service or the time required to provide it.

(c) *Staffing.* The agency must designate a position whose incumbent is responsible for:

(1) The development, organization, and administration of the volunteer program; and

(2) Coordination of the program with related functions.

(d) *Recruitment, selection, training, and supervision.* The agency must have:

(1) Methods of recruitment and selection that assure participation of volunteers of all income levels, in planning capacities and service provision; and

(2) A program of organized training and supervision of volunteers.

(e) *Reimbursement of expenses.* The agency must—

(1) Reimburse volunteers for actual expenses incurred in providing services; and

(2) Assure that no volunteer is deprived of the opportunity to serve because of the expenses involved.

(f) *Progressive expansion.* The agency must provide for annual increase in the number of volunteers used until the volunteer program is adequate for the achievement of the agency's service goals.

Subpart C—Staffing and Training Expenditures

§ 432.45 Applicability of provisions in subpart.

The rates of FFP specified in this subpart C do not apply to State personnel who conduct survey activities and certify facilities for participation in Medicaid, as provided for under section 1902(a)(33)(B) of the Act.

[50 FR 46663, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 432.50 FFP: Staffing and training costs.

(a) *Availability of FFP.* FFP is available in expenditures for salary or other compensation, fringe benefits, travel, per diem, and training, at rates determined on the basis of the individual's position, as specified in paragraph (b) of this section.

(b) *Rates of FFP.* (1) For skilled professional medical personnel and directly supporting staff of the Medicaid agency or of other public agencies (as defined in § 432.2), the rate is 75 percent.

(2) For personnel engaged directly in the operation of mechanized claims processing and information retrieval systems, the rate is 75 percent.

(3) For personnel engaged in the design, development, or installation of

mechanized claims processing and information retrieval systems, the rate is 50 percent for training and 90 percent for all other costs specified in paragraph (a) of this section.

(4) [Reserved]

(5) For personnel administering family planning services and supplies, the rate is 90 percent.

(6) For all other staff of the Medicaid agency or other public agencies providing services to the Medicaid agency, and for training and other expenses of volunteers, the rate is 50 percent.

(c) *Application of rates.* (1) FFP is prorated for staff time that is split among functions reimbursed at different rates.

(2) Rates of FFP in excess of 50 percent apply only to those portions of the individual's working time that are spent carrying out duties in the specified areas for which the higher rate is authorized.

(3) The allocation of personnel and staff costs must be based on either the actual percentages of time spent carrying out duties in the specified areas, or another methodology approved by CMS.

(d) *Other limitations for FFP rate for skilled professional medical personnel and directly supporting staff*—(1) *Medicaid agency personnel and staff.* The rate of 75 percent FFP is available for skilled professional medical personnel and directly supporting staff of the Medicaid agency if the following criteria, as applicable, are met:

(i) The expenditures are for activities that are directly related to the administration of the Medicaid program, and as such do not include expenditures for medical assistance;

(ii) The skilled professional medical personnel have professional education and training in the field of medical care or appropriate medical practice. ''Professional education and training'' means the completion of a 2-year or longer program leading to an academic degree or certificate in a medically related profession. This is demonstrated by possession of a medical license, certificate, or other document issued by a recognized National or State medical licensure or certifying organization or a degree in a medical field issued by a college or university certified by a professional medical organization. Experience in the administration, direction, or implementation of the Medicaid program is not considered the equivalent of professional training in a field of medical care.

(iii) The skilled professional medical personnel are in positions that have duties and responsibilities that require those professional medical knowledge and skills.

(iv) A State-documented employer-employee relationship exists between the Medicaid agency and the skilled professional medical personnel and directly supporting staff; and

(v) The directly supporting staff are secretarial, stenographic, and copying personnel and file and records clerks who provide clerical services that are directly necessary for the completion of the professional medical responsibilities and functions of the skilled professional medical staff. The skilled professional medical staff must directly supervise the supporting staff and the performance of the supporting staff's work.

(2) *Staff of other public agencies.* The rate of 75 percent FFP is available for staff of other public agencies if the requirements specified in paragraph (d)(1) of this section are met and the public agency has a written agreement with the Medicaid agency to verify that these requirements are met.

(e) *Limitations on FFP rates for staff in mechanized claims processing and information retrieval systems.* The special matching rates for persons working on mechanized claims processing and information retrieval systems (paragraphs (b)(2) and (3) of this section) are applicable only if the design, development and installation, or the operation, have been approved by the Administrator in accordance with part 433, subchapter C, of this chapter.

[43 FR 45199, Sept. 29, 1978, as amended at 46 FR 48566, Oct. 1, 1981; 50 FR 46663, Nov. 12, 1985]

§ 432.55 Reporting training and administrative costs.

(a) *Scope.* This section identifies activities and costs to be reported as training or administrative costs on quarterly estimate and expenditure reports to CMS.

(b) *Activities and costs to be reported on training expenditures.* (1) For fulltime training (with no assigned agency duties): Salaries, fringe benefits, dependency allowances, travel, tuition, books, and educational supplies.

(2) For part-time training: Travel, per diem, tuition, books and educational supplies.

(3) For State and local Medicaid agency staff development personnel (including supporting staff) assigned fulltime training functions: Salaries, fringe benefits, travel, and per diem. Costs for staff spending less than full time on training for the Medicaid program must be allocated between training and administration in accordance with §433.34 of this subchapter.

(4) For experts engaged to develop or conduct special programs: Salary, fringe benefits, travel, and per diem.

(5) For agency training activities directly related to the program: Use of space, postage, teaching supplies, and purchase or development of teaching materials and equipment, for example, books and audiovisual aids.

(6) For field instruction in Medicaid: Instructors' salaries and fringe benefits, rental of space, travel, clerical assistance, teaching materials and equipment such as books and audiovisual aids.

(c) *Activities and costs not to be reported as training expenditures.* The following activities are to be reported as administrative costs:

(1) Salaries of supervisors (day-to-day supervision of staff is not a training activity); and

(2) Cost of employing students on a temporary basis, for instance, during summer vacation.

[43 FR 45199, Sept. 29, 1978, as amended at 44 FR 17935, Mar. 23, 1979]

PART 433—STATE FISCAL ADMINISTRATION

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

SOURCE: 43 FR 45201, Sept. 29, 1978, unless otherwise noted.

§ 433.1 Purpose.

This part specifies the rates of FFP for services and administration, and prescribes requirements, prohibitions, and FFP conditions relating to State fiscal activities.

Subpart A—Federal Matching and General Administration Provisions

§ 433.8 [Reserved]

§ 433.10 Rates of FFP for program services.

(a) *Basis.* Sections 1903(a)(1), 1903(g), and 1905(b) provide for payments to States, on the basis of a Federal medical assistance percentage, for part of their expenditures for services under an approved State plan.

(b) *Federal medical assistance percentage (FMAP)—Computations.* The FMAP is determined by the formula described in section 1905(b) of the Act. Under the formula, if a State's per capita income is equal to the national average per capita income, the Federal share is 55 percent. If a State's per capita income exceeds the national average, the Federal share is lower, with a statutory minimum of 50 percent. If a State's per capita income is lower than the national average, the Federal share is increased, with a statutory maximum of 83 percent. The formula used in determining the State and Federal share is as follows:

$$\text{State Share} = [(\text{State per capita income})^2/(\text{National per capita income})^2] \times 45 \text{ percent}$$

Federal share=100 percent minus the State share (with a minimum of 50 percent and a maximum of 83 percent)

The formula provides for squaring both the State and national average per capita incomes; this procedure magnifies any difference between the State's income and the national average. Consequently, Federal matching to lower income States is increased, and Federal matching to higher income States is decreased, within the statutory 50–83 percent limits. The FMAP for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is set by statute at 50 percent and is subject to dollar limitations specified in section 1108 of the Act.

(c) *Special provisions.* (1) Under section 1903(a)(5) of the Act, the Federal

share of State expenditures for family planning services is 90 percent.

(2) Under section 1905(b), the Federal share of State expenditures for services provided through Indian Health Service facilities is 100 percent.

(3) Under section 1903(g), the FMAP is reduced if the State does not have an effective program to control use of institutional services.

(4) Under section 1905(b) of the Social Security Act, the Federal share of State expenditures described in §433.11(a) for services provided to children, is the enhanced FMAP rate determined in accordance with §457.622(b) of this chapter, subject to the conditions explained in §433.11(b).

(5)(i) Under section 1933(d) of the Act, the Federal share of State expenditures for Medicare Part B premiums described in section 1905(p)(3)(A)(ii) of the Act on behalf of Qualifying Individuals described in section 1902(a)(10)(E)(iv) of the Act, is 100 percent, to the extent that the assistance does not exceed the State's allocation under paragraph (c)(5)(ii) of this section. To the extent that the assistance exceeds that allocation, the Federal share is 0 percent.

(ii) Under section 1933(c)(2) of the Act and subject to paragraph (c)(5)(iii) of this section, the allocation to each State is equal to the total allocation specified in section 1933(g) of the Act multiplied by the Secretary's estimate of the ratio of the total number of individuals described in section 1902(a)(10)(E)(iv) of the Act in the State to the total number of individuals described in section 1902(a)(10)(E)(iv) of the Act for all eligible States. In estimating that ratio, the Secretary will use data from the U.S. Census Bureau.

(iii) If, based on projected expenditures for a fiscal year, or for a shorter period for which funding is available under section 1933 of the Act, the Secretary determines that the expenditures described in paragraph (c)(5)(i) of this section for one or more States are projected to exceed the allocation made to the State, the Secretary may adjust each State's fiscal year allocation, as follows:

(A) The Secretary will compare each State's projected total expenditures for the expenses described in paragraph (c)(5)(i) of this section to the State's initial allocation determined under paragraph (c)(5)(ii) of this section, to determine the extent of each State's projected surplus or deficit.

(B) The surplus of each State with a projected surplus, as determined in accordance with paragraph (c)(5)(iii)(A) of this section will be added together to arrive at the Total Projected Surplus.

(C) The deficit of each State with a projected deficit, as determined in accordance with paragraph (c)(5)(iii)(A) of this section will be added together to arrive at the Total Projected Deficit.

(D) Each State with a projected deficit will receive an additional allocation equal to the amount of its projected deficit, or a prorated amount of such deficit, if the Total Projected Deficit is greater than the Total Projected Surplus. Except as described in paragraph (c)(5)(iii)(E) of this section, the amount to be reallocated from each State with a projected surplus will be equal to $A \times B$, where A equals the Total Projected Deficit and B equals the amount of the State's projected surplus as a percentage of the Total Projected Surplus.

(E) If the Total Projected Deficit determined under paragraph (c)(5)(iii)(C) of this section is greater than the Total Projected Surplus determined under paragraph (c)(5)(iii)(B) of this section, each State with a projected deficit will receive an additional allocation amount equal to the amount of the Total Projected Surplus multiplied by the amount of the projected deficit for such State as a percentage of the Total Projected Deficit. The amount to be reallocated from each State with a projected surplus will be equal to the amount of the projected surplus.

(iv) CMS will notify States of any changes in allotments resulting from any reallocations.

(v) The provisions in paragraph (c)(5) of this section will be in effect through the end of the period for which funding

authority is available under section 1933 of the Act.

(Sections 1902(a)(10), 1933 of the Social Security Act (42 U.S.C. 1396a), and Pub. L. 105–33)

[43 FR 45201, Sept. 29, 1978, as amended at 46 FR 48559, Oct. 1, 1981; 51 FR 41350, Nov. 14, 1986; 54 FR 21066, May 16, 1989; 66 FR 2666, Jan. 11, 2001; 70 FR 50220, Aug. 26, 2005; 71 FR 25092, Apr. 28, 2006; 73 FR 70893, Nov. 24, 2008]

§ 433.11 Enhanced FMAP rate for children.

(a) Subject to the conditions in paragraph (b) of this section, the enhanced FMAP determined in accordance with § 457.622 of this chapter will be used to determine the Federal share of State expenditures, except any expenditures pursuant to section 1923 of the Act for payments to disproportionate share hospitals for—

(1) Services provided to optional targeted low-income children described in § 435.4 or § 436.3 of this chapter; and

(2) Services provided to children born before October 1, 1983, with or without group health coverage or other health insurance coverage, who would be described in section 1902(l)(1)(D) of the Act (poverty-level-related children's groups) if—

(i) They had been born on or after that date; and

(ii) They would not qualify for medical assistance under the State plan in effect on March 31, 1997.

(b) Enhanced FMAP is not available if—

(1) A State adopts income and resource standards and methodologies for purposes of determining a child's eligibility under the Medicaid State plan that are more restrictive than those applied under policies of the State plan (as described in the definition of optional targeted low-income children at § 435.4 of this chapter) in effect on June 1, 1997; or

(2) No funds are available in the State's title XXI allotment, as determined under part 457, subpart F of this chapter for the quarter enhanced FMAP is claimed; or

(3) The State fails to maintain a valid method of identifying services provided on behalf of children listed in paragraph (a) of this section.

[66 FR 2666, Jan. 11, 2001]

§ 433.15 Rates of FFP for administration.

(a) *Basis.* Section 1903(a) (2) through (5) and (7) of the Act provide for payments to States, on the basis of specified percentages, for part of their expenditures for administration of an approved State plan.

(b) *Activities and rates.* (1) [Reserved]

(2) Administration of family planning services: 90 percent. (Section 1903 (a)(5); 42 CFR 432.50(b)(5).)

(3) Design, development, or installation of mechanized claims processing and information retrieval systems: 90 percent. (Section 1903(a)(3)(A)(i); 42 CFR part 433, subpart C, and § 432.50 (b)(3).)

(4) Operation of mechanized claims processing and information retrieval systems: 75 percent. (Section 1903(a)(3)(B); 42 CFR part 433, subpart C and § 432.50(b)(2).)

(5) Compensation and training of skilled professional medical personnel and staff directly supporting those personnel if the criteria specified in § 432.50 (c) and (d) are met: 75 percent. (Section 1903(a)(2); 42 CFR 432.50(b)(1).)

(6)(i) Funds expended for the performance of medical and utilization review by a QIO under a contract entered into under section 1902(d) of the Act: 75 percent (section 1903(a)(3)(C) of the Act).

(ii) If a State contracts for medical and utilization review with any individual or organization not designated under Part B of Title XI of the Act, funds expended for such review will be reimbursed as provided in paragraph (b)(7) of this section.

(7) All other activities the Secretary finds necessary for proper and efficient administration of the State plan: 50 percent. (Section 1903(a)(7).) (See also § 455.300 of this subchapter for FFP at 90 percent for State Medicaid fraud control units under section 1903(a)(6).)

(8) Nurse aide training and competency evaluation programs and competency evaluation programs described in 1919(e)(1) of the Act: for calendar quarters beginning on or after July 1, 1988 and before July 1, 1990: The lesser of 90% or the Federal medical assistance percentage plus 25 percentage points; for calendar quarters beginning

on or after October 1, 1990: 50%. (Section 1903(a)(2)(B) of the Act.)

(9) Preadmission screening and annual resident review (PASARR) activities conducted by the State: 75 percent. (Sections 1903(a)(2)(C) and 1919(e)(7); 42 CFR part 483, subparts C and E.)

(10) Funds expended for the performance of external quality review or the related activities described in § 438.358 of this chapter when they are performed by an external quality review organization as defined in § 438.320 of this chapter: 75 percent.

[43 FR 45201, Sept. 29, 1978, as amended at 46 FR 48566, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981; 50 FR 15327, Apr. 17, 1985; 50 FR 46664, Nov. 12, 1985; 56 FR 48918, Sept. 26, 1991; 57 FR 56506, Nov. 30, 1992; 68 FR 3635, Jan. 24, 2003]

§ 433.32 Fiscal policies and accountability.

A State plan must provide that the Medicaid agency and, where applicable, local agencies administering the plan will—

(a) Maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements;

(b) Retain records for 3 years from date of submission of a final expenditure report;

(c) Retain records beyond the 3-year period if audit findings have not been resolved; and

(d) Retain records for nonexpendable property acquired under a Federal grant for 3 years from the date of final disposition of that property.

[44 FR 17935, Mar. 23, 1979]

§ 433.34 Cost allocation.

A State plan under Title XIX of the Social Security Act must provide that the single or appropriate Agency will have an approved cost allocation plan on file with the Department in accordance with the requirements contained in subpart E of 45 CFR part 95. Subpart E also sets forth the effect on FFP if the requirements contained in that subpart are not met.

[47 FR 17490, Apr. 23, 1982]

§ 433.35 Equipment—Federal financial participation.

Claims for Federal financial participation in the cost of equipment under the Medicaid Program are determined in accordance with subpart G of 45 CFR part 95. Requirements concerning the management and disposition of equipment under the Medicaid Program are also prescribed in subpart G of 45 CFR part 95.

[47 FR 41564, Sept. 21, 1982]

§ 433.36 Liens and recoveries.

(a) *Basis and purpose.* This section implements sections 1902(a)(18) and 1917(a) and (b) of the Act, which describe the conditions under which an agency may impose a lien against a recipient's property, and when an agency may make an adjustment or recover funds in satisfaction of the claim against the individual's estate or real property.

(b) *Definition of property.* For purposes of this section, ''property'' includes the homestead and all other personal and real property in which the recipient has a legal interest.

(c) *State plan requirement.* If a State chooses to impose a lien against an individual's real property (or as provided in paragraph (g)(1) of this section, personal property), the State plan must provide that the provisions of paragraphs (d) through (i) of this section are met.

(d) *Procedures.* The State plan must specify the process by which the State will determine that an institutionalized individual cannot reasonably be expected to be discharged from the medical institution and return home as provided in paragraph (g)(2)(ii) of this section. The description of the process must include the type of notice to be given the individual, the process by which the individual will be given the opportunity for a hearing, the hearing procedures, and by whom and on what basis the determination that the individual cannot reasonably be expected to be discharged from the institution will be made. The notice to the individual must explain what is meant by the term lien, and that imposing a lien does not mean that the individual will lose ownership of the home.

(e) *Definitions.* The State plan must define the following terms used in this section:

(1) Individual's home.

(2) Equity interest in home.

(3) Residing in the home for at least 1 (or 2) year(s).

(4) On a continuing basis.

(5) Discharge from the medical institution and return home.

(6) Lawfully residing.

(f) *Exception.* The State plan must specify the criteria by which a son or daughter can establish to the agency's satisfaction that he or she has been providing care which permitted the individual to reside at home rather than in an institution, as provided in paragraph (h)(2)(iii)(B) of this section.

(g) *Lien provisions*—(1) *Incorrect payments.* The agency may place a lien against an individual's property, both personal and real, before his or her death because of Medicaid claims paid or to be paid on behalf of that individual following a court judgement which determined that benefits were incorrectly paid for that individual.

(2) *Correct payments.* Except as provided in paragraph (g)(3) of this section, the agency may place a lien against the real property of an individual at any age before his or her death because of Medicaid claims paid or to be paid for that individual when—

(i) An individual is an inpatient of a medical institution and must, as a condition of receiving services in the institution under the State plan, apply his or her income to the cost of care as provided in §§ 435.725, 435.832 and 436.832; and

(ii) The agency determines that he or she cannot reasonably be expected to be discharged and return home. The agency must notify the individual of its intention to make that determination and provide an opportunity for a hearing in accordance with State established procedures before the determination is made. The notice to an individual must include an explanation of liens and the effect on an individual's ownership of property.

(3) *Restrictions on placing liens.* The agency may not place a lien on an individual's home under paragraph (g)(2) of this section if any of the following individuals is lawfully residing in the home:

(i) The spouse;

(ii) The individual's child who is under age 21 or blind or disabled as defined in the State plan; or

(iii) The individual's sibling (who has an equity interest in the home, and who was residing in the individual's home for at least one year immediately before the date the individual was admitted to the medical institution).

(4) *Termination of lien.* Any lien imposed on an individual's real property under paragraph (g)(2) of this section will dissolve when that individual is discharged from the medical institution and returns home.

(h) *Adjustments and recoveries.* (1) The agency may make an adjustment or recover funds for Medicaid claims correctly paid for an individual as follows:

(i) From the estate of any individual who was 65 years of age or older when he or she received Medicaid; and

(ii) From the estate or upon sale of the property subject to a lien when the individual is institutionalized as described in paragraph (g)(2) of this section.

(2) The agency may make an adjustment or recovery under paragraph (h)(1) of this section only:

(i) After the death of the individual's surviving spouse; and

(ii) When the individual has no surviving child under age 21 or blind or disabled as defined in the State plan; and

(iii) In the case of liens placed on an individual's home under paragraph (g)(2) of this section, when there is no—

(A) Sibling of the individual residing in the home, who has resided there for at least one year immediately before the date of the individual's admission to the institution, and has resided there on a continuous basis since that time; or

(B) Son or daughter of the individual residing in the home, who has resided there for at least two years immediately before the date of the individual's admission to the institution, has resided there on a continuous basis since that time, and can establish to the agency's satisfaction that he or she

has been providing care which permitted the individual to reside at home rather than in an institution.

(i) *Prohibition of reduction of money payments.* No money payment under another program may be reduced as a means of recovering Medicaid claims incorrectly paid.

[43 FR 45201, Sept. 29, 1978, as amended at 47 FR 43647, Oct. 1, 1982; 47 FR 49847, Nov. 3, 1982]

§ 433.37 Reporting provider payments to Internal Revenue Service.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes requirements concerning—

(1) Identification of providers; and

(2) Compliance with the information reporting requirements of the Internal Revenue Code.

(b) *Identification of providers.* A State plan must provide for the identification of providers by—

(1) Social security number if—

(i) The provider is in solo practice; or

(ii) The provider is not in solo practice but billing is by the individual practitioner; or

(2) Employer identification number for all other providers.

(c) *Compliance with section 6041 of the Internal Revenue Code.* The plan must provide that the Medicaid agency complies with the information reporting requirements of section 6041 of the Internal Revenue Code (26 U.S.C. 6041). Section 6041 requires the filing of annual information returns showing amounts paid to providers, who are identified by name, address, and social security number or employer identification number.

§ 433.38 Interest charge on disallowed claims for FFP.

(a) *Basis and scope.* This section is based on section 1903(d)(5) of the Act, which requires that the Secretary charge a State interest on the Federal share of claims that have been disallowed but have been retained by the State during the administrative appeals process under section 1116(d) of the Act and the Secretary later recovers after the administrative appeals process has been completed. This section does not apply to—

(1) Claims that have been deferred by the Secretary and disallowed within the time limits of § 430.40 of this chapter. Deferral of claims for FFP; or

(2) Claims for expenditures that have never been paid on a grant award; or

(3) Disallowances of any claims for services furnished before October 1, 1980, regardless of the date of the claim submitted to CMS.

(b) *General principles.* (1) CMS will charge a State interest on FFP when—

(i) CMS has notified the Medicaid agency under 45 CFR 74.304 that a State claim for FFP is not allowable;

(ii) The agency has appealed the disallowance to the Grant Appeals Board under 45 CFR Part 16 and has chosen to retain the FFP during the administrative appeals process in accordance with paragraph (c)(2) of this section; and

(iii)(A) The Board has made a final determination upholding part or all of the disallowance; (B) the agency has withdrawn its appeal on all or part of the disallowance; or (C) the agency has reversed its decision to retain the funds without withdrawing its appeal and the Board upholds all or part of the disallowance.

(2) If the courts overturn, in whole or in part, a Board decision that has sustained a disallowance, CMS will return the principal and the interest collected on the funds that were disallowed, upon the completion of all judicial appeals.

(3) Unless an agency decides to withdraw its appeal on part of the disallowance and therefore returns only that part of the funds on which it has withdrawn its appeal, any decision to retain or return disallowed funds must apply to the entire amount in dispute.

(4) If the agency elects to have CMS recover the disputed amount, it may not reverse that election.

(c) *State procedures.* (1) If the Medicaid agency has appealed a disallowance to the Board and wishes to retain the disallowed funds until the Board issues a final determination, the agency must notify the CMS Regional Administrator in writing of its decision to do so.

(2) The agency must mail its notice to the CMS Regional Administrator within 30 days of the date of receipt of

the notice of the disallowance, as established by the certified mail receipt accompanying the notices.

(3) If the agency withdraws either its decision to retain the FFP or its appeal on all or part of the FFP or both, the agency must notify CMS in writing.

(4) If the agency does not notify the CMS Regional Administrator within the time limit set forth in paragraph (c)(2) of this section. CMS will recover the amount of the disallowed funds from the next possible Medicaid grant award to the State.

(d) *Amount of interest charged.* (1) If the agency retains funds that later become subject to an interest charge under paragraph (b) of this section, CMS will offset from the next Medicaid grant award to the State the amount of the funds subject to the interest charge, plus interest on that amount.

(2) The interest charge is at the rate CMS determines to be the average of the bond equivalent of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged.

(e) *Duration of interest.* (1) The interest charge on the amount of disallowed FFP retained by the agency will begin on the date of the disallowance notice and end—

(i) On the date of the final determination by the Board;

(ii) On the date CMS receives written notice from the State that it is withdrawing its appeal on all of the disallowed funds; or

(iii) If the agency withdraws its appeal on part of the funds, on (A) the date CMS receives written notice from the agency that it is withdrawing its appeal on a specified part of the disallowed funds for the part on which the agency withdraws its appeal; and (B) the date of the final determination by the Board on the part for which the agency pursues its appeal; or

(iv) The date CMS receives written notice from the agency that it no longer chooses to retain the funds.

(2) CMS will not charge interest on FFP retained by an agency for more than 12 months for disallowances of FFP made between October 1, 1980 and August 13, 1981.

[48 FR 29485, June 27, 1983]

§ 433.40 Treatment of uncashed or cancelled (voided) Medicaid checks.

(a) *Purpose.* This section provides the rules to ensure that States refund the Federal portion of uncashed or cancelled (voided) checks under title XIX.

(b) *Definitions.* As used in this section—

Cancelled (voided) check means a Medicaid check issued by a State or fiscal agent which prior to its being cashed is cancelled (voided) by the State or fiscal agent, thus preventing disbursement of funds.

Check means a check or warrant that a State or local agency uses to make a payment.

Fiscal agent means an entity that processes or pays vendor claims for the Medicaid State agency.

Uncashed check means a Medicaid check issued by a State or fiscal agent which has not been cashed by the payee.

Warrant means an order by which the State agency or local agency without the authority to issue checks recognizes a claim. Presentation of a warrant by the payee to a State officer with authority to issue checks will result in release of funds due.

(c) *Refund of Federal financial participation (FFP) for uncashed checks*—(1) *General provisions.* If a check remains uncashed beyond a period of 180 days from the date it was issued; i.e., the date of the check, it will no longer be regarded as an allowable program expenditure. If the State has claimed and received FFP for the amount of the uncashed check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State must identify those checks which remain uncashed beyond a period of 180 days after issuance. The State agency must refund all FFP that it received for uncashed checks by adjusting the Quarterly Statement of Expenditures for that quarter. If an uncashed check is cashed after the refund is made, the State may file a claim. The claim will be considered to be an adjustment to the costs for the quarter in which the check was originally claimed. This claim will be paid if otherwise allowed by the Act and the regulations issued pursuant to the Act.

(3) If the State does not refund the appropriate amount as specified in paragraph (c)(2) of this section, the amount will be disallowed.

(d) *Refund of FFP for cancelled (voided) checks*—(1) *General provision.* If the State has claimed and received FFP for the amount of a cancelled (voided) check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State agency must identify those checks which were cancelled (voided). The State must refund all FFP that it received for cancelled (voided) checks by adjusting the Quarterly Statement of Expenditures for that quarter.

(3) If the State does not refund the appropriate amount as specified in paragraph (d)(2) of this section, the amount will be disallowed.

[51 FR 36227, Oct. 9, 1986]

Subpart B—General Administrative Requirements State Financial Participation

SOURCE: 57 FR 55138, Nov. 24, 1992, unless otherwise noted.

§ 433.50 Basis, scope, and applicability.

(a) *Basis.* This subpart interprets and implements—(1) Section 1902(a)(2) and section 1903(w)(7)(G) of the Act, which require States to share in the cost of medical assistance expenditures and permit State and local units of government to participate in the financing of the non-Federal portion of medical assistance expenditures.

(i) A unit of government is a State, a city, a county, a special purpose district, or other governmental unit in the State that: has taxing authority, has direct access to tax revenues, is a State university teaching hospital with direct appropriations from the State treasury, or is an Indian tribe as defined in Section 4 of the Indian Self-Determination and Education Assistance Act, as amended [25 U.S.C. 450b].

(ii) A health care provider may be considered a unit of government only when it is operated by a unit of government as demonstrated by a showing of the following:

(A) The health care provider has generally applicable taxing authority; or

(B) The health care provider has direct access to generally applicable tax revenues. This means the health care provider is able to directly access funding as an integral part of a unit of government with taxing authority which is legally obligated to fund the health care provider's expenses, liabilities, and deficits, so that a contractual arrangement with the State or local government is not the primary or sole basis for the health care provider to receive tax revenues;

(C) The health care provider receives appropriated funding as a State university teaching hospital providing supervised teaching experiences to graduate medical school interns and residents enrolled in a State university in the State; or

(D) The health care provider is an Indian Tribe or Tribal organization (as those terms are defined in Section 4 of the Indian Self-Determination and Education Assistance Act (ISDEAA); 25 U.S.C. 450b) and meets the following criteria:

(*1*) If the entity is a Tribal organization, it is—

(*a*) Carrying out health programs of the IHS, including health services which are eligible for reimbursement by Medicaid, under a contract or compact entered into between the Tribal organization and the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act, Public Law 93–638, as amended, and

(*b*) Either the recognized governing body of an Indian tribe, or an entity which is formed solely by, wholly owned or comprised of, and exclusively controlled by Indian tribes.

(2) Section 1903(a) of the Act, which requires the Secretary to pay each State an amount equal to the Federal medical assistance percentage of the total amount expended as medical assistance under the State's plan.

(3) Section 1903(w) of the Act, which specifies the treatment of revenues from provider-related donations and health care-related taxes in determining a State's medical assistance expenditures for which Federal financial

participation (FFP) is available under the Medicaid program.

(b) *Scope.* This subpart—

(1) Specifies State plan requirements for State financial participation in expenditures for medical assistance.

(2) Defines provider-related donations and health care-related taxes that may be received without a reduction in FFP.

(3) Specifies rules for revenues received from provider-related donations and health care-related taxes during a transition period.

(4) Establishes limitations on FFP when States receive funds from provider-related donations and revenues generated by health care-related taxes.

(c) *Applicability.* The provisions of this subpart apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

[57 FR 55138, Nov. 24, 1992; 58 FR 6095, Jan. 26, 1993; 72 FR 29832, May 29, 2007; 72 FR 29832, May 29, 2007]

§ 433.51 Funds from units of government as the State share of financial participation.

(a) Funds from units of government may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (b) and (c) of this section.

(b) The funds from units of government are appropriated directly to the State or local Medicaid agency, or are transferred from other units of government (including Indian tribes) to the State or local agency and are under its administrative control, or are certified by the contributing unit of government as representing expenditures eligible for FFP under this section. Certified public expenditures must be expenditures within the meaning of 45 CFR 95.13 that are supported by auditable documentation in a form approved by the Secretary that, at a minimum—

(1) Identifies the relevant category of expenditures under the State plan;

(2) Explains whether the contributing unit of government is within the scope of the exception to limitations on provider-related taxes and donations;

(3) Demonstrates the actual expenditures incurred by the contributing unit of government in providing services to eligible individuals receiving medical assistance or in administration of the State plan; and

(4) Is subject to periodic State audit and review.

(c) The funds from units of government are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

[72 FR 29833, May 29, 2007]

§ 433.52 General definitions.

As used in this subpart—

Entity related to a health care provider means—

(1) An organization, association, corporation, or partnership formed by or on behalf of a health care provider;

(2) An individual with an ownership or control interest in the provider, as defined in section 1124(a)(3) of the Act;

(3) An employee, spouse, parent, child, or sibling of the provider, or of a person with an ownership or control interest in the provider, as defined in section 1124(a)(3) of the Act; or

(4) A supplier of health care items or services or a supplier to providers of health care items or services.

Health care provider means the individual or entity that receives any payment or payments for health care items or services provided.

Provider-related donation means a donation or other voluntary payment (in cash or in kind) made directly or indirectly to a State or unit of local government by or on behalf of a health care provider, an entity related to such a health care provider, or an entity providing goods or services to the State for administration of the State's Medicaid plan.

(1) Donations made by a health care provider to an organization, which in turn donates money to the State, may be considered to be a donation made indirectly to the State by a health care provider.

(2) When an organization receives less than 25 percent of its revenues from providers and/or provider-related entities, its donations will not generally be presumed to be provider-related donations. Under these circumstances, a provider-related donation to an organization will not be considered a donation made indirectly to

the State. However, if the donations from providers to an organization are subsequently determined to be indirect donations to the State or unit of local government for administration of the State's Medicaid program, then such donations will be considered to be health care related.

(3) When the organization receives more than 25 percent of its revenue from donations from providers or provider-related entities, the organization always will be considered as acting on behalf of health care providers if it makes a donation to the State. The amount of the organization's donation to the State, in a State fiscal year, that will be considered health care related, will be based on the percentage of donations the organization received from the providers during that period.

§ 433.53 State plan requirements.

A State plan must provide that—

(a) State (as distinguished from local) funds will be used both for medical assistance and administration;

(b) State funds will be used to pay at least 40 percent of the non-Federal share of total expenditures under the plan; and

(c) State and Federal funds will be apportioned among the political subdivisions of the State on a basis that assures that—

(1) Individuals in similar circumstances will be treated similarly throughout the State; and

(2) If there is local financial participation, lack of funds from local sources will not result in lowering the amount, duration, scope, or quality of services or level of administration under the plan in any part of the State.

[57 FR 55138, Nov. 24, 1992; 58 FR 6095, Jan. 26, 1993]

§ 433.54 Bona fide donations.

(a) A bona fide donation means a provider-related donation, as defined in § 433.52, made to the State or unit of local government, that has no direct or indirect relationship, as described in paragraph (b) of this section, to Medicaid payments made to—

(1) The health care provider;

(2) Any related entity providing health care items and services; or

(3) Other providers furnishing the same class of items or services as the provider or entity.

(b) Provider-related donations will be determined to have no direct or indirect relationship to Medicaid payments if those donations are not returned to the individual provider, the provider class, or related entity under a hold harmless provision or practice, as described in paragraph (c) of this section.

(c) A hold harmless practice exists if any of the following applies:

(1) The State (or other unit of government) provides for a direct or indirect non-Medicaid payment to those providers or others making, or responsible for, the donation, and the payment amount is positively correlated to the donation. A positive correlation includes any positive relationship between these variables, even if not consistent over time.

(2) All or any portion of the Medicaid payment to the donor, provider class, or related entity, varies based only on the amount of the donation, including where Medicaid payment is conditional on receipt of the donation.

(3) The State (or other unit of government) receiving the donation provides for any direct or indirect payment, offset, or waiver such that the provision of that payment, offset, or waiver directly or indirectly guarantees to return any portion of the donation to the provider (or other parties responsible for the donation).

(d) CMS will presume provider-related donations to be bona fide if the voluntary payments, including, but not limited to, gifts, contributions, presentations or awards, made by or on behalf of individual health care providers to the State, county, or any other unit of local government does not exceed—

(1) $5,000 per year in the case of an individual provider donation; or

(2) $50,000 per year in the case of a donation from any health care organizational entity.

(e) To the extent that a donation presumed to be bona fide contains a hold harmless provision, as described in paragraph (c) of this section, it will not be considered a bona fide donation. When provider-related donations are not bona fide, CMS will deduct this

amount from the State's medical assistance expenditures before calculating FFP. This offset will apply to all years the State received such donations and any subsequent fiscal year in which a similar donation is received.

[57 FR 55138, Nov. 24, 1992, as amended at 73 FR 9698, Feb. 22, 2008]

§ 433.55 Health care-related taxes defined.

(a) A health care-related tax is a licensing fee, assessment, or other mandatory payment that is related to—

(1) Health care items or services;

(2) The provision of, or the authority to provide, the health care items or services; or

(3) The payment for the health care items or services.

(b) A tax will be considered to be related to health care items or services under paragraph (a)(1) of this section if at least 85 percent of the burden of the tax revenue falls on health care providers.

(c) A tax is considered to be health care related if the tax is not limited to health care items or services, but the treatment of individuals or entities providing or paying for those health care items or services is different than the tax treatment provided to other individuals or entities.

(d) A health care-related tax does not include payment of a criminal or civil fine or penalty, unless the fine or penalty was imposed instead of a tax.

(e) Health care insurance premiums and health maintenance organization premiums paid by an individual or group to ensure coverage or enrollment are not considered to be payments for health care items and services for purposes of determining whether a health care-related tax exists.

§ 433.56 Classes of health care services and providers defined.

(a) For purposes of this subpart, each of the following will be considered as a separate class of health care items or services:

(1) Inpatient hospital services;

(2) Outpatient hospital services;

(3) Nursing facility services (other than services of intermediate care facilities for the mentally retarded);

(4) Intermediate care facility services for the mentally retarded, and similar services furnished by community-based residences for the mentally retarded, under a waiver under section 1915(c) of the Act, in a State in which, as of December 24, 1992, at least 85 percent of such facilities were classified as ICF/MRs prior to the grant of the waiver;

(5) Physician services;

(6) Home health care services;

(7) Outpatient prescription drugs;

(8) Services of managed care organizations (including health maintenance organizations, preferred provider organizations);

(9) Ambulatory surgical center services, as described for purposes of the Medicare program in section 1832(a)(2)(F)(i) of the Social Security Act. These services are defined to include facility services only and do not include surgical procedures;

(10) Dental services;

(11) Podiatric services;

(12) Chiropractic services;

(13) Optometric/optician services;

(14) Psychological services;

(15) Therapist services, defined to include physical therapy, speech therapy, occupational therapy, respiratory therapy, audiological services, and rehabilitative specialist services;

(16) Nursing services, defined to include all nursing services, including services of nurse midwives, nurse practitioners, and private duty nurses;

(17) Laboratory and x-ray services, defined as services provided in a licensed, free-standing laboratory or x-ray facility. This definition does not include laboratory or x-ray services provided in a physician's office, hospital inpatient department, or hospital outpatient department;

(18) Emergency ambulance services; and

(19) Other health care items or services not listed above on which the State has enacted a licensing or certification fee, subject to the following:

(i) The fee must be broad based and uniform or the State must receive a waiver of these requirements;

(ii) The payer of the fee cannot be held harmless; and

(iii) The aggregate amount of the fee cannot exceed the State's estimated

cost of operating the licensing or certification program.

(b) Taxes that pertain to each class must apply to all items and services within the class, regardless of whether the items and services are furnished by or through a Medicaid-certified or licensed provider.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43180, Aug. 13, 1993; 73 FR 9698, Feb. 22, 2008]

§ 433.57 General rules regarding revenues from provider-related donations and health care-related taxes.

Effective January 1, 1992, CMS will deduct from a State's expenditures for medical assistance, before calculating FFP, funds from provider-related donations and revenues generated by health care-related taxes received by a State or unit of local government, in accordance with the requirements, conditions, and limitations of this subpart, if the donations and taxes are not—

(a) Permissible provider-related donations, as specified in § 433.66(b); or

(b) Health care-related taxes, as specified in § 433.68(b).

[57 FR 55138, Nov. 24, 1992, as amended at 73 FR 9698, Feb. 22, 2008]

§§ 433.58–433.60 [Reserved]

§ 433.66 Permissible provider-related donations.

(a) *General rule.* (1) Except as specified in paragraph (a)(2) of this section, a State may receive revenues from provider-related donations without a reduction in FFP, only in accordance with the requirements of this section.

(2) The provisions of this section relating to provider-related donations for outstationed eligibility workers are effective on October 1, 1992.

(b) *Permissible donations.* Subject to the limitations specified in § 433.67, a State may receive, without a reduction in FFP, provider-related donations that meet at least one of the following requirements:

(1) The donations must be bona fide donations, as defined in § 433.54; or

(2) The donations are made by a hospital, clinic, or similar entity (such as a Federally-qualified health center) for the direct costs of State or local agency personnel who are stationed at the facility to determine the eligibility (including eligibility redeterminations) of individuals for Medicaid or to provide outreach services to eligible (or potentially eligible) Medicaid individuals. Direct costs of outstationed eligibility workers refers to the costs of training, salaries and fringe benefits associated with each outstationed worker and similar allocated costs of State or local agency support staff, and a prorated cost of outreach activities applicable to the outstationed workers at these sites. The prorated costs of outreach activities will be calculated taking the percent of State outstationed eligibility workers at a facility to total outstationed eligibility workers in the State, and multiplying the percent by the total cost of outreach activities in the State. Costs for such items as State agency overhead and provider office space are not allowable for this purpose.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43180, Aug. 13, 1993; 73 FR 9698, Feb. 22, 2008]

§ 433.67 Limitations on level of FFP for permissible provider-related donations.

(a)(1) *Limitations on bona fide donations.* There are no limitations on the amount of bona fide provider-related donations that a State may receive without a reduction in FFP, as long as the bona fide donations meet the requirements of § 433.66(b)(1).

(2) *Limitations on donations for outstationed eligibility workers.* Effective October 1, 1992, the maximum amount of provider-related donations for outstationed eligibility workers, as described in § 433.66(b)(2), that a State may receive without a reduction in FFP may not exceed 10 percent of a State's medical assistance administrative costs (both the Federal and State share), excluding the costs of family planning activities. The 10 percent limit for provider-related donations for outstationed eligibility workers is not included in the limit in effect through September 30, 1995, for health care-related taxes as described in § 433.70.

(b) *Calculation of FFP.* CMS will deduct from a State's quarterly medical

assistance expenditures, before calculating FFP, any provider-related donations received in that quarter that do not meet the requirements of § 433.66(b)(1) and provider donations for outstationed eligibility workers in excess of the limits specified under paragraph (a)(2) of this section.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43180, Aug. 13, 1993; 73 FR 9698, Feb. 22, 2008]

§ 433.68 Permissible health care-related taxes.

(a) *General rule.* A State may receive health care-related taxes, without a reduction in FFP, only in accordance with the requirements of this section.

(b) *Permissible health care-related taxes.* Subject to the limitations specified in § 433.70, a State may receive, without a reduction in FFP, health care-related taxes if all of the following are met:

(1) The taxes are broad based, as specified in paragraph (c) of this section;

(2) The taxes are uniformly imposed throughout a jurisdiction, as specified in paragraph (d) of this section; and

(3) The tax program does not violate the hold harmless provisions specified in paragraph (f) of this section.

(c) *Broad based health care-related taxes.* (1) A health care-related tax will be considered to be broad based if the tax is imposed on at least all health care items or services in the class or providers of such items or services furnished by all non-Federal, non-public providers in the State, and is imposed uniformly, as specified in paragraph (d) of this section.

(2) If a health care-related tax is imposed by a unit of local government, the tax must extend to all items or services or providers (or to all providers in a class) in the area over which the unit of government has jurisdiction.

(3) A State may request a waiver from CMS of the requirement that a tax program be broad based, in accordance with the procedures specified in § 433.72. Waivers from the uniform and broad-based requirements will automatically be granted in cases of variations in licensing and certification fees for providers if the amount of such fees is not more than $1,000 annually per provider and the total amount raised by the State from the fees is used in the administration of the licensing or certification program.

(d) *Uniformly imposed health care-related taxes.* A health care-related tax will be considered to be imposed uniformly even if it excludes Medicaid or Medicare payments (in whole or in part), or both; or, in the case of a health care-related tax based on revenues or receipts with respect to a class of items or services (or providers of items or services), if it excludes either Medicaid or Medicare revenues with respect to a class of items or services, or both. The exclusion of Medicaid revenues must be applied uniformly to all providers being taxed.

(1) A health care-related tax will be considered to be imposed uniformly if it meets any one of the following criteria:

(i) If the tax is a licensing fee or similar tax imposed on a class of health care services (or providers of those health care items or services), the tax is the same amount for every provider furnishing those items or services within the class.

(ii) If the tax is a licensing fee or similar tax imposed on a class of health care items or services (or providers of those items or services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of those items or services in the class.

(iii) If the tax is imposed on provider revenue or receipts with respect to a class of items or services (or providers of those health care items or services), the tax is imposed at a uniform rate for all services (or providers of those items or services) in the class on all the gross revenues or receipts, or on net operating revenues relating to the provision of all items or services in the State, unit, or jurisdiction. Net operating revenue means gross charges of facilities less any deducted amounts for bad debts, charity care, and payer discounts.

(iv) The tax is imposed on items or services on a basis other than those specified in paragraphs (d)(1) (i)

through (iii) of this section, e.g., an admission tax, and the State establishes to the satisfaction of the Secretary that the amount of the tax is the same for each provider of such items or services in the class.

(2) A tax imposed with respect to a class of health care items or services will not be considered to be imposed uniformly if it meets either one of the following two criteria:

(i) The tax provides for credits, exclusions, or deductions which have as its purpose, or results in, the return to providers of all, or a portion, of the tax paid, and it results, directly or indirectly, in a tax program in which—

(A) The net impact of the tax and payments is not generally redistributive, as specified in paragraph (e) of this section; and

(B) The amount of the tax is directly correlated to payments under the Medicaid program.

(ii) The tax holds taxpayers harmless for the cost of the tax, as described in paragraph (f) of this section.

(3) If a tax does not meet the criteria specified in paragraphs (d)(1)(i) through (iv) of this section, but the State establishes that the tax is imposed uniformly in accordance with the procedures for a waiver specified in § 433.72, the tax will be treated as a uniform tax.

(e) *Generally redistributive.* A tax will be considered to be generally redistributive if it meets the requirements of this paragraph. If the State desires waiver of only the broad-based tax requirement, it must demonstrate compliance with paragraph (e)(1) of this section. If the State desires waiver of the uniform tax requirement, whether or not the tax is broad-based, it must demonstrate compliance with paragraph (e)(2) of this section.

(1) *Waiver of broad-based requirement only.* This test is applied on a per class basis to a tax that is imposed on all revenues but excludes certain providers. For example, a tax that is imposed on all revenues (including Medicare and Medicaid) but excludes teaching hospitals would have to meet this test. This test cannot be used when a State excludes any or all Medicaid revenue from its tax in addition to the exclusion of providers, since the test compares the proportion of Medicaid revenue being taxed under the proposed tax with the proportion of Medicaid revenue being taxed under a broad-based tax.

(i) A State seeking waiver of the broad-based tax requirement only must demonstrate that its proposed tax plan meets the requirement that its plan is generally redistributive by:

(A) Calculating the proportion of the tax revenue applicable to Medicaid if the tax were broad based and applied to all providers or activities within the class (called P1);

(B) Calculating the proportion of the tax revenue applicable to Medicaid under the tax program for which the State seeks a waiver (called P2); and

(C) Calculating the value of P1/P2.

(ii) If the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 1, CMS will automatically approve the waiver request.

(iii) If a tax is enacted and in effect prior to August 13, 1993, and the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 0.90, CMS will review the waiver request. Such a waiver will be approved only if the following two criteria are met:

(A) The value of P1/P2 is at least 0.90; and

(B) The tax excludes or provides credits or deductions only to one or more of the following providers of items and services within the class to be taxed:

(*1*) Providers that furnish no services within the class in the State;

(*2*) Providers that do not charge for services within the class;

(*3*) Rural hospitals (defined as any hospital located outside of an urban area as defined in § 412.62(f)(1)(ii) of this chapter);

(*4*) Sole community hospitals as defined in § 412.92(a) of this chapter;

(*5*) Physicians practicing primarily in medically underserved areas as defined in section 1302(7) of the Public Health Service Act;

(*6*) Financially distressed hospitals if:

(*i*) A financially distressed hospital is defined by the State law;

(*ii*) The State law specifies reasonable standards for determining financially distressed hospitals, and these

standards are applied uniformly to all hospitals in the State; and

(*iii*) No more than 10 percent of non-public hospitals in the State are exempt from the tax;

(*7*) Psychiatric hospitals; or

(*8*) Hospitals owned and operated by HMOs.

(iv) If a tax is enacted and in effect after August 13, 1993, and the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 0.95, CMS will review the waiver request. Such a waiver request will be approved only if the following two criteria are met:

(A) The value of P1/P2 is at least 0.95; and

(B) The tax complies with the provisions of § 433.68(e)(1)(iii)(B).

(2) *Waiver of uniform tax requirement.* This test is applied on a per class basis to all taxes that are not uniform. This includes those taxes that are neither broad based (as specified in § 433.68(c)) nor uniform (as specified in § 433.68(d)).

(i) A State seeking waiver of the uniform tax requirement (whether or not the tax is broad based) must demonstrate that its proposed tax plan meets the requirement that its plan is generally redistributive by:

(A) Calculating, using ordinary least squares, the slope (designated as (*B*) (that is. the value of the x coefficient) of two linear regressions, in which the dependent variable is each provider's percentage share of the total tax paid by all taxpayers during a 12-month period, and the independent variable is the taxpayer's ''Medicaid Statistic''. The term ''Medicaid Statistic'' means the number of the provider's taxable units applicable to the Medicaid program during a 12-month period. If, for example, the State imposed a tax based on provider charges, the amount of a provider's Medicaid charges paid during a 12-month period would be its ''Medicaid Statistic''. If the tax were based on provider inpatient days, the number of the provider's Medicaid days during a 12-month period would be its ''Medicaid Statistic''. For the purpose of this test, it is not relevant that a tax program exempts Medicaid from the tax.

(B) Calculating the slope (designated as B1) of the linear regression, as described in paragraph (e)(2)(i) of this section, for the State's tax program, if it were broad based and uniform.

(C) Calculating the slope (designated as B2) of the linear regression, as described in paragraph (e)(2)(i) of this section, for the State's tax program, as proposed.

(ii) If the State demonstrates to the Secretary's satisfaction that the value of B1/B2 is at least 1, CMS will automatically approve the waiver request.

(iii) If the State demonstrates to the Secretary's satisfaction that the value of B1/B2 is at least 0.95, CMS will review the waiver request. Such a waiver will be approved only if the following two criteria are met:

(A) The value of B1/B2 is at least 0.95; and

(B) The tax excludes or provides credits or deductions only to one or more of the following providers of items and services within the class to be taxes:

(*1*) Providers that furnish no services within the class in the State;

(*2*) Providers that do not charge for services within the class;

(*3*) Rural hospitals (defined as any hospital located outside of an urban area as defined in § 412.62(f)(1)(ii) of this chapter;

(*4*) Sole community hospitals as defined in § 412.92(a) of this chapter;

(*5*) Physicians practicing primarily in medically underserved areas as defined in section 1302(7) of the Public Health Service Act;

(*6*) Financially distressed hospitals if:

(*i*) A financially distressed hospital is defined by the State law;

(*ii*) The State law specifies reasonable standards for determining financially distressed hospitals, and these standards are applied uniformly to all hospitals in the State; and

(*iii*) No more than 10 percent of non-public hospitals in the State are exempt from the tax;

(*7*) Psychiatric hospitals; or

(*8*) Providers or payers with tax rates that vary based exclusively on regions, but only if the regional variations are coterminous with preexisting political (and not special purpose) boundaries. Taxes within each regional boundary must meet the broad-based and uniformity requirements as specified in paragraphs (c) and (d) of this section.

(iv) A B1/B2 value of 0.70 will be applied to taxes that vary based exclusively on regional variations, and enacted and in effect prior to November 24, 1992, to permit such variations.

(f) *Hold harmless.* A taxpayer will be considered to be held harmless under a tax program if any of the following conditions applies:

(1) The State (or other unit of government) imposing the tax provides for a direct or indirect non-Medicaid payment to those providers or others paying the tax and the payment amount is positively correlated to either the tax amount or to the difference between the Medicaid payment and the tax amount. A positive correlation includes any positive relationship between these variables, even if not consistent over time.

(2) All or any portion of the Medicaid payment to the taxpayer varies based only on the tax amount, including where Medicaid payment is conditional on receipt of the tax amount.

(3) The State (or other unit of government) imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of that payment, offset, or waiver directly or indirectly guarantees to hold taxpayers harmless for all or any portion of the tax amount.

(i)(A) An indirect guarantee will be determined to exist under a two prong ''guarantee'' test. If the health care-related tax or taxes on each health care class are applied at a rate that produces revenues less than or equal to 6 percent of the revenues received by the taxpayer, the tax or taxes are permissible under this test. The phrase ''revenues received by the taxpayer'' refers to the net patient revenue attributable to the assessed permissible class of health care items or services. However, for the period of January 1, 2008 through September 30, 2011, the applicable percentage of net patient service revenue is 5.5 percent. Compliance in State fiscal year 2008 will be evaluated from January 1, 2008 through the last day of State fiscal year 2008. Beginning with State fiscal year 2009 the 5.5 percent tax collection will be measured on an annual State fiscal year basis.

(B) When the tax or taxes produce revenues in excess of the applicable percentage of the revenue received by the taxpayer, CMS will consider an indirect hold harmless provision to exist if 75 percent or more of the taxpayers in the class receive 75 percent or more of their total tax costs back in enhanced Medicaid payments or other State payments. The second prong of the indirect hold harmless test is applied in the aggregate to all health care taxes applied to each class. If this standard is violated, the amount of tax revenue to be offset from medical assistance expenditures is the total amount of the taxpayers' revenues received by the State.

(ii) [Reserved]

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43181, Aug. 13, 1993; 62 FR 53572, Oct. 15, 1997; 73 FR 9698, Feb. 22, 2008]

§ 433.70 Limitation on level of FFP for revenues from health care-related taxes.

(a) *Limitations.* Beginning October 1, 1995, there is no limitation on the amount of health care-related taxes that a State may receive without a reduction in FFP, as long as the health care-related taxes meet the requirements specified in § 433.68.

(b) *Calculation of FFP.* CMS will deduct from a State's medical assistance expenditures, before calculating FFP, revenues from health care-related taxes that do not meet the requirements of § 433.68 and any health care-related taxes in excess of the limits specified in paragraph (a)(1) of this section.

[57 FR 55138, Nov. 24, 1992, as amended at 73 FR 9699, Feb. 22, 2008]

§ 433.72 Waiver provisions applicable to health care-related taxes.

(a) *Bases for requesting waiver.* (1) A State may submit to CMS a request for a waiver if a health care-related tax does not meet any or all of the following:

(i) The tax does not meet the broad based criteria specified in § 433.68c); and/or

(ii) The tax is not imposed uniformly but meets the criteria specified in § 433.68(d)(2) or (d)(3).

(2) When a tax that meets the criteria specified in paragraph (a)(1) of this section is imposed on more than

one class of health care items or services, a separate waiver must be obtained for each class of health care items and services subject to the tax.

(b) *Waiver conditions.* In order for CMS to approve a waiver request that would permit a State to receive tax revenue (within specified limitations) without a reduction in FFP, the State must demonstrate, to CMS's satisfaction, that its tax program meets all of the following requirements:

(1) The net impact of the tax and any payments made to the provider by the State under the Medicaid program is generally redistributive, as described in § 433.68(e);

(2) The amount of the tax is not directly correlated to Medicaid payments; and

(3) The tax program does not fall within the hold harmless provisions specified in § 433.68(f).

(c) *Effective date.* A waiver will be effective:

(1) The date of enactment of the tax for programs in existence prior to August 13, 1993 or;

(2) For tax programs commencing on or after August 13, 1993, on the first day in the quarter in which the waiver is received by CMS.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§ 433.74 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993, each State must submit to CMS quarterly summary information on the source and use of all provider-related donations (including all bona fide and presumed-to-be bona fide donations) received by the State or unit of local government, and health care-related taxes collected. Each State must also provide any additional information requested by the Secretary related to any other donations made by, or any taxes imposed on, health care providers. States' reports must present a complete, accurate, and full disclosure of all of their donation and tax programs and expenditures.

(b) Each State must provide the summary information specified in paragraph (a) of this section on a quarterly basis in accordance with procedures established by CMS.

(c) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description and legal basis for each donation and tax program being reported, as well as the source and use of all donations received and taxes collected. This information must be made available to Federal reviewers upon request.

(d) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP CMS estimates is attributable to the sums raised by tax and donation programs as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released when the State complies with all reporting requirements.

Subpart C—Mechanized Claims Processing and Information Retrieval Systems

§ 433.110 Basis, purpose, and applicability.

(a) This subpart implements the following sections of the Act:

(1) Section 1903(a)(3) of the Act, which provides for FFP in State expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems and for the operation of certain systems. Additional HHS regulations and CMS procedures for implementing these regulations are in 45 CFR part 74, 45 CFR part 95, subpart F, and part 11, State Medicaid Manual; and

(2) Section 1903(r) of the Act, which—

(i) Requires reductions in FFP otherwise due a State under section 1903(a) if a State fails to meet certain deadlines for operating a mechanized claims processing and information retrieval system or if the system fails to meet certain conditions of approval or conditions of reapproval;

(ii) Requires a Federal performance review at least every three years of the

mechanized claims processing and information retrieval systems; and

(iii) Allows waivers of conditions of approval, conditions of reapproval, and FFP reductions under certain circumstances.

(b) The requirements under section 1903(r) of the Act do not apply to Puerto Rico, Guam, the Virgin Islands, American Samoa and the Northern Mariana Islands.

[50 FR 30846, July 30, 1985, as amended at 54 FR 41973, Oct. 13, 1989]

§433.111 Definitions.

For purposes of this section:

(a) The following terms are defined at 45 CFR part 95, subpart F §95.605:

''Advance Planning Document''; ''Design'' or ''System Design''; ''Development''; ''Enhancement''; ''Hardware''; ''Installation''; ''Operation''; and, ''Software''.

(b) ''Mechanized claims processing and information retrieval system'' or ''system'' means the system of software and hardware used to process Medicaid claims from providers of medical care and services for the medical care and services furnished to recipients under the medical assistance program and to retrieve and produce service utilization and management information required by the Medicaid single State agency and Federal Government for program administration and audit purposes. The system consists of

(1) Required subsystems specified in the State Medicaid Manual;

(2) Required changes to the required system or subsystem that are published in accordance with §433.123 of this subpart and specified in the State Medicaid Manual; and

(3) Approved enhancements to the system. Eligibility determination systems are not part of mechanized claims processing and information retrieval systems or enhancements to those systems.

[51 FR 45330, Dec. 18, 1986, as amended at 54 FR 41973, Oct. 13, 1989]

§433.112 FFP for design, development, installation or enhancement of mechanized claims processing and information retrieval systems.

(a) FFP is available at the 90 percent rate in State expenditures for the design, development, installation, or enhancement of a mechanized claims processing and information retrieval system only if the APD is approved by CMS prior to the State's expenditure of funds for these purposes.

(b) CMS will approve the system described in the APD if the following conditions are met:

(1) CMS determines the system is likely to provide more efficient, economical, and effective administration of the State plan.

(2) The system meets the system requirements and performance standards in Part 11 of the State Medicaid Manual, as periodically amended.

(3) The system is compatible with the claims processing and information retrieval systems used in the administration of Medicare for prompt eligibility verification and for processing claims for persons eligible for both programs.

(4) The system supports the data requirements of quality improvement organizations established under Part B of title XI of the Act.

(5) The State owns any software that is designed, developed, installed or improved with 90 percent FFP.

(6) The Department has a royalty free, non-exclusive, and irrevocable license to reproduce, publish, or otherwise use and authorize others to use, for Federal Government purposes, software, modifications to software, and documentation that is designed, developed, installed or enhanced with 90 percent FFP.

(7) The costs of the system are determined in accordance with 45 CFR 74.171.

(8) The Medicaid agency agrees in writing to use the system for the period of time specified in the advance planning document approved by CMS or for any shorter period of time that CMS determines justifies the Federal funds invested.

(9) The agency agrees in writing that the information in the system will be safeguarded in accordance with subpart F, part 431 of this subchapter.

(c) Eligibility determination systems are not part of mechanized claims processing and information retrieval systems and are not eligible for 75 percent FFP under this subpart. These

systems are also not eligible for 90 percent FFP for any APD approved after November 13, 1989.

[43 FR 45201, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979; 45 FR 14213, Mar. 5, 1980; 50 FR 30846, July 30, 1985; 51 FR 45330, Dec. 18, 1986; 54 FR 41973, Oct. 13, 1989; 55 FR 1820, Jan. 19, 1990; 55 FR 4375, Feb. 7, 1990]

§ 433.113 Reduction of FFP for failure to operate a system and obtain initial approval.

(a) Except as waived under § 433.130 or 433.131, FFP will be reduced as specified in paragraph (b) of this section unless the Medicaid agency has in continuous operation a mechanized claims processing and information retrieval system that meets the following conditions:

(1) The APD for the system was approved by CMS;

(2) The system is operational by September 30, 1985; and

(3) The system is initially approved by the last day of the fourth quarter that begins after the date the system became operational as determined by CMS.

(b) CMS will reduce FFP in expenditures for compensation and training of skilled professional medical personnel and support staff under section 1903(a)(2) of the Act, and for general administration under section 1903(a)(7) of the Act, by the following increments applied separately to those two categories of expenditures:

(1) Five percentage points for the first two quarters beginning after a deadline in paragraph (a) of this section;

(2) An additional five percentage points during each additional two-quarter period, through the quarter in which the State achieves compliance with the conditions for initial operation or initial approval of an operating system. FFP reductions will not exceed 25 percentage points for each type of reduction.

(c) The amount of FFP (determined under section 1903(a)(3)(B)) that would be available retroactively for operating a system that later receives initial approval will be reduced by CMS by the same percentage points for the identical periods of time described in subparagraph (b)(1) of this section, until the system is initially approved. No reduction will be made after the first quarter during which the system is initially approved.

[50 FR 30847, July 30, 1985, as amended at 54 FR 41973, Oct. 13, 1989]

§ 433.114 Procedures for obtaining initial approval; notice of decision.

(a) To obtain initial approval, the Medicaid agency must inform CMS in writing that the system meets the conditions specified in § 433.116(c) through (h).

(b) If CMS disapproves the system, or determines that the system met requirements for initial approval on a date later than the date required under § 433.113(a)(3), the notice will include—

(1) The findings of fact upon which the determination was made; and

(2) The procedures for appeal of the determination in the context of a reconsideration of the resulting disallowance, to the Departmental Appeals Board.

[50 FR 30847, July 30, 1985, as amended at 54 FR 41973, Oct. 13, 1989]

§ 433.116 FFP for operation of mechanized claims processing and information retrieval systems.

(a) Subject to 42 CFR 433.113(c), FFP is available at 75 percent of expenditures for operation of a mechanized claims processing and information retrieval system approved by CMS, from the first day of the calendar quarter after the date the system met the conditions of initial approval, as established by CMS (including a retroactive adjustment of FFP if necessary to provide the 75 percent rate beginning on the first day of that calendar quarter). Subject to 45 CFR 95.611(a), the State shall obtain prior written approval from CMS when it plans to acquire ADP equipment or services, when it anticipates the total acquisition costs will exceed thresholds, and meets other conditions of the subpart.

(b) CMS will approve the system operation if the conditions specified in paragraphs (c) through (h) of this section are met.

(c) The conditions of § 433.112(b) (1) through (4) and (7) through (9), as periodically modified under § 433.112(b)(2), must be met.

(d) The system must have been operating continuously during the period for which FFP is claimed.

(e) The system must provide individual notices, within 45 days of the payment of claims, to all or a sample group of the persons who received services under the plan.

(f) The notice required by paragraph (e) of this section—

(1) Must specify—

(i) The service furnished;

(ii) The name of the provider furnishing the service;

(iii) The date on which the service was furnished; and

(iv) The amount of the payment made under the plan for the service; and

(2) Must not specify confidential services (as defined by the State) and must not be sent if the only service furnished was confidential.

(g) The system must provide both patient and provider profiles for program management and utilization review purposes.

(h) If the State has a Medicaid fraud control unit certified under section 1903(q) of the Act and §455.300 of this chapter, the Medicaid agency must have procedures to assure that information on probable fraud or abuse that is obtained from, or developed by, the system is made available to that unit. (See §455.21 of this chapter for State plan requirements.)

[45 FR 14213, Mar. 5, 1980. Redesignated and amended at 50 FR 30847, July 30, 1985; 55 FR 4375, Feb. 7, 1990]

§433.117 Initial approval of replacement systems.

(a) A replacement system must meet all conditions of initial approval of a mechanized claims processing and information retrieval system.

(b) The agency must submit a APD that includes—

(1) The date the replacement system will be in operation; and

(2) A plan for orderly transition from the system being replaced to the replacement system.

(c) FFP is available at—

(1) 90 percent in expenditures for design, development, and installation in accordance with the provisions of §433.112; and

(2) 75 percent in expenditures for operation of an approved replacement system in accordance with the provisions of §433.116(b) through (h), from the date that the system met the conditions of initial approval, as established by CMS.

(d) FFP is available at 75 percent in expenditures for the operation of an approved system that is being replaced (or at a reduced rate determined under §433.120 of this subpart for a system that has been disapproved) until the replacement system is in operation and approved.

[50 FR 30847, July 30, 1985]

§433.119 Conditions for reapproval; notice of decision.

(a) CMS will review at least once every three years each system operation initially approved under §433.114 and reapprove it for FFP at 75 percent of expenditures if the following conditions are met:

(1) The system meets the conditions of §433.112(b) (1), (3), (4), and (7) through (9).

(2) The system meets the conditions of §433.116 (d) through (h).

(3) The system meets the performance standards for reapproval and the system requirements in part 11 of the State Medicaid Manual as periodically amended.

(4) Automated eligibility determination systems approved or operating on or before November 13, 1989, will not qualify for FFP at 75 percent of expenditures after November 13, 1989.

(b) CMS may review an entire system operation or focus its review on parts of the operation. However, at a minimum, CMS will review standards, system requirements and other conditions of reapproval that have demonstrated weakness in a previous review or reviews.

(c) CMS will issue to each Medicaid agency, by the end of the first quarter after the review period, a written notice informing the agency whether its system is reapproved or disapproved. If the system is disapproved, the notice will also include—

(1) CMS's decision to reduce FFP for system operations, and the percentage to which it is reduced, beginning with the next calender quarter;

(2) The findings of fact upon which the determination was made; and

(3) A statement that State claims in excess of the reduced FFP rate will be disallowed and that any such disallowance will be appealable to the Departmental Appeals Board.

[54 FR 41973, Oct. 13, 1989; 55 FR 1820, Jan. 19, 1990]

§ 433.120 Procedures for reduction of FFP after reapproval review.

(a) If CMS determines after the reapproval review that the system no longer meets the conditions of reapproval in § 433.119, CMS will reduce FFP for system operations for at least four quarters. However, no system will be subject to reduction of FFP for at least the first four quarters after the quarter in which the system is initially approved as eligible for 75 percent FFP.

(b) CMS will reduce FFP in expenditures for system operations from 75 percent to no more than 70 percent and no less than 50 percent; however, CMS will not reduce FFP by more than 10 percentage points in any four-quarter period. The percentage to which the FFP is reduced will depend primarily on the following criteria:

(1) The number of conditions judged unsatisfactory;

(2) The extent to which conditions were not met;

(3) The significance of the unsatisfactory conditions in overall mechanized claims processing and information retrieval system operations; and

(4) The actual and potential program impact attributable to the unsatisfactory conditions.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989]

§ 433.121 Reconsideration of the decision to reduce FFP after reapproval review.

(a) The agency may appeal to the Departmental Appeals Board under 45 CFR part 16, a disallowance concerning a reduction in FFP claimed for system operation caused by a disapproval of the State's system. If the Board finds such a disallowance to be appropriate, the discretionary determination to reduce FFP by a particular percentage amount (instead of by a lesser percentage) is not subject to review by the Board unless the percentage reduction exceeds the range authorized by section 1903(r)(4)(B) of the Act.

(b) The decisions concerning whether to restore any FFP retroactively and the actual number of quarters for which FFP will be restored under § 433.122 of this subpart are not subject to administrative appeal to the Departmental Appeals Board under 45 CFR part 16.

(c) An agency's request for a reconsideration before the Board under paragraph (a) of this section does not delay implementation of the reduction in FFP. However, any reduction is subject to retroactive adjustment if required by the Board's determination on reconsideration.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989; 55 FR 1820, Jan. 19, 1990]

§ 433.122 Reapproval of a disapproved system.

When FFP has been reduced under § 433.120(a), and CMS determines upon subsequent review that the system meets all current performance standards, system requirements and other conditions of reapproval, the following provisions apply:

(a) CMS will resume FFP in expenditures for system operations at the 75 percent level beginning with the quarter following the review determination that the system again meets conditions of reapproval.

(b) CMS may retroactively waive a reduction of FFP in expenditures for system operations if CMS determines that the waiver could improve the administration of the State Medicaid plan. However, CMS cannot waive this reduction for any quarter before the fourth quarter immediately preceding the quarter in which CMS issues the determination (as part of the review process) stating that the system is reapproved.

[54 FR 41974, Oct. 13, 1989]

§ 433.123 Notification of changes in system requirements, performance standards or other conditions for approval or reapproval.

(a) Whenever CMS modifies system requirements or other conditions for

approval under §433.112 or §433.116, CMS will—

(1) Publish a notice in the FEDERAL REGISTER making available the proposed changes for public comment;

(2) Respond in a subsequent FEDERAL REGISTER notice to comments received; and

(3) Issue the new or modified requirements or conditions in the State Medicaid Manual.

(b) For changes in system requirements or other conditions for approval, CMS will allow an appropriate period for Medicaid agencies to meet the requirement determining this period on the basis of the requirement's complexity and other relevant factors.

(c) Whenever CMS modifies performance standards and other conditions for reapproval under §433.119, CMS will notify Medicaid agencies at least one calendar quarter before the review period to which the new or modified standards or conditions apply.

[57 FR 38782, Aug. 27, 1992]

§433.127 Termination of FFP for failure to provide access to claims processing and information retrieval systems.

CMS will terminate FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to the system, including onsite inspection. CMS may request such access at any time to determine whether the conditions in this subpart are being met.

[43 FR 45201, Sept. 29, 1978. Redesignated and amended at 50 FR 30847 and 30848, July 30, 1985]

§433.130 Waiver of conditions of initial operation and approval.

(a) CMS will waive requirements for initial operation and approval of systems under §433.113 for a State meeting the requirements of paragraph (b) of this section and that had a 1976 population of less than one million and made total Federal and State Medicaid expenditures of less than $100 million in fiscal year 1976. Population figures are those reported by the Bureau of the Census. Expenditures for fiscal year 1976 are those reported by the State for that year.

(b) To be eligible for this waiver, the agency must submit its reasons to CMS in writing and demonstrate to CMS's satisfaction that a system will not significantly improve the efficiency of the administration of the State plan.

(c) If CMS denies the waiver request, the notice of denial will include—

(1) The findings of fact upon which the denial was made; and

(2) The procedures for appeal of the denial.

(d) If CMS determines, after granting a waiver, that a system would significantly improve the administration of the State Medicaid program, CMS may withdraw the waiver and require that a State obtain initial approval of a system within two years of the date of waiver withdrawal.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989]

§433.131 Waiver for noncompliance with conditions of approval and reapproval.

If a State is unable to comply with the conditions of approval or of reapproval and the noncompliance will cause a percentum reduction in FFP, CMS will waive the FFP reduction in the following circumstances:

(a) *Good cause.* If CMS determines that good cause existed, CMS will waive the FFP reduction attributable to those items for which the good cause existed. A waiver of FFP consequences of the failure to meet the conditions of approval or reapproval based upon good cause will not extend beyond two consecutive quarters.

(b) *Circumstances beyond the control of a State.* The State must satisfactorily explain the circumstances that are beyond its control. When CMS grants the waiver, CMS will also defer all other system deadlines for the same length of time that the waiver applies.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989]

Subpart D—Third Party Liability

SOURCE: 45 FR 8984, Feb. 11, 1980, unless otherwise noted.

§ 433.135 Basis and purpose.

This subpart implements sections 1902(a)(25), 1902(a)(45), 1903(d)(2), 1903(o), 1903(p), and 1912 of the Act by setting forth State plan requirements concerning—

(a) The legal liability of third parties to pay for services provided under the plan;

(b) Assignment to the State of an individual's rights to third party payments; and

(c) Cooperative agreements between the Medicaid agency and other entities for obtaining third party payments.

[50 FR 46664, Nov. 12, 1985]

§ 433.136 Definitions.

For purposes of this subpart—

Private insurer means:

(1) Any commercial insurance company offering health or casualty insurance to individuals or groups (including both experience-rated insurance contracts and indemnity contracts);

(2) Any profit or nonprofit prepaid plan offering either medical services or full or partial payment for services included in the State plan; and

(3) Any organization administering health or casualty insurance plans for professional associations, unions, fraternal groups, employer-employee benefit plans, and any similar organization offering these payments or services, including self-insured and self-funded plans.

Third party means any individual, entity or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan.

Title IV-D agency means the organizational unit in the State that has the responsibility for administering or supervising the administration of a State plan for child support enforcement under title IV-D of the Act.

[49 FR 8984, Feb. 11, 1980, as amended at 50 FR 46664, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 433.137 State plan requirements.

(a) A State plan must provide that the requirements of §§ 433.138 and 433.139 are met for identifying third parties liable for payment of services under the plan and for payment of claims involving third parties.

(b) A State plan must provide that—

(1) The requirements of §§ 433.145 through 433.148 are met for assignment of rights to benefits, cooperation with the agency in obtaining medical support or payments, and cooperation in identifying and providing information to assist the State in pursuing any liable third parties; and

(2) The requirements of §§ 433.151 through 433.154 are met for cooperative agreements and incentive payments for third party collections.

(c) The requirements of paragraph (b)(1) of this section relating to assignment of rights to benefits and cooperation in obtaining medical support or payments and paragraph (b)(2) of this section are effective for medical assistance furnished on or after October 1, 1984. The requirements of paragraph (b)(1) of this section relating to cooperation in identifying and providing information to assist the State in pursuing liable third parties are effective for medical assistance furnished on or after July 1, 1986.

[50 FR 46665, Nov. 12, 1985, as amended at 55 FR 48606, Nov. 21, 1990; 55 FR 52130, Dec. 19, 1990; 60 FR 35502, July 10, 1995]

§ 433.138 Identifying liable third parties.

(a) *Basic provisions.* The agency must take reasonable measures to determine the legal liability of the third parties who are liable to pay for services furnished under the plan. At a minimum, such measures must include the requirements specified in paragraphs (b) through (k) of this section, unless waived under paragraph (l) of this section.

(b) *Obtaining health insurance information: Initial application and redetermination processes for Medicaid eligibility.* (1) If the Medicaid agency determines eligibility for Medicaid, it must, during the initial application and each redetermination process, obtain from the applicant or recipient such health insurance information as would be useful in identifying legally liable third party resources so that the agency may process claims under the third party liability payment procedures specified in

§433.139 (b) through (f). Health insurance information may include, but is not limited to, the name of the policy holder, his or her relationship to the applicant or recipient, the social security number (SSN) of the policy holder, and the name and address of insurance company and policy number.

(2) If Medicaid eligibility is determined by the Federal agency administering the supplemental security income program under title XVI in accordance with a written agreement under section 1634 of the Act, the Medicaid agency must take the following action. It must enter into an agreement with CMS or must have, prior to February 1, 1985, executed a modified section 1634 agreement that is still in effect to provide for—

(i) Collection, from the applicant or recipient during the initial application and each redetermination process, of health insurance information in the form and manner specified by the Secretary; and

(ii) Transmittal of the information to the Medicaid agency.

(3) If Medicaid eligibility is determined by any other agency in accordance with a written agreement, the Medicaid agency must modify the agreement to provide for—

(i) Collection, from the applicant or recipient during the initial application and each redetermination process, of such health insurance information as would be useful in identifying legally liable third party resources so that the Medicaid agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f). Health insurance information may include, but is not limited to, those elements described in paragraph (b)(1) of this section; and

(ii) Transmittal of the information to the Medicaid agency.

(c) *Obtaining other information.* Except as provided in paragraph (l) of this section, the agency must, for the purpose of implementing the requirements in paragraphs (d)(1)(ii) and (d)(4)(i) of this section, incorporate into the eligibility case file the names and SSNs of absent or custodial parents of Medicaid recipients to the extent such information is available.

(d) *Exchange of data.* Except as provided in paragraph (l) of this section, to obtain and use information for the purpose of determining the legal liability of the third parties so that the agency may process claims under the third party liability payment procedures specified in §433.139(b) through (f), the agency must take the following actions:

(1) Except as specified in paragraph (d)(2) of this section, as part of the data exchange requirements under §435.945 of this chapter, from the State wage information collection agency (SWICA) defined in §435.4 of this chapter and from the SSA wage and earnings files data as specified in §435.948(a)(2) of this chapter, the agency must—

(i) Use the information that identifies Medicaid recipients that are employed and their employer(s); and

(ii) Obtain and use, if their names and SSNs are available to the agency under paragraph (c) of this section, information that identifies employed absent or custodial parents of recipients and their employer(s).

(2) If the agency can demonstrate to CMS that it has an alternate source of information that furnishes information as timely, complete and useful as the SWICA and SSA wage and earnings files in determining the legal liability of third parties, the requirements of paragraph (d)(1) of this section are deemed to be met.

(3) The agency must request, as required under §435.948(a)(6)(i), from the State title IV-A agency, information not previously reported that identifies those Medicaid recipients that are employed and their employer(s).

(4) Except as specified in paragraph (d)(5) of this section, the agency must attempt to secure agreements (to the extent permitted by State law) to provide for obtaining—

(i) From State Workers' Compensation or Industrial Accident Commission files, information that identifies Medicaid recipients and, (if their names and SSNs were available to the agency under paragraph (c) of this section) absent or custodial parents of Medicaid recipients with employment-related injuries or illnesses; and

(ii) From State Motor Vehicle accident report files, information that

identifies those Medicaid recipients injured in motor vehicle accidents, whether injured as pedestrians, drivers, passengers, or bicyclists.

(5) If unable to secure agreements as specified in paragraph (d)(4) of this section, the agency must submit documentation to the regional office that demonstrates the agency made a reasonable attempt to secure these agreements. If CMS determines that a reasonable attempt was made, the requirements of paragraph (d)(4) of this section are deemed to be met.

(e) *Diagnosis and trauma code edits.* (1) Except as specified under paragraph (e)(2) or (l) of this section, or both, the agency must take action to identify those paid claims for Medicaid recipients that contain diagnosis codes 800 through 999 International Classification of Disease, 9th Revision, Clinical Modification, Volume 1 (ICD–9–CM) inclusive, for the purpose of determining the legal liability of third parties so that the agency may process claims under the third party liability payment procedures specified in § 433.139(b) through (f).

(2) The agency may exclude code 994.6, Motion Sickness, from the edits required under paragraph (e)(1) of this section.

(f) *Data exchanges and trauma code edits: Frequency.* Except as provided in paragraph (l) of this section, the agency must conduct the data exchanges required in paragraphs (d)(1) and (d)(3) of this section in accordance with the intervals specified in § 435.948 of this chapter, and diagnosis and trauma edits required in paragraphs (d)(4) and (e) of this section on a routine and timely basis. The State plan must specify the frequency of these activities.

(g) *Followup procedures for identifying legally liable third party resources.* Except as provided in paragraph (l) of this section, the State must meet the requirements of this paragraph.

(1) *SWICA, SSA wage and earnings files, and title IV-A data exchanges.* With respect to information obtained under paragraphs (d)(1) through (d)(3) of this section—

(i) Except as specified in § 435.952(d) of this chapter, within 45 days, the agency must followup (if appropriate) on such information in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f); and

(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(1)(i) of this section.

(2) *Health insurance information and workers' compensation data exchanges.* With respect to information obtained under paragraphs (b) and (d)(4)(i) of this section—

(i) Within 60 days, the agency must followup on such information (if appropriate) in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f); and

(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(2)(i) of this section.

(3) *State motor vehicle accident report file data exchanges.* With respect to information obtained under paragraph (d)(4)(ii) of this section—

(i) The State plan must describe the methods the agency uses for following up on such information in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify timeframes for incorporation of the information.

(4) *Diagnosis and trauma code edits.* With respect to the paid claims identified under paragraph (e) of this section—

(i) The State plan must describe the methods the agency uses to follow up on such claims in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f) (Methods must include a procedure for periodically identifying those trauma codes that yield the highest third party collections and giving priority to following up on those codes.);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify the timeframes for incorporation of the information.

(h) *Obtaining other information and data exchanges: Safeguarding information.* (1) The agency must safeguard information obtained from and exchanged under this section with other agencies in accordance with the requirements set forth in part 431, subpart F of this chapter.

(2) Before requesting information from, or releasing information to other agencies to identify legally liable third party resources under paragraph (d) of this section the agency must execute data exchange agreements with those agencies. The agreements, at a minimum, must specify—

(i) The information to be exchanged;

(ii) The titles of all agency officials with the authority to request third party information;

(iii) The methods, including the formats to be used, and the timing for requesting and providing the information;

(iv) The safeguards limiting the use and disclosure of the information as required by Federal or State law or regulations; and

(v) The method the agency will use to reimburse reasonable costs of furnishing the information if payment is requested.

(i) *Reimbursement.* The agency must, upon request, reimburse an agency for the reasonable costs incurred in furnishing information under this section to the Medicaid agency.

(j) *Reports.* The agency must provide such reports with respect to the data exchanges and trauma code edits set forth in paragraphs (d)(1) through (d)(4) and paragraph (e) of this section, respectively, as the Secretary prescribes for the purpose of determining compliance under §433.138 and evaluating the effectiveness of the third party liability identification system. However, if the State is not meeting the provisions of paragraph (e) of this section because it has been granted a waiver of those provisions under paragraph (l) of this section, it is not required to provide the reports required in this paragraph.

(k) *Integration with the State mechanized claims processing and information retrieval system. Basic requirement—Development of an action plan.* (1) If a State has a mechanized claims processing and information retrieval system approved by CMS under subpart C of this part, the agency must have an action plan for pursuing third party liability claims and the action plan must be integrated with the mechanized claims processing and information retrieval system.

(2) The action plan must describe the actions and methodologies the State will follow to—

(i) Identify third parties;

(ii) Determine the liability of third parties;

(iii) Avoid payment of third party claims as required in §433.139;

(iv) Recover reimbursement from third parties after Medicaid claims payment as required in §433.139; and,

(v) Record information and actions relating to the action plan.

(3) The action plan must be consistent with the conditions for reapproval set forth in §433.119. The portion of the plan which is integrated with MMIS is monitored in accordance with those conditions and if the conditions are not met; it is subject to FFP reduction in accordance with procedures set forth in §433.120. The State is not subject to any other penalty as a result of other monitoring, quality control, or auditing requirements for those items in the action plan.

(4) The agency must submit its action plan to the CMS Regional Office within 120 days from the date CMS issues implementing instructions for

the State Medicaid Manual. If a State does not have an approved MMIS on the date of issuance of the State Medicaid Manual but subsequently implements an MMIS, the State must submit its action plan within 90 days from the date the system is operational. The CMS Regional Office approves or disapproves the action plan.

(l) *Waiver of requirements.* (1) The agency may request initial and continuing waiver of the requirements to determine third party liability found in paragraphs (c), (d)(4), (d)(5), (e), (f), (g)(1), (g)(2), (g)(3), and (g)(4) of this section if the State determines the activity to be not cost-effective. An activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the State.

(i) The agency must submit a request for waiver of the requirement in writing to the CMS regional office.

(ii) The request must contain adequate documentation to establish that to meet a requirement specified by the agency is not cost-effective. Examples of documentation are claims recovery data and a State analysis documenting a cost-effective alternative that accomplished the same task.

(iii) The agency must agree, if a waiver is granted, to notify CMS of any event that occurs that changes the conditions upon which the waiver was approved.

(2) CMS will review a State's request to have a requirement specified under paragraph (l)(1) of this section waived and will request additional information from the State, if necessary. CMS will notify the State of its approval or disapproval determination within 30 days of receipt of a properly documented request.

(3) CMS may rescind a waiver at any time that it determines that the agency no longer meets the criteria for approving the waiver. If the waiver is rescinded, the agency has 6 months from the date of the rescission notice to meet the requirement that had been waived.

[52 FR 5975, Feb. 27, 1987, as amended at 54 FR 8741, Mar. 2, 1989; 55 FR 1432, Jan. 16, 1990; 55 FR 5118, Feb. 13, 1990; 60 FR 35502, July 10, 1995]

§ 433.139 Payment of claims.

(a) *Basic provisions.* (1) For claims involving third party liability that are processed on or after May 12, 1986, the agency must use the procedures specified in paragraphs (b) through (f) of this section.

(2) The agency must submit documentation of the methods (e.g., cost avoidance, pay and recover later) it uses for payment of claims involving third party liability to the CMS Regional Office.

(b) *Probable liability is established at the time claim is filed.* Except as provided in paragraph (e) of this section—

(1) If the agency has established the probable existence of third party liability at the time the claim is filed, the agency must reject the claim and return it to the provider for a determination of the amount of liability. The establishment of third party liability takes place when the agency receives confirmation from the provider or a third party resource indicating the extent of third party liability. When the amount of liability is determined, the agency must then pay the claim to the extent that payment allowed under the agency's payment schedule exceeds the amount of the third party's payment.

(2) The agency may pay the full amount allowed under the agency's payment schedule for the claim and then seek reimbursement from any liable third party to the limit of legal liability if the claim is for labor and delivery and postpartum care. (Costs associated with the inpatient hospital stay for labor and delivery and postpartum care must be cost-avoided.)

(3) The agency must pay the full amount allowed under the agency's payment schedule for the claim and seek reimbursement from any liable third party to the limit of legal liability (and for purposes of paragraph (b)(3)(ii) of this section, from a third party, if the third party liability is derived from an absent parent whose obligation to pay support is being enforced

by the State title IV-D agency), consistent with paragraph (f) of this section if—

(i) The claim is prenatal care for pregnant women, or preventive pediatric services (including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B of this chapter), that is covered under the State plan; or

(ii) The claim is for a service covered under the State plan that is provided to an individual on whose behalf child support enforcement is being carried out by the State title IV-D agency. The agency prior to making any payment under this section must assure that the following requirements are met:

(A) The State plan specifies whether or not providers are required to bill the third party.

(B) The provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited 30 days from the date of the service and has not received payment from the third party.

(C) The State plan specifies the method used in determining the provider's compliance with the billing requirements.

(c) *Probable liability is not established or benefits are not available at the time claim is filed.* If the probable existence of third party liability cannot be established or third party benefits are not available to pay the recipient's medical expenses at the time the claim is filed, the agency must pay the full amount allowed under the agency's payment schedule.

(d) *Recovery of reimbursement.* (1) If the agency has an approved waiver under paragraph (e) of this section to pay a claim in which the probable existence of third party liability has been established and then seek reimbursement, the agency must seek recovery of reimbursement from the third party to the limit of legal liability within 60 days after the end of the month in which payment is made unless the agency has a waiver of the 60-day requirement under paragraph (e) of this section.

(2) Except as provided in paragraph (e) of this section, if the agency learns of the existence of a liable third party after a claim is paid, or benefits become available from a third party after a claim is paid, the agency must seek recovery of reimbursement within 60 days after the end of the month it learns of the existence of the liable third party or benefits become available.

(3) Reimbursement must be sought unless the agency determines that recovery would not be cost effective in accordance with paragraph (f) of this section.

(e) *Waiver of requirements.* (1) The agency may request initial and continuing waiver of the requirements in paragraphs (b)(1), (d)(1), and (d)(2) of this section, if it determines that the requirement is not cost-effective. An activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the State.

(i) The agency must submit a request for waiver of the requirement in writing to the CMS regional office.

(ii) The request must contain adequate documentation to establish that to meet a requirement specified by the agency is not cost-effective. Examples of documentation are costs associated with billing, claims recovery data, and a State analysis documenting a cost-effective alternative that accomplishes the same task.

(iii) The agency must agree, if a waiver is granted, to notify CMS of any event that occurs that changes the conditions upon which the waiver was approved.

(2) CMS will review a State's request to have a requirement specified under paragraph (e)(1) of this section waived and will request additional information from the State, if necessary. CMS will notify the State of its approval or disapproval determination within 30 days of receipt of a properly documented request.

(3) CMS may rescind the waiver at any time that it determines that the State no longer meets the criteria for approving the waiver. If the waiver is rescinded, the agency has 6 months from the date of the rescission notice

to meet the requirement that had been waived.

(4) An agency requesting a waiver of the requirements specifically concerning either the 60-day limit in paragraph (d)(1) or (d)(2) of this section must submit documentation of written agreement between the agency and the third party, including Medicare fiscal intermediaries and carriers, that extension of the billing requirement is agreeable to all parties.

(f) *Suspension or termination of recovery of reimbursement.* (1) An agency must seek reimbursement from a liable third party on all claims for which it determines that the amount it reasonably expects to recover will be greater than the cost of recovery. Recovery efforts may be suspended or terminated only if they are not cost effective.

(2) The State plan must specify the threshold amount or other guideline that the agency uses in determining whether to seek recovery of reimbursement from a liable third party, or describe the process by which the agency determines that seeking recovery of reimbursement would not be cost effective.

(3) The State plan must also specify the dollar amount or period of time for which it will accumulate billings with respect to a particular liable third party in making the decision whether to seek recovery of reimbursement.

[50 FR 46665, Nov. 12, 1985, as amended at 51 FR 16319, May 2, 1986; 60 FR 35503, July 10, 1995; 62 FR 23140, Apr. 29, 1997]

§ 433.140 FFP and repayment of Federal share.

(a) FFP is not available in Medicaid payments if—

(1) The agency failed to fulfill the requirements of §§ 433.138 and 433.139 with regard to establishing liability and seeking reimbursement from a third party;

(2) The agency received reimbursement from a liable third party; or

(3) A private insurer would have been obligated to pay for the service except that its insurance contract limits or excludes payments if the individual is eligible for Medicaid.

(b) FFP is available at the 50 percent rate for the agency's expenditures in carrying out the requirements of this subpart.

(c) If the State receives FFP in Medicaid payments for which it receives third party reimbursement, the State must pay the Federal government a portion of the reimbursement determined in accordance with the FMAP for the State. This payment may be reduced by the total amount needed to meet the incentive payment in § 433.153.

ASSIGNMENT OF RIGHTS TO BENEFITS

§ 433.145 Assignment of rights to benefits—State plan requirements.

(a) A State plan must provide that, as a condition of eligibility, each legally able applicant or recipient is required to:

(1) Assign to the Medicaid agency his or her rights, or the rights of any other individual eligible under the plan for whom he or she can legally make an assignment, to medical support and to payment for medical care from any third party;

(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section 1902(l)(1)(A) of the Act (poverty level pregnant women), who are exempt from cooperating in establishing paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(3) Cooperate in identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan, unless the individual establishes good cause for not cooperating.

(b) A State plan must provide that the requirements for assignments, cooperation in establishing paternity and obtaining support, and cooperation in identifying and providing information to assist the State in pursuing any liable third party under §§ 433.146 through 433.148 are met.

(c) A State plan must provide that the assignment of rights to benefits obtained from an applicant or recipient is

effective only for services that are reimbursed by Medicaid.

[55 FR 48606, Nov. 21, 1990, as amended at 58 FR 4907, Jan. 19, 1993]

§ 433.146 Rights assigned; assignment method.

(a) Except as specified in paragraph (b) of this section, the agency must require the individual to assign to the State—

(1) His own rights to any medical care support available under an order of a court or an administrative agency, and any third party payments for medical care; and

(2) The rights of any other individual eligible under the plan, for whom he can legally make an assignment.

(b) Assignment of rights to benefits may not include assignment of rights to Medicare benefits.

(c) If assignment of rights to benefits is automatic because of State law, the agency may substitute such an assignment for an individual executed assignment, as long as the agency informs the individual of the terms and consequences of the State law.

§ 433.147 Cooperation in establishing paternity and in obtaining medical support and payments and in identifying and providing information to assist in pursuing third parties who may be liable to pay.

(a) *Scope of requirement.* The agency must require the individual who assigns his or her rights to cooperate in—

(1) Establishing paternity of a child born out of wedlock and obtaining medical support and payments for himself or herself and any other person for whom the individual can legally assign rights, except that individuals described in section 1902(l)(1)(A) of the Act (poverty level pregnant women) are exempt from these requirements involving paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(2) Identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan.

(b) *Essentials of cooperation.* As part of a cooperation, the agency may require an individual to—

(1) Appear at a State or local office designated by the agency to provide information or evidence relevant to the case;

(2) Appear as a witness at a court or other proceeding;

(3) Provide information, or attest to lack of information, under penalty of perjury;

(4) Pay to the agency any support or medical care funds received that are covered by the assignment of rights; and

(5) Take any other reasonable steps to assist in establishing paternity and securing medical support and payments, and in identifying and providing information to assist the State in pursuing any liable third party.

(c) *Waiver of cooperation for good cause.* The agency must waive the requirements in paragraphs (a) and (b) of this section if it determines that the individual has good cause for refusing to cooperate.

(1) With respect to establishing paternity of a child born out of wedlock or obtaining medical care support and payments, or identifying or providing information to assist the State in pursuing any liable third party for a child for whom the individual can legally assign rights, the agency must find the cooperation is against the best interests of the child, in accordance with factors specified for the Child Support Enforcement Program at 45 CFR part 232. If the State title IV-A agency has made a finding that good cause for refusal to cooperate does or does not exist, the Medicaid agency must adopt that finding as its own for this purpose.

(2) With respect to obtaining medical care support and payments for an individual and identifying and providing information to assist in pursuing liable third parties in any case not covered by paragraph (c)(1) of this section, the agency must find that cooperation is against the best interests of the individual or the person to whom Medicaid is being furnished because it is anticipated that cooperation will result in reprisal against, and cause physical or emotional harm to, the individual or other person.

(d) *Procedures for waiving cooperation.* With respect to establishing paternity, obtaining medical care support and payments, or identifying and providing information to assist the State in pursuing liable third parties for a child for whom the individual can legally assign rights, the agency must use the procedures specified for the Child Support Enforcement Program at 45 CFR part 232. With respect to obtaining medical care support and payments or to identifying and providing information to assist the State in pursuing liable third parties for any other individual, the agency must adopt procedures similar to those specified in 45 CFR part 232, excluding those procedures applicable only to children.

[45 FR 8984, Feb. 11, 1980, as amended at 55 FR 48606, Nov. 21, 1990; 58 FR 4907, Jan. 19, 1993]

§ 433.148 Denial or termination of eligibility.

In administering the assignment of rights provision, the agency must:

(a) Deny or terminate eligibility for any applicant or recipient who—

(1) Refuses to assign his own rights or those of any other individual for whom he can legally make an assignment; or

(2) Refuses to cooperate as required under § 433.147(a) unless cooperation has been waived;

(b) Provide Medicaid to any individual who—

(1) Cannot legally assign his own rights; and

(2) Would otherwise be eligible for Medicaid but for the refusal, by a person legally able to assign his rights, to assign his rights or to cooperate as required by this subpart; and

(c) In denying or terminating eligibility, comply with the notice and hearing requirements of part 431, subpart E of this subchapter.

COOPERATIVE AGREEMENTS AND INCENTIVE PAYMENTS

§ 433.151 Cooperative agreements and incentive payments—State plan requirements.

For medical assistance furnished on or after October 1, 1984—

(a) A State plan must provide for entering into written cooperative agreements for enforcement of rights to and collection of third party benefits with at least one of the following entities: The State title IV-D agency, any appropriate agency of any State, and appropriate courts and law enforcement officials. The agreements must be in accordance with the provisions of § 433.152.

(b) A State plan must provide that the requirements for making incentive payments and for distributing third party collections specified in §§ 433.153 and 433.154 are met.

[50 FR 46665, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 433.152 Requirements for cooperative agreements for third party collections.

(a) Except as specified in paragraph (b) of this section, the State agency may develop the specific terms of cooperative agreements with other agencies as it determines appropriate for individual circumstances.

(b) Agreements with title IV-D agencies must specify that the Medicaid agency will—

(1) Meet the requirements of the Office of Child Support Enforcement for cooperative agreements under 45 CFR Part 306; and

(2) Provide reimbursement to the IV-D agency only for those child support services performed that are not reimbursable by the Office of Child Support Enforcement under title IV-D of the Act and that are necessary for the collection of amounts for the Medicaid program.

[50 FR 46666, Nov. 12, 1985]

§ 433.153 Incentive payments to States and political subdivisions.

(a) *When payments are required.* The agency must make an incentive payment to a political subdivision, a legal entity of the subdivision such as a prosecuting or district attorney or a friend of the court, or another State that enforces and collects medical support and payments for the agency.

(b) *Amount and source of payment.* The incentive payment must equal 15 percent of the amount collected, and must be made from the Federal share of that amount.

(c) *Payment to two or more jurisdictions.* If more than one State or political subdivision is involved in enforcing and collecting support and payments:

(1) The agency must pay all of the incentive payment to the political subdivision, legal entity of the subdivision, or another State that collected medical support and payments at the request of the agency.

(2) The political subdivision, legal entity or other State that receives the incentive payment must then divide the incentive payment equally with any other political subdivisions, legal entities, or other States that assisted in the collection, unless an alternative allocation is agreed upon by all jurisdictions involved.

§433.154 Distribution of collections.

The agency must distribute collections as follows—

(a) To itself, an amount equal to State Medicaid expenditures for the individual on whose right the collection was based.

(b) To the Federal Government, the Federal share of the State Medicaid expenditures, minus any incentive payment made in accordance with §433.153.

(c) To the recipient, any remaining amount. This amount must be treated as income or resources under part 435 or part 436 of this subchapter, as appropriate.

Subpart E [Reserved]

Subpart F—Refunding of Federal Share of Medicaid Overpayments to Providers

SOURCE: 54 FR 5460, Feb. 3, 1989, unless otherwise noted.

§433.300 Basis.

This subpart implements—

(a) Section 1903(d)(2)(A) of the Act, which directs that quarterly Federal payments to the States under title XIX (Medicaid) of the Act are to be reduced or increased to make adjustment for prior overpayments or underpayments that the Secretary determines have been made.

(b) Section 1903(d)(2) (C) and (D) of the Act, which provides that a State has 60 days from discovery of an overpayment for Medicaid services to recover or attempt to recover the overpayment from the provider before adjustment in the Federal Medicaid payment to the State is made; and that adjustment will be made at the end of the 60 days, whether or not recovery is made, unless the State is unable to recover from a provider because the overpayment is a debt that has been discharged in bankruptcy or is otherwise uncollectable.

(c) Section 1903(d)(3) of the Act, which provides that the Secretary will consider the pro rata Federal share of the net amount recovered by a State during any quarter to be an overpayment.

§433.302 Scope of subpart.

This subpart sets forth the requirements and procedures under which States have 60 days following discovery of overpayments made to providers for Medicaid services to recover or attempt to recover that amount before the States must refund the Federal share of these overpayments to CMS, with certain exceptions.

§433.304 Definitions.

As used in this subpart—

Abuse (in accordance with §455.2) means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

Discovery (or *discovered*) means identification by any State Medicaid agency official or other State official, the Federal Government, or the provider of an overpayment, and the communication of that overpayment finding or the initiation of a formal recoupment action without notice as described in §433.316.

Fraud (in accordance with §455.2) means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to

himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Overpayment means the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act.

Provider (in accordance with § 400.203) means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

Recoupment means any formal action by the State or its fiscal agent to initiate recovery of an overpayment without advance official notice by reducing future payments to a provider.

Third party (in accordance with § 433.136) means an individual, entity, or program that is or may be liable to pay for all or part of the expenditures for medical assistance furnished under a State plan.

[54 FR 5460, Feb. 3, 1989; 54 FR 8435, Feb. 28, 1989]

§ 433.310 Applicability of requirements.

(a) *General rule.* Except as provided in paragraphs (b) and (c) of this section, the provisions of this subpart apply to—

(1) Overpayments made to providers that are discovered by the State;

(2) Overpayments made to providers that are initially discovered by the provider and made known to the State agency; and

(3) Overpayments that are discovered through Federal reviews.

(b) *Third party payments and probate collections.* The requirements of this subpart do not apply to—

(1) Cases involving third party liability because, in these situations, recovery is sought for a Medicaid payment that would have been made had another party not been legally responsible for payment; and

(2) Probate collections from the estates of deceased Medicaid recipients, as they represent the recovery of payments properly made from resources later determined to be available to the State.

(c) *Unallowable costs paid under rate-setting systems.* (1) Unallowable costs for a prior year paid to an institutional provider under a rate-setting system that a State recovers through an adjustment to the per diem rate for a subsequent period do not constitute overpayments that are subject to the requirements of this subpart.

In such cases, the State is not required to refund the Federal share explicitly related to the original overpayment in accordance with the regulations in this subpart. Refund of the Federal share occurs when the State claims future expenditures made to the provider at a reduced rate.

(2) Unallowable costs for a prior year paid to an institutional provider under a rate-setting system that a State seeks to recover in a lump sum, by an installment repayment plan, or through reduction of future payments to which the provider would otherwise be entitled constitute overpayments that are subject to the requirements of this subpart.

(d) *Recapture of depreciation upon gain on the sale of assets.* Depreciation payments are considered overpayments for purposes of this subpart if a State requires their recapture in a discrete amount(s) upon gain on the sale of assets.

§ 433.312 Basic requirements for refunds.

(a) *Basic rules.* (1) Except as provided in paragraph (b) of this section, the Medicaid agency has 60 days from the date of discovery of an overpayment to a provider to recover or seek to recover the overpayment before the Federal share must be refunded to CMS.

(2) The agency must refund the Federal share of overpayments at the end of the 60-day period following discovery in accordance with the requirements of this subpart, whether or not the State has recovered the overpayment from the provider.

(b) *Exception.* The agency is not required to refund the Federal share of an overpayment made to a provider when the State is unable to recover the overpayment amount because the provider has been determined bankrupt or out of business in accordance with § 433.318.

(c) *Applicability.* (1) The requirements of this subpart apply to overpayments made to Medicaid providers that occur and are discovered in any quarter that begins on or after October 1, 1985.

(2) The date upon which an overpayment occurs is the date upon which a State, using its normal method of reimbursement for a particular class of provider (e.g., check, interfund transfer), makes the payment involving unallowable costs to a provider.

§433.316 When discovery of overpayment occurs and its significance.

(a) *General rule.* The date on which an overpayment is discovered is the beginning date of the 60-calendar day period allowed a State to recover or seek to recover an overpayment before a refund of the Federal share of an overpayment must be made to CMS.

(b) *Requirements for notification.* Unless a State official or fiscal agent of the State chooses to initiate a formal recoupment action against a provider without first giving written notification of its intent, a State Medicaid agency official or other State official must notify the provider in writing of any overpayment it discovers in accordance with State agency policies and procedures and must take reasonable actions to attempt to recover the overpayment in accordance with State law and procedures.

(c) *Overpayments resulting from situations other than fraud or abuse.* An overpayment resulting from a situation other than fraud or abuse is discovered on the earliest of—

(1) The date on which any Medicaid agency official or other State official first notifies a provider in writing of an overpayment and specifies a dollar amount that is subject to recovery;

(2) The date on which a provider initially acknowledges a specific overpaid amount in writing to the medicaid agency; or

(3) The date on which any State official or fiscal agent of the State initiates a formal action to recoup a specific overpaid amount from a provider without having first notified the provider in writing.

(d) *Overpayments resulting from fraud or abuse.* An overpayment that results from fraud or abuse is discovered on the date of the final written notice of the State's overpayment determination that a Medicaid agency official or other State official sends to the provider.

(e) *Overpayments identified through Federal reviews.* If a Federal review at any time indicates that a State has failed to identify an overpayment or a State has identified an overpayment but has failed to either send written notice of the overpayment to the provider that specified a dollar amount subject to recovery or initiate a formal recoupment from the provider without having first notified the provider in writing, CMS will consider the overpayment as discovered on the date that the Federal official first notifies the State in writing of the overpayment and specifies a dollar amount subject to recovery.

(f) *Effect of changes in overpayment amount.* Any adjustment in the amount of an overpayment during the 60-day period following discovery (made in accordance with the approved State plan, Federal law and regulations governing Medicaid, and the appeals resolution process specified in State administrative policies and procedures) has the following effect on the 60-day recovery period:

(1) A downward adjustment in the amount of an overpayment subject to recovery that occurs after discovery does not change the original 60-day recovery period for the outstanding balance.

(2) An upward adjustment in the amount of an overpayment subject to recovery that occurs during the 60-day period following discovery does not change the 60-day recovery period for the original overpayment amount. A new 60-day period begins for the incremental amount only, beginning with the date of the State's written notification to the provider regarding the upward adjustment.

(g) *Effect of partial collection by State.* A partial collection of an overpayment amount by the State from a provider during the 60-day period following discovery does not change the 60-day recovery period for the original overpayment amount due to CMS.

(h) *Effect of administrative or judicial appeals.* Any appeal rights extended to

a provider do not extend the date of discovery.

[54 FR 5460, Feb. 3, 1989; 54 FR 8435, Feb. 28, 1989]

§ 433.318 Overpayments involving providers who are bankrupt or out of business.

(a) *Basic rules.* (1) The agency is not required to refund the Federal share of an overpayment made to a provider as required by § 433.312(a) to the extent that the State is unable to recover the overpayment because the provider has been determined bankrupt or out of business in accordance with the provisions of this section.

(2) The agency must notify the provider that an overpayment exists in any case involving a bankrupt or out-of-business provider and, if the debt has not been determined uncollectable, take reasonable actions to recover the overpayment during the 60-day recovery period in accordance with policies prescribed by applicable State law and administrative procedures.

(b) *Overpayment debts that the State need not refund.* Overpayments are considered debts that the State is unable to recover within the 60-day period following discovery if the following criteria are met:

(1) The provider has filed for bankruptcy, as specified in paragraph (c) of this section; or

(2) The provider has gone out of business and the State is unable to locate the provider and its assets, as specified in paragraph (d) of this section.

(c) *Bankruptcy.* The agency is not required to refund to CMS the Federal share of an overpayment at the end of the 60-day period following discovery, if—

(1) The provider has filed for bankruptcy in Federal court at the time of discovery of the overpayment or the provider files a bankruptcy petition in Federal court before the end of the 60-day period following discovery; and

(2) The State is on record with the court as a creditor of the petitioner in the amount of the Medicaid overpayment.

(d) *Out of business.* (1) The agency is not required to refund to CMS the Federal share of an overpayment at the end of the 60-day period following discovery if the provider is out of business on the date of discovery of the overpayment or if the provider goes out of business before the end of the 60-day period following discovery.

(2) A provider is considered to be out of business on the effective date of a determination to that effect under State law. The agency must—

(i) Document its efforts to locate the party and its assets. These efforts must be consistent with applicable State policies and procedures; and

(ii) Make available an affidavit or certification from the appropriate State legal authority establishing that the provider is out of business and that the overpayment cannot be collected under State law and procedures and citing the effective date of that determination under State law.

(3) A provider is not out of business when ownershp is transferred within the State unless State law and procedures deem a provider that has transferred ownership to be out of business and preclude collection of the overpayment from the provider.

(e) *Circumstances requiring refunds.* If the 60-day recovery period has expired before an overpayment is found to be uncollectable under the provisions of this section, if the State recovers an overpayment amount under a court-approved discharge of bankruptcy, or if a bankruptcy petition is denied, the agency must refund the Federal share of the overpayment in accordance with the procedures specified in § 433.320.

[54 FR 5460, Feb. 3, 1989; 54 FR 8435, Feb. 28, 1989]

§ 433.320 Procedures for refunds to CMS.

(a) *Basic requirements.* (1) The agency must refund the Federal share of overpayments that are subject to recovery to CMS through a credit on its Quarterly Statement of Expenditures (Form CMS–64).

(2) The Federal share of overpayments subject to recovery must be credited on the Form CMS–64 report submitted for the quarter in which the 60-day period following discovery, established in accordance with § 433.316, ends.

(3) A credit on the Form CMS–64 must be made whether or not the overpayment has been recovered by the State from the provider.

(b) *Effect of reporting collections and submitting reduced expenditure claims.* (1) The State is not required to refund the Federal share of an overpayment when the State reports a collection or submits an expenditure claim reduced by a discrete amount to recover an overpayment prior to the end of the 60-day period following discovery.

(2) The State is not required to report on the Form CMS–64 any collections made on overpayment amounts for which the Federal share has been refunded previously.

(3) If a State has refunded the Federal share of an overpayment as required under this subpart and the State subsequently makes recovery by reducing future provider payments by a discrete amount, the State need not reflect that reduction in its claim for Federal financial participation.

(c) *Reclaiming overpayment amounts previously refunded to CMS.* If the amount of an overpayment is adjusted downward after the agency has credited CMS with the Federal share, the agency may reclaim the amount of the downward adjustment on the Form CMS–64. Under this provision—

(1) Downward adjustment to an overpayment amount previously credited to CMS is allowed only if it is properly based on the approved State plan, Federal law and regulations governing Medicaid, and the appeals resolution processes specified in State administrative policies and procedures.

(2) The 2-year filing limit for retroactive claims for Medicaid expenditures does not apply. A downward adjustment is not considered a retroactive claim but rather a reclaiming of costs previously claimed.

(d) *Expiration of 60-day recovery period.* If an overpayment has not been determined uncollectable in accordance with the requirements of §433.318 at the end of the 60-day period following discovery of the overpayment, the agency must refund the Federal share of the overpayment to CMS in accordance with the procedures specified in paragraph (a) of this section.

(e) *Court-approved discharge of bankruptcy.* If the State recovers any portion of an overpayment under a court-approved discharge of bankruptcy, the agency must refund to CMS the Federal share of the overpayment amount collected on the next quarterly expenditure report that is due to CMS for the period that includes the date on which the collection occurs.

(f) *Bankruptcy petition denied.* If a provider's petition for bankruptcy is denied in Federal court, the agency must credit CMS with the Federal share of the overpayment on the later of—

(1) The Form CMS–64 submission due to CMS immediately following the date of the decision of the court; or

(2) The Form CMS–64 submission for the quarter in which the 60-day period following discovery of the overpayment ends.

(g) *Reclaim of refunds.* (1) If a provider is determined bankrupt or out of business under this section after the 60-day period following discovery of the overpayment ends and the State has not been able to make complete recovery, the agency may reclaim the amount of the Federal share of any unrecovered overpayment amount previously refunded to CMS. CMS allows the reclaim of a refund by the agency if the agency submits to CMS documentation that it has made reasonable efforts to obtain recovery.

(2) If the agency reclaims a refund of the Federal share of an overpayment—

(i) In bankruptcy cases, the agency must submit to CMS a statement of its efforts to recover the overpayment during the period before the petition for bankruptcy was filed; and

(ii) In out-of-business cases, the agency must submit to CMS a statement of its efforts to locate the provider and its assets and to recover the overpayment during any period before the provider is found to be out of business in accordance with §433.318.

(h) *Supporting reports.* The agency must report the following information to support each Quarterly Statement of Expenditures Form CMS–64:

(1) Amounts of overpayments not collected during the quarter but refunded because of the expiration of the 60-day period following discovery;

(2) Upward and downward adjustments to amounts credited in previous quarters;

(3) Amounts of overpayments collected under court-approved discharges of bankruptcy;

(4) Amounts of previously reported overpayments to providers certified as bankrupt or out of business during the quarter; and

(5) Amounts of overpayments previously credited and reclaimed by the State.

§ 433.322 Maintenance of records.

The Medicaid agency must maintain a separate record of all overpayment activities for each provider in a manner that satisfies the retention and access requirements of 45 CFR part 74, subpart D.

PART 434—CONTRACTS

Subpart A—General Provisions

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434.1 Basis and scope.
434.2 Definitions.
434.4 State plan requirement.
434.6 General requirements for all contracts and subcontracts.

Subpart B—Contracts with Fiscal Agents and Private Nonmedical Institutions

434.10 Contracts with fiscal agents.
434.12 Contracts with private nonmedical institutions.
434.14 [Reserved]

Subpart C [Reserved]

Subpart D—Contracts With Health Insuring Organizations

434.40 Contract requirements.

Subpart E [Reserved]

Subpart F—Federal Financial Participation

434.70 Conditions for Federal Financial Participation (FFP).
434.76 Costs under fiscal agent contracts.
434.78 Right to reconsideration of disallowance.

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

SOURCE: 48 FR 54020, Nov. 30, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 434.1 Basis and scope.

(a) *Statutory basis.* This part is based on section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) *Scope.* This part sets forth the requirements for contracts with certain organizations for furnishing Medicaid services or processing or paying Medicaid claims, or enchancing the agency's capability for effective administration of the program.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983, as amended at 67 FR 41095, June 14, 2002]

§ 434.2 Definitions.

As used in this part, unless the context indicates otherwise—

Fiscal agent means an entity that processes or pays vendor claims for the agency.

Health care projects grant center means an entity that—

(a) Is supported in whole or in part by Federal project grant financial assistance; and

(b) Provides or arranges for medical services to recipients.

Private nonmedical institution means an institution (such as a child-care facility or a maternity home) that—

(a) Is not, as a matter of regular business, a health insuring organization or a community health care center;

(b) Provides medical care to its residents through contracts or other arrangements with medical providers; and

(c) Receives capitation payments from the Medicaid agency, under a nonrisk contract, for its residents who are eligible for Medicaid.

Professional management service or consultant firm means a firm that performs management services such as auditing or staff training, or carries out studies or provides consultation aimed at improving State Medicaid operations, for example, with respect to reimbursement formulas or accounting systems.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983, as amended at 52 FR 22322, June 11, 1987; 55 FR 51295, Dec. 13, 1990; 67 FR 41095, June 14, 2002]

§ 434.4 State plan requirement.

If the State plan provides for contracts of the types covered by this part, the plan must also provide for meeting the applicable requirements of this part.

§ 434.6 General requirements for all contracts and subcontracts.

(a) *Contracts.* All contracts under this part must—

(1) Include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74;

(2) Identify the population covered by the contract;

(3) Specify any procedures for enrollment or reenrollment of the covered population;

(4) Specify the amount, duration, and scope of medical services to be provided or paid for;

(5) Provide that the agency and HHS may evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract;

(6) Specify procedures and criteria for terminating the contract, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding Medicaid claims;

(7) Provide that the contractor maintains an appropriate record system for services to enrolled recipients;

(8) Provide that the contractor safeguards information about recipients as required by part 431, subpart F of this chapter;

(9) Specify any activities to be performed by the contractor that are related to third party liability requirements in part 433, subpart D of this chapter;

(10) Specify which functions may be subcontracted; and

(11) Provide that any subcontracts meet the requirements of paragraph (b) of this section.

(b) *Subcontracts.* All subcontracts must be in writing and fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(c) *Continued responsibility of contractor.* No subcontract terminates the legal responsibility of the contractor to the agency to assure that all activities under the contract are carried out.

[48 FR 54020, Nov. 30, 1983, as amended at 67 FR 41095, June 14, 2002]

Subpart B—Contracts with Fiscal Agents and Private Nonmedical Institutions

§ 434.10 Contracts with fiscal agents.

Contracts with fiscal agents must—

(a) Meet the requirements of § 434.6;

(b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—

(1) Computer programs;

(2) Data files;

(3) User and operation manuals, and other documentation;

(4) System and program documentation; and

(5) Training programs for Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;

(c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent's subcontractor has a proprietary right to material specified in paragraph (b) of this section:

(1) Purchasing the material; or

(2) Purchasing the use of the material through leasing or other means; and

(d) State that payment to providers will be made in accordance with part 447 of this chapter.

§ 434.12 Contracts with private nonmedical institutions.

Contracts with private nonmedical institutions must—

(a) Meet the requirements of § 434.6;

(b) Specify a capitation fee based on the cost of the services provided, in accordance with the reimbursement requirements prescribed in part 447 of this chapter; and

(c) Specify when the capitation fee must be paid.

§ 434.14 [Reserved]

Subpart C [Reserved]

Subpart D—Contracts With Health Insuring Organizations

§ 434.40 Contract requirements.

(a) Contracts with health insuring organizations that are not subject to the requirements in section 1903(m)(2)(A) must:

(1) Meet the general requirements for all contracts and subcontracts specified in § 434.6;

(2) Specify that the contractor assumes at least part of the underwriting risk and;

(i) If the contractor assumes the full underwriting risk, specify that payment of the capitation fees to the contractor during the contract period constitutes full payment by the agency for the cost of medical services provided under the contract;

(ii) If the contractor assumes less than the full underwriting risk, specify how the risk is apportioned between the agency and the contractor;

(3) Specify whether the contractor returns to the agency part of any savings remaining after the allowable costs are deducted from the capitations fees, and if savings are returned, the apportionment between agency and the contractor; and

(4) Specify the extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk.

(b) The contract must—

(1) Specify that the capitation fee will not exceed the limits set forth under part 447 of this chapter.

(2) Specify that, except as permitted under paragraph (b) of this section, the capitation fee paid on behalf of each recipient may not be renegotiated—

(i) During the contract period if the contract period is 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year.

(3) Specify that the capitation fee will not include any amount for recoupment of any specific losses suffered by the contractor for risks assumed under the same contract or a prior contract with the agency; and

(4) Specify the actuarial basis for computation of the capitation fee.

(c) The capitation fee may be renegotiated more frequently than annually for recipients who are not enrolled at the time of renegotiation or if the renegotiation is required by changes in Federal or State law.

[55 FR 51295, Dec. 13, 1990]

Subpart E [Reserved]

Subpart F—Federal Financial Participation

SOURCE: 48 FR 54020, Nov. 20, 1983, unless otherwise noted. Redesignated at 55 FR 51295, Dec. 13, 1990.

§ 434.70 Conditions for Federal Financial Participation (FFP).

(a) *Basic requirements.* FFP is available only for periods during which the contract—

(1) Meets the requirements of this part;

(2) Meets the applicable requirements of 45 CFR part 74; and

(3) Is in effect.

(b) *Basis for withholding.* CMS may withhold FFP for any period during which the State fails to meet the State plan requirements of this part.

[67 FR 41095, June 14, 2002]

§ 434.76 Costs under fiscal agent contracts.

Under each contract with a fiscal agent—

(a) The amount paid to the provider of medical services is a medical assistance cost; and

(b) The amount paid to the contractor for performing the agreed-upon functions is an administrative cost.

§ 434.78 Right to reconsideration of disallowance.

A Medicaid agency dissatisfied with a disallowance of FFP under this subpart may request and will be granted reconsideration in accordance with 45 CFR part 16.

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

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OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

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

SOURCE: 43 FR 45204, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 435.2 Purpose and applicability.

This part sets forth, for the 50 States, the District of Columbia, the Northern Mariana Islands, and American Samoa—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that the Medicaid agency must use in determining and redetermining eligibility, and requirements it may not use;

(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan; and

(e) Other requirements concerning eligibility determinations, such as use of an institutionalized individual's income for the cost of care.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979; 51 FR 41350, Nov. 14, 1986]

§ 435.3 Basis.

(a) This part implements the following sections of the Act and public laws that mandate eligibility requirements and standards:

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.
402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.
414(g) Eligibility of certain individuals participating in work supplementation programs.
473(b) Eligibility of children in foster care and adopted children who are deemed AFDC recipients.
1619(b) Benefits for blind individuals or those with disabling impairments whose income equals or exceeds a specific SSI limit.
1634(b) Preservation of benefit status for disabled widows and widowers who lost SSI benefits because of 1983 changes in actuarial reduction formula.
1634(d) Individuals who lose eligibility for SSI benefits due to entitlement to early widow's or widower's social security disability benefits under section 202(e) or (f) of the Act.
1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
1902(a)(10) Required and optional groups.
1902(a)(12) Determination of blindness.
1902(a)(17) Standards for determining eligibility: flexibility in the application of income eligibility standards.
1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.
1902(a)(34) Three-month retroactive eligibility.
1902(a) (second paragraph after (47)) Eligibility despite increased monthly insurance benefits under title II.
1902(a)(55) Mandatory use of outstation locations other than welfare offices to receive and initially process applications of certain low-income pregnant women, infants, and children under age 19.
1902(b) Prohibited conditions for eligibility: Age requirement of more that 65 years;
State residence requirements excluding individuals who reside in the state; and
Citizenship requirement excluding United States citizens.
1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.
1902(e)(2) Minimum eligibility period for recipient enrolled in an HMO.
1902(e)(3) Optional coverage of certain disabled children being cared for at home.
1902(e)(4) Eligibility of newborn children of Medicaid eligible women.
1902(e)(5) Eligibility of pregnant woman for extended coverage for specified postpartum period after pregnancy ends.
1902(f) State option to restrict Medicaid eligibility for aged, blind, or disabled individuals to those who would have been eligible under State plan in effect in January 1972.
1902(j) Medicaid program in American Samoa.
1903(f) Income limitations for medically needy and individuals covered by State supplement eligibility requirements.
1903(v) Payment for emergency services under Medicaid provided to aliens.
1905(a) (clause following (21)) Prohibitions against providing Medicaid to certain institutionalized individuals.
1905(a) (second sentence) Definition of essential person.
1905(a)(i)–(viii) List of eligible individuals.
1905(d)(2) Definition of resident of an intermediate care facility for the mentally retarded.

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1905(k) Eligibility of essential spouses of eligible individuals.
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1912(a) Conditions of eligibility.
1915(c) Home or community-based services.
1915(d) Home or community-based services for individuals age 65 or older.
412(e)(5) of Immigration and Nationality Act—Eligibility of certain refugees.
Pub. L. 93–66, section 230 Deemed eligibility of certain essential persons.
Pub. L. 93–66, section 231 Deemed eligibility of certain persons in medical institutions.
Pub. L. 93–66, section 232 Deemed eligibility of certain blind and disabled medically indigent persons.
Pub. L. 93–233, section 13(c) Deemed eligibility of certain individuals receiving mandatory State supplementary payments.
Pub. L. 94–566, section 503 Deemed eligibility of certain individuals who would be eligible for supplemental security income benefits but for cost-of-living increases in social security benefits.
Pub. L. 96–272, section 310(b)(1) Continued eligibility of certain recipients of Veterans Administration pensions.
Pub. L. 99–509, section 9406 Payment for emergency medical services provided to aliens.
Pub. L. 99–603, section 201 Aliens granted legalized status under section 245A of the Immigration and Nationality Act (8 U.S.C. 1255a) may under certain circumstances be eligible for Medicaid.
Pub. L. 99–603, section 302 Aliens granted legalized status under section 210 of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1160).
Pub. L. 99–603, section 303 Aliens granted legal status under section 210A of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1161).

(b) This part implements the following other provisions of the Act or public laws that establish additional State plan requirements:

1618 Requirement for operation of certain State supplementation programs.
Pub. L. 93–66, section 212(a) Required mandatory minimum State supplementation of SSI benefits programs.

[52 FR 43071, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987, as amended at 55 FR 36819, Sept. 7, 1990; 55 FR 48607, Nov. 21, 1990; 57 FR 29155, June 30, 1992; 59 FR 48809, Sept. 23, 1994]

§435.4 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act;

AB means aid to the blind under title X of the Act;

AFDC means aid to families with dependent children under title IV-A of the Act;

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Categorically needy refers to families and children, aged, blind, or disabled individuals, and pregnant women, described under subparts B and C of this part who are eligible for Medicaid. Subpart B of this part describes the mandatory eligibility groups who, generally, are receiving or deemed to be receiving cash assistance under the Act. These mandatory groups are specified in sections 1902(a)(10)(A)(i), 1902(e), 1902(f), and 1928 of the Act. Subpart C of this part describes the optional eligibility groups of individuals who, generally, meet the categorical requirements or income or resource requirements that are the same as or less restrictive than those of the cash assistance programs and who are not receiving cash payments. These optional groups are specified in sections 1902(a)(10)(A)(ii), 1902(e), and 1902(f) of the Act.

Families and children refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90, 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but are financially eligible under AFDC rules or medically needy rules (see optional coverage group, §435.222). It does not include individuals under age 21 whose eligibility for Medicaid is based on blindness or disability—for these individuals, SSI rules govern;

Mandatory State supplement means a cash payment a State is required to make under section 212, Pub. L. 93–66 (July 9, 1973) to an aged, blind, or disabled individual. Its purpose is to provide an individual with the same amount of cash assistance he was receiving under OAA, AB, APTD, or

AABD if his SSI payment is less than that amount;

Medically needy refers to families, children, aged, blind, or disabled individuals, and pregnant women listed under subpart D of this part who are not listed in subparts B and C of this part as categorically needy but who may be eligible for Medicaid under this part because their income and resources are within limits set by the State under its Medicaid plan (including persons whose income and resources fall within these limits after their incurred expenses for medical or remedial care are deducted) (Specific financial requirements for determining eligibility of the medically needy appear in subpart I of this part.);

OAA means old age assistance under title I of the Act;

OASDI means old age, survivors, and disability insurance under title II of the Act;

Optional State supplement means a cash payment made by a State, under section 1616 of the Act, to an aged, blind, or disabled individual;

Optional targeted low-income child means a child under age 19 who meets the financial and categorical standards described below.

(1) *Financial need.* An optional targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved; and

(ii) Resides in a State with no Medicaid applicable income level (as defined at § 457.10 of this chapter); or

(iii) Resides in a State that has a Medicaid applicable income level (as defined at § 457.10 of this chapter) and has family income that either:

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points; or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under the policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage and State maintenance of effort.* An optional targeted low-income child is not covered under a group health plan or health insurance coverage, or would not be eligible for Medicaid under the policies of the State plan in effect on March 31, 1997; except that, for purposes of this standard—

(i) A child shall not be considered to be covered by health insurance coverage based on coverage offered by the State under a program in operation prior to July 1, 1997 if that program received no Federal financial participation;

(ii) A child shall not be considered to be covered under a group health plan or health insurance coverage if the child did not have reasonable geographic access to care under that coverage.

(3) For purposes of this section, policies of the State plan a under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

SSI means supplemental security income under title XVI of the Act.

SWICA means the State Wage Information Collection Agency under section 1137(a) of the Act. It is the State agency administering the State unemployment compensation law; a separate agency administering a quarterly wage reporting system; or a State agency administering an alternative system which has been determined by the Secretary of Labor, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, to be as effective and timely in providing employment related income and eligibility data.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 46 FR 6909, Jan. 22, 1981; 46 FR 47984, Sept. 30, 1981; 51 FR 7211, Feb. 28, 1986; 58 FR 4925, Jan. 19, 1993; 66 FR 2666, Jan. 11, 2001]

§ 435.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom Medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§435.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

MANDATORY COVERAGE OF FAMILIES AND CHILDREN

§435.110 Individuals receiving aid to families with dependent children.

(a) A Medicaid agency must provide Medicaid to individuals receiving AFDC.

(b) For purposes of this section, an individual is receiving AFDC if his needs are included in determining the amount of the AFDC payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient (see 45 CFR 233.20(a)(2)(vi)) and who could be a recipient under the State's AFDC plan if that plan were as broad as allowed under the Act for FFP.

§435.112 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

§435.113 Individuals who are ineligible for AFDC because of requirements that do not apply under title XIX of the Act.

The agency must provide Medicaid to:

(a) Individuals denied AFDC solely because of policies requiring the deeming of income and resources of the following individuals who are not included as financially responsible relatives under section 1902(a)(17)(D) of the Act;

(1) Stepparents who are not legally liable for support of stepchildren under a State law of general applicability;

(2) Grandparents;

(3) Legal guardians;

(4) Alien sponsors who are not organizations; and

(5) Siblings.

(b) [Reserved]

[58 FR 4926, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§435.114 Individuals who would be eligible for AFDC except for increased OASDI income under Pub. L. 92–336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving AFDC; or

(2) He would have been eligible for AFDC if he had applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for AFDC if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for AFDC except that the increase in OASDI under Pub. L. 92–336 raised his income over the limit allowed under AFDC. This includes an individual who—

(1) Meets all current AFDC requirements except for the requirement to file an application; or

(2) Would meet all current AFDC requirements if he were not in a medical institution or intermediate care facility, and the current Medicaid plan covers this optional group.

§ 435.115 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

(e) The State must deem to be receiving AFDC individuals described in section 473(a)(1) of the Act—

(1) For whom an adoption assistance agreement is in effect under title IV-E of the Act, whether or not adoption assistance is being provided or an interlocutory or other judicial decree of adoption has been issued; or

(2) For whom foster care maintenance payments are made under title IV-E of the Act.

(f) The State must deem an individual to be receiving AFDC if a new collection or increased collection of child or spousal support under title IV-D of the Social Security Act results in the termination of AFDC eligibility in accordance with section 406(h) of the Social Security Act. States must continue to provide Medicaid for four consecutive calendar months, beginning with the first month of AFDC ineligibility, to each dependent child and each relative with whom such a child is living (including the eligible spouse of such relative as described in section 406(b) of the Social Security Act) who:

(1) Becomes ineligible for AFDC on or after August 16, 1984; and

(2) Has received AFDC for at least three of the six months immediately preceding the month in which the individual becomes ineligible for AFDC; and

(3) Becomes ineligible for AFDC wholly or partly as a result of the initiation of or an increase in the amount of the child or spousal support collection under title IV-D.

(g)(1) Except as provided in paragraph (g)(2) of this section, individuals who are eligible for extended Medicaid lose this coverage if they move to another State during the 4-month period. However, if they move back to and reestablish residence in the State in which they have extended coverage, they are eligible for any of the months remaining in the 4-month period in which they are residents of the State.

(2) If a State has chosen in its State plan to provide Medicaid to non-residents, the State may continue to provide the 4-month extended benefits to individuals who have moved to another State.

(h) For purposes of paragraph (f) of this section:

(1) The new collection or increased collection of child or spousal support results in the termination of AFDC eligibility when it actively causes or contributes to the termination. This occurs when:

(i) The change in support collection in and of itself is sufficient to cause ineligibility. This rule applies even if the support collection must be added to other, stable income. It also applies even if other independent factors, alone or in combination with each other, might simultaneously cause ineligibility; or

(ii) The change in support contributes to ineligibility but does not by itself cause ineligibility. Ineligibility must result when the change in support is combined with other changes in

income or changes in other circumstances and the other changes in income or circumstances cannot alone or in combination result in termination without the change in support.

(2) In cases of increases in the amounts of both support collections and earned income, eligibility under this section does not preclude eligibility under 45 CFR 233.20(a)(14) or section 1925 of the Social Security Act (which was added by section 303(a) of the Family Support Act of 1988 (42 U.S.C. 1396r–6)). Extended periods resulting from both an increase in the amount of the support collection and from an increase in earned income must run concurrently.

[46 FR 47985, Sept. 30, 1981, as amended at 52 FR 43071, Nov. 9, 1987; 55 FR 48607, Nov. 21, 1990; 59 FR 59376, Nov. 17, 1994]

MANDATORY COVERAGE OF PREGNANT WOMEN, CHILDREN UNDER 8, AND NEWBORN CHILDREN

§ 435.116 Qualified pregnant women and children who are not qualified family members.

(a) The agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for an AFDC cash payment if coverage under the State's AFDC plan included an AFDC-unemployed parents program) if her child had been born and was living with her in the month of payment;

(2) Is a member of a family that would be eligible for an AFDC cash payment if the State's AFDC plan included an AFDC-unemployed parents program; or

(3) Meets the income and resource requirements of the State's approved AFDC plan. In determining whether the woman meets the AFDC income and resource requirements, the unborn child or children are considered members of the household, and the woman's family is treated as though deprivation exists.

(b) The provisions of paragraphs (a)(1) and (2) of this section are effective October 1, 1984. The provisions of paragraph (a)(3) of this section are effective July 1, 1986.

(c) The agency must provide Medicaid to children who meet all of the following criteria:

(1) They are born after September 30, 1983;

(2) Effective October 1, 1988, they are under age 6 (or if designated by the State, any age that exceeds age 6 but does not exceed age 8), and effective October 1, 1989, they are under age 7 (or if designated by the State, any age that exceeds age 7 but does not exceed age 8); and

(3) They meet the income and resource requirements of the State's approved AFDC plan.

[52 FR 43071, Nov. 9, 1987, as amended at 55 FR 48607, Nov. 21, 1990; 58 FR 48614, Sept. 17, 1993]

§ 435.117 Newborn children.

(a) The agency must provide Medicaid eligibility to a child born to a woman who has applied for, has been determined eligible and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible for one year so long as the woman remains (or would remain if pregnant) eligible and the child is a member of the woman's household. This provision applies in instances where the labor and delivery services were furnished prior to the date of application and covered by Medicaid based on retroactive eligibility.

(b) The agency must provide Medicaid eligibility in the same manner described in paragraph (a) of this section to a child born to an otherwise-eligible qualified alien woman subject to the 5-year bar so long as the woman has filed a complete Medicaid application, including but not limited to meeting residency, income and resource requirements, has been determined eligible, is receiving Medicaid on the date of the child's birth, and remains (or would remain if pregnant) Medicaid eligible. All standard Medicaid application procedures apply, including timely determination of eligibility and adequate notice of the agency's decision concerning eligibility. A 5-year bar qualified alien receiving emergency

medical services only under § 435.139 is considered to be Medicaid-eligible and receiving Medicaid for purposes of this provision. With respect to whether the mother remains (or would remain if pregnant) eligible for Medicaid after the birth of the child, the State must determine whether a 5-year bar qualified alien would remain eligible for emergency services under § 435.139. In determining whether the woman would remain eligible for these services, the State must consider whether the woman would remain eligible if pregnant. This provision applies in instances where the labor and delivery services were furnished prior to the date of application and covered by Medicaid based on retroactive eligibility.

(c) The agency must provide Medicaid eligibility in the same manner described in paragraph (a) of this section to a child born to an otherwise-eligible non-qualified alien woman so long as the woman has filed a complete Medicaid application (other than providing a social security number or demonstrating immigration status), including but not limited to meeting residency, income and resource requirements, has been determined eligible, is receiving Medicaid on the date of the child's birth, and remains (or would remain if pregnant) Medicaid eligible. All standard Medicaid application procedures apply, including timely determination of eligibility and adequate notice of the agency's decision concerning eligibility. A non-qualified alien receiving emergency medical services only under § 435.139 is considered to be Medicaid-eligible and receiving Medicaid for purposes of this provision. With respect to whether the mother remains (or would remain if pregnant) eligible for Medicaid after the birth of the child, the State must determine whether a non-qualified alien would remain eligible for emergency services under § 435.139. In determining whether the woman would remain eligible for these services, the State must consider whether the woman would remain eligible if pregnant. This provision applies in instances where the labor and delivery services were furnished prior to the date of application and covered by Medicaid based on retroactive eligibility.

(d) A redetermination of eligibility must be completed on behalf of the children described in this provision in accordance with the procedures at § 435.916. At that time, the State must collect documentary evidence of citizenship and identity as required under § 435.406.

[72 FR 38690, July 13, 2007]

MANDATORY COVERAGE OF QUALIFIED FAMILY MEMBERS

§ 435.119 Qualified family members.

(a) *Definition.* A *qualified family member* is any member of a family, including pregnant women and children eligible for Medicaid under § 435.116 of this subpart, who would be receiving AFDC cash benefits on the basis of the unemployment of the principal wage earner under section 407 of the Act had the State not chosen to place time limits on those benefits as permitted under section 407(b)(2)(B)(i) of the Act.

(b) *State plan requirement.* The State plan must provide that the State makes Medicaid available to any individual who meets the definition of ''qualified family member'' as specified in paragraph (a) of this section.

(c) *Applicability.* The provisions in this section are applicable in the 50 States and the District of Columbia from October 1, 1990, through September 30, 1998. The provisions are applicable in American Samoa from October 1, 1992, through September 30, 1998.

[58 FR 48614, Sept. 17, 1993]

MANDATORY COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.120 Individuals receiving SSI.

Except as allowed under § 435.121, the agency must provide Medicaid to aged, blind, and disabled individuals or couples who are receiving or are deemed to be receiving SSI. This includes individuals who are—

(a) Receiving SSI pending a final determination of blindness or disability;

(b) Receiving SSI under an agreement with the Social Security Administration to dispose of resources that exceed the SSI dollar limits on resources; or

(c) Receiving benefits under section 1619(a) of the Act or in section 1619(b) status (blind individuals or those with disabling impairments whose income equals or exceeds a specific Supplemental Security Income limit). (Regulations at 20 CFR 416.260 through 416.269 contain requirements governing determinations of eligibility under this provision.) For purposes of this paragraph (c), this mandatory categorically needy group of individuals includes those qualified severely impaired individuals defined in section 1905(q) of the Act.

[55 FR 33705, Aug. 17, 1990]

§435.121 Individuals in States using more restrictive requirements for Medicaid than the SSI requirements.

(a) *Basic eligibility group requirements.* (1) If the agency does not provide Medicaid under §435.120 to aged, blind, and disabled individuals who are SSI recipients, the agency must provide Medicaid to aged, blind, and disabled individuals who meet eligibility requirements that are specified in this section.

(2) Except to the extent provided in paragraph (a)(3) of this section, the agency may elect to apply more restrictive eligibility requirements to the aged, blind, and disabled that are more restrictive than those of the SSI program. The more restrictive requirements may be no more restrictive than those requirements contained in the State's Medicaid plan in effect on January 1, 1972. If any of the State's 1972 Medicaid plan requirements were more liberal than of the SSI program, the State must use the SSI requirement instead of the more liberal requirements, except to the extent the State elects to use more liberal criteria under §435.601.

(3) The agency must not apply a more restrictive requirement under the provisions of paragraph (a)(2) of this section if:

(i) The requirement conflicts with the requirements of section 1924 of the Act, which governs the eligibility and post-eligibility treatment of income and resources of institutionalized individuals with community spouses;

(ii) The requirement conflicts with a more liberal requirement which the agency has elected to use under §435.601; or

(iii) The more restrictive requirement conflicts with a more liberal requirement the State has elected to use under §435.234(c) in determining eligibility for State supplementary payments.

(b) *Mandatory coverage.* If the agency chooses to apply more restrictive requirements than SSI to aged, blind, or disabled individuals, it must provide Medicaid to:

(1) Individuals who meet the requirements of section 1619(b)(3) of the Act even though they may not continue to meet the requirements of this section; and

(2) Qualified Medicare beneficiaries described in section 1905(p) of the Act and qualified working disabled individuals described in section 1905(s) of the Act without consideration of the more restrictive eligibility requirements specified in this section.

(3) Individuals who:

(i) Qualify for benefits under section 1619(a) or are in eligibility status under section 1619(b)(1) of the Act as determined by SSA; and

(ii) Were eligible for Medicaid under the more restrictive criteria in the State's approved Medicaid plan in the reference month—the month immediately preceding the first month in which they became eligible under section 1619(a) or (b)(1) of the Act. ''Were eligible for Medicaid'' means that individuals were issued Medicaid cards by the State for the reference month. Under this provision, the reference month for determining Medicaid eligibility for all individuals under section 1619 of the Act is the month immediately preceding the first month of the most recent period of eligibility under section 1619 of the Act.

(c) *Group composition.* The agency may apply more restrictive requirements only to the aged, to the blind, to the disabled, or to any combination of these groups. For example, the agency may apply more restrictive requirements to the aged and disabled under this provision and provide Medicaid to all blind individuals who are SSI recipients.

(d) *Nonfinancial conditions.* The agency may apply more restrictive requirements that are nonfinancial conditions of eligibility. For example, the agency may use a more restrictive definition of disability or may limit eligibility of the disabled to individuals age 18 and older, or both. If the agency limits eligibility of disabled individuals to individuals age 18 or older, it must provide Medicaid to individuals under age 18 who receive SSI benefits and who would be eligible to receive AFDC under the State's approved plan if they did not receive SSI. If the agency imposed an age limit for disabled individuals under its 1972 approved State plan but does not use that limit, it must apply the same nonfinancial requirement to individuals under age 18 that it applies to disabled individuals age 18 and older.

(e) *Financial conditions.* (1) The agency may apply more restrictive requirements that are financial conditions of eligibility.

(2) Any income eligibility standards that the agency applies must:

(i) Equal the income standard (or Federal Benefit Rate (FBR)) that would be used under SSI based on an individual's living arrangement; or

(ii) Be a more restrictive standard which is no more restrictive than that under the approved State's January 1, 1972 Medicaid plan.

(3) If the categorically needy income standard established under paragraph (e)(2) of this section is less than the optional categorically needy standard established under § 435.230, the agency must provide Medicaid to all aged, blind, and disabled individuals who have income equal to or below the higher standard.

(4) In a State that does not have a medically needy program that covers aged, blind, and disabled individuals, the agency must allow individuals to deduct from income incurred medical and remedial expenses (that is, spend down) to become eligible under this section. However, individuals with income above the categorically needy standards may only spend down to the standard selected by the State under paragraph (e)(2) of this section which applies to the individual's living arrangement.

(5) In a State that elects to provide medically needy coverage to aged, blind, and disabled individuals, the agency must allow individuals to deduct from income incurred medical and remedial care expenses (spend down) to become categorically needy when they are SSI recipients (including individuals deemed to be SSI recipients under §§ 435.135, 435.137, and 435.138), eligible spouses of SSI recipients, State supplement recipients, and individuals who are eligible for a supplement but who do not receive supplementary payments. Such persons may only spend down to the standard selected by the State under paragraph (e)(2) of this section. Individuals who are not SSI recipients, eligible spouses of SSI recipients, State supplement recipients, or individuals who are eligible for a supplement must spend down to the State's medically needy income standards for aged, blind, and disabled individuals in order to become Medicaid eligible.

(f) *Deductions from income.* (1) In addition to any income disregards specified in the approved State plan in accordance with § 435.601(b), the agency must deduct from income:

(i) SSI payments;

(ii) State supplementary payments that meet the conditions specified in §§ 435.232 and 435.234; and

(iii) Expenses incurred by the individual or financially responsible relatives for necessary medical and remedial services that are recognized under State law and are not subject to payment by a third party, unless the third party is a public program of a State or political subdivision of a State. These expenses include Medicare and other health insurance premiums, deductions and coinsurance charges, and copayments or deductibles imposed under § 447.51 or § 447.53 of this chapter. The agency may set reasonable limits on the amounts of incurred medical expenses that are deducted.

(2) For purposes of counting income with respect to individuals who are receiving benefits under section 1619(a) f the Act or are in section 1619(b)(1) of the Act status but who do not meet the requirements of paragraph (b)(3)(ii) of this section, the agency may disregard

some or all of the amount of the individual's income that is in excess of the SSI Federal benefit rate under section 1611(b) of the Act.

[58 FR 4926, Jan. 19, 1993]

§ 435.122 Individuals who are ineligible for SSI or optional State supplements because of requirements that do not apply under title XIX of the Act.

If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or optional State supplements, it must provide Medicaid to individuals who would be eligible for SSI or optional State supplements except for an eligibility requirement used in those programs that is specifically prohibited under title XIX.

[47 FR 43648, Oct. 1, 1982; 47 FR 49847, Nov. 3, 1982]

§ 435.130 Individuals receiving mandatory State supplements.

The agency must provide Medicaid to individuals receiving mandatory State supplements.

§ 435.131 Individuals eligible as essential spouses in December 1973.

(a) The agency must provide Medicaid to any person who was eligible for Medicaid in December 1973 as an essential spouse of an aged, blind, or disabled individual who was receiving cash assistance, if the conditions in paragraph (b) of this section are met. An ''essential spouse'' is defined in section 1905(a) of the Act as one who is living with the individual; whose needs were included in determining the amount of cash payment to the individual under OAA, AB, APTD, or AABD; and who is determined essential to the individual's well-being.

(b) The agency must continue Medicaid if—

(1) The aged, blind, or disabled individual continues to meet the December 1973 eligibility requirements of the applicable State cash assistance plan; and

(2) The essential spouse continues to meet the conditions that were in effect in December 1973 under the applicable cash assistance plan for having his needs included in computing the payment to the aged, blind, or disabled individual.

§ 435.132 Institutionalized individuals who were eligible in December 1973.

The agency must provide Medicaid to individuals who were eligible for Medicaid in December 1973, or any part of that month, as inpatients of medical institutions or residents of intermediate care facilities that were participating in the Medicaid program and who—

(a) For each consecutive month after December 1973—

(1) Continue to meet the requirements for Medicaid eligibility that were in effect under the State's plan in December 1973 for institutionalized individuals; and

(2) Remain institutionalized; and

(b) Are determined by the State or a professional standards review organization to continue to need institutional care.

§ 435.133 Blind and disabled individuals eligible in December 1973.

The agency must provide Medicaid to individuals who—

(a) Meet all current requirements for Medicaid eligibility except the criteria for blindness or disability;

(b) Were eligible for Medicaid in December 1973 as blind or disabled individuals, whether or not they were receiving cash assistance in December 1973; and

(c) For each consecutive month after December 1973, continue to meet the criteria for blindness or disability and the other conditions of eligibility used under the Medicaid plan in December 1973.

§ 435.134 Individuals who would be eligible except for the increase in OASDI benefits under Pub. L. 92–336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving OAA, AB, APTD, or AABD; or

(2) He would have been eligible for one of those programs except that he had not applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for one of those programs if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for SSI or a State supplement except that the increase in OASDI under Pub. L. 92–336 raised his income over the limit allowed under SSI. This includes an individual who—

(1) Meets all current SSI requirements except for the requirement to file an application; or

(2) Would meet all current SSI requirements if he were not in a medical institution or intermediate care facility, and the State's Medicaid plan covers this optional group.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

§ 435.135 Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977.

(a) If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, it must provide Medicaid to individuals who—

(1) Are receiving OASDI;

(2) Were eligible for and receiving SSI or State supplements but became ineligible for those payments after April 1977; and

(3) Would still be eligible for SSI or State supplements if the amount of OASDI cost-of-living increases paid under section 215(i) of the Act, after the last month after April 1977 for which those individuals were both eligible for and received SSI or a State supplement and were entitled to OASDI, were deducted from current OASDI benefits.

(b) Cost-of-living increases include the increases received by the individual or his or her financially responsible spouse or other family member (e.g., a parent).

(c) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or State supplements. If the individual incurs enough medical expenses to reduce his or her income to the financial eligibility standard for the categorically needy, the agency must cover that individual as categorically needy. In determining the amount of his or her income, the agency may deduct the cost-of-living increases paid under section 215(i) after the last month after April 1977 for which that individual was both eligible for and received SSI or a State supplement and was entitled to OASDI, up to the amount that made him or her ineligible for SSI.

[51 FR 12330, Apr. 10, 1986]

§ 435.136 State agency implementation requirements for one-time notice and annual review system.

An agency must—

(a) Provide a one-time notice of potential Medicaid eligibility under § 435.135 to all individuals who meet the requirements of § 435.135 (a) or (c) who were not receiving Medicaid as of March 9, 1984; and

(b) Establish an annual review system to identify individuals who meet the requirements of § 435.135 (a) or (c) and who lose categorically needy eligibility for Medicaid because of a loss of SSI. States without medically needy programs must send notices of potential eligibility for Medicaid to these individuals for 3 consecutive years following their identification through the annual review system.

[51 FR 12330, Apr. 10, 1986]

§ 435.137 Disabled widows and widowers who would be eligible for SSI except for the increase in disability benefits resulting from elimination of the reduction factor under Pub. L. 98–21.

(a) If the agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, the agency much provide Medicaid to disabled widows and widowers who—

(1) Became ineligible for SSI or a mandatory or optional State supplement as a result of the elimination of the additional reduction factor for disabled widows and widowers under age 60 required by section 134 of Pub. L. 98–21, and for purposes of title XIX, are

deemed to be title XVI payment recipients under section 1634(b) of the Social Security Act; and

(2) Meet the conditions of paragraphs (b) and (e) of this section.

(b) The individuals must meet the following conditions:

(1) They were entitled to monthly OASDI benefits under title II of the Act for December 1983:

(2) They were entitled to and received widow's or widower's disability benefits under section 202(e) or (f) of the Act for January 1984;

(3) They became ineligible for SSI or a mandatory or optional State supplement in the first month in which the increase under Pub. L. 98–21 was paid (and in which a retroactive payment for that increase for prior months was not made);

(4) They have been continously entitled to widow's or widower's disability benefits under section 202(e) or (f) from the first month that the increase under Pub. L. 98–21 was received; and

(5) They would be eligible for SSI benefits or a mandatory or optional State supplement if the amount of the increase under Pub. L. 98–21 and subsequent cost-of-living adjustments in widow's or widower's benefits under section 215(i) of the Act were deducted from their income.

(c) If the agency adopts more restrictive requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or a mandatory or optional State supplement. The State must consider the individuals specified in paragraph (a) of this section to have no more income than the SSI Federal benefit rate if the individual was eligible for SSI in the month prior to the first month in which the increase under Public Law 98–21 was paid (and in which retroactive payments for that increase for prior months was not being made), and the individual would be eligible for SSI except for the amount of the increase under Public Law 98–21 and subsequent cost-of-living adjustments in his or her widow's or widower's benefits under section 215(i) of the Act. The State must consider individuals who qualify under paragraph (a) of this section on the basis of loss of a mandatory or optional State supplementary payment, rather than the loss of SSI, to have no more income than the relevant SSP rate. If the State's income eligibility level is lower than the SSP or SSI Federal benefit rates, individuals qualifying under paragraph (a) of this section who are deemed to have income at either the SSP rate or the SSI Federal benefit rate may further reduce their countable income by incurring medical expenses in the amount by which their income exceeds the State's income eligibility standard. When the individual has reduced his or her income by this amount, he or she will be eligible for Medicaid as categorically needy.

(d) The agency must notify each individual who may be eligible for Medicaid under this section of his or her potential eligibility, in accordance with instructions issued by the Secretary.

(e)(1) Except as provided in paragraph (e)(2) of this section, the provisions of this section apply only to those individuals who filed a written application for Medicaid on or before June 30, 1988, to obtain protected Medicaid coverage.

(2) Individuals who may be eligible under this section residing in States that use a more restrictive income standard than that of the SSI program, under section 1902(f) of the Act, have up to six months after the State sends notice pursuant to the District Court's order in *Darling* v. *Bowen* (685 F. Supp. 1125 (W.D.Mo. 1988) to file a written application to obtain protected Medicaid coverage.

[55 FR 48607, Nov. 21, 1990]

§435.138 Disabled widows and widowers aged 60 through 64 who would be eligible for SSI except for early receipt of social security benefits.

(a) If the agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, the agency must provide Medicaid to disabled widows and widowers who—

(1) Are at least age 60;

(2) Are not entitled to hospital insurance benefits under Medicare Part A; and

(3) Become ineligible for SSI or a State supplement because of mandatory application (under section 1611(e)(2)) for and receipt of widow's or widower's social security disability benefits under section 202(e) or (f) (or any other provision of section 202 if they are also eligible for benefits under subsections (e) or (f)) of the Act.

For purposes of title XIX, individuals who meet these requirements are deemed to be title XVI payment recipients under section 1634(d) of the Act.

(b) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or a mandatory or optional State supplement. If the individual incurs enough medical expenses to reduce his or her income to the financial eligibility standard for the categorically needy under the State's more restrictive eligibility criteria, the agency must cover the individual as categorically needy. In determining the amount of his or her income, the agency may deduct all, part, or none of the amount of the social security disability benefits that made him or her ineligible for SSI or a State supplement, up to the amount that made him or her ineligible for SSI.

(c) Individuals who may be eligible under this section must file a written application for Medicaid. Medicaid coverage may begin no earlier than July 1, 1988.

(d) The agency must determine whether individuals may be eligible for Medicaid under this section.

[55 FR 48608, Nov. 21, 1990]

MANDATORY COVERAGE OF CERTAIN ALIENS

§ 435.139 Coverage for certain aliens.

The agency must provide services necessary for the treatment of an emergency medical condition, as defined in § 440.255(c) of this chapter, to those aliens described in § 435.406(c) of this subpart.

[55 FR 36819, Sept. 7, 1990]

MANDATORY COVERAGE OF ADOPTION ASSISTANCE AND FOSTER CARE CHILDREN

§ 435.145 Children for whom adoption assistance or foster care maintenance payments are made.

The agency must provide Medicaid to children for whom adoption assistance or foster care maintenance payments are made under title IV-E of the Act.

[47 FR 28665, July 1, 1982. Redesignated at 55 FR 48607, Nov. 21, 1990. Redesignated at 58 FR 48614, Sept. 17, 1993]

MANDATORY COVERAGE OF SPECIAL GROUPS

§ 435.170 Pregnant women eligible for extended coverage.

(a) The agency must provide categorically needy Medicaid eligibility for an extended period following termination of pregnancy to women who, while pregnant, applied for, were eligible for, and received Medicaid services on the day that their pregnancy ends. This period extends from the last day of pregnancy through the end of the month in which a 60-day period, beginning on the last day of the pregnancy, ends. Eligibility must be provided regardless of changes in the woman's financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(b) The provisions of paragraph (a) of this section apply to Medicaid furnished on or after April 7, 1986.

[55 FR 48608, Nov. 21, 1990]

Subpart C—Options for Coverage as Categorically Needy

§ 435.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 435.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any

group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart:

(1) Aged individuals (65 years of age of older);

(2) Blind individuals (as defined in §435.530);

(3) Disabled individuals (as defined in §435.541);

(4) Individuals under age 21 (or, at State option, under age 20, 19, or 18) or reasonable classifications of these individuals;

(5) Specified relatives under section 406(b)(1) of the Act who have in their care an individual who is determined to be dependent (or would, if needy, be dependent) as specified in §435.510; and

(6) Pregnant women.

(b) If the agency provides Medicaid to any individual in an optional group specified in paragraph (a) of this section, the agency must provide Medicaid to all individuals who apply and are found eligible to be members of that group.

(c) States that elect to use more restrictive eligibility requirements for Medicaid than the SSI requirements for any group or groups of aged, blind, and disabled individuals under §435.121 must apply the specific requirements of §435.230 in establishing eligibility of these groups of individuals as optional categorically needy.

[58 FR 4927, Jan. 19, 1993]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN AND THE AGED, BLIND, AND DISABLED

§435.210 Individuals who meet the income and resource requirements of the cash assistance programs.

The agency may provide Medicaid to any group or groups of individuals specified in §435.201 (a)(1) through (a)(3) and (a)(5) and (a)(6) who are not mandatory categorically needy, who meet the income and resource requirements of the appropriate cash assistance program for their status (that is, the State's approved AFDC plan or SSI, or optional State supplements in States that provide Medicaid to optional State supplement recipients).

[58 FR 4927, Jan. 19, 1993]

§435.211 Individuals who would be eligible for cash assistance if they were not in medical institutions.

The agency may provide Medicaid to any group or groups of individuals specified in §435.201(a) who are in title XIX reimbursable medical institutions and who:

(a) Are ineligible for the cash assistance program appropriate for their status (that is, AFDC or SSI, or optional State supplements in States that provide Medicaid to optional State supplement recipients) because of lower income standards used under the program to determine eligibility for institutionalized individuals; but

(b) Would be eligible for aid or assistance under the State's approved AFDC plan, SSI, or an optional State supplement as specified in §§435.232 and 435.234 if they were not institutionalized.

[58 FR 4927, Jan. 19, 1993]

§435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a recipient who is enrolled in an MCO or PCCM and who becomes ineligible for Medicaid is considered to continue to be eligible—

(a) For a period specified by the agency, ending no later than 6 months from the date of enrollment; and

(b) Except for family planning services (which the recipient may obtain from any qualified provider) only for services furnished to him or her as an MCO enrollee.

[56 FR 8849, Mar. 1, 1991, as amended at 67 FR 41095, June 14, 2002]

§435.217 Individuals receiving home and community-based services.

The agency may provide Medicaid to any group or groups of individuals in the community who meet the following requirements:

(a) The group would be eligible for Medicaid if institutionalized.

(b) In the absence of home and community-based services under a waiver granted under part 441—

(1) Subpart G of this subchapter, the group would otherwise require the level

of care furnished in a hospital, NF, or an ICF/MR; or

(2) Subpart H of this subchapter, the group would otherwise require the level of care furnished in an NF and are age 65 or older.

(c) The group receives the waivered services.

[57 FR 29155, June 30, 1992]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

§ 435.220 Individuals who would meet the income and resource requirements under AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 435.201 (a)(4), (a)(5), and (a)(6) who would meet the income and resource requirements under the State's approved AFDC plan if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

[43 FR 45204, Sept. 29, 1978, as amended at 58 FR 4927, Jan. 19, 1993]

§ 435.221 [Reserved]

§ 435.222 Individuals under age 21 who meet the income and resource requirements of AFDC.

(a) The agency may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18); or reasonable categories of these individuals as specified in paragraph (b) of this section, who are not receiving cash assistance under any program but who meet the income and resource requirements of the State's approved AFDC plan.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals under age 21 receiving active treatment as inpatients in pyschiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47985, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981, as amended at 58 FR 4927, Jan. 19, 1993]

§ 435.223 Individuals who would be eligible for AFDC if coverage under the State's AFDC plan were as broad as allowed under title IV-A.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 435.210 (a)(4), (a)(5), and (a)(6) who:

(1) Would be eligible for AFDC if the State's AFDC plan included individuals whose coverage under title IV-A is optional (for example, Medicaid may be provided to members of families with an unemployed parent even though AFDC is not available to them under the State's AFDC plan); or

(2) Would be eligible for AFDC if the State's AFDC plan did not contain eligibility requirements more restrictive than, or in addition to, those required under title IV-A.

(b) The agency may cover any AFDC optional group without covering all such groups.

[46 FR 47985, Sept. 30, 1981, as amended at 58 FR 4927, Jan. 19, 1993]

§ 435.225 Individuals under age 19 who would be eligible for Medicaid if they were in a medical institution.

(a) The agency may provide Medicaid to children 18 years of age or younger who qualify under section 1614(a) of the Act, who would be eligible for Medicaid

if they were in a medical institution, and who are receiving, while living at home, medical care that would be provided in a medical institution.

(b) If the agency elects the option provided by paragraph (a) of this section, it must determine, in each case, that the following conditions are met:

(1) The child requires the level of care provided in a hospital, SNF, or ICF.

(2) It is appropriate to provide that level of care outside such an institution.

(3) The estimated Medicaid cost of care outside an institution is no higher than the estimated Medicaid cost of appropriate institutional care.

(c) The agency must specify in its State plan the method by which it determines the cost-effectiveness of caring for disabled children at home.

[55 FR 48608, Nov. 21, 1990]

§ 435.227 Individuals under age 21 who are under State adoption assistance agreements.

(a) The agency may provide Medicaid to individuals under the age of 21 (or, at State option, age 20, 19, or 18)—

(1) For whom an adoption agreement (other than an agreement under title IV-E) between the State and the adoptive parent(s) is in effect;

(2) Who, the State agency responsible for adoption assistance, has determined cannot be placed with adoptive parents without Medicaid because the child has special needs for medical or rehabilitative care; and

(3) Who meet either of the following:

(i) Were eligible for Medicaid under the State plan before the adoption agreement was entered into; or

(ii) Would have been eligible for Medicaid before the adoption agreement was entered into, if the eligibility standards and methodologies of the title IV-E foster care program were used without employing the threshold title IV-A eligibility determination.

(b) For adoption assistance agreements entered into before April 7, 1986—

(1) The agency must deem the requirements of paragraphs (a)(1) and (2) of this section to be met if the State adoption assistance agency determines that—

(i) At the time of the adoption placement, the child had special needs for medical or rehabilitative care that made the child difficult to place; and

(ii) There is in effect an adoption assistance agreement between the State and the adoptive parent(s).

(2) The agency must deem the requirements of paragraph (a)(3) of this section to be met if the child was found by the State to be eligible for Medicaid before the adoption assistance agreement was entered into.

[55 FR 48608, Nov. 21, 1990]

§ 435.229 Optional targeted low-income children.

The agency may provide Medicaid to—

(a) All individuals under age 19 who are optional targeted low-income children as defined in § 435.4; or

(b) Reasonable categories of these individuals.

[66 FR 2667, Jan. 11, 2001]

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.230 Aged, blind, and disabled individuals in States that use more restrictive requirements for Medicaid than SSI requirements: Optional coverage.

(a) *Basic optional coverage rule.* If the agency elects the option under § 435.121 to provide mandatory eligibility for aged, blind, and disabled SSI recipients using more restrictive requirements than those used under SSI, the agency may provide eligibility as optional categorically needy to additional individuals who meet the requirements of this section.

(b) *Group composition.* Subject to the conditions specified in paragraphs (d) and (e) of this section, the agency may provide Medicaid to individuals who:

(1) Meet the nonfinancial criteria that the State has elected to apply under § 435.121;

(2) Meet the resource requirements that the State has elected to apply under § 435.121; and

(3) Meet the income eligibility standards specified in paragraph (c) of this section.

(c) *Criteria for income standards.* The agency may provide Medicaid to the

following individuals who meet the requirements of paragraphs (b)(1) and (b)(2) of this section:

(1) Individuals who are financially eligible for but not receiving SSI benefits and who, before deduction of incurred medical and remedial expenses, meet the State's more restrictive eligibility requirements described in § 435.121;

(2) Individuals who meet the income standards of the following eligibility groups:

(i) Individuals who would be eligible for cash assistance except for institutional status described in § 435.211;

(ii) Individuals who are enrolled in an HMO or other entity and who are deemed to continue to be Medicaid eligible for a period specified by the agency up to 6 months from the date of enrollment and who became ineligible during the specified enrollment period, as described in § 435.212;

(iii) Individuals receiving home and community-based waiver services described in § 435.217;

(iv) Individuals receiving only optional State supplements described in § 435.234;

(v) Institutionalized individuals with income below a special income level described in § 435.236;

(vi) Aged and disabled individuals who have income below 100 percent of the Federal poverty level described in section 1905(m) of the Act.

(3) Individuals who qualify for special status under §§ 435.135 and 435.138, and with respect to whom the State elects to disregard some or the maximum amount of title II payments permitted to be disregarded under those sections.

(d) *Use of more liberal methods.* The agency may elect to apply more liberal methods of counting income and resources that are approved for this eligibility group under the provisions of § 435.601.

[58 FR 4928, Jan. 19, 1993]

§ 435.232 Individuals receiving only optional State supplements.

(a) If the agency provides Medicaid to individuals receiving SSI under § 435.120, it may provide Medicaid, in one or more of the following classifications, to individuals who receive only an optional State supplement that meets the conditions specified in paragraph (b) of this section and who would be eligible for SSI except for the level of their income.

(1) All aged individuals.

(2) All blind individuals.

(3) All disabled individuals.

(4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(7) Individuals receiving a federally administered optional State supplement that meets the conditions specified in this section.

(8) Individuals in additional classifications specified by the Secretary for federally administered supplementary payments under 20 CFR 416.2020(d).

(9) Reasonable groups of individuals, as specified by the State, receiving State-administered supplementary payments.

(b) Payments under the optional supplement program must be—

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual's countable income and the income standard used to determine eligibility for supplement. Countable income is income remaining after deductions required under SSI or, at State option, more liberal deductions are made (see § 435.1006 for limitations on FFP in Medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in each classification in paragraph (a) of this section and available on a statewide basis. However, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.

[43 FR 45204, Sept. 29, 1978. Redesignated and amended at 58 FR 4928, Jan. 19, 1993]

§435.234 Individuals receiving only optional State supplements in States using more restrictive eligibility requirements than SSI and certain States using SSI criteria.

(a) In States using more restrictive eligibility requirements than SSI or in States that use SSI criteria but do not have section 1616 or 1634 agreements with the Social Security Administration for eligibility determinations, the agency may provide Medicaid to individuals specified in paragraph (b) of this section who receive only a State supplement if the State supplement meets the conditions specified in paragraph (c) of this section.

(b) The agency may provide Medicaid to all individuals receiving only State supplements if, except for their income, the individuals meet the more restrictive eligibility requirements under §435.121 or SSI criteria, or to one or more of the following classifications of individuals who meet these criteria:

(1) All aged individuals.

(2) All blind individuals.

(3) All disabled individuals.

(4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(7) Individuals receiving a Federally-administered optional State supplement that meets the conditions specified in this section.

(8) Individuals in additional classifications specified by the Secretary.

(9) Reasonable groups of individuals, as specified by the State, receiving State-administered supplementary payments.

(c) Payments under the optional supplement program must be:

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual's countable income and the income standard used to determine eligibility for supplements. Countable income is income remaining after deductions are applied. The income deductions may be more restrictive than required under SSI (see §435.1006 for limitations on FFP in Medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in each classification in paragraph (b) of this section and available on a statewide basis. However, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.

[58 FR 4928, Jan. 19, 1993]

§435.236 Individuals in institutions who are eligible under a special income level.

(a) If the agency provides Medicaid under §435.211 to individuals in institutions who would be eligible for AFDC, SSI, or State supplements except for their institutional status, it may also cover aged, blind, and disabled individuals in institutions who—

(1) Because of their income, would not be eligible for SSI or State supplements if they were not institutionalized; but

(2) Have income below a level specified in the plan under §435.722. (See §435.1005 for limitations on FFP in Medicaid expenditures for individuals specified in this section.)

(b) The agency may cover individuals under this section whether or not the State pays optional supplements.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980. Redesignated at 58 FR 4928, Jan. 19, 1993]

Subpart D—Optional Coverage of the Medically Needy

§435.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§435.301 General rules.

(a) An agency may provide Medicaid to individuals specified in this subpart who:

(1) Either:

(i) Have income that meets the applicable standards in §§435.811 and 435.814; or

(ii) If their income is more than allowed under the standard, have incurred medical expenses at least equal to the difference between their income

and the applicable income standard; and

(2) Have resources that meet the applicable standards in §§ 435.840 and 435.843.

(b) If the agency chooses this option, the following provisions apply:

(1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:

(i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B or C of this part;

(ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under subpart B of this part;

(iii) All newborn children born on or after October 1, 1984, to a woman who is eligible as medically needy and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as medically needy for one year so long as the woman remains eligible and the child is a member of the woman's household. If the woman's basis of eligibility changes to categorically needy, the child is eligible as categorically needy under § 435.117. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(iv) Women who, while pregnant, applied for, were eligible for, and received Medicaid services as medically needy on the day that their pregnancy ends. The agency must provide medically needy eligibility to these women for an extended period following termination of pregnancy. This period extends from the last day of the pregnancy through the end of the month in which a 60-day period, beginning on the last day of pregnancy, ends. Eligibility must be provided, regardless of changes in the woman's financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(2) The agency may provide Medicaid to any of the following groups of individuals;

(i) Individuals under age 21 (§ 435.308).

(ii) Specified relatives (§ 435.310).

(iii) Aged (§ 435.330.320 and 435.330).

(iv) Blind (§§ 435.322, 435.330 and 435.340).

(v) Disabled (§§ 435.324, 435.330, and 435.340).

(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

[46 FR 47986, Sept. 30, 1981, as amended at 52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987; 55 FR 48609, Nov. 21, 1990; 58 FR 4929, Jan. 19, 1993]

§ 435.308 Medically needy coverage of individuals under age 21.

(a) If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18), as specified in paragraph (b) of this section:

(1) Who would not be covered under the mandatory medically needy group of individuals under 18 under § 435.301(b)(1)(ii); and

(2) Who meet the income and resource requirements of subpart I of this part.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. When the agency covers

such individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47986, Sept. 30, 1981, as amended at 58 FR 4929, Jan. 19, 1993]

§ 435.310 Medically needy coverage of specified relatives.

(a) If the agency provides for the medically needy, it may provide Medicaid to specified relatives, as defined in paragraph (b) of this section, who meet the income and resource requirements of subpart I of this part.

(b) *Specified relatives* means individuals who:

(1) Are listed under section 406(b)(1) of the Act and 45 CFR 233.90(c)(1)(v)(A); and

(2) Have in their care an individual who is determined to be (or would, if needy, be) dependent, as specified in § 435.510.

[58 FR 4929, Jan. 19, 1993]

§ 435.320 Medically needy coverage of the aged in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to individuals who—

(a) Are 65 years of age and older, as specified in § 435.520; and

(b) Meet the income and resource requirements of subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.322 Medically needy coverage of the blind in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to blind individuals who meet—

(a) The requirements for blindness, as specified in §§ 435.530 and 435.531; and

(b) The income and resource requirements of subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.324 Medically needy coverage of the disabled in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to disabled individuals who meet—

(a) The requirements for disability, as specified in §§ 435.540 and 435.541; and

(b) The income and resource requirements of Subpart I of this part.

[46 FR 47986, Sept. 30, 1981; 46 FR 54743, Nov. 11, 1981]

§ 435.326 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

If the agency provides Medicaid to the categorically needy under § 435.212, it may provide it under the same rules to medically needy recipients who are enrolled in MCOs or PCCMs.

[67 FR 41095, June 14, 2002]

§ 435.330 Medically needy coverage of the aged, blind, and disabled in States using more restrictive eligibility requirements for Medicaid than those used under SSI.

(a) If an agency provides Medicaid as categorically needy only to those aged, blind, or disabled individuals who meet more restrictive requirements than used under SSI and elects to cover the medically needy, it may provide Medicaid as medically needy to those aged, blind, or disabled individuals who:

(1) Do not qualify for Medicaid as categorically needy under § 435.121 or § 435.230; and

(2) If applying as blind or disabled, meet the definition of blindness or disability established under § 435.121.

(b) Except as specified in paragraph (c) of this section, the agency must apply to individuals covered under the option of this section the same financial and nonfinancial requirements that are applied to individuals covered as categorically needy under §§ 435.121 and 435.230.

(c) In determining the financial eligibility of individuals who are considered as medically needy under this section, the agency must apply the financial

eligibility requirements of subparts G and I of this part.

[58 FR 4929, Jan. 19, 1993]

§ 435.340 Protected medically needy coverage for blind and disabled individuals eligible in December 1973.

If an agency provides Medicaid to the medically needy, it must cover individuals who—

(a) Where eligible as medically needy under the Medicaid plan in December 1973 on the basis of the blindness or disability criteria of the AB, APTD, or AABD plan;

(b) For each consecutive month after December 1973, continue to meet—

(1) Those blindness or disability criteria; and

(2) The eligibility requirements for the medically needy under the December 1973 Medicaid plan; and

(c) Meet the current requirements for eligibility as medically needy under the Medicaid plan except for blindness or disability criteria.

[46 FR 47987, Sept. 30, 1981]

§ 435.350 Coverage for certain aliens.

If an agency provides Medicaid to the medically needy, it must provide the services necessary for the treatment of an emergency medical condition, as defined in § 440.255(c) of this chapter, to those aliens described in § 435.406(c) of this subpart.

[55 FR 36819, Sept. 7, 1990]

Subpart E—General Eligibility Requirements

§ 435.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part.

§ 435.401 General rules.

(a) A Medicaid agency may not impose any eligibility requirement that is prohibited under Title XIX of the Act.

(b) The agency must base any optional group covered under subparts B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and that are consistent with the objectives of Title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are—

(1) For families and children, more restrictive than those used under the State's AFDC plan; and

(2) For aged, blind, and disabled individuals, more restrictive than those used under SSI, except for individuals receiving an optional State supplement as specified in § 435.230 or individuals in categories specified by the agency under § 435.121.

§ 435.402 [Reserved]

§ 435.403 State residence.

(a) *Requirement.* The agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. The conditions under which payment for services is provided to out-of-State residents are set forth in § 431.52 of this chapter.

(b) *Definition.* For purposes of this section—*Institution* has the same meaning as *Institution* and *Medical institution,* as defined in § 435.1010. For purposes of State placement, the term also includes *foster care homes*, licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.

(c) *Incapability of indicating intent.* For purposes of this section, an individual is considered incapable of indicating intent if the individual—

(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State:

(2) Is judged legally incompetent; or

(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the State in the field of mental retardation.

(d) *Who is a State resident.* A resident of a State is any individual who:

(1) Meets the conditions in paragraphs (e) through (i) of this section; or

(2) Meets the criteria specified in an interstate agreement under paragraph (k) of this section.

(e) *Placement by a State in an out-of-State institution*—(1) *General rule.* Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual's State of residence.

(2) Any action beyond providing information to the individual and the individual's family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State's Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State, provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual's State of residence for Medicaid purposes is the State where the individual is physically located.

(4) Where a placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual's State of residence for Medicaid purposes.

(f) *Individuals receiving a State supplementary payment (SSP).* For individuals of any age who are receiving an SSP, the State of residence is the State paying the SSP.

(g) *Individuals receiving Title IV-E payments.* For individuals of any age who are receiving Federal payments for foster care and adoption assistance under title IV-E of the Social Security Act, the State of residence is the State where the child lives.

(h) *Individuals under Age 21.* (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parent's or legal guardian's State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's); or

(ii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State or residence of the guardian is used instead of the parent's).

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(i) *Individuals Age 21 and over.* (1) For any individual not residing in an institution as defined in paragraph (b), the State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parent applying for Medicaid on the individual's behalf, if the parents reside in separate States (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's);

(ii) The parent's or legal guardian's State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's); or

(iii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's).

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(3) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(j) *Specific prohibitions.* (1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident's Medicaid eligibility because of that person's temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(k) *Interstate agreements.* A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (i) of this section, but must not include criteria that result in loss of residency in both States or that are prohibited by paragraph (j) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case. States may use interstate agreeements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(l) *Continued Medicaid for institutionalized recipients.* If an agency is providing Medicaid to an institutionalized recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984, unless it makes arrangements with another State of residence to provide Medicaid at an earlier date: and

(2) Those arrangements must not include provisions prohibited by paragraph (h) of this section.

(m) *Cases of disputed residency.* Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

[49 FR 13531, Apr. 5, 1984, as amended at 55 FR 48609, Nov. 21, 1990; 71 FR 39222, July 12, 2006]

§ 435.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

§ 435.406 Citizenship and alienage.

(a) The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(1) Citizens: (i) Under a declaration required by section 1137(d) of the Act that the individual is a citizen or national of the United States; and

(ii) The individual has provided satisfactory documentary evidence of citizenship or national status, as described in §435.407.

(iii) An individual for purposes of the declaration and citizenship documentation requirements discussed in paragraphs (a)(1)(i) and (a)(1)(ii) of this section includes both applicants and recipients under a section 1115 demonstration (including a family planning demonstration project) for which a State receives Federal financial participation in their expenditures, as though the expenditures were for medical assistance.

(iv) Individuals must declare their citizenship and the State must document the individual's citizenship in the individual's eligibility file on initial applications and initial redeterminations effective July 1, 2006.

(v) The following groups of individuals are exempt from the requirements in paragraph (a)(1)(ii) of this section:

(A) Individuals receiving SSI benefits under title XVI of the Act.

(B) Individuals entitled to or enrolled in any part of Medicare.

(C) Individuals receiving disability insurance benefits under section 223 of the Act or monthly benefits under section 202 of the Act, based on the individual's disability (as defined in section 223(d) of the Act).

(D) Individuals who are in foster care and who are assisted under Title IV-B of the Act, and individuals who are recipients of foster care maintenance or adoption assistance payments under Title IV–E of the Act.

(2)(i) Except as specified in 8 U.S.C. 1612(b)(1) (permitting States an option with respect to coverage of certain qualified aliens), qualified aliens as described in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1641) (including qualified aliens subject to the 5-year bar) who have provided satisfactory documentary evidence of Qualified Alien status, which status has been verified with the Department of Homeland Security (DHS) under a declaration required by section 1137(d) of the Act that the applicant or recipient is an alien in a satisfactory immigration status.

(ii) The eligibility of qualified aliens who are subject to the 5-year bar in 8 U.S.C. 1613 is limited to the benefits described in paragraph (b) of this section.

(b) The agency must provide payment for the services described in §440.255(c) of this chapter to residents of the State who otherwise meet the eligibility requirements of the State plan (except for receipt of AFDC, SSI, or State Supplementary payments) who are qualified aliens subject to the 5-year bar or who are non-qualified aliens who meet all Medicaid eligibility criteria, except non-qualified aliens need not present a social security number or document immigration status.

[55 FR 36819, Sept. 7, 1990, as amended at 56 FR 10807, Mar. 14, 1991; 71 FR 39222, July 12, 2006; 72 FR 38691, July 13, 2007]

§435.407 Types of acceptable documentary evidence of citizenship.

For purposes of this section, the term ''citizenship'' includes status as a ''national of the United States'' as defined by section 101(a)(22) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(22)) to include both citizens of the United States and non-citizen nationals of the United States.

(a) *Primary evidence of citizenship and identity*. The following evidence must be accepted as satisfactory documentary evidence of both identity and citizenship:

(1) *A U.S. passport*. The Department of State issues this. A U.S. passport does not have to be currently valid to be accepted as evidence of U.S. citizenship, as long as it was originally issued without limitation. NOTE: Spouses and children were sometimes included on one passport through 1980. U.S. passports issued after 1980 show only one person. Consequently, the citizenship and identity of the included person can be established when one of these passports is presented. Exception: Do not accept any passport as evidence of U.S. citizenship when it was issued with a limitation. However, such a passport may be used as proof of identity.

(2) *A Certificate of Naturalization (DHS Forms N–550 or N–570.)* Department of

Homeland Security issues for naturalization.

(3) *A Certificate of U.S. Citizenship (DHS Forms N–560 or N–561.)* Department of Homeland Security issues certificates of citizenship to individuals who derive citizenship through a parent.

(4) A valid State-issued driver's license, but only if the State issuing the license requires proof of U.S. citizenship before issuance of such license or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen. (This provision is not effective until such time as a State makes providing evidence of citizenship a condition of issuing a driver's license and evidence that the license holder is a citizen is included on the license or in a system of records available to the Medicaid agency. The State must ensure that the process complies with this statutory provision in section 6036 of the Deficit Reduction Act of 2005. CMS will monitor compliance of States implementing this provision.).

(b) *Secondary evidence of citizenship.* If primary evidence from the list in paragraph (a) of this section is unavailable, an applicant or recipient should provide satisfactory documentary evidence of citizenship from the list specified in this section to establish citizenship and satisfactory documentary evidence from paragraph (e) of this section to establish identity, in accordance with the rules specified in this section.

(1) A U.S. public birth certificate showing birth in one of the 50 States, the District of Columbia, Puerto Rico (if born on or after January 13, 1941), Guam (on or after April 10, 1899), the Virgin Islands of the U.S. (on or after January 17, 1917), American Samoa, Swain's Island, or the Northern Mariana Islands (after November 4, 1986 (NMI local time)). A State, at its option, may use a cross match with a State vital statistics agency to document a birth record. The birth record document may be issued by the State, Commonwealth, Territory, or local jurisdiction. It must have been recorded before the person was 5 years of age. A delayed birth record document that is recorded at or after 5 years of age is considered fourth level evidence of citizenship. (NOTE: If the document shows the individual was born in Puerto Rico, the Virgin Islands of the U.S., or the Northern Mariana Islands before these areas became part of the U.S., the individual may be a collectively naturalized citizen. Collective naturalization occurred on certain dates listed for each of the territories.) The following will establish U.S. citizenship for collectively naturalized individuals:

(i) *Puerto Rico:*

(A) Evidence of birth in Puerto Rico on or after April 11, 1899 and the applicant's statement that he or she was residing in the U.S., a U.S. possession, or Puerto Rico on January 13, 1941; or

(B) Evidence that the applicant was a Puerto Rican citizen and the applicant's statement that he or she was residing in Puerto Rico on March 1, 1917 and that he or she did not take an oath of allegiance to Spain.

(ii) *U.S. Virgin Islands:*

(A) Evidence of birth in the U.S. Virgin Islands, and the applicant's statement of residence in the U.S., a U.S. possession, or the U.S. Virgin Islands on February 25, 1927; or

(B) The applicant's statement indicating residence in the U.S. Virgin Islands as a Danish citizen on January 17, 1917 and residence in the U.S., a U.S. possession, or the U.S. Virgin Islands on February 25, 1927, and that he or she did not make a declaration to maintain Danish citizenship; or

(C) Evidence of birth in the U.S. Virgin Islands and the applicant's statement indicating residence in the U.S., a U.S. possession or Territory, or the Canal Zone on June 28, 1932.

(iii) *Northern Mariana Islands (NMI) (formerly part of the Trust Territory of the Pacific Islands (TTPI)):*

(A) Evidence of birth in the NMI, TTPI citizenship and residence in the NMI, the U.S., or a U.S. Territory or possession on November 3, 1986 NMI local time) and the applicant's statement that he or she did not owe allegiance to a foreign State on November 4, 1986 (NMI local time); or

(B) Evidence of TTPI citizenship, continuous residence in the NMI since before November 3, 1981 (NMI local

time), voter registration before January 1, 1975 and the applicant's statement that he or she did not owe allegiance to a foreign State on November 4, 1986 (NMI local time); or

(C) Evidence of continuous domicile in the NMI since before January 1, 1974 and the applicant's statement that he or she did not owe allegiance to a foreign State on November 4, 1986 (NMI local time).

(D) NOTE: If a person entered the NMI as a nonimmigrant and lived in the NMI since January 1, 1974, this does not constitute continuous domicile and the individual is not a U.S. citizen.

(2) *A Certification of Report of Birth (DS–1350).* The Department of State issues a DS–1350 to U.S. citizens in the U.S. who were born outside the U.S. and acquired U.S. citizenship at birth, based on the information shown on the FS–240. When the birth was recorded as a Consular Report of Birth (FS–240), certified copies of the Certification of Report of Birth Abroad (DS–1350) can be issued by the Department of State in Washington, DC. The DS–1350 contains the same information as that on the current version of Consular Report of Birth FS–240. The DS–1350 is not issued outside the U.S.

(3) *A Report of Birth Abroad of a U.S. Citizen (Form FS–240).* The Department of State consular office prepares and issues this. A Consular Report of Birth can be prepared only at an American consular office overseas while the child is under the age of 18. Children born outside the U.S. to U.S. military personnel usually have one of these.

(4) *A Certification of birth issued by the Department of State (Form FS–545 or DS–1350).* Before November 1, 1990, Department of State consulates also issued Form FS–545 along with the prior version of the FS–240. In 1990, U.S. consulates ceased to issue Form FS–545. Treat an FS–545 the same as the DS–1350.

(5) *A U.S. Citizen I.D. card.* (This form was issued until the 1980s by INS. Although no longer issued, holders of this document may still use it consistent with the provisions of section 1903(x) of the Act.) INS issued the I–179 from 1960 until 1973. It revised the form and renumbered it as Form I–197. INS issued the I–197 from 1973 until April 7, 1983. INS issued Form I–179 and I–197 to naturalized U.S. citizens living near the Canadian or Mexican border who needed it for frequent border crossings. Although neither form is currently issued, either form that was previously issued is still valid.

(6) *A Northern Mariana Identification Card (I–873).* (Issued by the DHS to a collectively naturalized citizen of the United States who was born in the Northern Mariana Islands before November 4, 1986.) The former Immigration and Naturalization Service (INS) issued the I–873 to a collectively naturalized citizen of the U.S. who was born in the NMI before November 4, 1986. The card is no longer issued, but those previously issued are still valid.

(7) *An American Indian Card (I–872) issued by the Department of Homeland Security with the classification code ''KIC.''* (Issued by DHS to identify U.S. citizen members of the Texas Band of Kickapoos living near the United States/Mexican border.) DHS issues this card to identify a member of the Texas Band of Kickapoos living near the U.S./Mexican border. A classification code ''KIC'' and a statement on the back denote U.S. citizenship.

(8) *A final adoption decree showing the child's name and U.S. place of birth.* The adoption decree must show the child's name and U.S. place of birth. In situations where an adoption is not finalized and the State in which the child was born will not release a birth certificate prior to final adoption, a statement from a State approved adoption agency that shows the child's name and U.S. place of birth is acceptable. The adoption agency must state in the certification that the source of the place of birth information is an original birth certificate.

(9) *Evidence of U.S. Civil Service employment before June 1, 1976.* The document must show employment by the U.S. government before June 1, 1976. Individuals employed by the U.S. Civil Service prior to June 1, 1976 had to be U.S. citizens.

(10) *U.S. Military Record showing a U.S. place of birth.* The document must show a U.S. place of birth (for example a DD–214 or similar official document showing a U.S. place of birth.)

(11) *A data verification with the Systematic Alien Verification for Entitlements (SAVE) Program for naturalized citizens.* A State may conduct a verification with SAVE to determine if an individual is a naturalized citizen, provided that such verification is conducted consistent with the terms of a Memorandum of Understanding or other agreement with the Department of Homeland Security (DHS) authorizing verification of claims to U.S. citizenship through SAVE, including but not limited to provision of the individual's alien registration number if required by DHS.

(12) *Child Citizenship Act.* Adopted or biological children born outside the United States may establish citizenship obtained automatically under section 320 of the Immigration and Nationality Act (8 U.S.C. 1431), as amended by the Child Citizenship Act of 2000 (Pub. L. 106–395, enacted on October 30, 2000). The State must obtain documentary evidence that verifies that at any time on or after February 27, 2001, the following conditions have been met:

(i) At least one parent of the child is a United States citizen by either birth or naturalization (as verified under the requirements of this Part);

(ii) The child is under the age of 18;

(iii) The child is residing in the United States in the legal and physical custody of the U.S. citizen parent;

(iv) The child was admitted to the United States for lawful permanent residence (as verified under the requirements of 8 U.S.C. 1641 pertaining to verification of qualified alien status); and

(v) If adopted, the child satisfies the requirements of section 101(b)(1) of the Immigration and Nationality Act (8 U.S.C. 1101(b)(1) pertaining to international adoptions (admission for lawful permanent residence as IR–3 (child adopted outside the United States)), or as IR–4 (child coming to the United States to be adopted) with final adoption having subsequently occurred).

(c) *Third level evidence of citizenship.* Third level evidence of U.S. citizenship is documentary evidence of satisfactory reliability that is used when both primary and secondary evidence is unavailable. Third level evidence may be used only when the applicant or recipient alleges being born in the U.S. A second document from paragraph (e) of this section to establish identity must also be presented:

(1) *Extract of a hospital record on hospital letterhead established at the time of the person's birth that was created 5 years before the initial application date and that indicates a U.S. place of birth.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Do not accept a souvenir ''birth certificate'' issued by the hospital.

(2) *Life, health, or other insurance record showing a U.S. place of birth that was created at least 5 years before the initial application date that indicates a U.S. place of birth.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Life or health insurance records may show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(3) *Religious record recorded in the U.S. within 3 months of birth showing the birth occurred in the U.S. and showing either the date of the birth or the individual's age at the time the record was made.* The record must be an official record recorded with the religious organization. CAUTION: In questionable cases (for example, where the child's religious record was recorded near a U.S. international border and the child may have been born outside the U.S.), the State must verify the religious record and/or document that the mother was in the U.S. at the time of birth.

(4) *Early school record showing a U.S. place of birth.* The school record must show the name of the child, the date of admission to the school, the date of birth, a U.S. place of birth, and the name(s) and place(s) of birth of the applicant's parents.

(d) *Fourth level evidence of citizenship.* Fourth level evidence of citizenship is documentary evidence of the lowest reliability. Fourth level evidence should only be used in the rarest of circumstances. This level of evidence is used only when primary, secondary and third level evidence is unavailable. With the exception of the affidavit

process described in paragraph (d)(5) of this section, the applicant may only use fourth level evidence of citizenship if alleging a U.S. place of birth. In addition, a second document establishing identity must be presented as described in paragraph (e) of this section.

(1) *Federal or State census record showing U.S. citizenship or a U.S. place of birth.* (Generally for persons born 1900 through 1950.) The census record must also show the applicant's age. NOTE: Census records from 1900 through 1950 contain certain citizenship information. To secure this information the applicant, recipient or State should complete a Form BC–600, Application for Search of Census Records for Proof of Age. Add in the remarks portion ''U.S. citizenship data requested.'' Also add that the purpose is for Medicaid eligibility. This form requires a fee.

(2) *One of the following documents that show a U.S. place of birth and was created at least 5 years before the application for Medicaid.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) This document must be one of the following and show a U.S. place of birth:

(i) Seneca Indian tribal census.

(ii) Bureau of Indian Affairs tribal census records of the Navajo Indians.

(iii) U.S. State Vital Statistics official notification of birth registration.

(iv) A delayed U.S. public birth record that is recorded more than 5 years after the person's birth.

(v) Statement signed by the physician or midwife who was in attendance at the time of birth.

(vi) The Roll of Alaska Natives maintained by the Bureau of Indian Affairs.

(3) *Institutional admission papers from a nursing facility, skilled care facility or other institution created at least 5 years before the initial application date that indicates a U.S. place of birth.* Admission papers generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(4) *Medical (clinic, doctor, or hospital) record created at least 5 years before the initial application date that indicates a U.S. place of birth.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.)

Medical records generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth. (NOTE:An immunization record is not considered a medical record for purposes of establishing U.S. citizenship.)

(5) *Written affidavit.* Affidavits should ONLY be used in rare circumstances. If the documentation requirement needs to be met through affidavits, the following rules apply:

(i) There must be at least two affidavits by two individuals who have personal knowledge of the event(s) establishing the applicant's or recipient's claim of citizenship (the two affidavits could be combined in a joint affidavit).

(ii) At least one of the individuals making the affidavit cannot be related to the applicant or recipient. Neither of the two individuals can be the applicant or recipient.

(iii) In order for the affidavit to be acceptable the persons making them must be able to provide proof of their own citizenship and identity.

(iv) If the individual(s) making the affidavit has (have) information which explains why documentary evidence establishing the applicant's claim or citizenship does not exist or cannot be readily obtained, the affidavit should contain this information as well.

(v) The State must obtain a separate affidavit from the applicant/recipient or other knowledgeable individual (guardian or representative) explaining why the evidence does not exist or cannot be obtained.

(vi) The affidavits must be signed under penalty of perjury and need not be notarized.

(e) *Evidence of identity.* The following documents may be accepted as proof of identity and must accompany a document establishing citizenship from the groups of documentary evidence of citizenship in the groups in paragraphs (b) through (d) of this section.

(1) Identity documents described in 8 CFR 274a.2(b)(1)(v)(B)(1).

(i) Driver's license issued by State or Territory either with a photograph of the individual or other identifying information of the individual such as

name, age, sex, race, height, weight or eye color.

(ii) School identification card with a photograph of the individual.

(iii) U.S. military card or draft record.

(iv) Identification card issued by the Federal, State, or local government with the same information included on drivers' licenses.

(v) Military dependent's identification card.

(vi) Certificate of Degree of Indian Blood, or other American Indian/Alaska Native Tribal document with a photograph or other personal identifying information relating to the individual. Acceptable if the document carries a photograph of the applicant or recipient, or has other personal identifying information relating to the individual such as age, weight, height, race, sex, and eye color.

(vii) U.S. Coast Guard Merchant Mariner card.

NOTE TO PARAGRAPH (e)(1): Exception: Do not accept a voter's registration card or Canadian driver's license as listed in 8 CFR 274a.2(b)(1)(v)(B)(1). CMS does not view these as reliable for identity.

(2) At State option, a State may use a cross match with a Federal or State governmental, public assistance, law enforcement or corrections agency's data system to establish identity if the agency establishes and certifies true identity of individuals. Such agencies may include food stamps, child support, corrections, including juvenile detention, motor vehicle, or child protective services. The State Medicaid Agency is still responsible for assuring the accuracy of the identity determination.

(3) At State option, a State may accept three or more documents that together reasonably corroborate the identity of an individual provided such documents have not been used to establish the individual's citizenship and the individual submitted second or third tier evidence of citizenship. The State must first ensure that no other evidence of identity is available to the individual prior to accepting such documents. Such documents must at a minimum contain the individual's name, plus any additional information establishing the individual's identity. All documents used must contain consistent identifying information. These documents include employer identification cards, high school and college diplomas from accredited institutions (including general education and high school equivalency diplomas), marriage certificates, divorce decrees and property deeds/titles.

(f) *Special identity rules for children.* For children under 16, a clinic, doctor, hospital or school record may be accepted for purposes of establishing identity. School records may include nursery or daycare records and report cards. If the State accepts such records, it must verify them with the issuing school. If none of the above documents in the preceding groups are available, an affidavit may be used. An affidavit is only acceptable if it is signed under penalty of perjury by a parent, guardian or caretaker relative (as defined in the regulations at 45 CFR 233.90(c)(v)) stating the date and place of the birth of the child and cannot be used if an affidavit for citizenship was provided. The affidavit is not required to be notarized. A State may accept an identity affidavit on behalf of a child under the age of 18 in instances when school ID cards and drivers' licenses are not available to the individual in that area until that age.

(g) *Special identity rules for disabled individuals in institutional care facilities.* A State may accept an identity affidavit signed under penalty of perjury by a residential care facility director or administrator on behalf of an institutionalized individual in the facility. States should first pursue all other means of verifying identity prior to accepting an affidavit. The affidavit is not required to be notarized.

(h) *Special populations needing assistance.* States must assist individuals to secure satisfactory documentary evidence of citizenship when because of incapacity of mind or body the individual would be unable to comply with the requirement to present satisfactory documentary evidence of citizenship in a timely manner and the individual lacks a representative to assist him or her.

(i) *Documentary evidence.* (1) All documents must be either originals or copies certified by the issuing agency.

Uncertified copies, including notarized copies, shall not be accepted.

(2) States must maintain copies of citizenship and identification documents in the case record or electronic data base and make these copies available for compliance audits.

(3) States may permit applicants and recipients to submit such documentary evidence without appearing in person at a Medicaid office. States may accept original documents in person, by mail, or by a guardian or authorized representative.

(4) If documents are determined to be inconsistent with pre-existing information, are counterfeit, or altered, States should investigate for potential fraud and abuse, including but not limited to, referral to the appropriate State and Federal law enforcement agencies.

(5) Presentation of documentary evidence of citizenship is a one time activity; once a person's citizenship is documented and recorded in a State database subsequent changes in eligibility should not require repeating the documentation of citizenship unless later evidence raises a question of the person's citizenship. The State need only check its databases to verify that the individual already established citizenship.

(6) CMS requires that as a check against fraud, using currently available automated capabilities, States will conduct a match of the applicant's name against the corresponding Social Security number that was provided. In addition, in cooperation with other agencies of the Federal government, CMS encourages States to use automated capabilities to verify citizenship and identity of Medicaid applicants. Automated capabilities may fall within the computer matching provisions of the Privacy Act of 1974, and CMS will explore any implementation issues that may arise with respect to those requirements. When these capabilities become available, States will be required to match files for individuals who used third or fourth tier documents to verify citizenship and documents to verify identity, and CMS will make available to States necessary information in this regard. States must ensure that all case records within this category will be so identified and made available to conduct these automated matches. CMS may also require States to match files for individuals who used first or second level documents to verify citizenship as well. CMS may provide further guidance to States with respect to actions required in a case of a negative match.

(j) *Record retention.* The State must retain documents in accordance with 45 CFR 74.53.

(k) *Reasonable opportunity to present satisfactory documentary evidence of citizenship.* States must give an applicant or recipient a reasonable opportunity to submit satisfactory documentary evidence of citizenship before taking action affecting the individual's eligibility for Medicaid. The time States give for submitting documentation of citizenship should be consistent with the time allowed to submit documentation to establish other facets of eligibility for which documentation is requested. (*See* §435.930 and §435.911.)

[71 FR 39222, July 12, 2006, as amended at 72 FR 38691, July 13, 2007]

Subpart F—Categorical Requirements for Eligibility

§435.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part.

DEPENDENCY

§435.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures set forth under the State's AFDC plan to determine whether—

(a) An individual is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

[43 FR 45204, Sept. 29, 1978, as amended at 58 FR 4929, Jan. 19, 1993]

AGE

§ 435.520 Age requirements for the aged.

The agency must not impose an age requirement of more than 65 years.

[58 FR 4929, Jan. 19, 1993]

§ 435.522 Determination of age.

(a) Except as specified in paragraphs (b) and (c) of this section, in determining age, the agency must use the common-law method (under which an age reached the day before the anniversary of birth).

(b) For families and children, the agency must use the popular usage method (under which an age is reached on the anniversary of birth), if this method is used under the State's AFDC plan.

(c) For aged, blind, or disabled individuals, the agency must use the popular usage method, if the plan provides under § 435.121, § 435.230, or § 435.330, for coverage of aged, blind, or disabled individuals who meet more restrictive eligibility requirements than those under SSI.

(d) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

[58 FR 4929, Jan. 19, 1993]

BLINDNESS

§ 435.530 Definition of blindness.

(a) *Definition.* The agency must use the same definition of blindness as used under SSI, except that—

(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of blindness that was used under the Medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the Medicaid plan on January 1, 1972.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 435.531 Determinations of blindness.

(a) Except as specified in paragraph (b) of this section, in determining blindness—

(1) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(2) The examiner must submit a report of examination to the Medicaid agency; and

(3) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(i) Whether the individual meets the definition of blindness; and

(ii) Whether and when re-examinations are necessary for periodic redeterminations of eligibility, as required under § 435.916 of this part.

(b) If an agency provides Medicaid to individuals receiving SSI on the basis of blindness, this section does not apply for those individuals.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979]

DISABILITY

§ 435.540 Definition of disability.

(a) *Definition.* The agency must use the same definition of disability as used under SSI, except that—

(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of disability that was used under the Medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the Medicaid plan on January 1, 1972.

(b) *State plan requirements.* The State plan must contain the definition of disability.

§ 435.541 Determinations of disability.

(a) *Determinations made by SSA.* The following rules and those under paragraph (b) of this section apply where an individual has applied for Medicaid on the basis of disability.

(1) If the agency has an agreement with the Social Security Administration (SSA) under section 1634 of the Act, the agency may not make a determination of disability when the only application is filed with SSA.

(2) The agency may not make an independent determination of disability if SSA has made a disability determination within the time limits set forth in §435.911 on the same issues presented in the Medicaid application. A determination of eligibility for SSI payments based on disability that is made by SSA automatically confers Medicaid eligibility, as provided for under §435.909.

(b) *Effect of SSA determinations.* (1) Except in the circumstances specified in paragraph (c)(3) of this section—

(i) An SSA disability determination is binding on an agency until the determination is changed by SSA.

(ii) If the SSA determination is changed, the new determination is also binding on the agency.

(2) The agency must refer to SSA all applicants who allege new information or evidence affecting previous SSA determinations of ineligibility based upon disability for reconsideration or reopening of the determination, except in cases specified in paragraph (c)(4) of this section.

(c) *Determinations made by the Medicaid agency.* The agency must make a determination of disability in accordance with the requirements of this section if any of the following circumstances exist:

(1) The individual applies for Medicaid as a non-cash recipient and has not applied to SSA for SSI cash benefits, whether or not a State has a section 1634 agreement with SSA; or an individual applies for Medicaid and has applied to SSA for SSI benefits and is found ineligible for SSI for a reason other than disability.

(2) The individual applies both to SSA for SSI and to the State Medicaid agency for Medicaid, the State agency has a section 1634 agreement with SSA, and SSA has not made an SSI disability determination within 90 days from the date of the individual's application for Medicaid.

(3) The individual applies to SSA for SSI and to the State Medicaid agency for Medicaid, the State does not have a section 1634 agreement with SSA, and either the State uses more restrictive criteria than SSI for determining Medicaid eligibility under its section 1902(f) option or, in the case of a State that uses SSI criteria, SSA has not made an SSI disability determination in time for the State to comply with the Medicaid time limit for making a prompt determination on an individual's application for Medicaid.

(4) The individual applies for Medicaid as a non-cash recipient, whether or not the State has a section 1634 agreement with SSA, and—

(i) Alleges a disabling condition different from, or in addition to, that considered by SSA in making its determination; or

(ii) Alleges more than 12 months after the most recent SSA determination denying disability that his or her condition has changed or deteriorated since that SSA determination and alleges a new period of disability which meets the durational requirements of the Act, and has not applied to SSA for a determination with respect to these allegations.

(iii) Alleges less than 12 months after the most recent SSA determination denying disability that his or her condition has changed or deteriorated since that SSA determination, alleges a new period of disability which meets the durational requirements of the Act, and—

(A) Has applied to SSA for reconsideration or reopening of its disability decision and SSA refused to consider the new allegations; and/or

(B) He or she no longer meets the nondisability requirements for SSI but may meet the State's nondisability requirements for Medicaid eligibility.

(d) *Basis for determinations.* The agency must make a determination of disability as provided in paragraph (c) of this section—

(1) On the basis of the evidence required under paragraph (e) of this section; and

(2) In accordance with the requirements for evaluating that evidence under the SSI program specified in 20 CFR 416.901 through 416.998.

(e) *Medical and nonmedical evidence.* The agency must obtain a medical report and other nonmedical evidence for individuals applying for Medicaid on the basis of disability. The medical report and nonmedical evidence must include diagnosis and other information in accordance with the requirements for evidence applicable to disability determinations under the SSI program specified in 20 CFR part 416, subpart I.

(f) *Disability review teams*—(1) *Function.* A review team must review the medical report and other evidence required under paragraph (e) of this section and determine on behalf of the agency whether the individual's condition meets the definition of disability.

(2) *Composition.* The review team must be composed of a medical or psychological consultant and another individual who is qualified to interpret and evaluate medical reports and other evidence relating to the individual's physical or mental impairments and, as necessary, to determine the capacities of the individual to perform substantial gainful activity, as specified in 20 CFR part 416, subpart J.

(3) *Periodic reexaminations.* The review team must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under § 435.916 of this part, using the principles set forth in 20 CFR 416.989 and 416.990. If a State uses the same definition of disability as SSA, as provided for under § 435.540, and a recipient is Medicaid eligible because he or she receives SSI, this paragraph (f)(3) does not apply. The reexamination will be conducted by SSA.

[54 FR 50761, Dec. 11, 1989]

Subpart G—General Financial Eligibility Requirements and Options

§ 435.600 Scope.

This subpart prescribes:

(a) General financial requirements and options for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part. Subparts H and I of this part prescribe additional financial requirements.

(b) [Reserved]

[58 FR 4929, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§ 435.601 Application of financial eligibility methodologies.

(a) *Definitions.* For purposes of this section, *cash assistance financial methodologies* refers to the income and resources methodologies of the AFDC, SSI, or State supplement programs, or, for aged, blind, and disabled individuals in States that use more restrictive criteria than SSI, the methodologies established in accordance with the requirements of §§ 435.121 and 435.230.

(b) *Basic rule for use of cash assistance methodologies.* Except as specified in paragraphs (c) and (d) of this section or in § 435.121 in determining financial eligibility of individuals as categorically and medically needy, the agency must apply the financial methodologies and requirements of the cash assistance program that is most closely categorically related to the individual's status.

(c) *Financial responsibility of relatives.* The agency must use the requirements for financial responsibility of relatives specified in § 435.602.

(d) *Use of less restrictive methodologies than those under cash assistance programs.* (1) At State option, and subject to the conditions of paragraphs (d)(2) through (d)(5) of this section, the agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies in determining eligibility of the following groups:

(i) Qualified pregnant women and children under the mandatory categorically needy group under § 435.116;

(ii) Low-income pregnant women, infants, and children specified in section 1902(a)(10)(i)(IV), 1902(a)(10)(A)(i)(VI), and 1902(a)(10)(A)(i)(VII) of the Act;

(iii) Qualified Medicare beneficiaries specified in sections 1902(a)(10)(E) and 1905(p) of the Act;

(iv) Optional categorically needy individuals under groups established under subpart C of this part and section 1902(a)(10)(A)(ii) of the Act;

(v) Medically needy individuals under groups established under subpart D of this part and section 1902(a)(10)(C)(i)(III) of the Act; and

(vi) Aged, blind, and disabled individuals in States using more restrictive eligibility requirements than SSI under groups established under §§ 435.121 and 435.230.

(2) The income and resource methodologies that an agency elects to apply to groups of individuals described in paragraph (d)(1) of this section may be less restrictive, but no more restrictive (except in States using more restrictive requirements than SSI), than:

(i) For groups of aged, blind, and disabled individuals, the SSI methodologies; or

(ii) For all other groups, the methodologies under the State plan most closely categorically related to the individual's status.

(3) A financial methodology is considered to be no more restrictive if, by using the methodology, additional individuals may be eligible for Medicaid and no individuals who are otherwise eligible are by use of that methodology made ineligible for Medicaid.

(4) The less restrictive methodology applied under this section must be comparable for all persons within each category of assistance (aged, or blind, or disabled, or AFDC related) within an eligibility group. For example, if the agency chooses to apply less restrictive income or resource methodology to an eligibility group of aged individuals, it must apply that methodology to all aged individuals within the selected group.

(5) The application of the less restrictive income and resource methodologies permitted under this section must be consistent with the limitations and conditions on FFP specified in subpart K of this part.

(e) [Reserved]

(f) *State plan requirements.* (1) The State plan must specify that, except to the extent precluded in § 435.602, in determining financial eligibility of individuals, the agency will apply the cash assistance financial methodologies and requirements, unless the agency chooses to apply less restrictive income and resource methodologies in accordance with paragraph (d) of this section.

(2) If the agency chooses to apply less restrictive income and resource methodologies, the State plan must specify:

(i) The less restrictive methodologies that will be used; and

(ii) The eligibility group or groups to which the less restrictive methodologies will be applied.

[58 FR 4929, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§ 435.602 Financial responsibility of relatives and other individuals.

(a) *Basic requirements.* Subject to the provisions of paragraphs (b) and (c) of this section, in determining financial responsibility of relatives and other persons for individuals under Medicaid, the agency must apply the following requirements and methodologies:

(1) Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not consider income and resources of any relative as available to an individual.

(2) In relation to individuals under age 21 (as described in section 1905(a)(i) of the Act), the financial responsibility requirements and methodologies that apply include considering the income and resources of parents or spouses whose income and resources would be considered if the individual under age 21 were dependent under the State's approved AFDC plan, whether or not they are actually contributed, except as specified under paragraphs (c) and (d) of this section. These requirements and methodologies must be applied in accordance with the provisions of the State's approved AFDC plan.

(3) When a couple ceases to live together, the agency must count only the income of the individual spouse in determining his or her eligibility, beginning the first month following the month the couple ceases to live together.

(4) In the case of eligible institutionalized spouses who are aged, blind, and disabled and who have shared the same room in a title XIX Medicaid institution, the agency has the option of considering these couples as eligible couples for purposes of counting income and resources or as eligible individuals, whichever is more advantageous to the couple.

(b) *Requirements for States using more restrictive requirements.* Subject to the

provisions of paragraph (c) of this section, in determining financial eligibility of aged, blind, or disabled individuals in States that apply eligibility requirements more restrictive than those used under SSI, the agency must apply:

(1) The requirements and methodologies for financial responsibility of relatives used under the SSI program; or

(2) More extensive requirements for relative responsibility than specified in § 435.602(a) but no more extensive than the requirements under the Medicaid plan in effect on January 1, 1972.

(c) *Use of less restrictive methodologies.* The agency may apply income and resources methodologies that are less restrictive than those used under the cash assistance programs as specified in the State Medicaid plan in accordance with § 435.601(d).

(d) [Reserved]

[58 FR 4930, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§ 435.604 [Reserved]

§ 435.606 [Reserved]

§ 435.608 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, retirement, and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

[43 FR 45204, Sept. 29, 1978. Redesignated at 58 FR 4931, Jan. 19, 1993]

§ 435.610 Assignment of rights to benefits.

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to:

(1) Assign rights to the Medicaid agency to medical support and to payment for medical care from any third party;

(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section 1902 (1)(1)(A) of the Act (poverty level pregnant women), who are exempt from cooperating in establishing paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(3) Cooperate in identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan, unless the individual establishes good cause for not cooperating.

(b) The requirements for assignment of rights must be applied uniformly for all groups covered under the plan.

(c) The requirements of paragraph (a) of this section for the assignment of rights to medical support and other payments and cooperation in obtaining medical support and payments are effective for medical assistance furnished on or after October 1, 1984. The requirement for cooperation in identifying and providing information for pursuing liable third parties is effective for medical assistance furnished on or after July 1, 1988.

[55 FR 48609, Nov. 21, 1990, as amended at 58 FR 4907, Jan. 19, 1993. Redesignated at 58 FR 4931, Jan. 19, 1993]

§ 435.622 Individuals in institutions who are eligible under a special income level.

(a) If an agency, under § 435.231, provides Medicaid to individuals in medical institutions, nursing facilities, and intermediate care facilities for the mentally retarded who would not be eligible for SSI or State supplements if they were not institutionalized, the agency must use income standards based on the greater need for financial assistance that the individuals would have if they were not in the institution. The standards may vary by the level of institutional care needed by the individual (hospital, nursing facility, or intermediate level care for the mentally retarded), or by other factors related to individual needs. (See § 435.1005 for FFP limits on income standards established under this section.)

(b) In determining the eligibility of individuals under the income standards established under this section, the agency must not take into account income that would be disregarded in determining eligibility for SSI or for an optional State supplement.

(c) The agency must apply the income standards established under this section effective with the first day of a period of not less than 30 consecutive days of institutionalization.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980; 53 FR 3595, Feb. 8, 1988. Redesignated and amended at 58 FR 4932, Jan. 19, 1993]

§435.631 General requirements for determining income eligibility in States using more restrictive requirements for Medicaid than SSI.

(a) *Income eligibility methods.* In determining income eligibility of aged, blind, and disabled individuals in a State using more restrictive eligibility requirements than SSI, the agency must use the methods for treating income elected under §§435.121 and 435.230, under §435.601. The methods used must be comparable for all individuals within each category of individuals under §435.121 and each category of individuals within each optional categorically needy group included under §435.230 and for each category of individuals under the medically needy option described under §435.800.

(b) *Categorically needy versus medically needy eligibility.* (1) Individuals who have income equal to, or below, the categorically needy income standards described in §§435.121 and 435.230 are categorically needy in States that include the medically needy under their plans.

(2) Categorically needy eligibility in States that do not include the medically needy is determined in accordance with the provisions of §435.121 (e)(4) and (e)(5).

[58 FR 4932, Jan. 19, 1993]

§435.640 Protected Medicaid eligibility for individuals eligible in December 1973.

In determining whether individuals continue to meet the income requirements used in December 1973, for purposes of determining eligibility under §§435.131, 435.132, and 435.133, the agency must deduct increased OASDI payments to the same extent that these deductions were in effect in December 1973. These deductions are required by section 306 of the Social Security Amendments of 1972 (Pub. L. 92–603) and section 1007 of Pub. L. 91–172 (enacted Dec. 30, 1969), modified by section 304 of Pub. L. 92–603.

[43 FR 45204, Sept. 29, 1978. Redesignated at 58 FR 4932, Jan. 19, 1993]

Subpart H—Specific Post-Eligibility Financial Requirements for the Categorically Needy

§435.700 Scope.

This subpart prescribes specific financial requirements for determining the post-eligibility treatment of income of categorically needy individuals, including requirements for applying patient income to the cost of care.

[58 FR 4931, Jan. 19, 1993]

§435.725 Post-eligibility treatment of income of institutionalized individuals in SSI States: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income,

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability.* This section applies to the following individuals in medical institutions and intermediate care facilities.

(1) Individuals receiving cash assistance under SSI or AFDC who are eligible for Medicaid under §435.110 or §435.120.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for Medicaid under §435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under § 435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) *Required deductions.* In reducing its payment to the institution, the agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) *Maintenance needs of spouse.* For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under § 435.811, if the agency provides Medicaid under the medically needy coverage option.

(3) *Maintenance needs of family.* For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under § 435.811, if the agency provides Medicaid under the medically needy coverage option for a family of the same size.

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) *Continued SSI and SSP benefits.* The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(3) For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received, or it may project monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and on medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980; 48 FR 5735, Feb. 8, 1983; 53 FR 3595, Feb. 8, 1988; 55 FR 33705, Aug. 17, 1990; 56 FR 8850, 8854, Mar. 1, 1991; 58 FR 4932, Jan. 19, 1993]

§435.726 Post-eligibility treatment of income of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraph (c) of this section from the individual's income.

(b) This section applies to individuals who are eligible for Medicaid under §435.217 and are receiving home and community-based services furnished under a waiver of Medicaid requirements specified in part 441, subpart G or H of this subchapter.

(c) In reducing its payment for home and community-based services, the agency must deduct the following amounts, in the following order, from the individual's total income (including amounts disregarded in determining eligibility):

(1) An amount for the maintenance needs of the individual that the State may set at any level, as long as the following conditions are met:

(i) The deduction amount is based on a reasonable assessment of need.

(ii) The State establishes a maximum deduction amount that will not be exceeded for any individual under the waiver.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under §435.230; or

(iii) The amount of the medically needy income standard for one person established under §§435.811 and 435.814, if the agency provides Medicaid under the medically needy coverage option.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard established under § 435.811 for a family of the same size.

(4) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

[46 FR 48539, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985; 57 FR 29155, June 30, 1992; 58 FR 4932, Jan. 19, 1993; 59 FR 37715, July 25, 1994]

§ 435.733 Post-eligibility treatment of income of institutionalized individuals in States using more restrictive requirements than SSI: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability.* This section applies to the following individuals in medical institutions and intermediate care facilities:

(1) Individuals receiving cash assistance under AFDC who are eligible for Medicaid under § 435.110 and individuals eligible under § 435.121.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for Medicaid under § 435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under § 435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) *Maintenance needs of spouse.* For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The amount of the medically needy income standard for one person established under § 435.811, if the agency provides Medicaid under the medically needy coverage option.

(3) *Maintenance needs of family.* For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under §435.811, if the agency provides Medicaid under the medically needy coverage option for a family of the same size.

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance permiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) *Continued SSI and SSP benefits.* The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received, or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses that may be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24884, Apr. 11, 1980, as amended at 48 FR 5735, Feb. 8, 1983; 53 FR 3596, Feb. 8, 1988; 55 FR 33705, Aug. 17, 1990; 56 FR 8850, 8854, Mar. 1, 1991; 58 FR 4932, Jan. 19, 1993]

§435.735 Post-eligibility treatment of income and resources of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraph (c) of this section from the individual's income.

(b) This section applies to individuals who are eligible for Medicaid under §435.217, and are eligible for home and community-based services furnished under a waiver of State plan requirements specified in part 441, subpart G or H of this subchapter.

(c) In reducing its payment for home and community-based services, the agency must deduct the following amounts, in the following order, from the individual's total income (including amounts disregarded in determining eligibility):

(1) An amount for the maintenance needs of the individual that the State may set at any level, as long as the following conditions are met:

(i) The deduction amount is based on a reasonable assessment of need.

(ii) The State establishes a maximum deduction amount that will not be exceeded for any individual under the waiver.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The medically needy standard for an individual.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under § 435.811 for a family of the same size.

(4) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

[46 FR 48540, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985; 57 FR 29155, June 30, 1992; 58 FR 4932, Jan. 19, 1993; 59 FR 37716, July 25, 1994]

Subpart I—Specific Eligibility and Post-Eligibility Financial Requirements for the Medically Needy

§ 435.800 Scope.

This subpart prescribes specific financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

[58 FR 4932, Jan. 19, 1993]

MEDICALLY NEEDY INCOME STANDARD

§ 435.811 Medically needy income standard: General requirements.

(a) Except as provided in paragraph (d)(2) of this section, to determine eligibility of medically needy individuals, a Medicaid agency must use a single income standard under this subpart that meets the requirements of this section.

(b) The income standard must take into account the number of persons in the assistance unit. Subject to the limitations specified in paragraph (e) of this section. The standard may not diminish by an increase in the number of persons in the assistance unit. For example, if the income level in the standard for an assistance unit of two is set at $400, the income level in the standard for an assistance unit of three may not be less than $400.

(c) In States that do not use more restrictive requirements than SSI, the income standard must be set at an amount that is no lower than the lowest income standards used under the cash assistance programs that are related to the State's covered medically needy eligibility group or groups of individuals under § 435.301. The amount of the income standard is subject to the limitations specified in paragraph (e) of this section.

(d) In States that use more restrictive requirements for aged, blind, and disabled individuals than SSI:

(1) For all individuals except aged, blind, and disabled individuals, the income standard must be set in accordance with paragraph (c) of this section; and

(2) For all aged, blind, and disabled individuals or any combination of these groups of individuals, the agency may establish a separate single medically needy income standard that is more restrictive than the single income standard set under paragraph (c) of this section. However, the amount of the more restrictive separate standard for aged, blind, or disabled individuals must be no lower than the higher of the lowest categorically needy income standard currently applied under the

State's more restrictive criteria under §435.121 or the medically needy income standard in effect under the State's Medicaid plan on January 1, 1972. The amount of the income standard is subject to the limitations specified in paragraph (e) of this section.

(e) The income standards specified in paragraphs (c) and (d) of this section must not exceed the maximum dollar amount of income allowed for purposes of FFP under §435.1007.

(f) The income standard may vary based on the variations between shelter costs in urban areas and rural areas.

[58 FR 4932, Jan. 19, 1993]

§435.814 Medically needy income standard: State plan requirements.

The State plan must specify the income standard for the covered medically needy groups.

[58 FR 4933, Jan. 19, 1993]

MEDICALLY NEEDY INCOME ELIGIBILITY

§435.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in accordance with this section.

(a) *Budget periods.* (1) The agency must use budget periods of not more than 6 months to compute income. The agency may use more than one budget period.

(2) The agency may include in the budget period in which income is computed all or part of the 3-month retroactive period specified in §435.914. The budget period can begin no earlier than the first month in the retroactive period in which the individual received covered services. This provision applies to all medically needy individuals except in groups for whom criteria more restrictive than that used in the SSI program apply.

(3) If the agency elects to begin the first budget period for the medically needy in any month of the 3-month period prior to the date of the application in which the applicant received covered services, this election applies to all medically needy groups.

(b) *Determining countable income.* The agency must deduct the following amounts from income to determine the individual's countable income.

(1) For individuals under age 21 and caretaker relatives, the agency must deduct amounts that would be deducted in determining eligibility under the State's AFDC plan.

(2) For aged, blind, or disabled individuals in States covering all SSI recipients, the agency must deduct amounts that would be deducted in determining eligibility under SSI. However, the agency must also deduct the highest amounts from income that would be deducted in determining eligibility for optional State supplements if these supplements are paid to all individuals who are receiving SSI or would be eligible for SSI except for their income.

(3) For aged, blind, or disabled individuals in States using income requirements more restrictive than SSI, the agency must deduct amounts that are no more restrictive than those used under the Medicaid plan on January 1, 1972 and no more liberal than those used in determining eligibility under SSI or an optional State supplement. However, the amounts must be at least the same as those that would be deducted in determining eligibility, under §435.121, of the categorically needy.

(c) *Eligibility based on countable income.* If countable income determined under paragraph (b) of this section is equal to or less than the applicable income standard under §435.814, the individual or family is eligible for Medicaid.

(d) *Deduction of incurred medical expenses.* If countable income exceeds the income standard, the agency must deduct from income medical expenses incurred by the individual or family or financially responsible relatives that are not subject to payment by a third party. An expense is incurred on the date liability for the expense arises. The agency must determine deductible incurred expenses in accordance with paragraphs (e), (f), and (g) of this section and deduct those expenses in accordance with paragraph (h) of this section.

(e) *Determination of deductible incurred expenses: Required deductions based on kinds of services.* Subject to the provisions of paragraph (g), in determining

incurred medical expenses to be deducted from income, the agency must include the following:

(1) Expenses for Medicare and other health insurance premiums, and deductibles or coinsurance charges, including enrollment fees, copayments, or deductibles imposed under § 447.51 or § 447.53 of this subchapter;

(2) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan;

(3) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan, including those that exceed agency limitations on amount, duration, or scope of services.

(f) *Determination of deductible incurred expenses: Required deductions based on the age of bills.* Subject to the provisions of paragraph (g), in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) For the first budget period or periods that include only months before the month of application for medical assistance, expenses incurred during such period or periods, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(2) For the first prospective budget period that also includes any of the 3 months before the month of application for medical assistance, expenses incurred during such budget period, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(3) For the first prospective budget period that includes none of the months preceding the month of application, expenses incurred during such budget period and any of the 3 preceding months, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(4) For any of the 3 months preceding the month of application that are not includable under paragraph (f)(2) of this section, expenses incurred in the 3-month period that were a current liability of the individual in any such month for which a spenddown calculation is made and that had not been previously deducted from income in establishing eligibility for medical assistance;

(5) Current payments (that is, payments made in the current budget period) on other expenses incurred before the current budget period and not previously deducted from income in any budget period in establishing eligibility for such period; and

(6) If the individual's eligibility for medical assistance was established in each such preceding period, expenses incurred before the current budget period but not previously deducted from income in establishing eligibility, to the extent that such expenses are unpaid and are:

(i) Described in paragraphs (e)(1) through (e)(3) of this section; and

(ii) Carried over from the preceding budget period or periods because the individual had a spenddown liability in each such preceding period that was met without deducting all such incurred, unpaid expenses.

(g) *Determination of deductible incurred medical expenses: Optional deductions.* In determining incurred medical expenses to be deducted from income, the agency—

(1) May include medical institutional expenses (other than expenses in acute care facilities) projected to the end of the budget period at the Medicaid reimbursement rate;

(2) May, to the extent determined by the State and specified in its approved plan, include expenses incurred earlier than the third month before the month of application (except States using more restrictive eligibility criteria under the option in section 1902(f) of the Act must deduct incurred expenses regardless of when the expenses were incurred); and

(3) May set reasonable limits on the amount to be deducted for expenses specified in paragraphs (e)(1), (e)(2), and (g)(2) of this section.

(h) *Order of deduction.* The agency must deduct incurred medical expenses that are deductible under paragraphs (e), (f), and (g) of this section in the

order prescribed under one of the following three options:

(1) *Type of service.* Under this option, the agency deducts expenses in the following order based on type of expense or service:

(i) Cost-sharing expenses as specified in paragraph (e)(1) of this section.

(ii) Services not included in the State plan as specified in paragraph (e)(2) of this section.

(iii) Services included in the State plan as specified in paragraph (e)(3) of this section but that exceed limitations on amounts, duration, or scope of services.

(iv) Services included in the State plan as specified in paragraph (e)(3) of this section but that are within agency limitations on amount, duration, or scope of services.

(2) *Chronological order by service date.* Under this option, the agency deducts expenses in chronological order by the date each service is furnished, or in the case of insurance premiums, coinsurance or deductible charges, the date such amounts are due. Expenses for services furnished on the same day may be deducted in any reasonable order established by the State.

(3) *Chronological order by bill submission date.* Under this option, the agency deducts expenses in chronological order by the date each bill is submitted to the agency by the individual. If more than one bill is submitted at one time, the agency must deduct the bills from income in the order prescribed in either paragraph (h)(1) or (h)(2) of this section.

(i) *Eligibility based on incurred medical expenses.* (1) Whether a State elects partial or full month coverage, an individual who is expected to contribute a portion of his or her income toward the costs of institutional care or home and community-based services under §§435.725, 435.726, 435.733, 435.735 or 435.832 is eligible on the first day of the applicable budget (spenddown) period—

(i) If his or her spenddown liability is met after the first day of the budget period; and

(ii) If beginning eligibility after the first day of the budget period makes the individual's share of health care expenses under §§435.725, 435.726, 435.733, 435.735 or 435.832 greater than the individual's contributable income determined under these sections.

(2) At the end of the prospective period specified in paragraphs (f)(2) and (f)(3) of this section, and any subsequent prospective period or, if earlier, when any significant change occurs, the agency must reconcile the projected amounts with the actual amounts incurred, or with changes in circumstances, to determine if the adjusted deduction of incurred expenses reduces income to the income standard.

(3) Except as provided in paragraph (i)(1) of this section, in States that elect partial month coverage, an individual is eligible for Medicaid on the day that the deduction of incurred health care expenses (and of projected institutional expenses if the agency elects the option under paragraph (g)(1) of this section) reduces income to the income standard.

(4) Except as provided in paragraph (i)(1) of this section, in States that elect full month coverage, an individual is eligible on the first day of the month in which spenddown liability is met.

(5) Expenses used to meet spenddown liability are not reimbursable under Medicaid. To the extent necessary to prevent the transfer of an individual's spenddown liability to the Medicaid program, States must reduce the amount of provider charges that would otherwise be reimbursable under Medicaid.

[59 FR 1672, Jan. 12, 1994]

§435.832 Post-eligibility treatment of income of institutionalized individuals: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability.* This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or diability.

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) *Maintenance needs of spouse.* For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under § 435.811.

(3) *Maintenance needs of family.* For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the highest of the following need standards for a family of the same size:

(A) The standard used to determine eligibility under the State's approved AFDC plan.

(B) The medically needy income standard established under § 435.811.

(4) Expenses not subject to third party payment. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance permiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24886, Apr. 11, 1980, as amended at 46 FR 47988, Sept. 30, 1981; 48 FR 5735, Feb. 8, 1983; 53 FR 3596, Feb. 8, 1988; 53 FR 5344, Feb. 23, 1988; 56 FR 8850, 8854, Mar. 1, 1991; 58 FR 4933, Jan. 19, 1993]

MEDICALLY NEEDY RESOURCE STANDARD

§ 435.840 Medically needy resource standard: General requirements.

(a) To determine eligibility of medically needy individuals, a Medicaid agency must use a single resource standard that meets the requirements of this section.

(b) In States that do not use more restrictive criteria than SSI for aged, blind, and disabled individuals, the resource standard must be established at an amount that is no lower than the lowest resource standard used under the cash assistance programs that relate to the State's covered medically needy eligibility group or groups of individuals under § 435.301.

(c) In States using more restrictive requirements than SSI:

(1) For all individuals except aged, blind, and disabled individuals, the resource standard must be set in accordance with paragraph (b) of this section; and

(2) For all aged, blind, and disabled individuals or any combination of these groups of individuals, the agency may establish a separate single medically needy resource standard that is more restrictive than the single resource standard set under paragraph (b) of this section. However, the amount of the more restrictive separate standard for aged, blind, or disabled individuals must be no lower than the higher of the lowest categorically needy resource standard currently applied under the State's more restrictive criteria under § 435.121 or the medically needy resource standard in effect under the State's Medicaid plan on January 1, 1972.

(d) The resource standard established under paragraph (a) of this section may not diminish by an increase in the number of persons in the assistance unit. For example, the resource standard for an assistance unit of three may not be less than that set for a unit of two.

[58 FR 4933, Jan. 19, 1993]

§ 435.843 Medically needy resource standard: State plan requirements.

The State plan must specify the resource standard for the covered medically needy groups.

[58 FR 4933, Jan. 19, 1993]

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 435.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must:

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives in § 435.602.

(b) Deduct the amounts that would be deducted in determining resource eligibility for the medically needy group as provided for in § 435.601 or under the criteria of States using more restrictive criteria than SSI as provided for in § 435.121. In determining the amount of an individual's resources for Medicaid eligibility, States must count amounts of resources that otherwise would not be counted under the conditional eligibility provisions of the SSI or AFDC programs.

(c) Apply the resource standard specified under § 435.840.

[58 FR 4933, Jan. 19, 1993]

§§ 435.850–435.852 [Reserved]

Subpart J—Eligibility in the States and District of Columbia

SOURCE: 44 FR 17937, Mar. 23, 1979, unless otherwise noted.

§ 435.900 Scope.

This subpart sets forth requirements for processing applications, determining eligibility, and furnishing Medicaid.

GENERAL METHODS OF ADMINISTRATION

§ 435.901 Consistency with objectives and statutes.

The Medicaid agency's standards and methods for determining eligibility must be consistent with the objectives of the program and with the rights of individuals under the United States Constitution, the Social Security Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and all other relevant provisions of Federal and State laws.

[44 FR 17937, Mar. 23, 1979. Redesignated at 59 FR 48809, Sept. 23, 1994]

§ 435.902 Simplicity of administration.

The agency's policies and procedures must ensure that eligibility is determined in a manner consistent with simplicity of administration and the best interests of the applicant or recipient.

[44 FR 17937, Mar. 23, 1979. Redesignated at 59 FR 48809, Sept. 23, 1994]

§ 435.903 Adherence of local agencies to State plan requirements.

The agency must—

(a) Have methods to keep itself currently informed of the adherence of local agencies to the State plan provisions and the agency's procedures for determining eligibility; and

(b) Take corrective action to ensure their adherence.

[44 FR 17937, Mar. 23, 1979. Redesignated at 59 FR 48809, Sept. 23, 1994]

§ 435.904 Establishment of outstation locations to process applications for certain low-income eligibility groups.

(a) *State plan requirements.* The Medicaid State plan must specify that the requirements of this section are met.

(b) *Opportunity to apply.* The agency must provide an opportunity for the following groups of low-income pregnant women, infants, and children under age 19 to apply for Medicaid at outstation locations other than AFDC offices:

(1) The groups of pregnant women or infants with incomes up to 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(IV) of the Act;

(2) The group of children age 1 up to age 6 with incomes at 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VI) of the Act;

(3) The group of children age 6 up to age 19 born after September 30, 1983, with incomes up to 100 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VII) of the Act; and

(4) The groups of pregnant women or infants, children age 1 up to age 6, and children age 6 up to age 19, who are not eligible as a mandatory group, with incomes up to 185 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(ii)(IX) of the Act.

(c) *Outstation locations: general requirements.* (1) The agency must establish either—

(i) Outstation locations at each disproportionate share hospital, as defined in section 1923(a)(1)(A) of the Act, and each Federally-qualified health center, as defined in section 1905(1)(2)(B) of the Act, participating in the Medicaid program and providing services to Medicaid-eligible pregnant women and children; or

(ii) Other outstation locations, which include at least some, disproportionate share hospitals and federally-qualified health centers, as specified under an alternative State plan that is submitted to and approved by CMS if the following conditions are met:

(A) The State must demonstrate that the alternative plan for outstationing

is equally effective as, or more effective than, a plan that would meet the requirements of paragraph (c)(1)(i) of this section in enabling the individuals described in paragraph (b) of this section to apply for and receive Medicaid; and

(B) The State must provide assurances that the level of staffing and funding committed by the State under the alternative plan equals or exceeds the level of staffing and funding under a plan that would meet the requirements of establishing the outstation locations at the sites specified in paragraph (c)(1)(i) of this section.

(2) The agency must establish outstation locations at Indian health clinics operated by a tribe or tribal organization as these clinics are specifically included in the definition of Federally-qualified health centers under section 1905(l)(2)(B) of the Act and are also included in the definition of rural health clinics under part 491, subpart A of this chapter.

(3) The agency may establish additional outstation locations at any other site where potentially eligible pregnant women or children receive services—for example, at school-linked service centers and family support centers. These additional sites may also include sites other than the main outstation location of those Federally-qualified health centers or disproportionate share hospitals providing services to Medicaid-eligible pregnant women and to children and that operate more than one site.

(4) The agency may, at its option, enter into reciprocal agreements with neighboring States to ensure that the groups described in paragraph (b) of this section who customarily receive services in a neighboring State have the opportunity to apply at outstation locations specified in paragraphs (c)(l) and (2) of this section.

(d) *Outstation functions.* (1) The agency must provide for the receipt and initial processing of Medicaid applications from the designated eligibility groups at each outstation location.

(2) ''Initial processing'' means taking applications, assisting applicants in completing the application, providing information and referrals, obtaining required documentation to complete processing of the application, assuring that the information contained on the application form is complete, and conducting any necessary interviews. It does not include evaluating the information contained on the application and the supporting documentation nor making a determination of eligibility or ineligibility.

(3) The agency may, at its option, allow appropriate State eligibility workers assigned to outstation locations to evaluate the information contained on the application and the supporting documentation and make a determination of eligibility if the workers are authorized to determine eligibility for the agency which determines Medicaid eligibility under §431.10 of this subchapter.

(e) *Staffing.* (1) Except for outstation locations that are infrequently used by the low-income eligibility groups, the State agency must have staff available at each outstation location during the regular office operating hours of the State Medicaid agency to accept applications and to assist applicants with the application process.

(2) The agency may station staff at one outstation location or rotate staff among several locations as workload and staffing availability dictate.

(3) The agency may use State employees, provider or contractor employees, or volunteers who have been properly trained to staff outstation locations under the following conditions:

(i) State outstation intake staff may perform all eligibility processing functions, including the eligibility determination, if the staff is authorized to do so at the regular Medicaid intake office.

(ii) Provider or contractor employees and volunteers may perform only initial processing functions as defined in paragraph (d)(2) of this section.

(4) Provider and contractor employees and volunteers are subject to the confidentiality of information rules specified in part 431, subpart F, of this subchapter, to the prohibition against reassignment of provider claims specified in §447.10 of this subchapter, and to all other State or Federal laws concerning conflicts of interest.

(5) At locations that are infrequently used by the designated low-income eligibility groups, the State agency may use volunteers, provider or contractor employees, or its own eligibility staff, or telephone assistance.

(i) The agency must display a notice in a prominent place at the outstation location advising potential applicants of when outstation intake workers will be available.

(ii) The notice must include a telephone number that applicants may call for assistance.

(iii) The agency must comply with Federal and State laws and regulations governing the provision of adequate notice to persons who are blind or deaf or who are unable to read or understand the English language.

[59 FR 48809, Sept. 23, 1994]

APPLICATIONS

§ 435.905 Availability of program information.

(a) The agency must furnish the following information in written form, and orally as appropriate, to all applicants and to all other individuals who request it:

(1) The eligibility requirements.

(2) Available Medicaid services.

(3) The rights and responsibilities of applicants and recipients.

(b) The agency must publish in quantity and make available bulletins or pamphlets that explain the rules governing eligibility and appeals in simple and understandable terms.

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980]

§ 435.906 Opportunity to apply.

The agency must afford an individual wishing to do so the opportunity to apply for Medicaid without delay.

§ 435.907 Written application.

(a) The agency must require a written application from the applicant, an authorized representative, or, if the applicant is incompetent or incapacitated, someone acting responsibly for the applicant.

(b) Subject to the conditions specified in paragraph (c) of this section, the application must be on a form prescribed by the agency and signed under a penalty of perjury.

(c) The application form used at outstation locations for low-income pregnant women, infants, and children specified in § 435.904 must not be the application form used to apply for AFDC. The application form (including any computerized application form) for these designated eligibility groups may be—

(1) A Medicaid-only form prescribed by the agency specifically for the designated eligibility groups;

(2) An existing Medicaid-only application; or

(3) A multiple-program application that contains clearly identifiable Medicaid-only sections or parts.

[59 FR 48810, Sept. 23, 1994]

§ 435.908 Assistance with application.

The agency must allow an individual or individuals of the applicant's choice to accompany, assist, and represent the applicant in the application process or a redetermination of eligibility.

§ 435.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

The agency must not require a separate application for Medicaid from an individual, if—

(a) The individual receives AFDC; or

(b) The agency has an agreement with the Social Security Administration (SSA) under section 1634 of the Act for determining Medicaid eligibility; and—

(1) The individual receives SSI;

(2) The individual receives a mandatory State supplement under either a federally-administered or State-administered program; or

(3) The individual receives an optional State supplement and the agency provides Medicaid to recipients of optional supplements under § 435.230.

§ 435.910 Use of social security number.

(a) The agency must require, as a condition of eligibility, that each individual (including children) requesting Medicaid services furnish each of his or her social security numbers (SSNs).

(b) The agency must advise the applicant of—

(1) [Reserved]

(2) The statute or other authority under which the agency is requesting the applicant's SSN; and

(3) The uses the agency will make of each SSN, including its use for verifying income, eligibility, and amount of medical assistance payments under §§435.940 through 435.960.

(c)–(d) [Reserved]

(e) If an applicant cannot recall his SSN or SSNs or has not been issued a SSN the agency must—

(1) Assist the applicant in completing an application for an SSN;

(2) Obtain evidence required under SSA regulations to establish the age, the citizenship or alien status, and the true identity of the applicant; and

(3) Either send the application to SSA or, if there is evidence that the applicant has previously been issued a SSN, request SSA to furnish the number.

(f) The agency must not deny or delay services to an otherwise eligible applicant pending issuance or verification of the individual's SSN by SSA.

(g) The agency must verify each SSN of each applicant and recipient with SSA, as prescribed by the Commissioner, to insure that each SSN furnished was issued to that individual, and to determine whether any others were issued.

(h) *Exception*. (1) A State may give a Medicaid identification number to an applicant who, because of well established religious objections, refuses to obtain a Social Security Number (SSN). The identification number may be either an SSN obtained by the State on the applicant's behalf or another unique identifier.

(2) The term *well established religious objections* means that the applicant—

(i) Is a member of a recognized religious sect or division of the sect; and

(ii) Adheres to the tenets or teachings of the sect or division of the sect and for that reason is conscientiously opposed to applying for or using a national identification number.

(3) A State may use the Medicaid identification number established by the State to the same extent as an SSN is used for purposes described in paragraph (b)(3) of this section.

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986; 66 FR 2667, Jan. 11, 2001]

DETERMINATION OF MEDICAID ELIGIBILITY

§435.911 Timely determination of eligibility.

(a) The agency must establish time standards for determining eligibility and inform the applicant of what they are. These standards may not exceed—

(1) Ninety days for applicants who apply for Medicaid on the basis of disability; and

(2) Forty-five days for all other applicants.

(b) The time standards must cover the period from the date of application to the date the agency mails notice of its decision to the applicant.

(c) The agency must determine eligibility within the standards except in unusual circumstances, for example—

(1) When the agency cannot reach a decision because the applicant or an examining physician delays or fails to take a required action, or

(2) When there is an administrative or other emergency beyond the agency's control.

(d) The agency must document the reasons for delay in the applicant's case record.

(e) The agency must not use the time standards—

(1) As a waiting period before determining eligibility; or

(2) As a reason for denying eligibility (because it has not determined eligibility within the time standards).

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980; 54 FR 50762, Dec. 11, 1989]

§435.912 Notice of agency's decision concerning eligibility.

The agency must send each applicant a written notice of the agency's decision on his application, and, if eligibility is denied, the reasons for the action, the specific regulation supporting the action, and an explanation of his right to request a hearing. (See subpart

E of part 431 of this subchapter for rules on hearings.)

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986]

§ 435.913 Case documentation.

(a) The agency must include in each applicant's case record facts to support the agency's decision on his application.

(b) The agency must dispose of each application by a finding of eligibility or ineligibility, unless—

(1) There is an entry in the case record that the applicant voluntarily withdrew the application, and that the agency sent a notice confirming his decision;

(2) There is a supporting entry in the case record that the applicant has died; or

(3) There is a supporting entry in the case record that the applicant cannot be located.

§ 435.914 Effective date.

(a) The agency must make eligibility for Medicaid effective no later than the third month before the month of application if the individual—

(1) Received Medicaid services, at any time during that period, of a type covered under the plan; and

(2) Would have been eligible for Medicaid at the time he received the services if he had applied (or someone had applied for him), regardless of whether the individual is alive when application for Medicaid is made.

(b) The agency may make eligiblity for Medicaid effective on the first day of a month if an individual was eligible at any time during that month.

(c) The State plan must specify the date on which eligibility will be made effective.

REDETERMINATIONS OF MEDICAID ELIGIBILITY

§ 435.916 Periodic redeterminations of Medicaid eligibility.

(a) The agency must redetermine the eligibility of Medicaid recipients, with respect to circumstances that may change, at least every 12 months, however—

(1) The agency may consider blindness as continuing until the review physician under § 435.531 determines that a recipient's vision has improved beyond the definition of blindness contained in the plan; and

(2) The agency may consider disability as continuing until the review team under § 435.541 determines that a recipient's disability no longer meets the definition of disability contained in the plan.

(b) *Procedures for reporting changes.* The agency must have procedures designed to ensure that recipients make timely and accurate reports of any change in circumstances that may affect their eligibility.

(c) *Agency action on information about changes.* (1) The agency must promptly redetermine eligibility when it receives information about changes in a recipient's circumstances that may affect his eligibility.

(2) If the agency has information about anticipated changes in a recipient's circumstances, it must redetermine eligibility at the appropriate time based on those changes.

§ 435.919 Timely and adequate notice concerning adverse actions.

(a) The agency must give recipients timely and adequate notice of proposed action to terminate, discontinue, or suspend their eligibility or to reduce or discontinue services they may receive under Medicaid.

(b) The notice must meet the requirements of subpart E of part 431 of this subchapter.

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980; 51 FR 7211, Feb. 28, 1986]

§ 435.920 Verification of SSNs.

(a) In redetermining eligibility, the agency must review case records to determine whether they contain the recipient's SSN or, in the case of families, each family member's SSN.

(b) If the case record does not contain the required SSNs, the agency must require the recipient to furnish them and meet other requirements of § 435.910.

(c) For any recipient whose SSN was established as part of the case record without evidence required under the SSA regulations as to age, citizenship,

alien status, or true identity, the agency must obtain verification of these factors in accordance with §435.910.

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986]

FURNISHING MEDICAID

§435.930 Furnishing Medicaid.

The agency must—

(a) Furnish Medicaid promptly to recipients without any delay caused by the agency's administrative procedures;

(b) Continue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible; and

(c) Make arrangements to assist applicants and recipients to get emergency medical care whenever needed, 24 hours a day and 7 days a week.

INCOME AND ELIGIBILITY VERIFICATION REQUIREMENTS

SOURCE: Sections 435.940 through 935.965 appear at 51 FR 7211, Feb. 28, 1986, unless otherwise noted.

§435.940 Basis and scope.

(a) Section 1137 of the Act requires certain Federally-funded, State-administered public assistance programs to establish procedures for obtaining, using and verifying information relevant to determinations as to eligibility and the amount of assistance. Section 1902(a)(4) of the Act allows the Secretary to prescribe methods of administration found necessary for the proper and efficient operation of a State's Medicaid plan.

(b) The agency must maintain information, as enumerated in §435.960, to exchange for the purpose of enabling any agency or program referenced in §435.945(b) to verify income, eligibility of, and the amount of assistance for its applicants and recipients.

§435.945 General requirements.

(a) The agency must request and use information timely in accordance with §§435.948, 435.952, and 435.953 of this subpart for verifying Medicaid eligibility and the amount of medical assistance payments.

(b) The agency must furnish timely to other agencies in the State and in other States and to Federal programs income, eligibility and medical assistance payment information for verifying eligibility or benefit amounts for the programs listed in §435.948(a)(6) of this subpart. In addition, the agency must furnish income and eligibility information to—

(1) The child support enforcement program under part D of title IV of the Act; and

(2) SSA for old age, survivors and disability benefits under title II and for SSI benefits under title XVI of the Act.

(c) The agency must, upon request, reimburse another agency listed in §435.948(a)(6) of this subpart or paragraph (b) of this section for reasonable costs incurred in furnishing information, including new developmental costs associated with furnishing the information to another agency.

(d) The agency must inform all applicants in writing at the time of application that the agency will obtain and use information available to it under section 1137 of the Act to verify income, eligibility and the correct amount of medical assistance payments. The agency must give each recipient the same notice when it redetermines eligibility. The requirements in this paragraph do not apply in the case of applicants or recipients whose eligibility is determined by AFDC or by SSA under section 1634 of the Act.

(e) The agency must report as the Secretary prescribes for the purposes of determining compliance with §§431.305, 431.800, 435.910, 435.919 and 435.940 through 435.965 of this chapter and of evaluating the effectiveness of the income and eligibility verification system.

(f) The agency must execute written agreements with other agencies before releasing data to or requesting data from, those agencies. The agreements, at a minimum, must specify:

(1) The information to be exchanged;

(2) The titles of all agency officials with the authority to request income and eligibility information;

(3) The methods, including the formats to be used, and the timing for requesting and providing the information (see also paragraph (f)(6) of this section);

(4) The safeguards limiting the use and disclosure of the information as required by Federal or State law or regulations;

(5) The method, if any, the agency will use to reimburse reasonable costs of furnishing the information; and

(6) In the case of an agreement between a SWICA or a UC agency and the Medicaid agency, that the Medicaid agency will obtain information on applicants at least twice monthly; and

(7) In the case of an agreement between any Federal agency and the Medicaid agency for data on individuals, provisions relating to—

(i) Purpose and legal authority;

(ii) Justification and expected results;

(iii) Records description (including specific identification of the system of records, the number of records, what data elements will be included in the match, and projected starting and completion dates);

(iv) Notice procedures;

(v) Verification procedures;

(vi) Disposition of matched items;

(vii) Security procedures;

(viii) Records usage, duplication and redisclosure restrictions;

(ix) Records accuracy assessments; and

(x) Access by the Comptroller General.

(g) SWICA that does not use the quarterly wages reported by employers as required by Section 1137 of the Act of unemployment insurance benefit calculations must maintain wage information that:

(1) Contains the SSN, full name, wages earned for the period of the report, and an identifier of the employer;

(2) Includes all employers covered by the States' UC law;

(3) Accumulates earnings reported by employers for no longer periods than calendar quarters;

(4) Is reported to the SWICA within 30 days after the end of the quarter;

(5) Is machine readable; and

(6) Is accessible to agencies in other States that have executed agreements as required in § 435.945(f) of this chapter and to SSA for use in making eligibility or benefit determinations under Title II or XVI of the Act.

[51 FR 7211, Feb. 28, 1986, as amended at 52 FR 5977, Feb. 27, 1987; 54 FR 8741, Mar. 2, 1989; 57 FR 46097, Oct. 7, 1992; 59 FR 4254, Jan. 31, 1994]

§ 435.948 Requesting information.

(a) Except as provided in paragraphs (d), (e), and (f) of this section, the agency must request information from the sources specified in this paragraph for verifying Medicaid eligibility and the correct amount of medical assistance payments for each applicant (unless obviously ineligible on the face of his or her application) and recipient. The agency must request—

(1) State wage information maintained by the SWICA during the application period and at least on a quarterly basis;

(2) Information about net earnings from self-employment, wage and payment of retirement income, maintained by SSA and available under Section 6103(l)(7)(A) of the Internal Revenue Code of 1954, for applicants during the application period and for recipients for whom the information has not previously been requested;

(3) Information about benefit and other eligibility related information available from SSA under titles II and XVI of the Social Security Act for applicants during the application period and for recipients for whom the information has not previously been requested;

(4) Unearned income information from the Internal Revenue Service available under Section 6103(l)(7)(B) of the Internal Revenue Code of 1954, during the application period and at least yearly;

(5) Unemployment compensation information maintained by the agency administering State unemployment compensation laws (under the provisions of section 3304 of the Internal Revenue Code and section 303 of the Act) as follows:

(i) For an applicant, during the application period and at least for each of the three subsequent months;

(ii) For a recipient that reports a loss of employment, at the time the recipient reports that loss and for at least each of the three subsequent months.

(iii) For an applicant or a recipient who is found to be receiving unemployment compensation benefits, at least for each month until the benefits are reported to be exhausted.

(6) Any additional income, resource, or eligibility information relevant to determinations concerning eligibility or correct amount of medical assistance payments available from agencies in the State or other States administering the following programs as provided in the agency's State plan:

(i) AFDC;

(ii) Medicaid;

(iii) State-administered supplementary payment programs under Section 1616(a) of the Act;

(iv) SWICA;

(v) Unemployment compensation;

(vi) Food stamps; and

(vii) Any State program administered under a plan approved under Title I (assistance to the aged), X (aid to the blind), XIV (aid to the permanently and totally disabled), or XVI (aid to the aged, blind, and disabled in Puerto Rico, Guam, and the Virgin Islands) of the Act.

(b) The agency must request information on applicants from the sources listed in paragraph (a)(1) through (a)(5) of this section at the first opportunity provided by these sources following the receipt of the application. If an applicant cannot provide an SSN at application, the agency must request the information at the next available opportunity after receiving the SSN.

(c) The agency must request the information required in paragraph (a) of this section by SSN, using each SSN furnished by the individual or received through verification.

(d) *Exception:* In cases where the individual is institutionalized, the agency needs to obtain and use information from SWICA only during the application period and on a yearly basis, and from unemployment compensation agencies only during the application period. An individual is institutionalized for purposes of this section when he or she is required to apply his or her income to the cost of medical care as required by §§435.725, 435.733, and 435.832.

(e) *Exception: Alternate sources*—(1) The Secretary may, upon application from a State agency, permit an agency to request and use income information from a source or sources alternative to those listed in paragraph (a) of this section. The agency must demonstrate to the Secretary that the alternative source(s) is as timely, complete and useful for verifying eligibility and benefit amounts. The Secretary will consult with the Secretary of Agriculture and the Secretary of Labor before determining whether an agency may use an alternate source.

(2) The agency must continue to meet the requirements of this section unless the Secretary has approved the request.

(f) *Exception:* If the agency administering the AFDC program, or SSA under section 1634 of the Act, determines the eligibility of an applicant or recipient, the requirements of this section do not apply to that applicant or recipient.

§435.952 Use of information.

(a) Except as provided under §435.953, the agency must review and compare against the case file all information received under §§435.940 through 435.960 to determine whether it affects the applicant's or recipient's eligibility or amount of medical assistance payment. The agency also must independently verify the information if required by §435.955 or if determined appropriate by agency experience.

(b) For applicants, if the information is received during the application period, it must be used, to the extent possible, making eligibility determinations. If it is received after the eligibility determination, it must be used as specified for recipients in paragraphs (c) and (d) of this section.

(c) Except as specified in §435.953 of this subpart and paragraph (d) of this section, for recipients, the agency must, within 45 days of receipt of an item of information, request verification (if appropriate), determine whether the information affects eligibility or the amount of medical assistance payment, and either initiate a notice of case action to advise the recipient of any adverse action the agency intends to take or make an entry in the casefile that no further action is necessary.

(d) Subject to paragraph (e) of this section, if the agency does not receive requested third party verification within the 45-day period after receipt of information, the agency may determine whether the information affects eligibility or correct amount of medical assistance payment after the 45-day period. However, the agency must make any delayed determinations permitted under this paragraph—

(1) Promptly, as required by § 435.916, if the verification is received before the next redetermination; or

(2) In conjunction with the next redetermination if no verification is received before that redetermination.

(e) The number of determinations delayed beyond 45 days from receipt of an item of information (as permitted by paragraph (d) of this section) must not exceed twenty percent of the number of items of information for which verification was requested.

(f) The agency must use appropriate procedures to monitor the timeliness requirements of this section.

(g) The requirements of this section do not relieve the agency of its responsibility for determinations of erroneous payments or the agency's liability for those erroneous payments, as defined in subpart P of part 431 of this chapter.

[51 FR 7211, Feb. 28, 1986, as amended at 53 FR 6648, March 2, 1988; 54 FR 8741, Mar. 2, 1989; 59 FR 4255, Jan. 31, 1994]

§ 435.953 Identifying items of information to use.

(a) With respect to information received on recipients under §§ 435.940 through 435.960, the agency may either review and compare against the case file all items of information received or it may identify (target) separately for each data source the information items that are most likely to be most productive in identifying and preventing ineligibility and incorrect payments.

(b) An agency that wishes to exclude categories of information items must submit for the Secretary's approval a follow-up plan describing the categories that it proposes to exclude. For each category, the agency must provide a reasonable justification that follow-up is not cost-effective; a formal cost/benefit analysis is not required.

(c) If an agency receives an item of unemployment compensation information from the Internal Revenue Service or earnings information from SSA that duplicates an item of information previously received from another source and followed up, the agency may exclude that information item without justification.

(d) An agency may submit a follow-up plan or alter its plan at any time by notifying the Secretary and submitting the necessary justification. The Secretary approves or disapproves categories of items to be excluded under the plan within 60 days of its submission. The categories approved by the Secretary constitute an approved agency follow-up plan for IEVS.

[54 FR 8742, Mar. 2, 1989]

§ 435.955 Additional requirements regarding information released by a Federal agency.

(a) Unless waived under paragraph (d) of this section, based on information received from a computerized data match in which information on an individual is provided to the agency by a Federal agency, the agency may not terminate, deny, suspend, or reduce medical assistance to that individual until it has taken appropriate steps to verify the information independently. The agency must independently verify information relating to—

(1) The amount of the income and resource that generated the income involved;

(2) Whether the applicant or recipient actually has (or had) access to the resource or income (or both) for his or her own use;

(3) The period or periods when the individual actually has (or had) access to the resource or income or both.

(b) The agency must verify the information by either

(1) Requesting the entity from which the information originally came to verify the fact and amount of income or resource; or

(2) Sending the applicant or recipient a letter informing that individual of the information received and asking him or her to respond within a specified period. The letter must clearly explain the information the agency has

and its possible relevance to the individual's past or future eligibility, and be as neutral in tone as possible.

(c)(1) If the original source of the income or resource or the applicant or recipient verifies the information, and the agency intends to reduce, suspend, terminate or deny medical assistance based on the information, the agency must send the applicant or recipient a notice of the action to be taken and include information on the right to appeal and opportunity for a hearing under §§431.200 through 431.246 of this chapter (see also §435.912 and §435.919).

(2) If the applicant or recipient fails to respond after reasonable attempts to contact him or her, the agency must proceed to deny, terminate, reduce or suspend medical assistance based on the applicant's or recipient's failure to cooperate.

(3) If the applicant or recipient disputes the information, the agency must obtain evidence (from the source of the data, applicant, recipient, or otherwise) to substantiate any negative case action it may take.

(d) The independent verification requirement concerning a category of data received from a Federal benefit agency may be waived if the Federal agency's Data Integrity Board approves the waiver. The Federal benefit agency involved in the data exchange will develop the request by petitioning its Data Integrity Board for a waiver of independent verification by a Medicaid State agency. The State agency must furnish the Federal agency with any information it needs to seek the Data Integrity Board's approval of the waiver.

(e) In accordance with the Federal agency's procedures, the agency must provide data on the costs and benefits of the matching program to the Federal agency from which it receives information on individuals.

(f) In accordance with the Federal agency's procedures, the agency must certify to the Federal agency that it will not take adverse action against an individual until the information has been independently verified and until 10 days (or sooner if permitted by §431.213 or §431.214) after the individual has been notified of the findings and given an opportunity to contest.

(g) In accordance with the Federal agency's procedures for renewals of matching programs, the agency must certify to the Federal agency that the terms of the agreement have been followed.

[59 FR 4255, Jan. 31, 1994]

§435.960 Standardized formats for furnishing and obtaining information to verifying income and eligibility.

(a) The agency must maintain for all applicants and recipients within an agency file the SSN, surname and other data elements in a format that at a minimum allows the agency to furnish and to obtain eligibility and income information from the agencies or programs referenced in §435.945(b) and §435.948(a).

(b) The format to be used will be prescribed by—

(1) CMS when the agency furnishes information to, or requests information from, any Federal or State agency, except SSA and the Internal Revenue Service as specified in paragraphs (b) (2) and (3), respectively;

(2) The Commissioner of Social Security when the agency requests information from SSA; and

(3) The Commissioner of Internal Revenue when the agency requests information from the Internal Revenue Service.

[52 FR 5977, Feb. 27, 1987]

§435.965 Delay of effective date.

(a) If the agency submits, by May 29, 1986, a plan describing a good faith effort to come into compliance with the requirements of section 1137 of the Act and of §§435.910 and 435.940 through 435.960 of this subpart, the Secretary may, after consultation with the Secretary of Agriculture and the Secretary of Labor, grant a delay in the effective date of §§435.910 and 435.940 through 435.960, but not beyond September 30, 1986.

(b) The Secretary may not grant a delay of the effective date of section 1137(c) of the Act, which is implemented by §435.955 (a) and (c). (The provisions of these statutory and regulation sections require the agency to follow certain procedures before taking

any adverse actions based on information from the Internal Revenue Service concerning unearned income.)

Subpart K—Federal Financial Participation

§ 435.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP IN EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 435.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in—

(1) Determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals; and

(2) Determining presumptive eligibility for children and providing services to presumptively eligible children.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

[43 FR 45204, Sept. 29, 1978, as amended at 66 FR 2667, Jan. 11, 2001]

§ 435.1002 FFP for services.

(a) Except for the limitations and conditions specified in §§ 435.1007, 35.1008, 435.1009, and 438.814 of this chapter, FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for Medicaid in the month in which the medical care or services were provided except that, for recipients who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability. (See §§ 435.914 and 436.901 of this subchapter for regulations on retroactive eligibility for Medicaid.)

(c) FFP is available in expenditures for services covered under the plan that are furnished—

(1) To children who are determined by a qualified entity to be presumptively eligible;

(2) During a period of presumptive eligibility;

(3) By a provider that is eligible for payment under the plan; and

(4) Regardless of whether the children are determined eligible for Medicaid following the period of presumptive eligibility.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979; 66 FR 2667, Jan. 11, 2001; 67 FR 41095, June 14, 2002; 71 FR 39225, July 12, 2006]

§ 435.1003 FFP for redeterminations.

(a) If the Social Security Administration (SSA) notifies an agency that a recipient has been determined ineligible for SSI, FFP is available in Medicaid expenditures for services to the recipient as follows:

(1) If the agency receives the SSA notice by the 10th day of the month, FFP is available under this section only through the end of the month unless the recipient requests a hearing under subpart E, part 431 of this subchapter.

(2) If the agency receives the SSA notice after the 10th day of the month, FFP is available only through the end of the following month, unless the recipient requests a hearing under subpart E, part 431 of this subchapter.

(3) If a recipient requests a hearing, FFP is available as specified in subpart E, part 431 of this subchapter.

(b) The agency must take prompt action to determine eligibility after receiving the SSA notice.

(c) When a change in Federal law affects the eligibility of substantial numbers of Medicaid recipients, the Secretary may waive the otherwise applicable FFP requirements and redetermination time limits of this section, in order to provide a reasonable time to complete such redeterminations. The Secretary will designate an additional amount of time beyond that allowed

under paragraphs (a) and (b) of this section, within which FFP will be available, to perform large numbers of redeterminations arising from a change in Federal law.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979; 62 FR 1685, Jan. 13, 1997]

§435.1004 Recipients overcoming certain conditions of eligibility.

(a) FFP is available, as specified in paragraph (b) of this section, in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

(b) FFP is available for a period not to exceed—

(1) The period during which a recipient of AFDC, SSI or an optional State supplement continues to receive cash payments while these conditions are being overcome; or

(2) For recipients eligible for Medicaid only and recipients of AFDC, SSI or an optional State supplement who do not continue to receive cash payments, the second month following the month in which the recipient's Medicaid eligibility would have been terminated.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980]

LIMITATIONS ON FFP

§435.1005 Recipients in institutions eligible under a special income standard.

For recipients in institutions whose Medicaid eligibility is based on a special income standard established under §435.236, FFP is available in expenditures for services provided to those individuals only if their income before deductions, as determined by SSI budget methodology, does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual in his own home who has no income or resources.

[58 FR 4933, Jan. 19, 1993]

§435.1006 Recipients of optional State supplements only.

FFP is available in expenditures for services provided to individuals receiving optional State supplements but not receiving SSI, if their income before deductions, as determined by SSI budget methodology, does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual who has no income and resources.

[45 FR 24887, Apr. 11, 1980]

§435.1007 Categorically needy, medically needy, and qualified Medicare beneficiaries.

(a) FFP is available in expenditures for covered services provided to categorically needy recipients, medically needy recipients, and qualified Medicare beneficiaries, subject to the restrictions contained in subpart K of this part and as provided in paragraphs (b) and (e) of this section. However, the restrictions listed in paragraphs (b) and (e) of this section do not apply to expenditures for medical assistance made on behalf of qualified Medicare beneficiaries under section 1905(p) of the Act; individuals receiving Medicaid as categorically needy under section 1902(a)(10)(A)(i) (I), (II), (III), (IV), (V), (VI), or (VII) and section 1902(a)(10)(A)(ii) (I), (IX), or (X) and section 1905(u) of the Act; individuals who are eligible to receive benefits (or would be eligible for those benefits if they were not in a medical institution); and any individuals deemed to be members of the groups identified in this sentence.

(b) Except as provided in paragraphs (c) and (d) of this section, FFP is not available in State expenditures for individuals (including the medically needy) whose annual income after deductions specified in §435.831(a) and (c) exceeds the following amounts, rounded to the next higher multiple of $100.

(c) In the case of a family consisting only of two individuals, both of whom are adults and at least one of whom is aged, blind, or disabled, the State of California may use the amount of the AFDC payment most frequently made to a family of one adult and two children for purposes of computing the

133⅓ percent limitation (under the authority of section 4106 of Public Law 100–230).

(d) For purposes of paragraph (b)(1) of this section, a State that as of June 1, 1989, has in its State plan (as defined in section 2373(c)(5) of Public Law 98–369 as amended by section 9 of Public Law 100–93) an amount for individuals that was reasonably related to 133⅓ percent of the highest amount of AFDC which would ordinarily be paid to a family of two without income or resources may use an amount based upon a reasonable relationship to such an AFDC standard for a family of two.

(e) FFP is not available in expenditures for services provided to categorically needy and medically needy recipients subject to the FFP limits if their annual income, after the cash assistance income deductions and any income disregards in the State plan authorized under section 1902(r)(2) of the Act are applied, exceeds the 133⅓ percent limitation described under paragraphs (b), (c), and (d) of this section.

(f) A State may use the less restrictive income methodologies included under its State plan as authorized under § 435.601 in determining whether a family's income exceeds the limitation described in paragraph (b) of this section.

[58 FR 4933, Jan. 19, 1993, as amended at 66 FR 2321, 2667, Jan. 11, 2001]

§ 435.1008 FFP in expenditures for medical assistance for individuals who have declared United States citizenship or nationality under section 1137(d) of the Act and with respect to whom the State has not documented citizenship and identity.

Except for individuals described in § 435.406(a)(1)(v), FFP will not be available to a State with respect to expenditures for medical assistance furnished to individuals unless the State has obtained satisfactory documentary evidence of citizenship or national status, as described in § 435.407 that complies with the requirements of section 1903(x) of the Act.

[72 FR 38694, July 13, 2007]

§ 435.1009 Institutionalized individuals.

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

(1) Individuals who are inmates of public institutions as defined in § 435.1010; or

(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for tuberculosis or mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient psychiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

[43 FR 45204, Sept. 29, 1978, as amended at 50 FR 13199, Apr. 3, 1985; 50 FR 38811, Sept. 25, 1985. Redesignated and amended at 71 FR 39225, July 12, 2006]

§ 435.1010 Definitions relating to institutional status.

For purposes of FFP, the following definitions apply:

Active treatment in intermediate care facilities for the mentally retarded means treatment that meets the requirements specified in the standard concerning active treatment for intermediate care facilities for persons with mental retardation under § 483.440(a) of this subchapter.

Child-care institution means a nonprofit private child-care institution, or a public child-care institution that accommodates no more than twenty-five children, which is licensed by the State in which it is situated, or has been approved by the agency of the State responsible for licensing or approval of institutions of this type, as meeting the standards established for licensing.

The term does not include detention facilities, forestry camps, training schools or any other facility operated primarily for the detention of children who are determined to be delinquent.

In an institution refers to an individual who is admitted to live there and receive treatment or services provided there that are appropriate to his requirements.

Inmate of a public institution means a person who is living in a public institution. An individual is not considered an inmate if—

(a) He is in a public educational or vocational training institution for purposes of securing education or vocational training; or

(b) He is in a public institution for a temporary period pending other arrangements appropriate to his needs.

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

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

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

Institution means an establishment that furnishes (in single or multiple facilities) food, shelter, and some treatment or services to four or more persons unrelated to the proprietor.

Institution for mental diseases means a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases, including medical attention, nursing care and related services. Whether an institution is an institution for mental diseases is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of individuals with mental diseases, whether or not it is licensed as such. An institution for the mentally retarded is not an institution for mental diseases.

Institution for the mentally retarded or persons with related conditions means an institution (or distinct part of an institution) that—

(a) Is primarily for the diagnosis, treatment, or rehabilitation of the mentally retarded or persons with related conditions; and

(b) Provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration of health or rehabilitative services to help each individual function at his greatest ability.

Institution for tuberculosis means an institution that is primarily engaged in providing diagnosis, treatment, or care of persons with tuberculosis, including medical attention, nursing care, and related services. Whether an institution is an institution for tuberculosis is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of tuberculosis, whether or not it is licensed as such.

Medical institution means an institution that—

(a) Is organized to provide medical care, including nursing and convalescent care;

(b) Has the necessary professional personnel, equipment, and facilities to manage the medical, nursing, and other health needs of patients on a continuing basis in accordance with accepted standards;

(c) Is authorized under State law to provide medical care; and

(d) Is staffed by professional personnel who are responsible to the institution for professional medical and nursing services. The services must include adequate and continual medical care and supervision by a physician; registered nurse or licensed practical nurse supervision and services and nurses' aid services, sufficient to meet nursing care needs; and a physician's guidance on the professional aspects of operating the institution.

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

bed is used or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward maintenance, improvement, or protection of health, or lessening of illness, disability, or pain.

Persons with related conditions means individuals who have a severe, chronic disability that meets all of the following conditions:

(a) It is attributable to—

(1) Cerebral palsy or epilepsy; or

(2) Any other condition, other than mental illness, found to be closely related to mental retardation because this condition results in impairment of general intellectual functioning or adaptive behavior similar to that of mentally retarded persons, and requires treatment or services similar to those required for these persons.

(b) It is manifested before the person reaches age 22.

(c) It is likely to continue indefinitely.

(d) It results in substantial functional limitations in three or more of the following areas of major life activity:

(1) Self-care.

(2) Understanding and use of language.

(3) Learning.

(4) Mobility.

(5) Self-direction.

(6) Capacity for independent living.

Public institution means an institution that is the responsibility of a governmental unit or over which a governmental unit exercises administrative control. The term ''public institution'' does not include—

(a) A medical institution as defined in this section;

(b) An intermediate care facility as defined in §§ 440.140 and 440.150 of this chapter;

(c) A publicly operated community residence that serves no more than 16 residents, as defined in this section; or

(d) A child-care institution as defined in this section with respect to—

(1) Children for whom foster care maintenance payments are made under title IV-E of the Act; and

(2) Children receiving AFDC—foster care under title IV-A of the Act.

Publicly operated community residence that serves no more than 16 residents is defined in 20 CFR 416.231(b)(6)(i). A summary of that definition is repeated here for the information of readers.

(a) In general, a publicly operated community residence means—

(1) It is publicly operated as defined in 20 CFR 416.231(b)(2).

(2) It is designed or has been changed to serve no more than 16 residents and it is serving no more than 16; and

(3) It provides some services beyond food and shelter such as social services, help with personal living activities, or training in socialization and life skills. Occasional medical or remedial care may also be provided as defined in 45 CFR 228.1; and

(b) A publicly operated community residence does not include the following facilities, even though they accommodate 16 or fewer residents:

(1) Residential facilities located on the grounds of, or immediately adjacent to, any large institution or multiple purpose complex.

(2) Educational or vocational training institutions that primarily provide an approved, accredited, or recognized program to individuals residing there.

(3) Correctional or holding facilities for individuals who are prisoners, have been arrested or detained pending disposition of charges, or are held under court order as material witnesses or juveniles.

(4) Hospitals, nursing facilities, and intermediate care facilities for the mentally retarded.

[43 FR 45204, Sept. 29, 1978, as amended at 47 FR 28655, July 1, 1982; 47 FR 31532, July 20, 1982; 51 FR 19181, May 28, 1986; 52 FR 47934, Dec. 17, 1987; 53 FR 657, Jan. 11, 1988; 53 FR 20495, June 3, 1988; 56 FR 8854, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 56233, Nov. 10, 1994. Redesignated at 71 FR 39225, July 12, 2006]

REQUIREMENTS FOR STATE SUPPLEMENTS

§ 435.1011 Requirement for mandatory State supplements.

(a) Except as specified in paragraph (b) of this section, FFP is not available in Medicaid expenditures in any quarter in which the State does not have in

effect an agreement with the Secretary under section 212 of Pub. L. 93–66 (July 9, 1973) for minimum mandatory State supplements of the basic SSI benefit.

(b) This section does not apply to any State that meets the conditions of section 212(f) of Pub. L. 93–66.

[43 FR 45204, Sept. 29, 1978. Redesignated at 71 FR 39225, July 12, 2006]

§435.1012 Requirement for maintenance of optional State supplement expenditures.

(a) This section applies to States that make optional State supplement payments under section 1616(a) of the Act and mandatory supplement payments under section 212(a) of Pub. L. 93–66.

(b) FFP in Medicaid expenditures is not available during any period in which the State does not have in effect an agreement with the Secretary under section 1618 of the Act to maintain its supplementary payments.

[43 FR 45204, Sept. 29, 1978, as amended at 55 FR 48609, Nov. 21, 1990. Redesignated at 71 FR 39225, July 12, 2006]

Subpart L—Option for Coverage of Special Groups

SOURCE: 66 FR 2667, Jan. 11, 2001, unless otherwise noted.

§435.1100 Basis and scope.

(a) *Statutory basis.* Section 1920A of the Act allows States to provide Medicaid services to children under age 19 during a period of presumptive eligibility, prior to a formal determination of Medicaid eligibility.

(b) Scope. This subpart prescribes the requirements for providing medical assistance to special groups who are not eligible for Medicaid as categorically or medically needy.

PRESUMPTIVE ELIGIBILITY FOR CHILDREN

§435.1101 Definitions related to presumptive eligibility for children.

Application form means at a minimum the form used to apply for Medicaid under the poverty-level-related eligibility groups described in section 1902(l) of the Act or a joint form for children to apply for the State Children's Health Insurance Program and Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a Medicaid application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf a Medicaid application has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish the regular Medicaid eligibility of a child of the age involved.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is authorized to determine eligibility of a child for medical assistance under the Medicaid State plan, or eligibility of a child for child health assistance under the State Children's Health Insurance Program;

(6) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(7) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(8) Is a State or Tribal child support enforcement agency;

(9) Is an organization that—

(i) Provides emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(ii) Is a State or Tribal office or entity involved in enrollment in the program under title XIX, Part A of title IV, or title XXI; or

(iii) Determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); and

(10) Any other entity the State so deems, as approved by the Secretary.

Services means all services covered under the plan including EPSDT (see part 440 of this chapter).

[66 FR 2667, Jan. 11, 2001, as amended at 66 FR 33822, June 25, 2001]

§ 435.1102 General rules.

(a) The agency may provide services to children under age 19 during one or more periods of presumptive eligibility following a determination by a qualified entity that the child's estimated gross family income or, at the State's option, the child's estimated family income after applying simple disregards, does not exceed the applicable income standard.

(b) If the agency elects to provide services to children during a period of presumptive eligibility, the agency must—

(1) Provide qualified entities with application forms for Medicaid and information on how to assist parents, caretakers and other persons in completing and filing such forms;

(2) Establish procedures to ensure that qualified entities—

(i) Notify the parent or caretaker of the child at the time a determination regarding presumptive eligibility is made, in writing and orally if appropriate, of such determination;

(ii) Provide the parent or caretaker of the child with a regular Medicaid application form;

(iii) Within five working days after the date that the determination is made, notify the agency that a child is presumptively eligible;

(iv) For children determined to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate, that—

(A) If a Medicaid application on behalf of the child is not filed by the last day of the following month, the child's presumptive eligibility will end on that last day; and

(B) If a Medicaid application on behalf of the child is filed by the last day of the following month, the child's presumptive eligibility will end on the day that a decision is made on the Medicaid application; and

(v) For children determined not to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate—

(A) Of the reason for the determination; and

(B) That he or she may file an application for Medicaid on the child's behalf with the Medicaid agency;

(3) Provide all services covered under the plan, including EPSDT; and

(4) Allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

(c) The agency must adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child in a given time frame.

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

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436.1102 General rules.

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

SOURCE: 43 FR 45218, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 436.1 Purpose and applicability.

This part sets forth, for Guam, Puerto Rico, and the Virgin Islands—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that a Medicaid agency must use in determining and redetermining eligibility, and requirements it may not use; and

(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

§ 436.2 Basis.

This part implements the following sections of the Act and public laws that state requirements and standards for eligibility:

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.
402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.
414(g) Eligibility of certain individuals participating in work supplementation programs.
473(b) Eligibility of children in foster care and adopted children who are deemed AFDC recipients.
1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
1902(a)(10) Required and optional groups.
1902(a)(12) Determination of blindness.
1902(a)(16) Out-of-State care for State residents.

1902(a)(17) Standards for determining eligibility; flexibility in the application of income eligibility standards.
1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.
1902(a)(34) Three-month retroactive eligibility.
1902(a) (second paragraph after (47)) Eligibility despite increased monthly insurance benefits under title II.
1902(a)(55) Mandatory use of outstation locations other than welfare offices to receive and initially process applications of certain low-income pregnant women, infants, and children under age 19.
1902(b) Prohibited conditions for eligibility: Age requirements of more than 65 years;
State residence requirements excluding individuals who reside in the State; and
Citizenship requirement excluding United States citizens.
1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.
1902(e)(2) Minimum eligibility period for recipients enrolled in HMO.
1902(e)(3) Optional coverage of certain disabled children at home.
1902(e)(4) Eligibility of newborn children of Medicaid-eligible women.
1902(e)(5) Eligibility of pregnant women for extended coverage for a specified period after pregnancy ends.
1903(v) Payment for emergency services under Medicaid provided to aliens.
1905(a) (i)-(viii) List of eligible individuals.
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Pub. L. 93–66, section 230 Deemed eligibility of certain essential persons.
Pub. L. 93–66, section 231 Deemed eligibility of certain persons in medical institutions.
Pub. L. 93–66, section 232 Deemed eligibility of certain blind and disabled medically indigent persons.
Pub. L. 96–272, section 310(b)(1) Continued eligibility of certain recipients of Veterans Administration pensions.
Pub. L. 99–509, section 9406 Payment for emergency medical services provided to aliens.
Pub. L. 99–603, section 201 Aliens granted legalized status under section 245A of the Immigration and Nationality Act (8 U.S.C. 1255a) may under certain circumstances be eligible for Medicaid.
Pub. L. 99–603, section 302 Aliens granted legalized status under section 210 of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1160).
Pub. L. 99–603, section 303 Aliens granted legal status under section 210A of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1161).

[52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987, as amended at 55 FR 36820, Sept. 7, 1990; 55 FR 48609, Nov. 21, 1990; 57 FR 29155, June 30, 1992; 59 FR 48811, Sept. 23, 1994]

§436.3 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act;

AB means aid to the blind under title X of the Act;

AFDC means aid to families with dependent children under title IV-A of the Act;

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Categorically needy refers to families and children, aged, blind or disabled individuals, and pregnant women listed under subparts B and C of this part who are eligible for Medicaid. Subpart B of this part describes the mandatory eligibility groups who, generally, are receiving or deemed to be receiving cash assistance under the Act. These mandatory groups are specified in sections 1902(a)(10)(A)(i) and 1902(e) of the Act. Subpart C of this part describes the optional eligibility groups of individuals who, generally, meet the categorical requirements that are the same as or less restrictive than those of the cash assistance programs but are not receiving cash payments. These optional groups are specified in sections 1902(a)(10)(A)(ii) and 1902(e) of the Act.

Families and children refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90; 233.100). In addition, this group includes individuals under age 21

who are not deprived of parental support or care but who are financially eligible under AFDC or medically needy rules (see optional coverage group, § 436.222);

Medically needy means families, children, aged, blind, or disabled individuals, and pregnant women listed in subpart D of this part who are not listed in subparts B and C of this part as categorically needy but who may be eligible for Medicaid under this part because their income and resources are within limits set by the State under its Medicaid plan (including persons whose income and resources fall within these limits after their incurred expenses for medical or remedial care are deducted). (Specific financial requirements for determining eligibility of the medically needy appear in subpart I of this part.)

OAA means old age assistance under title I of the Act;

OASDI means old age, survivors, and disability insurance under Title II of the Act.

Optional targeted low-income child means a child under age 19 who meets the financial and categorical standards described below.

(1) *Financial need.* An optional targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved;

(ii) Resides in a State with no Medicaid applicable income level (as defined in § 457.10 of this chapter); or,

(iii) Resides in a State that has a Medicaid applicable income level (as defined in § 457.10) and has family income that either:

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points (expressed as a percentage of the Federal poverty line); or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under the policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage and State maintenance of effort.* An optional targeted low-income child is not covered under a group health plan or health insurance coverage, or would not be eligible for Medicaid under the policies of the State plan in effect on March 31, 1997; except that, for purposes of this standard—

(i) A child shall not be considered to be covered by health insurance coverage based on coverage offered by the State under a program in operation prior to July 1, 1997 if that program received no Federal financial participation;

(ii) A child shall not be considered to be covered under a group health plan or health insurance coverage if the child did not have reasonable geographic access to care under that coverage.

(3) For purposes of this section, policies of the State plan under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 46 FR 47989, Sept. 30, 1981; 58 FR 4934, Jan. 19, 1993; 66 FR 2668, Jan. 11, 2001]

§ 436.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom Medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 436.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

§ 436.110 Individuals receiving cash assistance.

(a) A Medicaid agency must provide Medicaid to individuals receiving cash assistance under OAA, AFDC, AB, APTD, or AABD.

(b) For purposes of this section, an individual is receiving cash assistance if his needs are considered in determining the amount of the payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient under the State's plan for OAA, AFDC, AB, APTD, or AABD if that plan were as broad as allowed under the Act for FFP.

§436.111 Individuals who are not eligible for cash assistance because of a requirement not applicable under Medicaid.

(a) The agency must provide Medicaid to individuals who would be eligible for OAA, AB, APTD, or AABD except for an eligibility requirement used in those programs that is specifically prohibited under title XIX of the Act.

(b) The agency also must provide Medicaid to:

(1) Individuals denied AFDC solely because of policies requiring the deeming of income and resources of the following individuals who are not included as financially responsible relatives under section 1902(a)(17)(D) of the Act:

(i) Stepparents who are not legally liable for support of stepchildren under a State law of general applicability;

(ii) Grandparents

(iii) Legal guardians;

(iv) Aliens sponsors who are not organizations; and

(v) Siblings.

(2) [Reserved]

[58 FR 4934, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§436.112 Individuals who would be eligible for cash assistance except for increased OASDI under Pub. L. 92–336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving cash assistance; or

(2) He would have been eligible for cash assistance if he had applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for cash assistance if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for cash assistance except that the increase in OASDI under Pub. L. 92–336 raised his income over the limit allowed under the cash assistance program. This includes an individual who—

(1) Meets all current requirements for cash assistance except for the requirement to file an application; or

(2) Would meet all current requirements for cash assistance if he were not in a medical institution or intermediate care facility, and the Medicaid plan covers this optional group.

§436.114 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

(e) The State must deem to be receiving AFDC individuals described in section 473(a)(1) of the Act—

(1) For whom an adoption assistance agreement is in effect under title IV-E

of the Act, whether or not adoption assistance is being provided or an interlocutory or other judicial decree of adoption has been issued; or

(2) For whom foster care maintenance payments are made under title IV-E of the Act.

(f) The State must deem an individual to be receiving AFDC if a new collection or increased collection of child or spousal support under title IV-D of the Social Security Act results in the termination of AFDC eligibility in accordance with section 406(h) of the Social Security Act. States must continue to provide Medicaid for four consecutive calendar months, beginning with the first month of AFDC ineligibility, to each dependent child and each relative with whom such a child is living (including the eligible spouse of such relative as described in section 406(b) of the Social Security Act) who:

(1) Becomes ineligible for AFDC on or after August 16, 1984; and

(2) Has received AFDC for at least three of the six months immediately preceding the month in which the individual becomes ineligible for AFDC; and

(3) Becomes ineligible for AFDC wholly or partly as a result of the initiation of or an increase in the amount of a child or spousal support collection under title IV-D.

(g)(1) Except as provided in paragraph (g)(2) of this section, individuals who are eligible for extended Medicaid lose this coverage if they move to another State during the 4-month period. However, if they move back to and reestablish residence in the State in which they have extended coverage, they are eligible for any of the months remaining in the 4-month period in which they are residents of the State.

(2) If a State has chosen in its State plan to provide Medicaid to non-residents, the State may continue to provide the 4-month extended benefits to individuals who have moved to another State.

(h) For purposes of paragraph (f) of this section:

(1) The new collection or increased collection of child or spousal support results in the termination of AFDC eligibility when it actively causes or contributes to the termination. This occurs when:

(i) The change in support collection in and of itself is sufficient to cause ineligibility. This rule applies even if the support collection must be added to other, stable income. It also applies even if other independent factors, alone or in combination with each other, might simultaneously cause ineligibility; or

(ii) The change in support contributes to ineligibility but does not by itself cause ineligibility. Ineligibility must result when the change in support is combined with other changes in income or changes in other circumstances and the other changes in income or circumstances cannot alone or in combination result in termination without the change in support.

(2) In cases of increases in the amounts of both the support collections and earned income, eligibility under this section does not preclude eligibility under 45 CFR 233.20(a)(14) or section 1925 of the Social Security Act (which was added by section 303(a) of the Family Support Act of 1988 (42 U.S.C. 1396r–6)). Extended periods resulting from both an increase in the amount of the support collection and from an increase in earned income must run concurrently.

[46 FR 47989, Sept. 30, 1981, as amended at 52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987; 55 FR 48610, Nov. 21, 1990; 59 FR 59377, Nov. 17, 1994]

§ 436.116 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If

AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980]

§ 436.118 Children for whom adoption assistance or foster care maintenance payments are made.

The agency must provide Medicaid to children for whom adoption assistance or foster care maintenance payments are made under title IV-E of the Act.

[47 FR 28656, July 1, 1982]

§ 436.120 Qualified pregnant women and children who are not qualified family members.

(a) The Medicaid agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for an AFDC cash payment if coverage under the State's AFDC plan included the AFDC-unemployed parents program) if her child had been born and was living with her in the month of payment;

(2) Is a member of a family that would be eligible for an AFDC cash payment if the State's AFDC plan included an AFDC-unemployed parents program; or

(3) Meets the income and resource requirements of the State's approved AFDC plan. In determining whether the woman meets the AFDC income and resource requirements, the unborn child or children are considered members of the household, and the woman's family is treated as though deprivation exists.

(b) The provisions of paragraphs (a)(1) and (2) of this section are effective October 1, 1984. The provisions of paragraph (a)(3) of this section are effective July 1, 1986.

(c) The agency must provide Medicaid to children who meet all of the following criteria:

(1) They are born after September 30, 1983;

(2) Effective October 1, 1988, they are under age 6 (or if designated by the State, any age that exceeds age 6 but does not exceed age 8), and effective October 1, 1989 they are under age 7 (or if designated by the State, any age that exceeds age 7 but does not exceed age 8); and

(3) They meet the income and resource requirements of the State's approved AFDC plan.

[52 FR 43072, Nov. 9, 1987, as amended at 55 FR 48610, Nov. 21, 1990; 58 FR 48614, Sept. 17, 1993]

§ 436.121 Qualified family members.

(a) *Definition.* A *qualified family member* is any member of a family, including pregnant women and children eligible for Medicaid under § 436.120 of this subpart, who would be receiving AFDC cash benefits on the basis of the unemployment of the principal wage earner under section 407 of the Act had the State not chosen to place time limits on those benefits as permitted under section 407(b)(2)(B)(i) of the Act.

(b) *State plan requirement.* The State plan must provide that the State makes Medicaid available to any individual who meets the definition of ''qualified family member'' as specified in paragraph (a) of this section.

(c) *Applicability.* The provisions in this section are applicable from October 1, 1992, through September 30, 1998.

[58 FR 48614, Sept. 17, 1993]

§ 436.122 Pregnant women eligible for extended coverage.

(a) The Medicaid agency must provide categorically needy Medicaid eligibility for an extended period following termination of pregnancy to women who, while pregnant, applied for, were eligible for, and received Medicaid services on the day that their pregnancy ends. This period extends from the last day of pregnancy through the end of the month in which a 60-day period, beginning on the last day of the pregnancy, ends. Eligibility must be provided, regardless of changes in the woman's financial circumstances that may occur within this extended period. These pregnant women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(b) The provisions of paragraph (a) of this section apply to Medicaid furnished on or after April 7, 1986.

[55 FR 48610, Nov. 21, 1990]

§ 436.124 Newborn children.

(a) The agency must provide Medicaid eligibility to a child born to a woman who has applied for, has been determined eligible and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible for one year so long as the woman remains (or would remain if pregnant) eligible and the child is a member of the woman's household. This provision applies in instances where the labor and delivery services were furnished prior to the date of application and covered by Medicaid based on retroactive eligibility.

(b) The agency must provide Medicaid eligibility in the same manner described in paragraph (a) of this section to a child born to an otherwise-eligible qualified alien woman subject to the 5-year bar so long as the woman has filed a complete Medicaid application, including but not limited to meeting residency, income and resource requirements, has been determined eligible, is receiving Medicaid on the date of the child's birth, and remains (or would remain if pregnant) Medicaid eligible. All standard Medicaid application procedures apply, including timely determination of eligibility and adequate notice of the agency's decision concerning eligibility. A 5-year bar qualified alien receiving emergency medical services only under § 435.139 of this chapter is considered to be Medicaid-eligible and receiving Medicaid for purposes of this provision. With respect to whether the mother remains (or would remain if pregnant) eligible for Medicaid after the birth of the child, the State must determine whether a 5-year bar qualified alien would remain eligible for emergency services under § 435.139 of this chapter. In determining whether the woman would remain eligible for these services, the State must consider whether the woman would remain eligible if pregnant. This provision applies in instances where the labor and delivery services were furnished prior to the date of application and covered by Medicaid based on retroactive eligibility.

(c) The agency must provide Medicaid eligibility in the same manner described in paragraph (a) of this section to a child born to an otherwise-eligible non-qualified alien woman so long as the woman has filed a complete Medicaid application (other than providing a social security number or demonstrating immigration status), including but not limited to meeting residency, income and resource requirements, has been determined eligible, is receiving Medicaid on the date of the child's birth, and remains (or would remain if pregnant) Medicaid eligible. All standard Medicaid application procedures apply, including timely determination of eligibility and adequate notice of the agency's decision concerning eligibility. A non-qualified alien receiving emergency medical services only under § 435.139 of this chapter is considered to be Medicaid-eligible and receiving Medicaid for purposes of this provision. With respect to whether the mother remains (or would remain if pregnant) eligible for Medicaid after the birth of the child, the State must determine whether a non-qualified alien would remain eligible for emergency services under § 435.139 of this chapter. In determining whether the woman would remain eligible for these services, the State must consider whether the woman would remain eligible if pregnant. This provision applies in instances where the labor and delivery services were furnished prior to the date of application and covered by Medicaid based on retroactive eligibility.

(d) A redetermination of eligibility must be completed on behalf of the children described in this provision in accordance with the procedures at § 435.916. At that time, the State must collect documentary evidence of citizenship and identity as required under § 436.406.

[52 FR 43073, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987, as amended at 72 FR 38694, July 13, 2007]

§436.128 Coverage for certain qualified aliens.

The agency must provide the services necessary for the treatment of an emergency medical condition as defined in §440.255(c) of this chapter to those aliens described in §436.406(c) of this subpart.

[55 FR 36820, Sept. 7, 1990]

Subpart C—Options for Coverage as Categorically Needy

§436.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§436.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart:

(1) Aged individuals (65 years of age or older);

(2) Blind individuals (as defined in §436.530);

(3) Disabled individuals (as defined in §436.541);

(4) Individuals under age 21 (or, at State option), under age 20, 19, or 18) or reasonable classifications of these individuals;

(5) Specified relatives under section 406(b)(1) of the Act who have in their care an individual who is determined to be dependent) as specified in §436.510;

(6) Pregnant women; and

(7) Essential spouses specified under §436.230.

(b) If the agency provides Medicaid to any individual in an optional group specified in paragraph (a) of this section, the agency must provide Medicaid to all individuals who apply and are found eligible to be members of that group.

[58 FR 4934, Jan. 19, 1993]

Options for Coverage of Families and Children and Aged, Blind, and Disabled Individuals, Including Pregnant Women

§436.210 Individuals who meet the income and resource requirements of the cash assistance programs.

The agency may provide Medicaid to any group or groups of individuals specified under §436.201(a)(1), (a)(2), (a)(3), (a)(5), and (a)(6) who are not mandatory categorically needy and who meet the income and resource requirements of the appropriate cash assistance program for their status (that is, OAA, AFDC, AB, APTD, or AABD).

[58 FR 4935, Jan. 19, 1993]

§436.211 Individuals who would be eligible for cash assistance if they were not in medical institutions.

The agency may provide Medicaid to any group or groups of individuals specified in §436.201(a) who are in title XIX reimbursable medical institutions and who:

(a) Are ineligible for the cash assistance program appropriate for their status (that is, OAA, AFDC, AB, APTD, or AABD) because of lower income standards used under the program to determine eligibility for institutionalized individuals; but

(b) Would be eligible for aid or assistance under the State's approved plan under OAA, AFDC, AB, APTD, or AABD if they were not institutionalized.

[58 FR 4935, Jan. 19, 1993]

§436.212 Individuals who would be eligible for cash assistance if the State plan for OAA, AFDC, AB, APTD, or AABD were as broad as allowed under the Act.

(a) The agency may provide Medicaid to any group or groups of individuals specified under §436.201(a) who:

(1) Would be eligible for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs included individuals whose coverage under title I, IV-A, X, XIV, or XVI of the Act is optional (for example, the agency may provide Medicaid to individuals who are 18

years of age and who are attending secondary school full-time and are expected to complete their education before age 19, even though the State's AFDC plan does not include them); or

(2) Would qualify for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs did not contain eligibility requirements more restrictive than, or in addition to, those required under the appropriate title of the Act. (For example, the agency may provide Medicaid to individuals who would meet the Federal definition of disability, 45 CFR 233.80, but who do not meet the State's more restrictive definitions.)

(b) The agency may cover one or more optional groups under any of the titles of the Act without covering all such groups.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 46 FR 47990, Sept. 30, 1981; 58 FR 4935, Jan. 19, 1993]

§ 436.217 Individuals receiving home and community-based services.

The agency may provide Medicaid to any group or groups of individuals in the community who meet the following requirements:

(a) The group would be eligible for Medicaid if institutionalized.

(b) In the absence of home and community-based services under a waiver granted under part 441—

(1) Subpart G of this subchapter, the group would otherwise require the level of care furnished in a hospital, NF, or an ICF/MR; or

(2) Subpart H of this subchapter, the group would otherwise require the level of care furnished in a NF and are age 65 or older.

(c) The group receives the waivered services.

[57 FR 29155, June 30, 1992]

§ 436.220 Individuals who would meet the income and resource requirements under AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 436.201(a)(4), (a)(5), and (a)(6) who would meet the income and resource requirements under the State's AFDC plan if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

[43 FR 45218, Sept. 29, 1978, as amended at 58 FR 4935, Jan. 19, 1993]

§ 436.222 Individuals under age 21 who meet the income and resource requirements of AFDC.

(a) The agency may provide Medicaid to individuals under age 21 (or at State option, under age 20, 19, or 18) or reasonable categories of these individuals as specified in paragraph (b) of this section, who are not receiving cash assistance but who meet the income and resource requirements of the State's approved AFDC plan.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47990, Sept. 30, 1981, as amended at 58 FR 4935, Jan. 19, 1993]

§436.224 Individuals under age 21 who are under State adoption assistance agreements.

(a) The agency may provide Medicaid to individuals under the age of 21 (or, at State option, age 20, 19, or 18)—

(1) For whom an adoption agreement (other than an agreement under title IV-E) between the State and adoptive parent(s) is in effect;

(2) Who, the State agency responsible for adoption assistance has determined, cannot be placed with adoptive parents without Medicaid because the child has special needs for medical or rehabilitative care; and

(3) Who meet either of the following:

(i) Were eligible for Medicaid under the State plan before the adoption agreement was entered into; or

(ii) Would have been eligible for Medicaid before the adoption agreement was entered into, if the eligibility standards and methodologies of the foster care program were used without employing the threshold title IV-A eligibility determination.

(b) For adoption assistance agreements entered into before April 7, 1986—

(1) The agency must deem the requirements of paragraph (a)(1) and (2) of this section to be met if the State adoption assistance agency determines that—

(i) At the time of the adoption placement, the child had special needs for medical or rehabilitative care that made the child difficult to place; and

(ii) There is in effect an adoption assistance agreement between the State and the adoptive parent(s).

(2) The agency must deem the requirements of paragraph (a)(3) of this section to be met if the child was found by the State to be eligible for Medicaid before the adoption assistance agreement was entered into.

[55 FR 48610, Nov. 21, 1990]

§436.229 Optional targeted low-income children.

The agency may provide Medicaid to—

(a) All individuals under age 19 who are optional targeted low-income children as defined in §436.3; or

(b) Reasonable categories of these individuals.

[66 FR 2668, Jan. 11, 2001]

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§436.230 Essential spouses of aged, blind, or disabled individuals receiving cash assistance.

The agency may provide Medicaid to the spouse of an individual receiving OAA, AB, APTD, or AABD, if—

(a) The spouse is living with the individual receiving cash assistance;

(b) The cash assistance agency has determined that the spouse is essential to the well-being of the individual and has considered the spouse's needs in determining the amount of cash assistance provided to the individual.

Subpart D—Optional Coverage of the Medically Needy

§436.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§436.301 General rules.

(a) A Medicaid agency may provide Medicaid to individuals specified in this subpart who:

(1) Either:

(i) Have income that meets the standard in §436.811; or

(ii) If their income is more than allowed under the standard, have incurred medical expenses at least equal to the difference between their income and the applicable income standards; and

(2) Have resources that meet the standard in §§436.840 and 436.843.

(b) If the agency chooses this option, the following provisions apply:

(1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:

(i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B and C of this part;

(ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under subpart B of this part;

(iii) All newborn children born on or after October 1, 1984, to a woman who is eligible as medically needy and receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as medically needy for ne year so long as the woman remains eligible and the child is a member of the woman's household. If the woman's basis of eligibility changes to categorically needy, the child is eligible as categorically needy under § 436.124. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(iv) Women who, while pregnant, applied for, were eligible for, and received Medicaid services as medically needed on the day that their pregnancy ends. The agency must provide medically needy eligibility to these women for an extended period following termination of pregnancy. This period begins on the last day of the pregnancy and extends through the end of the month in which a 60-day period following termination of pregnancy ends. Eligibility must be provided, regardless of changes in the women's financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(2) The agency may provide Medicaid to any or all of the following groups of individuals:

(i) Individuals under age 21 (§ 436.308).

(ii) Specified relatives (§ 436.310).

(iii) Aged (§ 436.320).

(iv) Blind (§ 436.321).

(v) Disabled (§ 436.322).

(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

[46 FR 47990, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981, as amended at 52 FR 43073, Nov. 9, 1987; 55 FR 48610, Nov. 21, 1990; 58 FR 4935, Jan. 19, 1993]

§ 436.308 Medically needy coverage of individuals under age 21.

(a) If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals under age 21 (or at State option, under age 20, 19, or 18) as specified in paragraph (b) of this section:

(1) Who would not be covered under the mandatory medically needy group of individuals under 18 under § 436.301(b)(1)(ii); and

(2) Who meet the income and resource requirements of subpart I of this part.

(b) The agency may cover all individuals in paragraph (a) of this section or individuals in reasonable classifications. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. When the agency covers such individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47990, Sept. 30, 1981, as amended at 58 FR 4935, Jan. 19, 1993]

§ 436.310 Medically needy coverage of specified relatives.

(a) If the agency provides for the medically needy, it may provide Medicaid to specified relatives, defined in paragraph (b) of this section, who meet the income and resource requirements of subpart I of this part.

(b) *Specified relatives* means individuals who:

(1) Are listed under section 406(b)(1) of the Act and in 45 CFR 233.90(c)(1)(v)(A); and

(2) Have in their care an individual who is determined to be (or would, if needy, be) dependent, as specified in § 436.510.

[58 FR 4936, Jan. 19, 1993]

§ 436.320 Medically needy coverage of the aged.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals who—

(a) Are 65 years of age and older, as provided for in § 436.520; and

(b) Meet the income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.321 Medically needy coverage of the blind.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to blind individuals who meet—

(a) The requirements for blindness, as specified in §§ 436.530 and 436.531; and

(b) The income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.322 Medically needy coverage of the disabled.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to disabled individuals who meet—

(a) The requirements for disability, as specified in §§ 436.540 and 436.541; and

(b) The income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.330 Coverage for certain aliens.

If an agency provides Medicaid to the medically needy, it must provide the services necessary for the treatment of an emergency medical condition, as defined in § 440.255(c) of this chapter to those aliens described in § 436.406(c) of this subpart.

[55 FR 36820, Sept. 7, 1990]

Subpart E—General Eligibility Requirements

§ 436.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of the part.

§ 436.401 General rules.

(a) The agency may not impose any eligibility requirement that is prohibited under title XIX.

(b) The agency must base any optional group covered under subparts B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and are consistent with the objectives of title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are more restrictive than those used under the State plans for OAA, AFDC, AB, APTD, or AABD.

§ 436.402 [Reserved]

§ 436.403 State residence.

(a) *Requirement.* The agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. The conditions under which payment for service is provided to out-of-State residents are set forth in § 431.52 of this chapter.

(b) *Definition.* For purposes of this section—*Institution* has the same meaning as *Institution* and *Medical institution,* as defined in § 435.1010 of this chapter. For purposes of State placement, the term also includes ''foster care homes'', licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.

(c) *Incapability of indicating intent.* For purposes of this section, an individual is considered incapable of indicating intent if the individual—

(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State;

(2) Is judged legally incompetent; or

(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the State in the field of mental retardation.

(d) *Who is a State resident.* A resident of a State is any individual who:

(1) Meets the conditions in paragraphs (e) through (h) of this section; or

(2) Meets the criteria specified in an interstate agreement under paragraph (j) of this section.

(e) *Placement by a State in an out-of-state institution*—(1) *General rule.* Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual's State of residence.

(2) Any action beyond providing information to the individual and the individual's family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State's Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual's State of residency for Medicaid purposes is the State where the individual is physically located.

(4) Where placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual's State of residence for Medicaid purposes.

(f) *Individuals receiving title IV-E payments.* For individuals of any age who are receiving Federal payment for foster care and adoption assistance under title IV-E of the Social Security Act, the State of residence is the State where the child lives.

(g) *Individuals under age 21.* (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parents' or legal guardian's current State of residence at the time of placement; or

(ii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and the parental rights are terminated, the State of residence of the guardian is used instead of the parent's.

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(h) *Individuals age 21 and over.* (1) For any individual not residing in an institution as defined in paragraph (b), the

State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parents applying for Medicaid on the individual's behalf, if the parents reside in separate States;

(ii) The parent's or legal guardian's State of residence at the time of placement; or

(iii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the legal parent's.

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(3) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(i) *Specific prohibitions.* (1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident's Medicaid eligibility because of that person's temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(j) *Interstate agreements.* A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (h) of this section, but must not include criteria that result in loss of residency in both States or that are prohibited by paragraph (i) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case.

States may use interstate agreements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(k) *Continued Medicaid for institutionalized recipients.* An agency is providing Medicaid to an institutionalized recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984 unless it makes arrangements with another State of residence to provide Medicaid at an earlier date; and

(2) Those arrangements must not include provisions prohibited by paragraph (g) of this section.

(l) *Cases of disputed residency.* Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

[49 FR 13533, Apr. 5, 1984, as amended at 55 FR 48610, Nov. 21, 1990; 71 FR 39225, July 12, 2006]

§ 436.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than

one category to have his eligibility determined for the category he selects.

§ 436.406 Citizenship and alienage.

(a) The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(1) Citizens: (i) Under a declaration required by section 1137(d) of the Act that the individual is a citizen or national of the United States; and

(ii) The individual has provided satisfactory documentary evidence of citizenship or national status, as described in § 435.407.

(iii) An individual for purposes of the declaration and citizenship documentation requirements discussed in paragraphs (a)(1)(i) and (a)(1)(ii) of this section includes both applicants and recipients under a section 1115 demonstration (including a family planning demonstration project) for which a State receives Federal financial participation in their expenditures, as though the expenditures were for medical assistance.

(iv) Individuals must declare their citizenship and the State must document an individual's eligibility file on initial applications and initial redeterminations effective July 1, 2006.

(v) The following groups of individuals are exempt from the requirements in paragraph (a)(1)(ii) of this section:

(A) Individuals receiving SSI benefits under title XVI of the Act;

(B) Individuals entitled to or enrolled in any part of Medicare;

(C) Individuals receiving disability insurance benefits under section 223 of the Act or monthly benefits under section 202 of the Act, based on the individual's disability (as defined in section 223(d) of the Act); and

(D) Individuals who are in foster care and who are assisted under Title IV–B of the Act, and individuals who are recipients of foster care maintenance or adoption assistance payments under Title IV-E of the Act.

(2)(i) Except as specified in 8 U.S.C. 1612(b)(1) (permitting States an option with respect to coverage of certain qualified aliens), qualified aliens as described in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1641) (including qualified aliens subject to the 5-year bar) who have provided satisfactory documentary evidence of Qualified Alien status, which status has been verified with the Department of Homeland Security (DHS) under a declaration required by section 1137(d) of the Act that the applicant or recipient is an alien in a satisfactory immigration status.

(ii) The eligibility of qualified aliens who are subject to the 5-year bar in 8 U.S.C. 1613 is limited to the benefits described in paragraph (b) of this section.

(b) The agency must provide payment for the services described in § 440.255(c) of this chapter to residents of the State who otherwise meet the eligibility requirements of the State plan (except for receipt of AFDC, SSI, or State Supplementary payments) who are qualified aliens subject to the 5-year bar or who are non-qualified aliens who meet all Medicaid eligibility criteria, except non-qualified aliens need not present a social security number or document immigration status.

[55 FR 36820, Sept. 7, 1990, as amended at 71 FR 39225, July 12, 2006; 72 FR 38694, July 13, 2007]

§ 436.407 Types of acceptable documentary evidence of citizenship.

For purposes of this section, the term ''citizenship'' includes status as a ''national of the United States'' as defined by section 101(a)(22) of the Immigration and Nationality Act (8 U.S.C. § 1101(a)(22)) to include both citizens of the United States and non-citizen nationals of the United States.

(a) *Primary evidence of citizenship and identity*. The following evidence must be accepted as satisfactory documentary evidence of both identity and citizenship:

(1) *A U.S. passport*. The Department of State issues this. A U.S. passport does not have to be currently valid to be accepted as evidence of U.S. citizenship, as long as it was originally issued without limitation. NOTE: Spouses and children were sometimes included on one passport through 1980. U.S. passports issued after 1980 show only one person. Consequently, the citizenship and identity of the included person can be established when one of these passports is presented. Exception: Do not accept any passport as evidence of U.S.

citizenship when it was issued with a limitation. However, such a passport may be used as proof of identity.

(2) *A Certificate of Naturalization (DHS Forms N–550 or N–570.)* Department of Homeland Security issues for naturalization.

(3) *A Certificate of U.S. Citizenship (DHS Forms N–560 or N–561.)* Department of Homeland Security issues certificates of citizenship to individuals who derive citizenship through a parent.

(4) *A valid State-issued driver's license,* but only if the State issuing the license requires proof of U.S. citizenship before issuance of such license or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen. (This provision is not effective until such time as a State makes providing evidence of citizenship a condition of issuing a driver's license and evidence that the license holder is a citizen is included on the license or in a system of records available to the Medicaid agency. States must ensure that the process complies with this statutory provision in section 6036 of the Deficit Reduction Act of 2005. CMS will monitor compliance of States implementing this provision.)

(b) *Secondary evidence of citizenship.* If primary evidence from the list in paragraph (a) of this section is unavailable, an applicant or recipient should provide satisfactory documentary evidence of citizenship from the list specified in this section to establish citizenship and satisfactory documentary evidence from paragraph (e) of this section to establish identity, in accordance with the rules specified in this section.

(1) A U.S. public birth certificate showing birth in one of the 50 States, the District of Columbia, Puerto Rico (if born on or after January 13, 1941), Guam (on or after April 10, 1899), the Virgin Islands of the U.S.(on or after January 17, 1917), American Samoa, Swain's Island, or the Northern Mariana Islands (after November 4, 1986 (NMI local time)). A State, at its option, may use a cross match with a State vital statistics agency to document a birth record. The birth record document may be issued by the State, Commonwealth, Territory, or local jurisdiction. It must have been recorded before the person was 5 years of age. A delayed birth record document that is recorded at or after 5 years of age is considered fourth level evidence of citizenship. (NOTE: If the document shows the individual was born in Puerto Rico, the Virgin Islands of the U.S., or the Northern Mariana Islands before these areas became part of the U.S., the individual may be a collectively naturalized citizen. Collective naturalization occurred on certain dates listed for each of the territories.) The following will establish U.S. citizenship for collectively naturalized individuals:

(i) *Puerto Rico*:

(A) Evidence of birth in Puerto Rico on or after April 11, 1899 and the applicant's statement that he or she was residing in the U.S., a U.S. possession, or Puerto Rico on January 13, 1941; or

(B) Evidence that the applicant was a Puerto Rican citizen and the applicant's statement that he or she was residing in Puerto Rico on March 1, 1917 and that he or she did not take an oath of allegiance to Spain.

(ii) *U.S. Virgin Islands:*

(A) Evidence of birth in the U.S. Virgin Islands, and the applicant's statement of residence in the U.S., a U.S. possession, or the U.S. Virgin Islands on February 25, 1927; or

(B) The applicant's statement indicating residence in the U.S. Virgin Islands as a Danish citizen on January 17, 1917 and residence in the U.S., a U.S. possession, or the U.S. Virgin Islands on February 25, 1927, and that he or she did not make a declaration to maintain Danish citizenship; or

(C) Evidence of birth in the U.S. Virgin Islands and the applicant's statement indicating residence in the U.S., a U.S. possession, or Territory or the Canal Zone on June 28, 1932.

(iii) *Northern Mariana Islands (NMI) (formerly part of the Trust Territory of the Pacific Islands (TTPI)):*

(A) Evidence of birth in the NMI, TTPI citizenship and residence in the NMI, the U.S., or a U.S. Territory or possession on November 3, 1986 (NMI

local time) and the applicant's statement that he or she did not owe allegiance to a foreign State on November 4, 1986 (NMI local time); or

(B) Evidence of TTPI citizenship, continuous residence in the NMI since before November 3, 1981 (NMI local time), voter registration before January 1, 1975 and the applicant's statement that he or she did not owe allegiance to a foreign State on November 4, 1986 (NMI local time); or

(C) Evidence of continuous domicile in the NMI since before January 1, 1974 and the applicant's statement that he or she did not owe allegiance to a foreign State on November 4, 1986 (NMI local time).

(D) NOTE: If a person entered the NMI as a nonimmigrant and lived in the NMI since January 1, 1974, this does not constitute continuous domicile and the individual is not a U.S. citizen.

(2) *A Certification of Report of Birth (DS–1350).* The Department of State issues a DS–1350 to U.S. citizens in the U.S. who were born outside the U.S. and acquired U.S. citizenship at birth, based on the information shown on the FS–240. When the birth was recorded as a Consular Report of Birth (FS–240), certified copies of the Certification of Report of Birth Abroad (DS–1350) can be issued by the Department of State in Washington, DC. The DS–1350 contains the same information as that on the current version of Consular Report of Birth FS–240. The DS–1350 is not issued outside the U.S.

(3) *A Report of Birth Abroad of a U.S. Citizen (Form FS–240).* The Department of State consular office prepares and issues this. A Consular Report of Birth can be prepared only at an American consular office overseas while the child is under the age of 18. Children born outside the U.S. to U.S. military personnel usually have one of these.

(4) *A Certification of birth issued by the Department of State (Form FS–545 or DS–1350).* Before November 1, 1990, Department of State consulates also issued Form FS–545 along with the prior version of the FS–240. In 1990, U.S. consulates ceased to issue Form FS–545. Treat an FS–545 the same as the DS–1350.

(5) *A U.S. Citizen I.D. card.* (This form was issued until the 1980s by INS. Although no longer issued, holders of this document may still use it consistent with the provisions of section 1903(x) of the Act.) INS issued the I–179 from 1960 until 1973. It revised the form and renumbered it as Form I–197. INS issued the I–197 from 1973 until April 7, 1983. INS issued Form I–179 and I–197 to naturalized U.S. citizens living near the Canadian or Mexican border who needed it for frequent border crossings. Although neither form is currently issued, either form that was previously issued is still valid.

(6) *A Northern Mariana Identification Card* (I–873). (Issued by the DHS to a collectively naturalized citizen of the United States who was born in the Northern Mariana Islands before November 4, 1986.) The former Immigration and Naturalization Service (INS) issued the I–873 to a collectively naturalized citizen of the U.S. who was born in the NMI before November 4, 1986. The card is no longer issued, but those previously issued are still valid.

(7) *An American Indian Card (I–872) issued by the Department of Homeland Security with the classification code ''KIC.''* (Issued by DHS to identify U.S. citizen members of the Texas Band of Kickapoos living near the United States/Mexican border.) DHS issues this card to identify a member of the Texas Band of Kickapoos living near the U.S./Mexican border. A classification code ''KIC'' and a statement on the back denote U.S. citizenship

(8) *A final adoption decree showing the child's name and U.S. place of birth.* The adoption decree must show the child's name and U.S. place of birth. In situations where an adoption is not finalized and the State in which the child was born will not release a birth certificate prior to final adoption, a statement from a State approved adoption agency that shows the child's name and U.S. place of birth is acceptable. The adoption agency must state in the certification that the source of the place of birth information is an original birth certificate.

(9) *Evidence of U.S. Civil Service employment before June 1, 1976.* The document must show employment by the U.S. government before June 1, 1976. Individuals employed by the U.S. Civil

Service prior to June 1, 1976 had to be U.S. citizens.

(10) *U.S. Military Record showing a U.S. place of birth.* T he document must show a U.S. place of birth (for example a DD–214 or similar official document showing a U.S. place of birth.)

(11) *A data verification with the Systematic Alien Verification for Entitlements (SAVE) Program for naturalized citizens.* A State may conduct a verification with SAVE to determine if an individual is a naturalized citizen, provided that such verification is conducted consistent with the terms of a Memorandum of Understanding or other agreement with the Department of Homeland Security (DHS) authorizing verification of claims to U.S. citizenship through SAVE, including but not limited to provision of the individual's alien registration number if required by DHS.

(12) *Child Citizenship Act.* Adopted or biological children born outside the United States may establish citizenship obtained automatically under section 320 of the Immigration and Nationality Act (8 U.S.C. 1431), as amended by the Child Citizenship Act of 2000 (Pub. L. 106–395, enacted on October 30, 2000). The State must obtain documentary evidence that verifies that at any time on or after February 27, 2001, the following conditions have been met:

(i) At least one parent of the child is a United States citizen by either birth or naturalization (as verified under the requirements of this Part);

(ii) The child is under the age of 18;

(iii) The child is residing in the United States in the legal and physical custody of the U.S. citizen parent;

(iv) The child was admitted to the United States for lawful permanent residence (as verified under the requirements of 8 U.S.C. 1641 pertaining to verification of qualified alien status); and

(v) If adopted, the child satisfies the requirements of section 101(b)(1) of the Immigration and Nationality Act (8 U.S.C. 1101(b)(1) pertaining to international adoptions (admission for lawful permanent residence as IR–3 (child adopted outside the United States)), or as IR–4 (child coming to the United States to be adopted) with final adoption having subsequently occurred).

(c) *Third level evidence of citizenship.* Third level evidence of U.S. citizenship is documentary evidence of satisfactory reliability that is used when both primary and secondary evidence is unavailable. Third level evidence may be used only when the applicant or recipient alleges birth in the U.S. A second document from paragraph (e) of this section to establish identity must also be presented:

(1) Extract of a hospital record on hospital letterhead established at the time of the person's birth that was created 5 years before the initial application date and that indicates a U.S. place of birth. (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Do not accept a souvenir ''birth certificate'' issued by the hospital.

(2) Life, health, or other insurance record showing a U.S. place of birth that was created at least 5 years before the initial application date that indicates a U.S. place of birth. (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Life or health insurance records may show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(3) Religious record recorded in the U.S. within 3 months of birth showing the birth occurred in the U.S. and showing either the date of the birth or the individual's age at the time the record was made. The record must be an official record recorded with the religious organization. Caution: In questionable cases (for example, where the child's religious record was recorded near a U.S. international border and the child may have been born outside the U.S.), the State must consider verifying the religious record and/or documenting that the mother was in the U.S. at the time of the birth.

(4) Early school record showing a U.S. place of birth. The school record must show the name of the child, the date of admission to the school, the date of birth (or age at the time the record was made), a U.S. place of birth,

and the name(s) and place(s) of birth of the applicant's parents.

(d) *Fourth level evidence of citizenship.* Fourth level evidence of citizenship is documentary evidence of the lowest reliability. Fourth level evidence should only be used in the rarest of circumstances. This level of evidence is used only when primary, secondary and third level evidence is unavailable. With the exception of the affidavit process described in paragraph (d)(5) of this section, the applicant may only use fourth level evidence of citizenship if alleging a U.S. place of birth. In addition, a second document establishing identity must be presented as described in paragraph (e) of this section

(1) *Federal or State census record showing U.S. citizenship or a U.S. place of birth.* (Generally for persons born 1900 through 1950.) The census record must also show the applicant's age. NOTE: Census records from 1900 through 1950 contain certain citizenship information. To secure this information the applicant, recipient or State should complete a Form BC–600, Application for Search of Census Records for Proof of Age. Add in the remarks portion ''U.S. citizenship data requested.'' Also add that the purpose is for Medicaid eligibility. This form requires a fee.

(2) One of the following documents that show a U.S. place of birth and was created at least 5 years before the application for Medicaid. (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) This document must be one of the following and show a U.S. place of birth:

(i) Seneca Indian tribal census.

(ii) Bureau of Indian Affairs tribal census records of the Navajo Indians.

(iii) U.S. State Vital Statistics official notification of birth registration.

(iv) A delayed U.S. public birth record that is recorded more than 5 years after the person's birth.

(v) Statement signed by the physician or midwife who was in attendance at the time of birth.

(vi) The Roll of Alaska Natives maintained by the Bureau of Indian Affairs.

(3) Institutional admission papers from a nursing facility, skilled care facility or other institution created at least 5 years before the initial application date that indicates a U.S. place of birth. Admission papers generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(4) Medical (clinic, doctor, or hospital) record created at least 5 years before the initial application date that indicates a U.S. place of birth. (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Medical records generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth. (NOTE: An immunization record is not considered a medical record for purposes of establishing U.S. citizenship.)

(5) *Written affidavit. Affidavits should ONLY be used in rare circumstances.* If the documentation requirement needs to be met through affidavits, the following rules apply:

(i) There must be at least two affidavits by two individuals who have personal knowledge of the event(s) establishing the applicant's or recipient's claim of citizenship (the two affidavits could be combined in a joint affidavit).

(ii) At least one of the individuals making the affidavit cannot be related to the applicant or recipient. Neither of the two individuals can be the applicant or recipient.

(iii) In order for the affidavit to be acceptable the persons making them must be able to provide proof of their own citizenship and identity.

(iv) If the individual(s) making the affidavit has (have) information which explains why documentary evidence establishing the applicant's claim or citizenship does not exist or cannot be readily obtained, the affidavit should contain this information as well.

(v) The State must obtain a separate affidavit from the applicant/recipient or other knowledgeable individual (guardian or representative) explaining why the evidence does not exist or cannot be obtained.

(vi) The affidavits must be signed under penalty of perjury and need not be notarized.

(e) *Evidence of identity*. The following documents may be accepted as proof of identity and must accompany a document establishing citizenship from the groups of documentary evidence of citizenship in the groups in paragraphs (b) through (d) of this section.

(1) Identity documents described in 8 CFR 274a.2(b)(1)(v)(B)(1).

(i) Driver's license issued by State or Territory either with a photograph of the individual or other identifying information of the individual such as name, age, sex, race, height, weight, or eye color.

(ii) School identification card with a photograph of the individual.

(iii) U.S. military card or draft record.

(iv) Identification card issued by the Federal, State, or local government with the same information included on driver's licenses.

(v) Military dependent's identification card.

(vi) Certificate of Degree of Indian Blood, or other American Indian/Alaska Native Tribal document with a photograph or other personal identifying information relating to the individual. Acceptable if the document carries a photograph of the applicant or recipient, or has other personal identifying information relating to the individual such as age, weight, height, race, sex, and eye color.

(vii) U.S. Coast Guard Merchant Mariner card.

NOTE TO PARAGRAPH (e)(1): Exception: Do not accept a voter's registration card or Canadian driver's license as listed in 8 CFR 274a.2(b)(1)(v)(B)(1). CMS does not view these as reliable for identity.

(2) At State option, a State may use a cross match with a Federal or State governmental, public assistance, law enforcement or corrections agency's data system to establish identity if the agency establishes and certifies true identity of individuals. Such agencies may include food stamps, child support, corrections, including juvenile detention, motor vehicle, or child protective services. The State Medicaid Agency is still responsible for assuring the accuracy of the identity determination.

(3) At State option, a State may accept three or more documents that together reasonably corroborate the identity of an individual provided such documents have not been used to establish the individual's citizenship and the individual submitted second or third tier evidence of citizenship. The State must first ensure that no other evidence of identity is available to the individual prior to accepting such documents. Such documents must at a minimum contain the individual's name, plus any additional information establishing the individual's identity. All documents used must contain consistent identifying information. These documents include employer identification cards, high school and college diplomas from accredited institutions (including general education and high school equivalency diplomas), marriage certificates, divorce decrees, and property deeds/titles.

(f) *Special identity rules for children*. For children under 16, a clinic, doctor, hospital or school record may be accepted for purposes of establishing identity. School records may include nursery or daycare records and report cards. If the State accepts such records, it must verify them with the issuing school. If none of the above documents in the preceding groups are available, an affidavit may be used. An affidavit is only acceptable if it is signed under penalty of perjury by a parent, guardian or caretaker relative (as defined in the regulations at 45 CFR 233.90(c)(v)) stating the date and place of the birth of the child and cannot be used if an affidavit for citizenship was provided. The affidavit is not required to be notarized. A State may accept an identity affidavit on behalf of a child under the age of 18 in instances when school ID cards and drivers' licenses are not available to the individual in that area until that age.

(g) *Special identity rules for disabled individuals in institutional care facilities.* A State may accept an identity affidavit signed under penalty of perjury by a residential care facility director or administrator on behalf of an institutionalized individual in the facility. States should first pursue all other means of verifying identity prior to accepting an affidavit. The affidavit is not required to be notarized.

(h) *Special populations needing assistance.* States must assist individuals to secure satisfactory documentary evidence of citizenship when because of incapacity of mind or body the individual would be unable to comply with the requirement to present satisfactory documentary evidence of citizenship in a timely manner and the individual lacks a representative to assist him or her.

(i) *Documentary evidence.* (1) All documents must be either originals or copies certified by the issuing agency. Uncertified copies, including notarized copies, shall not be accepted.

(2) States must maintain copies of citizenship and identification documents in the case record or electronic data base and make these copies available for compliance audits.

(3) States may permit applicants and recipients to submit such documentary evidence without appearing in person at a Medicaid office. States may accept original documents in person, by mail, or by a guardian or authorized representative.

(4) If documents are determined to be inconsistent with pre-existing information, are counterfeit, or altered, States should investigate for potential fraud and abuse, including but not limited to, referral to the appropriate State and Federal law enforcement agencies.

(5) Presentation of documentary evidence of citizenship is a one time activity; once a person's citizenship is documented and recorded in a State database subsequent changes in eligibility should not require repeating the documentation of citizenship unless later evidence raises a question of the person's citizenship. The State need only check its databases to verify that the individual already established citizenship.

(6) CMS requires that as a check against fraud, using currently available automated capabilities, States will conduct a match of the applicant's name against the corresponding Social Security number that was provided. In addition, in cooperation with other agencies of the Federal government, CMS encourages States to use automated capabilities to verify citizenship and identity of Medicaid applicants. Automated capabilities may fall within the computer matching provisions of the Privacy Act of 1974, and CMS will explore any implementation issues that may arise with respect to those requirements. When these capabilities become available, States will be required to match files for individuals who used third or fourth tier documents to verify citizenship and documents to verify identity, and CMS will make available to States necessary information in this regard. States must ensure that all case records within this category will be so identified and made available to conduct these automated matches. CMS may also require States to match files for individuals who used first or second level documents to verify citizenship as well. CMS may provide further guidance to States with respect to actions required in a case of a negative match.

(j) *Record retention.* The State must retain documents in accordance with 45 CFR 74.53.

(k) *Reasonable opportunity to present satisfactory documentary evidence of citizenship.* States must give an applicant or recipient a reasonable opportunity to submit satisfactory documentary evidence of citizenship before taking action affecting the individual's eligibility for Medicaid. The time States give for submitting documentation of citizenship should be consistent with the time allowed to submit documentation to establish other facets of eligibility for which documentation is requested. (See § 435.930 and § 435.911 of this chapter.)

[71 FR 39226, July 12, 2006, as amended at 72 FR 38695, July 13, 2007]

§ 436.408 [Reserved]

Subpart F—Categorical Requirements for Medicaid Eligibility

§ 436.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part.

DEPENDENCY

§ 436.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures used under the State's AFDC plan to determine whether—

(a) An individual is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

[43 FR 45218, Sept. 29, 1978, as amended at 58 FR 4936, Jan. 19, 1993]

AGE

§ 436.520 Age requirements for the aged.

The agency must not impose an age requirement of more than 65 years.

[58 FR 4936, Jan. 19, 1993]

§ 436.522 Determination of age.

(a) In determining age, the agency must use the common law method (under which an age is reached the day before the anniversary of birth) or the popular usage method (under which a specific age is reached on the anniversary of birth), whichever is used under the corresponding State plan for OAA, AFDC, AB, APTD, or AABD.

(b) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

[58 FR 4936, Jan. 19, 1993]

BLINDNESS

§ 436.530 Definition of blindness.

(a) *Definition.* The agency must use the definition of blindness that is used in the State plan for AB or AABD.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 436.531 Determination of blindness.

In determining blindness—

(a) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(b) The examiner must submit a report of examination to the Medicaid agency; and

(c) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(1) Whether the individual meets the definition of blindness; and

(2) Whether and when reexaminations are necessary for periodic redeterminations of eligibility, as required under § 435.916 of this subchapter. Blindness is considered to continue until the reviewing physician determines that the recipient's vision no longer meets the definition.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

DISABILITY

§ 436.540 Definition of disability.

(a) *Definition.* The agency must use the definition of permanent and total disability that is used in the State plan for APTD or AABD. (See 45 CFR 233.80(a)(1) for the Federal recommended definition of permanent and total disability.)

(b) *State plan requirement.* The State plan must contain the definition of permanent and total disability.

§ 436.541 Determination of disability.

(a) *Basic requirements.* (1) At a minimum, the agency must use the review team, information, and evidence requirements specified in paragraph (b) through (d) of this section in making a determination of disability.

(2) If the requirements or determining disability under the State's APTD or AABD program are more restrictive than the minimum requirements specified in this section, the agency must use the requirements applied under the APTD or AABD program.

(b) The agency must obtain a medical report and a social history for individuals applying for Medicaid on the basis of disability. The medical report must include a diagnosis based on medical

evidence. The social history must contain enough information to enable the agency to determine disability.

(c) A physician and social worker, qualified by professional training and experience, must review the medical report and social history and determine on behalf of the agency whether the individual meets the definition of disability. The physician must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under § 435.916 of this subchapter.

(d) In subsequently determining disability, the physician and social worker must review reexamination reports and the social history and determine whether the individual continues to meet the definition. Disability is considered to continue until this determination is made.

[54 FR 50762, Dec. 11, 1989]

Subpart G—General Financial Eligibility Requirements and Options

§ 436.600 Scope.

This subpart prescribes:

(a) General financial requirements and options for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part. Subparts H and I of this part prescribe additional financial requirements.

(b) [Reserved]

[58 FR 4936, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§ 436.601 Application of financial eligibility methodologies.

(a) *Definitions.* For purposes of this section, *cash assistance financial methodologies* refers to the income and resources methodologies of the OAA, AFDC, AB, APTD, and AABD programs.

(b) *Basic rule for use of cash assistance methodologies.* Except as specified in paragraphs (c) and (d) of this section, in determining financial eligibility of individuals as categorically and medically needy, the agency must apply the cash assistance financial methodologies and requirements of the cash assistance program that is most closely categorically related to the individual's status.

(c) *Financial responsibility of relatives.* The agency must use the requirements for financial responsibility of relatives specified in § 436.602.

(d) *Use of less restrictive methodologies than under cash assistance program.* (1) At State option, and subject to the conditions of paragraphs (d)(2) through (d)(5) of this section, the agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies in determining financial eligibility of the following groups:

(i) Qualified pregnant women and children under the mandatory categorically needy group under § 436.120;

(ii) Low-income pregnant women, infants, and children specified in section 1902(a)(10)(i) (IV), (VI), and (VII) of the Act;

(iii) Qualified Medicare beneficiaries specified in sections 1902(a)(10)(E) and 1905(p) of the Act;

(iv) Optional categorically needy individuals under groups established under subpart C of this part and section 1902(a)(10)(A)(ii) of the Act; and

(v) Medically needy individuals under groups established under subpart D of this part and section 1902(a)(10)(C)(i)(III) of the Act.

(2) The income and resource methodologies that an agency elects to apply to groups of individuals under paragraph (c)(1) of this section may be less restrictive, but no more restrictive, than:

(i) For groups of aged, blind, and disabled individuals, the SSI methodologies; or

(ii) For all other groups, the methodologies under the State plan most closely categorically related to the individual's status.

(3) A financial methodology is considered to be no more restrictive if, by using the methodology, additional individuals may be eligible for Medicaid and no individuals who are otherwise eligible are by use of that methodology made ineligible for Medicaid.

(4) The less restrictive methodology applied under this section must be comparable for all persons within each category of assistance (aged, or blind,

or disabled, or AFDC-related) within each eligibility group. For example, if the agency chooses to apply a less restrictive income or resource methodology to aged individuals, it must apply that methodology to an eligibility group of all aged individuals within the selected group.

(5) The application of the less restrictive income and resource methodologies permitted under this section must be consistent with the limitations and conditions on FFP specified in subpart K of this part.

(e) [Reserved]

(f) *State plan requirements.* (1) The State plan must specify that, except to the extent precluded by § 436.602 in determining financial eligibility of individuals, the agency will apply the cash assistance financial methodologies and requirements, unless the agency chooses to apply less restrictive income and resource methodologies, in accordance with paragraph (d) of this section.

(2) If the agency chooses to apply less restrictive income and resource methodologies, the State plan must specify:

(i) The less restrictive methodologies that will used; and

(ii) The eligibility groups or groups to which the less restrictive methodologies will be applied.

[58 FR 4936, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§ 436.602 Financial responsibility of relatives and other individuals.

(a) Subject to the provisions of paragraphs (b) and (c) of this section, in determining financial responsibility of relatives and other persons for individuals under Medicaid, the agency must use the following financial eligibility requirements and methodologies.

(1) Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not consider income and resources of any relative as available to an individual.

(2) In relation to individuals under 21 (as described in section 1905(a)(i) of the Act), the financial responsibility requirements and methodologies include considering the income and resources of parents or spouses whose income and resources would be considered if the individual under age 21 were dependent under the State's approved AFDC plan, whether or not they are actually contributed. These requirements and methodologies must be applied in accordance with provisions of the State's approved AFDC plan.

(3) When a couple ceases to live together, the agency must count only the income and resources of the individual in determining his or her eligibility, beginning the first month following the month the couple ceases to live together.

(b) The agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies as specified in the State plan in accordance with § 436.601(d).

(c) [Reserved]

[58 FR 4936, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§ 436.604 [Reserved]

§ 436.606 [Reserved]

§ 436.608 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, and retirement and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, and retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

[43 FR 45218, Sept. 29, 1978. Redesignated at 58 FR 4937, Jan. 19, 1993]

§ 436.610 Assignment of rights to benefits.

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to:

(1) Assign rights to the Medicaid agency to medical support and to payment for medical care from any third party;

(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section

1902(l)(1)(A) of the Act (poverty level pregnant women), who are exempt from cooperating in establishing paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(3) Cooperate in identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan, unless the individual establishes good cause for not cooperating.

(b) The requirements for assignment of rights must be applied uniformly for all groups covered under the plan.

(c) The requirements of paragraph (a) of this section for assignment of rights to medical support and other payments and cooperation in obtaining medical support and payments are effective for medical assistance furnished on or after October 1, 1984. The requirement for cooperation in identifying and providing information for pursuing liable third parties is effective for medical assistance furnished on or after July 1, 1986.

[55 FR 48610, Nov. 21, 1990; 55 FR 52130, Dec. 19, 1990, as amended at 58 FR 4908, Jan. 19, 1993. Redesignated at 58 FR 4937, Jan. 19, 1993]

Subpart H [Reserved]

Subpart I—Financial Requirements for the Medically Needy

§ 436.800 Scope.

This subpart prescribes financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

MEDICALLY NEEDY INCOME STANDARD

§ 436.811 Medically needy income standard: General requirements.

(a) To determine eligibility of medically needy individuals, the agency must use a single income standard for all covered medically needy groups that meets the requirements of this section.

(b) The income standard must take into account the number of persons in the assistance unit. The standard may not diminish by the number of persons in the unit (for example, if the income level in the standard for an assistance unit of two is set at $400, the income level in the standard for an assistance unit of three may not be less than $400).

(c) The income standard must be set at an amount that is no lower than the lowest income standard used on or after January 1, 1966, to determine eligibility under the cash assistance programs that are related to the State's covered medically needy group or groups of individuals under § 436.301.

(d) The income standard may vary based on the variations between shelter costs in urban areas and rural areas.

[58 FR 4938, Jan. 19, 1993]

§ 436.814 Medically needy income standard: State plan requirements.

The State plan must specify the income standard for the covered medically needy groups.

[58 FR 4938, Jan. 19, 1993]

MEDICALLY NEEDY INCOME ELIGIBILITY AND LIABILITY FOR PAYMENT OF MEDICAL EXPENSES

§ 436.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in accordance with this section.

(a) *Budget periods.* (1) The agency must use budget periods of not more than 6 months to compute income. The agency may use more than one budget period.

(2) The agency must include in the budget period in which income is computed all or part of the 3-month retroactive period specified in § 435.914. The budget period can begin no earlier then the first month in the retroactive period in which the individual received covered services.

(3) If the agency elects to begin the first budget period for the medically needy in any month of the 3-month period prior to the date of application in which the applicant received covered services, this election applies to all medically needy groups.

(b) *Determining countable income.* The agency must, to determine countable income, deduct amounts that would be deducted in determining eligibility

under the State's approved plan for OAA, AFDC, AB, APTD, or AABD.

(c) *Eligibility based on countable income.* If countable income determined under paragraph (b) of this section is equal to or less than the applicable income standard under §436.814, the individual is eligible for Medicaid.

(d) *Deduction of incurred medical expenses.* If countable income exceeds the income standard, the agency must deduct from income medical expenses incurred by the individual or family or financially responsible relatives that are not subject to payment by a third party. An expense is incurred on the date liability for the expense arises. The agency must determine deductible incurred expenses in accordance with paragraphs (e), (f) and (g) of this section and deduct those expenses in accordance with paragraph (h) of this section.

(e) *Determination of deductible incurred expenses: Required deductions based on kinds of services.* Subject to the provisions of paragraph (g) of this section, in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) Expenses for Medicare and other health insurance premiums, and deductibles or coinsurance charges, including enrollment fees, copayments, or deductibles imposed under §447.51 or §447.53 of this chapter;

(2) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan;

(3) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan, including those that exceed agency limitations on amount, duration or scope of services;

(f) *Determination of deductible incurred expenses: Required deductions based on the age of bills.* Subject to the provisions of paragraph (g) of this section, in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) For the first budget period or periods that include only months before the month of application for medical assistance, expenses incurred during such period or periods, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(2) For the first prospective budget period that also includes any of the 3 months before the month of application for medical assistance, expenses incurred during such budget period, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(3) For the first prospective budget period that includes none of the months preceding the month of application, expenses incurred during such budget period and any of the 3 preceding months, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(4) For any of the 3 months preceding the month of application that are not includable under paragraph (f)(2) of this section, expenses incurred in the 3-month period that were a current liability of the individual in any such month for which a spenddown calculation is made and that had not been previously deducted from income in establishing eligibility for medical assistance;

(5) Current payments (that is, payments made in the current budget period) on other expenses incurred before the current budget period and not previously deducted from income in any budget period in establishing eligibility for such period; and

(6) If the individual's eligibility for medical assistance was established in each such preceding period, expenses incurred before the current budget period but not previously deducted from income, to the extent that such expenses are unpaid and are:

(i) Described in paragraphs (e)(1) through (e)(3) of this section; and

(ii) Are carried over from the preceding budget period or periods because the individual had a spenddown liability in each such preceding period that was met without deducting all such incurred, unpaid expenses.

(g) *Determination of deductible incurred medical expenses: Optional deductions.* In determining incurred medical expenses

to be deducted from income, the agency—

(1) May include medical institutional expenses (other than expenses in acute care facilities) projected to the end of the budget period at the Medicaid reimbursement rate;

(2) May, to the extent determined by the agency and specified in its approved plan, include expenses incurred earlier than the third month before the month of application; and

(3) May set reasonable limits on the amount to be deducted for expenses specified in paragraphs (e)(1), (e)(2), and (g)(2) of this section.

(h) *Order of deduction.* The agency must deduct incurred medical expenses that are deductible under paragraphs (e), (f), and (g) of this section, in the order prescribed under one of the following three options:

(1) *Type of service.* Under this option, the agency deducts expenses in the following order based on type of service:

(i) Cost-sharing expenses as specified in paragraph (e)(1) of this section.

(ii) Services not included in the State plan as specified in paragraph (e)(2) of this section.

(iii) Services included in the State plan as specified in paragraph (e)(3) of this section but that exceed agency limitations on amount, duration, or scope of services.

(iv) Services included in the State plan as specified in paragraph (e)(3) of this section but that are within agency limitations on amount, duration, or scope of services.

(2) *Chronological order by service date.* Under this option, the agency deducts expenses in chronological order by the date each service is furnished, or in the case of insurance premiums, coinsurance, or deductibles charges the date such amounts are due. Expenses for services furnished on the same day may be deducted in any reasonable order established by the State.

(3) *Chronological order by bill submission date.* Under this option, the agency deducts expenses in chronological order by the date each bill is submitted to the agency by the individual. If more than one bill is submitted at one time, the agency must deduct the bills from income in the order prescribed in either paragraph (h)(1) or (h)(2) of this section.

(i) *Eligibility based on incurred medical expenses.* (1) Whether a State elects partial or full month coverage, an individual who is expected to contribute a portion of his or her income toward the costs of institutional care or home and community-based services under § 436.832 is eligible on the first day of the applicable budget (spenddown) period—

(i) If his or her spenddown liability is met after the first day of the budget period; and

(ii) If beginning eligibility after the first day of the budget period makes the individual's share of health care expenses under § 436.832 greater than the individual's contributable income determined under this section.

(2) At the end of the prospective period specified in paragraph (f)(2) or (f)(3) of this section and any subsequent prospective period or, if earlier, when any significant change occurs, the agency must reconcile the projected amounts with the actual amounts incurred, or with changes in circumstances, to determine if the adjusted deduction of incurred expenses reduces income to the income standard.

(3) Except as provided in paragraph (i)(1) of this section, if agencies elect partial month coverage, an individual is eligible for Medicaid on the day that the deduction of incurred health care expenses (and of projected institutional expenses if the agency elects the option under paragraph (g)(1) of this section) reduces income to the income standard.

(4) Except as provided in paragraph (i)(1) of this section, if agencies elect full month coverage, an individual is eligible on the first day of the month in which spenddown liability is met.

(5) Expenses used to meet spenddown liability are not reimbursable under Medicaid. Therefore, to the extent necessary to prevent the transfer of an individual's spenddown liability to the Medicaid program, States must reduce the amount of provider charges that would otherwise be reimbursable under Medicaid.

[59 FR 1674, Jan. 12, 1994]

§436.832 Post-eligibility treatment of income of institutionalized individuals: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability.* This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, or disabled.

(2) *Maintenance needs of spouse.* For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The amount of the highest need standard for an individual without income and resources under the State's approved plan for OAA, AFDC, AB, APTD, or AABD; or

(ii) The amount of the highest medically needy income standard for one person established under §436.811.

(3) *Maintenance needs of family.* For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the highest of the following need standards for a family of the same size:

(A) The standard used to determine eligibility under the State's Medicaid plan, as provided for in §436.811.

(B) The standard used to determine eligibility under the State's approved AFDC plan.

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received or it may project total

monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24888, Apr. 11, 1980, as amended at 46 FR 47991, Sept. 30, 1981; 48 FR 5735, Feb. 8, 1983; 53 FR 3597, Feb. 8, 1988; 56 FR 8851, 8854, Mar. 1, 1991; 58 FR 4938, Jan. 19, 1993]

MEDICALLY NEEDY RESOURCE STANDARD

§ 436.840 Medically needy resource standard: General requirements.

(a) To determine eligibility of medically needy individuals, the Medicaid agency must use a single resource standard that is set at an amount that is no lower than the lowest resource standard used on or after January 1, 1966, to determine eligibility under the cash assistance programs that are related to the State's covered medically needy group or groups of individuals under § 436.301.

(b) The resource standard established under paragraph (a) of this section may not diminish by an increase in the number of persons in the assistance unit. For example, the resource level in the standard for an assistance unit of three may not be less than that set for an assistance unit of two.

[58 FR 4938, Jan. 19, 1993]

§ 436.843 Medically needy resource standard: State plan requirements.

The State plan must specify the resource standard for the covered medically needy groups.

[58 FR 4938, Jan. 19, 1993]

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 436.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must—

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives under § 436.602;

(b) Consider only resources available during the period for which income is computed under § 436.831(a);

(c) Deduct the value of resources that would be deducted in determining eligibility under the State's plan for OAA, AFDC, AB, APTD, or AABD or under the State's less restrictive financial methodology specified in the State Medicaid plan in accordance with § 436.601. In determining the amount of an individual's resources for Medicaid eligibility, States must count amounts of resources that otherwise would not be counted under the conditional eligibility provisions of the AFDC program.

(d) Apply the resource standards established under § 436.840.

[43 FR 45218, Sept. 29, 1978, as amended at 46 FR 47992, Sept. 30, 1981; 58 FR 4938, Jan. 19, 1993]

Subpart J—Eligibility in Guam, Puerto Rico, and the Virgin Islands

SOURCE: 44 FR 17939, Mar. 23, 1979, unless otherwise noted.

§ 436.900 Scope.

This subpart sets forth requirements for processing applications, determining eligibility, and furnishing Medicaid.

§436.901 General requirements.

The Medicaid agency must comply with all the requirements of part 435, subpart J, of this subchapter, except those specified in §435.909.

§436.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

The agency may not require a separate application for Medicaid from an individual if the individual receives cash assistance under a State plan for OAA, AFDC, AB, APTD, or AABD.

Subpart K—Federal Financial Participation (FFP)

§436.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP FOR EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§436.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in—

(1) Determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals; and

(2) Determining presumptive eligibility for children and providing services to presumptively eligible children.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

[43 FR 45218, Sept. 29, 1978, as amended at 66 FR 2668, Jan. 11, 2001]

§436.1002 FFP for services.

(a) FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for Medicaid in the month in which the medical care or services were provided, except that, for recipients who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability.

(c) FFP is available in expenditures for services covered under the plan that are furnished—

(1) To children who are determined by a qualified entity to be presumptively eligible;

(2) During a period of presumptive eligibility;

(3) By a provider that is eligible for payment under the plan; and

(4) Regardless of whether the children are determined eligible for Medicaid following the period of presumptive eligibility.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17940, Mar. 23, 1979; 66 FR 2669, Jan. 11, 2001]

§436.1003 Recipients overcoming certain conditions of eligibility.

FFP is available for a temporary period specified in the State plan in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

[45 FR 24888, Apr. 11, 1980]

§436.1004 FFP in expenditures for medical assistance for individuals who have declared United States citizenship or nationality under section 1137(d) of the Act and with respect to whom the State has not documented citizenship and identity.

Except for individuals described in §436.406(a)(1)(v), FFP will not be available to a State with respect to expenditures for medical assistance furnished to individuals unless the State has obtained satisfactory documentary evidence of citizenship or national status, as described in §436.407 of this chapter that complies with the requirements of section 1903(x) of the Act.

[72 FR 38697, July 13, 2007]

§ 436.1005 Institutionalized individuals.

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

(1) Individuals who are inmates of public institutions as defined in § 435.1010 of this chapter; or

(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient pyschiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

[43 FR 45204, Sept. 29, 1978, as amended at 50 FR 13200, Apr. 3, 1985; 50 FR 38811, Sept. 25, 1985. Redesignated and amended at 71 FR 39229, July 12, 2006]

§ 436.1006 Definitions relating to institutional status.

For purposes of FFP, the definitions in § 435.1010 of this chapter apply to this part.

[44 FR 17939, Mar. 23, 1979. Redesignated and amended at 71 FR 39229, July 12, 2006]

Subpart L—Option for Coverage of Special Groups

SOURCE: 66 FR 2669, Jan. 11, 2001, unless otherwise noted.

§ 436.1100 Basis and scope.

(a) *Statutory basis.* Section 1920A of the Act allows States to provide Medicaid services to children under age 19 during a period of presumptive eligibility, prior to a formal determination of Medicaid eligibility.

(b) *Scope.* This subpart prescribes the requirements for providing medical assistance to special groups who are not eligible for Medicaid as categorically or medically needy.

PRESUMPTIVE ELIGIBILITY FOR CHILDREN

§ 436.1101 Definitions related to presumptive eligibility period for children.

Application form means at a minimum the form used to apply for Medicaid under the poverty-level-related eligibility groups described in section 1902(l) of the Act or a joint form for children to apply for the State Children's Health Insurance Program and Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a Medicaid application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf a Medicaid application has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish the regular Medicaid eligibility of a child of the age involved.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive

assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is authorized to determine eligibility of a child for medical assistance under the Medicaid State plan, or eligibility of a child for child health assistance under the State Children's Health Insurance Program;

(6) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(7) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(8) Is a State or Tribal child support enforcement agency;

(9) Is an organization that—

(i) Provides emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(ii) Is a State or Tribal office or entity involved in enrollment in the program under this title, Part A of title IV, or title XXI; or

(iii) Determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); and

(10) Any other entity the State so deems, as approved by the Secretary.

Services means all services covered under the plan including EPSDT (see part 440 of this chapter.)

[66 FR 2669, Jan. 11, 2001, as amended at 66 FR 33822, June 25, 2001]

§436.1102 General rules.

(a) The agency may provide services to children under age 19 during one or more periods of presumptive eligibility following a determination made by a qualified entity that the child's estimated gross family income or, at the State's option, the child's estimated family income after applying simple disregards, does not exceed the applicable income standard.

(b) If the agency elects to provide services to children during a period of presumptive eligibility, the agency must—

(1) Provide qualified entities with application forms for Medicaid and information on how to assist parents, caretakers and other persons in completing and filing such forms;

(2) Establish procedures to ensure that qualified entities—

(i) Notify the parent or caretaker of the child at the time a determination regarding presumptive eligibility is made, in writing and orally if appropriate, of such determination;

(ii) Provide the parent or caretaker of the child with a Medicaid application form;

(iii) Within 5 working days after the date that the determination is made, notify the agency that a child is presumptively eligible;

(iv) For children determined to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate, that—

(A) If a Medicaid application on behalf of the child is not filed by the last day of the following month, the child's presumptive eligibility will end on that last day; and

(B) If a Medicaid application on behalf of the child is filed by the last day of the following month, the child's presumptive eligibility will end on the day that a decision is made on the Medicaid application; and

(v) For children determined not to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate—

(A) Of the reason for the determination; and

(B) That he or she may file an application for Medicaid on the child's behalf with the Medicaid agency; and

(3) Provide all services covered under the plan, including EPSDT.

(4) Allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

(c) The agency must adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child in a given time frame.

PART 438—MANAGED CARE

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

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Subpart A—General Provisions

§438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State plan. The application of the requirements of this part to PIHPs and PAHPs that do not meet the statutory definition of an MCO or a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

(iv) Requires States to develop a quality assessment and performance improvement strategy;

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PIHPs, PAHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§438.2 Definitions.

As used in this part—

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) FQHC services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

Health care professional means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech-language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

Health insuring organization (*HIO*) means a county operated entity, that in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers;

(2) Under a comprehensive risk contract with the State; and

(3) Meets the following criteria—

(i) First became operational prior to January 1, 1986; or

(ii) Is described in section 9517(e)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990).

Managed care organization (*MCO*) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which a PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§438.6 Contract requirements.

(a) *Regional office review.* The CMS Regional Office must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in §438.806.

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts*—(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to compensate for distortions in costs, utilization, or the number of eligibles.

(iii) *Cost neutral* means that the mechanism used to smooth data, share risk, or adjust for risk will recognize both higher and lower expected costs and is not intended to create a net aggregate gain or loss across all payments.

(iv) *Incentive arrangement* means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

(v) *Risk corridor* means a risk sharing mechanism in which States and contractors share in both profits and losses under the contract outside of predetermined threshold amount, so that after an initial corridor in which the contractor is responsible for all losses or retains all profits, the State contributes a portion toward any additional losses, and receives a portion of any additional profits.

(2) *Basic requirements.* (i) All payments under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as medical trend inflation, incomplete data, MCO, PIHP, or PAHP administration (subject to the limits in paragraph (c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by—

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are—

(A) Based only upon services covered under the State plan (or costs directly related to providing these services, for example, MCO, PIHP, or PAHP administration).

(B) Provided under the contract to Medicaid-eligible individuals.

(iii) The State's projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies must be computed on an actuarially sound basis.

(ii) If risk corridor arrangements result in payments that exceed the approved capitation rates, these excess payments will not be considered actuarially sound to the extent that they result in total payments that exceed the amount Medicaid would have paid, on a fee-for-service basis, for the State plan services actually furnished to enrolled individuals, plus an amount for MCO, PIHP, or PAHP administrative costs directly related to the provision of these services.

(iii) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound.

(iv) For all incentive arrangements, the contract must provide that the arrangement is—

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Made available to both public and private contractors;

(D) Not conditioned on intergovernmental transfer agreements; and

(E) Necessary for the specified activities and targets.

(v) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, and PCCMs must provide as follows:

(1) The MCO, PIHP, PAHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO, PIHP, or PAHP contract may cover, for enrollees, services that are in addition to those covered under the State plan, although the cost of these

services cannot be included when determining the payment rates under §438.6(c).

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *Physician incentive plans.* (1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§422.208 and 422.210 of this chapter, references to ''M+C organization'', ''CMS'', and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP'', ''State agency'' and ''Medicaid recipients'', respectively.

(i) *Advance directives.* (1) All MCO and PIHP contracts must provide for compliance with the requirements of §422.128 of this chapter for maintaining written policies and procedures for advance directives.

(2) All PAHP contracts must provide for compliance with the requirements of §422.128 of this chapter for maintaining written policies and procedures for advance directives if the PAHP includes, in its network, any of those providers listed in §489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the recipient's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with §438.56(c).

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

§438.8 Provisions that apply to PIHPs and PAHPs.

(a) The following requirements and options apply to PIHPs, PIHP contracts, and States with respect to PIHPs, to the same extent that they apply to MCOs, MCO contracts, and States for MCOs.

(1) The contract requirements of §438.6, except for requirements that pertain to HIOs.

(2) The information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The enrollee rights and protection provisions in subpart C of this part.

(6) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PIHP.

(7) The grievance system provisions in subpart F of this part.

(8) The certification and program integrity protection provisions set forth in subpart H of this part.

(b) The following requirements and options for PAHPs apply to PAHPs, PAHP contracts, and States.

(1) The contract requirements of § 438.6, except requirements for—

(i) HIOs.

(ii) Advance directives (unless the PAHP includes any of the providers listed in § 489.102) of this chapter.

(2) All applicable portions of the information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The provisions on enrollee rights and protections in subpart C of this part.

(6) Designated portions of subpart D of this part.

(7) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(8) Prohibitions against affiliations with individuals debarred by Federal agencies in § 438.610.

[67 FR 41095, June 14, 2002, as amended at 67 FR 65505, Oct. 25, 2002]

§ 438.10 Information requirements.

(a) *Terminology*. As used in this section, the following terms have the indicated meanings:

Enrollee means a Medicaid recipient who is currently enrolled in an MCO, PIHP, PAHP, or PCCM in a given managed care program.

Potential enrollee means a Medicaid recipient who is subject to mandatory enrollment or may voluntarily elect to enroll in a given managed care program, but is not yet an enrollee of a specific MCO, PIHP, PAHP, or PCCM.

(b) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, and PCCM must provide all enrollment notices, informational materials, and instructional materials relating to enrollees and potential enrollees in a manner and format that may be easily understood.

(2) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(3) Each MCO and PIHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(c) *Language.* The State must do the following:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. ''Prevalent'' means a non-English language spoken by a significant number or percentage of potential enrollees and enrollees in the State.

(2) Make available written information in each prevalent non-English language.

(3) Require each MCO, PIHP, PAHP, and PCCM to make its written information available in the prevalent non-English languages in its particular service area.

(4) Make oral interpretation services available and require each MCO, PIHP, PAHP, and PCCM to make those services available free of charge to each potential enrollee and enrollee. This applies to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify enrollees and potential enrollees, and require each MCO, PIHP, PAHP, and PCCM to notify its enrollees—

(i) That oral interpretation is available for any language and written information is available in prevalent languages; and

(ii) How to access those services.

(d) *Format.* (1) Written material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) All enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats.

(e) *Information for potential enrollees.* (1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary program, or is first required to enroll in a mandatory enrollment program.

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, or PCCMs.

(2) The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program; and

(C) MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO, PIHP, PAHP, or PCCM program operating in potential enrollee's service area. A summary of the following information is sufficient, but the State must provide more detailed information upon request:

(A) Benefits covered.

(B) Cost sharing, if any.

(C) Service area.

(D) Names, locations, telephone numbers of, and non-English language spoken by current contracted providers, and including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs, this includes at a minimum information on primary care physicians, specialists, and hospitals.

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service.

(f) *General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs.* Information must be furnished to MCO, PIHP, PAHP, and PCCM enrollees as follows:

(1) The State must notify all enrollees of their disenrollment rights, at a minimum, annually. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 days before the start of each enrollment period.

(2) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must notify all enrollees of their right to request and obtain the information listed in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least once a year.

(3) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must furnish to each of its enrollees the information specified in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, within a reasonable time after the MCO, PIHP, PAHP, or PCCM receives, from the State or its contracted representative, notice of the recipient's enrollment.

(4) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified in paragraphs (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least 30 days before the intended effective date of the change.

(5) The MCO, PIHP, and, when appropriate, the PAHP or PCCM, must make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a

regular basis by, the terminated provider.

(6) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must provide the following information to all enrollees:

(i) Names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists, and hospitals.

(ii) Any restrictions on the enrollee's freedom of choice among network providers.

(iii) Enrollee rights and protections, as specified in § 438.100.

(iv) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in § 438.10(g)(1), and for PAHP enrollees, the information specified in § 438.10(h)(1).

(v) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

(vi) Procedures for obtaining benefits, including authorization requirements.

(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.

(viii) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes emergency medical condition, emergency services, and poststabilization services, with reference to the definitions in § 438.114(a).

(B) The fact that prior authorization is not required for emergency services.

(C) The process and procedures for obtaining emergency services, including use of the 911-telephone system or its local equivalent.

(D) The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and poststabilization services covered under the contract.

(E) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(ix) The poststabilization care services rules set forth at § 422.113(c) of this chapter.

(x) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(xi) Cost sharing, if any.

(xii) How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM need not furnish information on how and where to obtain the service. The State must provide information on how and where to obtain the service.

(g) *Specific information requirements for enrollees of MCOs and PIHPs.* In addition to the requirements in § 438.10(f), the State, its contracted representative, or the MCO and PIHP must provide the following information to their enrollees:

(1) Grievance, appeal, and fair hearing procedures and timeframes, as provided in §§ 438.400 through 438.424, in a State-developed or State-approved description, that must include the following:

(i) For State fair hearing—

(A) The right to hearing;

(B) The method for obtaining a hearing; and

(C) The rules that govern representation at the hearing.

(ii) The right to file grievances and appeals.

(iii) The requirements and timeframes for filing a grievance or appeal.

(iv) The availability of assistance in the filing process.

(v) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

(vi) The fact that, when requested by the enrollee—

(A) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and

(B) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(vii) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

(2) Advance directives, as set forth in § 438.6(i)(2).

(3) Additional information that is available upon request, including the following:

(i) Information on the structure and operation of the MCO or PIHP.

(ii) Physician incentive plans as set forth in § 438.6(h) of this chapter.

(h) *Specific information for PAHPs.* The State, its contracted representative, or the PAHP must provide the following information to their enrollees:

(1) The right to a State fair hearing, including the following:

(i) The right to a hearing.

(ii) The method for obtaining a hearing.

(iii) The rules that govern representation.

(2) Advance directives, as set forth in § 438.6(i)(2), to the extent that the PAHP includes any of the providers listed in § 489.102(a) of this chapter.

(3) Upon request, physician incentive plans as set forth in § 438.6(h).

(i) *Special rules: States with mandatory enrollment under State plan authority*—(1) *Basic rule.* If the State plan provides for mandatory enrollment under § 438.50, the State or its contracted representative must provide information on MCOs and PCCMs (as specified in paragraph (i)(3) of this section), either directly or through the MCO or PCCM.

(2) *When and how the information must be furnished.* The information must be furnished as follows:

(i) For potential enrollees, within the timeframe specified in § 438.10(e)(1).

(ii) For enrollees, annually and upon request.

(iii) In a comparative, chart-like format.

(3) *Required information.* Some of the information is the same as the information required for potential enrollees under paragraph (e) of this section and for enrollees under paragraph (f) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (i)(2) of this section, and includes the following for each contracting MCO or PCCM in the potential enrollees and enrollee's service area:

(i) The MCO's or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO or PCCM.

(iv) To the extent available, quality and performance indicators, including enrollee satisfaction.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate for the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals, an MCO, PIHP, or PAHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO, PIHP, or PAHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO, PIHP, or PAHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO, PIHP, or PAHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid recipients to enroll in

managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

(1) Section 1903(m) of the Act, for MCOs and MCO contracts.

(2) Section 1905(t) of the Act, for PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, for MCOs and PCCMs.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.6(c), for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

(e) *Priority for enrollment.* The State must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An ''existing provider-recipient relationship'' is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

(4) A provider is considered to have ''traditionally served'' Medicaid recipients if it has experience in serving the Medicaid population.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PIHP, PAHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.* (1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, PAHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph (b)(1) of this section, must permit the recipient—

(i) To choose from at least two physicians or case managers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, PAHP, or PCCM network.

(B) The provider is not part of the network, but is the main source of a service to the recipient, provided that—

(*1*) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, PAHP, or PCCM network as other network providers of that type.

(*2*) If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The recipient's primary care provider or other provider determines that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph, ''rural area'' is any area other than an ''urban area'' as defined in § 412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The recipient who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PIHP, PAHP, or HIO under paragraph (b) or (c) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PIHP, a PAHP, or a PCCM.

(b) *Disenrollment requested by the MCO, PIHP, PAHP, or PCCM.* All MCO, PIHP, PAHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PIHP, PAHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PIHP, PAHP, or PCCM may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, or PCCM seriously impairs the entity's ability to furnish

services to either this particular enrollee or other enrollees); and

(3) Specify the methods by which the MCO, PIHP, PAHP, or PCCM assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, and PCCM contracts must provide that a recipient may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the recipient's initial enrollment with the MCO, PIHP, PAHP, or PCCM, or the date the State sends the recipient notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(3).

(d) *Procedures for disenrollment*—(1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PIHP, PAHP, or PCCM, if the State permits MCOs, PIHP, PAHPs, and PCCMs to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee moves out of the MCO's, PIHP's, PAHP's, or PCCM's service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PIHP, PAHP, or PCCM action on request.* (i) An MCO, PIHP, PAHP, or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the recipient, or one referred by the MCO, PIHP, PAHP, or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PIHP, PAHP, or PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PIHP, PAHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PIHP, PAHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in § 438.56(e)(1).

(iii) If, as a result of the grievance process, the MCO, PIHP, PAHP, or PCCM approves the disenrollment, the State agency is not required to make a determination.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PIHP, PAHP, or PCCM files the request.

(2) If the MCO, PIHP, PAHP, or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the default enrollment process specified in §438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO, PIHP, or PAHP for services available under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are provided for in title XIX of the Act, in 42 CFR, or when the State agency has adjusted the capitation rates paid under the contract, in accordance with §438.6(c)(5)(v), to make payments for graduate medical education.

§438.62 Continued services to recipients.

The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, or PCCM for any reason other than ineligibility for Medicaid.

§438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's, PIHP's, or PAHP's operations, including, at a minimum, operations related to the following:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

Subpart C—Enrollee Rights and Protections

§438.100 Enrollee rights.

(a) *General rule.* The State must ensure that—

(1) Each MCO and PIHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.

(b) *Specific rights*—(1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, or PCCM has the following rights: The right to—

(i) Receive information in accordance with §438.10.

(ii) Be treated with respect and with due consideration for his or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(f)(6)(xii).)

(iv) Participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR § 164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, and PCCM complies with any other applicable Federal and State laws (such as: title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and titles II and III of the Americans with Disabilities Act; and other laws regarding privacy and confidentiality).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or nontreatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1) An MCO, PIHP, or PAHP that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO, PIHP, or PAHP to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(f)(4)

requires the State, its contracted representative, or MCO, PIHP, or PAHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in §438.10, paragraphs (e) and (f), the information that MCOs, PIHPs, and PAHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (a)(2) of this section.

(c) *Information requirements: State responsibility*. For each service excluded by an MCO, PIHP, or PAHP under paragraph (a)(2) of this section, the State must provide information on how and where to obtain the service, as specified in §438.10, paragraphs (e)(2)(ii)(E) and (f)(6)(xii).

(d) *Sanction*. An MCO that violates the prohibition of paragraph (a)(1) of this section is subject to intermediate sanctions under subpart I of this part.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§438.104 Marketing activities.

(a) *Terminology*. As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PIHP, PAHP, or PCCM to a Medicaid recipient who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the recipient to enroll in that particular MCO's, PIHP's, PAHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, or PCCM's Medicaid product.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to potential enrollees.

MCO, PIHP, PAHP, or PCCM include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements*. Each contract with an MCO, PIHP, PAHP, or PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of §438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any private insurance; and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PIHP, PAHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PIHP, PAHP, or PCCM is endorsed by CMS, the Federal or State government, or similar entity.

(c) *State agency review*. In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under §431.12 of this chapter or an advisory committee with similar membership.

§438.106 Liability for payment.

Each MCO, PIHP, and PAHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's, PIHP's, or PAHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO, PIHP, or PAHP; or

(2) The State, or the MCO, PIHP, or PAHP does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO, PIHP, or PAHP provided the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

§ 438.114 Emergency and poststabilization services.

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

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(1) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(2) Serious impairment to bodily functions.

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

Emergency services means covered inpatient and outpatient services that are as follows:

(1) Furnished by a provider that is qualified to furnish these services under this title.

(2) Needed to evaluate or stabilize an emergency medical condition.

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

(b) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and poststabilization care services.

(1) The MCO, PIHP, or PAHP.

(2) The PCCM that has a risk contract that covers these services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(c) *Coverage and payment: Emergency services*—(1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, or PCCM; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2), and (3) of the definition of *emergency medical condition* in paragraph (a) of this section.

(B) A representative of the MCO, PIHP, PAHP, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

(ii) Pay for the services if the manager's contract is a risk contract that covers those services.

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

(i) Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, PIHP, PAHP or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to ''M+C organization'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section.

(f) *Applicability to PIHPs and PAHPs.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP or PAHP is responsible, the rules under this section apply.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.116 Solvency standards.

(a) *Requirement for assurances* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO or PIHP, must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PIHP, that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs, PIHPs, and PAHPs. It also establishes standards that States, MCOs, PIHPs, and PAHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PIHP must do the following:

(a) Have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs.

(b) Obtain the input of recipients and other stakeholders in the development of the strategy and make the strategy available for public comment before adopting it in final.

(c) Ensure that MCOs, PIHPs, and PAHPs comply with standards established by the State, consistent with this subpart.

(d) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy periodically, as needed.

(e) Submit to CMS the following:

(1) A copy of the initial strategy, and a copy of the revised strategy whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following:

(a) The MCO and PIHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures that—

(1) Assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, and to individuals with special health care needs.

(2) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PIHP for each Medicaid enrollee at the time of enrollment.

(3) Regularly monitor and evaluate the MCO and PIHP compliance with the standards.

(c) For MCOs and PIHPs, any national performance measures and levels that may be identified and developed by CMS in consultation with States and other relevant stakeholders.

(d) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO and PIHP contract.

(e) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

ACCESS STANDARDS

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, and each PIHP and PAHP consistent with the scope of the PIHP's or PAHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO, PIHP, and PAHP must consider the following:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services, taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP.

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO or PIHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(c) *Furnishing of services.* The State must ensure that each MCO, PIHP, and PAHP contract complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services.

(ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid fee-for-service, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by providers.

(v) Monitor providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply.

(2) *Cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of supporting documentation.* Each MCO, PIHP, and PAHP must submit documentation to the State, in a format specified by the State to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of preventive, primary care, and specialty services that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(c) *Timing of documentation.* Each MCO, PIHP, and PAHP must submit the documentation described in paragraph (b) of this section as specified by the State, but no less frequently than the following:

(1) At the time it enters into a contract with the State.

(2) At any time there has been a significant change (as defined by the State) in the MCO's, PIHP's, or PAHP's operations that would affect adequate capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area or payments; or

(ii) Enrollment of a new population in the MCO, PIHP, or PAHP.

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP, the State must certify to CMS that the MCO, PIHP, or PAHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure through its contracts, that each MCO, PIHP, and PAHP complies with the requirements of this section.

(2) *PIHP and PAHP exception.* For PIHPs and PAHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed

care services, whether a particular PIHP or PAHP is required to—

(i) Meet the primary care requirement of paragraph (b)(1) of this section; and

(ii) Implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For each MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare+Choice plan, the State determines to what extent the MCO must meet the primary care coordination, identification, assessment, and treatment planning provisions of paragraphs (b) and (c) of this section with respect to dually eligible individuals.

(ii) The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

(b) *Primary care and coordination of health care services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver primary care to and coordinate health care service for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:

(1) Ensure that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee with the services the enrollee receives from any other MCO, PIHP, or PAHP.

(3) Share with other MCOs, PIHPs, and PAHPs serving the enrollee with special health care needs the results of its identification and assessment of that enrollee's needs to prevent duplication of those activities.

(4) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

(c) *Additional services for enrollees with special health care needs*—(1) *Identification.* The State must implement mechanisms to identify persons with special health care needs to MCOs, PIHPs and PAHPs, as those persons are defined by the State. These identification mechanisms—

(i) Must be specified in the State's quality improvement strategy in § 438.202; and

(ii) May use State staff, the State's enrollment broker, or the State's MCOs,

PIHPs and PAHPs.

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP by the State as having special health care needs in order to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. The assessment mechanisms must use appropriate health care professionals.

(3) *Treatment plans.* If the State requires MCOs, PIHPs, and PAHPs to produce a treatment plan for enrollees with special health care needs who are determined through assessment to need a course of treatment or regular care monitoring, the treatment plan must be—

(i) Developed by the enrollee's primary care provider with enrollee participation, and in consultation with any specialists caring for the enrollee;

(ii) Approved by the MCO, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP; and

(iii) In accord with any applicable State quality assurance and utilization review standards.

(4) *Direct access to specialists.* For enrollees with special health care needs determined through an assessment by appropriate health care professionals (consistent with § 438.208(c)(2)) to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a

standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.

§438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under fee-for-service Medicaid, as set forth in §440.230.

(3) Provide that the MCO, PIHP, or PAHP—

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished.

(ii) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary;

(iii) May place appropriate limits on a service—

(A) On the basis of criteria applied under the State plan, such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(3)(i) of this section; and

(4) Specify what constitutes ''medically necessary services'' in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.

(B) The ability to achieve age-appropriate growth and development.

(C) The ability to attain, maintain, or regain functional capacity.

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(ii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs and PIHPs, the notice must meet the requirements of §438.404, except that the notice to the provider need not be in writing.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) *Standard authorization decisions.* For standard authorization decisions, provide notice as expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) *Expedited authorization decisions.* (i) For cases in which a provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the MCO, PIHP, or PAHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.

(ii) The MCO, PIHP, or PAHP may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Compensation for utilization management activities.* Each contract must provide that, consistent with § 438.6(h), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

STRUCTURE AND OPERATION STANDARDS

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

(b) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that each MCO, PIHP, and PAHP must follow.

(2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing of providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP.

(c) *Nondiscrimination.* MCO, PIHP, and PAHP provider selection policies and procedures, consistent with § 438.12, must not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* MCOs, PIHPs, and PAHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

[67 FR 41095, June 14, 2002; 67 FR 54532, Aug. 22, 2002]

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality.

The State must ensure, through its contracts, that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO, PIHP, and PAHP uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO, PIHP, and PAHP contract complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.228 Grievance systems.

(a) The State must ensure, through its contracts, that each MCO and PIHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO or PIHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO or PIHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

(a) *General rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP—

(1) Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and

(2) Meets the conditions of paragraph (b) of this section.

(b) *Specific conditions.* (1) Before any delegation, each MCO, PIHP, and PAHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that—

(i) Specifies the activities and report responsibilities delegated to the subcontractor; and

(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

(3) The MCO, PIHP, or PAHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

(4) If any MCO, PIHP, or PAHP identifies deficiencies or areas for improvement, the MCO, PIHP, or PAHP and the subcontractor take corrective action.

MEASUREMENT AND IMPROVEMENT STANDARDS

§ 438.236 Practice guidelines.

(a) *Basic rule:* The State must ensure, through its contracts, that each MCO and, when applicable, each PIHP and PAHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and, when applicable, each PIHP and PAHP adopts practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO, PIHP, and PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO and PIHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) CMS, in consultation with States and other stakeholders, may specify performance measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs.

(b) *Basic elements of MCO and PIHP quality assessment and performance improvement programs.* At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

(1) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction.

(2) Submit performance measurement data as described in paragraph (c) of this section.

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Performance measurement.* Annually each MCO and PIHP must—

(1) Measure and report to the State its performance, using standard measures required by the State including those that incorporate the requirements of § 438.204(c) and § 438.240(a)(2);

(2) Submit to the State, data specified by the State, that enables the State to measure the MCO's or PIHP's performance; or

(3) Perform a combination of the activities described in paragraphs (c)(1) and (c)(2) of this section.

(d) *Performance improvement projects.* (1) MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and nonclinical areas, and that involve the following:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of system interventions to achieve improvement in quality.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each MCO and PIHP must report the status and results of each project to the State as requested, including those that incorporate the requirements of § 438.240(a)(2). Each performance improvement project must be completed in a reasonable time period so as to generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. The review must include—

(i) The MCO's and PIHP's performance on the standard measures on which it is required to report; and

(ii) The results of each MCO's and PIHP's performance improvement projects.

(2) The State may require that an MCO or PIHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts, that each MCO and PIHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system must provide information on areas including, but not limited to, utilization, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PIHP comply with the following:

(1) Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

(2) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data;

(ii) Screening the data for completeness, logic, and consistency; and

(iii) Collecting service information in standardized formats to the extent feasible and appropriate.

(3) Make all collected data available to the State and upon request to CMS, as required in this subpart.

Subpart E—External Quality Review

SOURCE: 68 FR 3635, Jan. 24, 2003, unless otherwise noted.

§ 438.310 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1932(c)(2), 1903(a)(3)(C)(ii), and 1902(a)(4) of the Act.

(b) *Scope.* This subpart sets forth requirements for annual external quality reviews of each contracting managed care organization (MCO) and prepaid inpatient health plan (PIHP), including—

(1) Criteria that States must use in selecting entities to perform the reviews;

(2) Specifications for the activities related to external quality review;

(3) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews; and

(4) Standards for making available the results of the reviews.

(c) *Applicability.* The provisions of this subpart apply to MCOs, PIHPs, and to health insuring organizations (HIOs) that began on or after January 1, 1986 that the statute does not explicitly exempt from requirements in section 1903(m) of the Act.

§ 438.320 Definitions.

As used in this subpart—

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO or PIHP, or their contractors furnish to Medicaid recipients.

External quality review organization means an organization that meets the competence and independence requirements set forth in § 438.354, and performs external quality review, other EQR-related activities as set forth in § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Quality, as it pertains to external quality review, means the degree to which an MCO or PIHP increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.350 State responsibilities.

Each State that contracts with MCOs or PIHPs must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each contracting MCO or PIHP;

(b) The EQRO has sufficient information to use in performing the review;

(c) The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358.

(d) For each EQR-related activity, the information must include the elements described in § 438.364(a)(1)(i) through (a)(1)(iv);

(e) The information provided to the EQRO in accordance with paragraph (c) of this section is obtained through methods consistent with the protocols established under § 438.352; and

(f) The results of the reviews are made available as specified in § 438.364.

§ 438.352 External quality review protocols.

Each protocol must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

§ 438.354 Qualifications of external quality review organizations.

(a) *General rule.* The State must ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid recipients, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors are independent from the State Medicaid agency and from the MCOs or PIHPs that they review. To qualify as ''independent''—

(1) A State agency, department, university, or other State entity may not have Medicaid purchasing or managed care licensing authority; and

(2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.

(3) An EQRO may not—

(i) Review a particular MCO or PIHP if either the EQRO or the MCO or PIHP exerts control over the other (as used in this paragraph, ''control'' has the meaning given the term in 48 CFR 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and

(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid recipients;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO or PIHP services, except for the related activities specified in § 438.358; or

(iv) Have a present, or known future, direct or indirect financial relationship with an MCO or PIHP that it will review as an EQRO.

§ 438.356 State contract options.

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities; and

(2) May contract with additional EQROs to conduct EQR-related activities as set forth in § 438.358.

(b) Each EQRO must meet the competence requirements as specified in § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in § 438.354(c).

(e) For each contract, the State must follow an open, competitive procurement process that is in accordance with State law and regulations and consistent with 45 CFR part 74 as it applies to State procurement of Medicaid services.

§ 438.358 Activities related to external quality review.

(a) *General rule.* The State, its agent that is not an MCO or PIHP, or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(b) *Mandatory activities.* For each MCO and PIHP, the EQR must use information from the following activities:

(1) Validation of performance improvement projects required by the State to comply with requirements set forth in § 438.240(b)(1) and that were underway during the preceding 12 months.

(2) Validation of MCO or PIHP performance measures reported (as required by the State) or MCO or PIHP performance measure calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.240(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO's or PIHP's compliance with standards (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) established by the State to comply with the requirements of § 438.204(g).

(c) *Optional activities.* The EQR may also use information derived during the

preceding 12 months from the following optional activities:

(1) Validation of encounter data reported by an MCO or PIHP.

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO or PIHP and validated by an EQRO.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO or PIHP and validated by an EQRO.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs or PIHPs to assist them in conducting activities related to the mandatory and optional activities that provide information for the EQR.

§438.360 Nonduplication of mandatory activities.

(a) *General rule.* To avoid duplication, the State may use, in place of a Medicaid review by the State, its agent, or EQRO, information about the MCO or PIHP obtained from a Medicare or private accreditation review to provide information otherwise obtained from the mandatory activities specified in §438.358 if the conditions of paragraph (b) or paragraph (c) of this section are met.

(b) *MCOs or PIHPs reviewed by Medicare or private accrediting organizations.* For information about an MCO's or PIHP's compliance with one or more standards required under §438.204(g), (except with respect to standards under §§438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) the following conditions must be met:

(1) The MCO or PIHP is in compliance with standards established by CMS for Medicare+Choice or a national accrediting organization. The CMS or national accreditation standards are comparable to standards established by the State to comply with §438.204(g) and the EQR-related activity under §438.358(b)(3).

(2) Compliance with the standards is determined either by—

(i) CMS or its contractor for Medicare; or

(ii) A private national accrediting organization that CMS has approved as applying standards at least as stringent as Medicare under the procedures in §422.158.

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review applicable to the standards provided for in §438.204(g); and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the standards for which the EQR will use information from Medicare or private accreditation reviews, and explains its rationale for why the standards are duplicative.

(c) *Additional provisions for MCOs or PIHPs serving only dually eligibles.* The State may use information obtained from the Medicare program in place of information produced by the State, its agent, or EQRO with respect to the mandatory activities specified in §438.358 (b)(1) and (b)(2) if the following conditions are met:

(1) The MCO or PIHP serves only individuals who receive both Medicare and Medicaid benefits.

(2) The Medicare review activities are substantially comparable to the State-specified mandatory activities in §438.358(b)(1) and (b)(2).

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare review from the activities specified under §438.358(b)(1) and (b)(2) and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the mandatory activities for which it has exercised this option and explains its rationale for why these activities are duplicative.

§438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO or PIHP from EQR if the following conditions are met:

(1) The MCO or PIHP has a current Medicare contract under part C of title

XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO or PIHP has been subject to EQR under this part, and found to be performing acceptably with respect to the quality, timeliness, and access to health care services it provides to Medicaid recipients.

(b) *Information on exempted MCOs or PIHPs.* When the State exercises this option, the State must obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO or PIHP that it exempts from EQR the most recent Medicare review findings reported on the MCO or PIHP including—

(i) All data, correspondence, information, and findings pertaining to the MCO's or PIHP's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities;

(ii) All measures of the MCO's or PIHP's performance; and

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for Medicare+Choice deeming.* (i) If an exempted MCO or PIHP has been reviewed by a private accrediting organization, the State must require the MCO or PIHP to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(B) To deem compliance with Medicare requirements, as provided in § 422.156 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

§ 438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR produces at least the following information:

(1) A detailed technical report that describes the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO or PIHP. The report must also include the following for each activity conducted in accordance with § 438.358:

(i) Objectives.

(ii) Technical methods of data collection and analysis.

(iii) Description of data obtained.

(iv) Conclusions drawn from the data.

(2) An assessment of each MCO's or PIHP's strengths and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid recipients.

(3) Recommendations for improving the quality of health care services furnished by each MCO or PIHP.

(4) As the State determines, methodologically appropriate, comparative information about all MCOs and PIHPs.

(5) An assessment of the degree to which each MCO or PIHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Availability of information.* The State must provide copies of the information specified in paragraph (a) of this section, upon request, through print or electronic media, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO or PIHP, recipient advocacy groups, and members of the general public. The State must make this information available in alternative formats for persons with sensory impairments, when requested.

(c) *Safeguarding patient identity.* The information released under paragraph

(b) of this section may not disclose the identity of any patient.

§438.370 Federal financial participation.

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and EQR-related activities set forth in §438.358 conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO.

Subpart F—Grievance System

§438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act.

(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Action means—

In the case of an MCO or PIHP—

(1) The denial or limited authorization of a requested service, including the type or level of service;

(2) The reduction, suspension, or termination of a previously authorized service;

(3) The denial, in whole or in part, of payment for a service;

(4) The failure to provide services in a timely manner, as defined by the State;

(5) The failure of an MCO or PIHP to act within the timeframes provided in §438.408(b); or

(6) For a resident of a rural area with only one MCO, the denial of a Medicaid enrollee's request to exercise his or her right, under §438.52(b)(2)(ii), to obtain services outside the network.

Appeal means a request for review of an action, as ''action'' is defined in this section.

Grievance means an expression of dissatisfaction about any matter other than an action, as ''action'' is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

§438.402 General requirements.

(a) *The grievance system.* Each MCO and PIHP must have a system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.

(b) *Filing requirements*—(1) *Authority to file.* (i) An enrollee may file a grievance and an MCO or PIHP level appeal, and may request a State fair hearing.

(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

(2) *Timing.* The State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PIHP's notice of action. Within that timeframe—

(i) The enrollee or the provider may file an appeal; and

(ii) In a State that does not require exhaustion of MCO and PIHP level appeals, the enrollee may request a State fair hearing.

(3) *Procedures.* (i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PIHP.

(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

§ 438.404 Notice of action.

(a) *Language and format requirements.* The notice must be in writing and must meet the language and format requirements of § 438.10(c) and (d) to ensure ease of understanding.

(b) *Content of notice.* The notice must explain the following:

(1) The action the MCO or PIHP or its contractor has taken or intends to take.

(2) The reasons for the action.

(3) The enrollee's or the provider's right to file an MCO or PIHP appeal.

(4) If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.

(5) The procedures for exercising the rights specified in this paragraph.

(6) The circumstances under which expedited resolution is available and how to request it.

(7) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The MCO or PIHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)(1).

(4) If the MCO or PIHP extends the timeframe in accordance with § 438.210(d)(1), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO and each PIHP must meet the following requirements:

(1) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(2) Acknowledge receipt of each grievance and appeal.

(3) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) *Special requirements for appeals.* The process for appeals must:

(1) Provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(2) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as

well as in writing. (The MCO or PIHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(3) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(4) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* The MCO or PIHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Specific timeframes*—(1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PIHP receives the grievance.

(2) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 45 days from the day the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) *Expedited resolution of appeals.* For expedited resolution of an appeal and notice to affected parties, the State must establish a timeframe that is no longer than 3 working days after the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes*—(1) The MCO or PIHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO or PIHP extends the timeframes, it must—for any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay.

(d) *Format of notice*—(1) *Grievances.* The State must establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance.

(2) *Appeals.* (i) For all appeals, the MCO or PIHP must provide written notice of disposition.

(ii) For notice of an expedited resolution, the MCO or PIHP must also make reasonable efforts to provide oral notice.

(e) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The results of the resolution process and the date it was completed.

(2) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State fair hearing, and how to do so;

(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and

(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PIHP's action.

(f) *Requirements for State fair hearings*—(1) *Availability.* The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days from whichever of the following dates applies—

(i) If the State requires exhaustion of the MCO or PIHP level appeal procedures, from the date of the MCO's or PIHP's notice of resolution; or

(ii) If the State does not require exhaustion of the MCO or PIHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PIHP's notice of action.

(2) *Parties.* The parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

§ 438.410 Expedited resolution of appeals.

(a) *General rule.* Each MCO and PIHP must establish and maintain an expedited review process for appeals, when the MCO or PIHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(b) *Punitive action.* The MCO or PIHP must ensure that punitive action is neither taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

(c) *Action following denial of a request for expedited resolution.* If the MCO or PIHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution in accordance with § 438.408(b)(2);

(2) Make reasonable efforts to give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice.

§ 438.414 Information about the grievance system to providers and subcontractors.

The MCO or PIHP must provide the information specified at § 438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping and reporting requirements.

The State must require MCOs and PIHPs to maintain records of grievances and appeals and must review the information as part of the State quality strategy.

§ 438.420 Continuation of benefits while the MCO or PIHP appeal and the State fair hearing are pending.

(a) *Terminology.* As used in this section, ''timely'' filing means filing on or before the later of the following:

(1) Within ten days of the MCO or PIHP mailing the notice of action.

(2) The intended effective date of the MCO's or PIHP's proposed action.

(b) *Continuation of benefits.* The MCO or PIHP must continue the enrollee's benefits if—

(1) The enrollee or the provider files the appeal timely;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

(3) The services were ordered by an authorized provider;

(4) The original period covered by the original authorization has not expired; and

(5) The enrollee requests extension of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal.

(2) Ten days pass after the MCO or PIHP mails the notice, providing the resolution of the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

(3) A State fair hearing Office issues a hearing decision adverse to the enrollee.

(4) The time period or service limits of a previously authorized service has been met.

(d) *Enrollee responsibility for services furnished while the appeal is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PIHP's action, the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the

appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

(b) *Services furnished while the appeal is pending.* If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PIHP or the State must pay for those services, in accordance with State policy and regulations.

Subpart G [Reserved]

Subpart H—Certifications and Program Integrity

§438.600 Statutory basis.

This subpart is based on sections 1902(a)(4), 1902(a)(19), 1903(m), and 1932(d)(1) of the Act.

(a) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

(c) Section 1903(m) establishes conditions for payments to the State with respect to contracts with MCOs.

(d) Section 1932(d)(1) prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals excluded under Federal regulations from participating in specified activities, or with affiliates of those individuals.

§438.602 Basic rule.

As a condition for receiving payment under the Medicaid managed care program, an MCO, PCCM, PIHP, or PAHP must comply with the applicable certification, program integrity and prohibited affiliation requirements of this subpart.

§438.604 Data that must be certified.

(a) *Data certifications.* When State payments to an MCO or PIHP are based on data submitted by the MCO or PIHP, the State must require certification of the data as provided in §438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Additional certifications.* Certification is required, as provided in §438.606, for all documents specified by the State.

§438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data specified in §438.604, the data the MCO or PIHP submits to the State must be certified by one of the following:

(1) The MCO's or PIHP's Chief Executive Officer.

(2) The MCO's or PIHP's Chief Financial Officer.

(3) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PIHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of the data.

(2) To the accuracy, completeness and truthfulness of the documents specified by the State.

(c) *Timing of certification.* The MCO or PIHP must submit the certification concurrently with the certified data.

§438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PIHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate

the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision for internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PIHP's contract.

§ 438.610 Prohibited affiliations with individuals debarred by Federal agencies.

(a) *General requirement.* An MCO, PCCM, PIHP, or PAHP may not knowingly have a relationship of the type described in paragraph (b) of this section with the following:

(1) An individual who is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

(b) *Specific requirements.* The relationships described in this paragraph are as follow:

(1) A director, officer, or partner of the MCO, PCCM, PIHP, or PAHP.

(2) A person with beneficial ownership of five percent or more of the MCO's, PCCM's, PIHP's, or PAHP's equity.

(3) A person with an employment, consulting or other arrangement with the MCO, PCCM, PIHP, or PAHP for the provision of items and services that are significant and material to the MCO's, PCCM's, PIHP's, or PAHP's obligations under its contract with the State.

(c) *Effect of Noncompliance.* If a State finds that an MCO, PCCM, PIHP, or PAHP is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

(d) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (c)(2) or (c)(3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines whether an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid

program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§422.208 and 422.210 of this chapter.

(c) A State determines whether an MCO, PIHP, PAHP or PCCM has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines whether—

(1) An MCO has violated any of the other requirements of sections1903(m) or 1932 of the Act, and any implementing regulations;

(2) A PCCM has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act and any implementing regulations;

(3) For any of the violations under paragraphs (d)(1) and (d)(2) of this section, only the sanctions specified in §438.702, paragraphs (a)(3), (a)(4), and (a)(5) may be imposed.

§438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in §438.704.

(2) Appointment of temporary management for an MCO as provided in §438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until CMS or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in §438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§438.704 Amounts of civil money penalties.

(a) *General rule.* The limit on, or the maximum civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under the following paragraphs of §438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (Failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is $100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to CMS or the State) of §438.700.

(3) The limit is $15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of §438.700. (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the maximum amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary management only if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that—

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act; or

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or section 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3), and must notify the affected enrollees of their right to terminate enrollment.

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM has failed to do either of the following:

(a) Carry out the substantive terms of its contract; or

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Due process: Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Except as provided in § 438.706(c), before imposing any of the intermediate sanctions specified in this subpart, the State must give the affected entity timely written notice that explains the following:

(1) The basis and nature of the sanction.

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing*—(1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures.* The State must do the following:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may do the following:

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract.

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give the CMS Regional Office written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must—

(1) Be given no later than 30 days after the State imposes or lifts a sanction; and

(2) Specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

§438.726 State plan requirement.

(a) The State plan must include a plan to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

(b) A contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by CMS under section 438.730(e).

§438.730 Sanction by CMS: Special rules for MCOs

(a) *Basis for sanction.* (1) A State agency may recommend that CMS impose the denial of payment sanction specified in paragraph (e) of this section on an MCO with a contract under this part if the agency determines that the MCO acts or fails to act as specified in §438.700(b)(1) through (b)(6).

(b) *Effect of an Agency Determination.* (1) The State agency's determination becomes CMS's determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the agency decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless CMS rejects this recommendation within 15 days.

(c) *Notice of sanction.* If the State agency's determination becomes CMS's determination under section (b)(2), the State agency takes the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction;

(2) Allows the MCO 15 days from the date it receives the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

(3) May extend the initial 15-day period for an additional 15 days if—

(i) the MCO submits a written request that includes a credible explanation of why it needs additional time;

(ii) the request is received by CMS before the end of the initial period; and

(iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation;

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision; and

(iii) Forwards the decision to CMS.

(2) The agency decision under paragraph (d)(1)(ii) of this section becomes CMS's decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State agency decision, the agency sends the MCO a copy of CMS's decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (b)(6) of §438.700, is affirmed on review under paragraph (d) of this section.

(ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under §438.726(b), CMS's denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (b) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in CMS's reconsideration notice.

(ii) If CMS, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (c)(1)(ii) of this section.

(g) *CMS's role.* (1) CMS retains the right to independently perform the functions assigned to the State agency under paragraphs (a) through (d) of this section.

(2) At the same time that the agency sends notice to the MCO under paragraph (c)(1)(i) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

(a) Meets the requirements of this part; and

(b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PIHP,

PAHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person;

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both, and;

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered ''independent'' if it—

(i) Is an MCO, PIHP, PAHP, PCCM or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(3) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

PART 440—SERVICES: GENERAL PROVISIONS

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

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

Subpart A—Definitions

§ 440.1 Basis and purpose.

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

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

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

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

1913 ''Swing-bed'' services. (See §§ 447.280 and 482.66 of this chapter for related provisions on ''swing-bed'' services.)

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

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

[57 FR 29155, June 30, 1992, as amended at 61 FR 38398, July 24, 1996; 73 FR 77530, Dec. 19, 2008]

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

(a) *Specific definitions.*

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

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

(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later

develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

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

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

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

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

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

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

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

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

(3) Are furnished in an institution that—

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

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

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

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

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

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

§ 440.20 Outpatient hospital services and rural health clinic services.

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

(1) Are furnished to outpatients;

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

(3) Are furnished by an institution that—

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

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

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

(b) *Rural health clinic services.* If nurse practitioners or physician assistants (as defined in § 481.1 of this chapter) are not prohibited by State law from furnishing primary health care, ''rural health clinic services'' means the following services when furnished by a rural health clinic that has been certified in accordance with part 491 of this chapter.

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

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

requirements specified in § 405.2414(a) of this chapter.

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

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

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

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

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

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

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

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

§ 440.30 Other laboratory and X-ray services.

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

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

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

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

[46 FR 42672, Aug. 24, 1981, as amended at 57 FR 7135, Feb. 28, 1992]

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

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

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

(ii) Provided by—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[56 FR 8851, Mar. 1, 1991]

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

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

(b) Chiropractors' services include only services that—

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

(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

§ 440.70 Home health services.

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

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

(2) On his or her physician's orders as part of a written plan of care that the physician reviews every 60 days, except as specified in paragraph (b)(3) of this section.

(b) Home health services include the following services and items. Those listed in paragraphs (b) (1), (2) and (3) of this section are required services; those in paragraph (b)(4) of this section are optional.

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

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

(ii) Receives written orders from the patient's physician;

(iii) Documents the care and services provided; and

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

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

(3) Medical supplies, equipment, and appliances suitable for use in the home.

(i) A recipient's need for medical supplies, equipment, and appliances must be reviewed by a physician annually.

(ii) Frequency of further physician review of a recipient's continuing need for the items is determined on a case-by-case basis, based on the nature of the item prescribed;

(4) Physical therapy, occupational therapy, or speech pathology and audiology services, provided by a home health agency or by a facility licensed by the State to provide medical rehabilitation services. (See § 441.15 of this subchapter.)

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

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

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

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

(i) Medical evaluation and services; and

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

(2) Is operated under competent medical supervision either—

(i) In connection with a hospital; or

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

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980; 62 FR 47902, Sept. 11, 1997; 63 FR 310, Jan. 5, 1998]

§ 440.80 Private duty nursing services.

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

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

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

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

(1) His or her own home;

(2) A hospital; or

(3) A skilled nursing facility.

[52 FR 47934, Dec. 17, 1987]

§ 440.90 Clinic services.

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

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

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

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

§ 440.100 Dental services.

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

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

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

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

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

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

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

(2) A ''qualified physical therapist'' is an individual who is—

(i) A graduate of a program of physical therapy approved by both the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Physical Therapy Association or its equivalent; and

(ii) Where applicable, licensed by the State.

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

(2) A ''qualified occupation therapist'' is an individual who is—

(i) Registered by the American Occupational Therapy Association; or

(ii) A graduate of a program in occupational therapy approved by the Committee on Allied Health Education and Accreditation of the American Medical Association and engaged in the supplemental clinical experience required before registration by the American Occupational Therapy Association.

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

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

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

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

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

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

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

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

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

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

a national examination in audiology approved by the Secretary.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980; 56 FR 8854, Mar. 1, 1991; 60 FR 19861, Apr. 21, 1995; 69 FR 30587, May 28, 2004]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Prolong life; and

(3) Promote physical and mental health and efficiency.

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

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

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

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

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

(b) *Nursing facility services.* ''Nursing facility services for individuals age 65 or older in institutions for mental diseases'' means nursing facility services as defined in § 440.40 and in subpart B of

part 483 of this chapter that are provided in institutions for mental diseases, as defined in §435.1010 of this chapter.

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

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

(a) ''ICF/MR services'' means those items and services furnished in an intermediate care facility for the mentally retarded if the following conditions are met:

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

(2) The primary purpose of the ICF/MR is to furnish health or rehabilitative services to persons with mental retardation or persons with related conditions;

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

(4) The recipient with mental retardation for whom payment is requested is receiving active treatment, as specified in §483.440 of this chapter.

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

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

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

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

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

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

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

[59 FR 56234, Nov. 10, 1994]

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

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

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

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

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

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

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

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

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

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

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

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

(1) Meets all requirements for a nursing facility;

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

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

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

(5) Is clearly identified; and

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

(d) If a State includes as nursing facility services those services provided

by a distinct part of a facility other than a nursing facility, it may not require transfer of a recipient within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the recipient.

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

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

§ 440.160 Inpatient psychiatric services for individuals under age 21.

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

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

(b) Are provided by—

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

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

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

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

§ 440.165 Nurse-midwife service.

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

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

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

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

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

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

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

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

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

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

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a

nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

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

§ 440.166 Nurse practitioner services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[60 FR 19861, Apr. 21, 1995]

§ 440.167 Personal care services.

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

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

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

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

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

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

[42 FR 47902, Sept. 11, 1997]

§ 440.168 Primary care case management services.

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

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

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

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

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

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

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

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

[67 FR 41115, June 14, 2002]

§ 440.169 Case management services.

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

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

(c) [Reserved]

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

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

(i) Taking client history.

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

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

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

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

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

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

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

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

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

(ii) Services in the care plan are adequate.

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

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

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

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

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

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

(3) ''Travel expenses'' include—

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

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

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

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

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

(A) Is selected through a competitive bidding process that is consistent with 45 CFR 92.36(b) through (i) and is based on the State's evaluation of the broker's experience, performance, references, resources, qualifications, and costs.

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

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

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

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

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

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

emergency transportation'' substituted for ''DHS''; or

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

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

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

(*2*) Transportation is so specialized that there is no other available Medicaid participating provider or other provider determined by the State to be qualified except the non-governmental broker.

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) Does not furnish, on the basis of its religious beliefs, through its personnel or otherwise, medical items and

services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

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

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

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

(ii) Requires that the reviews be made by a committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

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

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

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

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

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

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

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

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

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

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

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

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

(i) The conditions for participation under Medicare; or

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

(f) [Reserved]

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

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

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

§440.180 Home or community-based services.

(a) *Description and requirements for services.* ''Home or community-based services'' means services, not otherwise

furnished under the State's Medicaid plan, that are furnished under a waiver granted under the provisions of part 441, subpart G of this chapter.

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

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

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

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

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services.

(7) Respite care services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Respite care services.

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

[57 FR 29156, June 30, 1992]

§ 440.185 Respiratory care for ventilator-dependent individuals.

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

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

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

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

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

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

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

(b) For purposes of paragraphs (a)(4) and (5) of this section, a recipient's home does not include a hospital, NF,

ICF/MR or other institution as defined in § 435.1010 of this chapter.

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

Subpart B—Requirements and Limits Applicable to All Services

§ 440.200 Basis, purpose, and scope.

(a) This subpart implements the following statutory requirements—

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

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

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

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

(5) Section 1907 on observance of religious beliefs;

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

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

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

[55 FR 36822, Sept. 7, 1990]

§ 440.210 Required services for the categorically needy.

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

(1) The services defined in §§ 440.10 through 440.50, 440.70, and (to the extent nurse-midwives and nurse practitioners are authorized to practice under State law or regulation) the services defined in §§ 440.165 and 440.166, respectively.

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

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

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

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

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

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

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

§ 440.220 Required services for the medically needy.

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

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

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

(i) Individuals under age 18; and

(ii) Groups of individuals entitled to institutional services.

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

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

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

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

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

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

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

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

§ 440.225 Optional services.

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

[60 FR 19862, Apr. 21, 1995]

§ 440.230 Sufficiency of amount, duration, and scope.

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

(1) The categorically needy; and

(2) Each covered group of medically needy.

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

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

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

[46 FR 47993, Sept. 30, 1981]

§ 440.240 Comparability of services for groups.

Except as limited in § 440.250—

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

(b) The plan must provide that the services available to any individual in the following groups are equal in amount, duration, and scope for all recipients within the group:

(1) The categorically needy.

(2) A covered medically needy group.

[46 FR 47993, Sept. 30, 1981]

§ 440.250 Limits on comparability of services.

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

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

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

(d) If covered under the plan, services to recipients in institutions for mental

diseases (§ 440.140) must be limited to those age 65 or older.

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

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

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

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

(1) Individuals under age 18; and

(2) Groups of individuals entitled to institutional services.

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

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

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

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

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

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

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

(p) A State may provide a greater amount, duration, or scope of services to pregnant women than it provides under its plan to other individuals who are eligible for Medicaid, under the following conditions:

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

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

(q) [Reserved]

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

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

(2) Targeted groups specified by the State.

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

§ 440.255 Limited services available to certain aliens.

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

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

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

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

(ii) Serious impairment to bodily functions; or

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

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

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

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

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

(ii) Serious impairment to bodily functions; or

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

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

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

§ 440.260 Methods and standards to assure quality of services.

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

§ 440.270 Religious objections.

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

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

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

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

§ 440.300 Basis.

This subpart implements section 1937 of the Act, which authorizes States to provide for medical assistance to one or more groups of Medicaid-eligible individuals, specified by the State under

an approved State plan amendment, through enrollment in coverage that provides benchmark or benchmark-equivalent health care benefit coverage.

§ 440.305 Scope.

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

(b) *Limitations.* A State may only apply the option in paragraph (a) of this section for an individual whose eligibility is based on an eligibility category under section 1905(a) of the Act that could have been covered under the State's plan on or before February 8, 2006.

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

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

§ 440.310 Applicability.

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

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

§ 440.315 Exempt individuals.

Individuals within one (or more) of the following categories are exempt from mandatory enrollment in benchmark or benchmark-equivalent coverage.

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

(b) The individual qualifies for medical assistance under the State plan on the basis of being blind or disabled (or being treated as being blind or disabled) without regard to whether the individual is eligible for Supplemental Security Income benefits under title XVI on the basis of being blind or disabled and including an individual who is eligible for medical assistance on the basis of section 1902(e)(3) of the Act.

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

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

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

(f) The individual is medically frail or otherwise an individual with special medical needs. For these purposes, the State's definition of individuals who are medically frail or otherwise have special medical needs must at least include those individuals described in § 438.50(d)(3) of this chapter, children with serious emotional disturbances, individuals with disabling mental disorders, individuals with serious and complex medical conditions, and individuals with physical and/or mental disabilities that significantly impair

their ability to perform one or more activities of daily living.

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

(h) The individual is an individual with respect to whom child welfare services are made available under part B of title IV to children in foster care and individuals with respect to whom adoption or foster care assistance is made available under part E of title IV, without regard to age.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§440.325 State plan requirements: Coverage and benefits.

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

(a) Benchmark coverage in accordance with § 440.330.

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

§ 440.330 Benchmark health benefits coverage.

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

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

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

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

(d) *Secretary-approved coverage.* Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage to meet the needs of the population provided that coverage. States wishing to elect Secretarial approved coverage should submit a full description of the proposed coverage, (including a benefit-by-benefit comparison of the proposed plan to one or more of the three other benchmark plans specified above or to the State's standard full Medicaid coverage package under section 1905(a) of the Act), and of the population to which the coverage would be offered. In addition, the State should submit any other information that would be relevant to a determination that the proposed health benefits coverage would be appropriate for the proposed population. The scope of a Secretary-approved health benefits package will be limited to benefits within the scope of the categories available under a benchmark coverage package or the standard full Medicaid coverage package under section 1905(a) of the Act.

§ 440.335 Benchmark-equivalent health benefits coverage.

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

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

(1) Inpatient and outpatient hospital services.

(2) Physicians' surgical and medical services.

(3) Laboratory and x-ray services.

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

(5) Emergency services.

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

(c) *Additional coverage.* (1) In addition to the categories of services of this section, benchmark-equivalent coverage may include coverage for any additional services in a category included in the benchmark plan or described in section 1905(a) of the Act.

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

(3) If the benchmark coverage package does not cover one of the four categories of services in paragraph (c)(2) of this section, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service.

§ 440.340 Actuarial report for benchmark-equivalent coverage.

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

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

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

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

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

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

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

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

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

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

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

§ 440.345 EPSDT services requirement.

(a) The State must assure access to early and periodic screening, diagnostic and treatment (EPSDT) services through benchmark or benchmark-equivalent plan benefits or as additional benefits provided by the State for any child under 21 years of age eligible under the State plan in a category under section 1902(a)(10)(A) of the Act.

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

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

(b) [Reserved]

§ 440.350 Employer-sponsored insurance health plans.

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

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

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

§ 440.355 Payment of premiums.

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

§ 440.360 State plan requirement for providing additional services.

In addition to the requirements of § 440.345 the State may elect to provide additional coverage to individuals enrolled in benchmark or benchmark-equivalent plans. The State plan must describe the populations covered and the payment methodology for these services. Additional services must be in categories that are within the scope of the benchmark coverage, or are described in section 1905(a) of the Act.

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

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

§ 440.370 Economy and efficiency.

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

§ 440.375 Comparability.

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

§ 440.380 Statewideness.

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

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

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

§ 440.390 Assurance of transportation.

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

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

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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).

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

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

§ 441.11 Continuation of FFP for institutional services.

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

(1) The Medicaid payments are for 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.]

§ 441.18 Case management services.

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

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

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

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

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

(5) [Reserved]

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

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

(i) The name of the individual.

(ii) The dates of the case management services.

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

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

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

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

(vii) A timeline for obtaining needed services.

(viii) A timeline for reevaluation of the plan.

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

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

(ii) Identifies the geographic area to be served.

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

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

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

(vi) [Reserved]

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

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

(i) The case management services to be furnished;

(ii) The qualifications of case management providers; or

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

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

(c) Case management does not include, and FFP is not available in expenditures for, services defined in § 441.169 of this chapter when the case management activities constitute the direct delivery of underlying medical, educational, social, or other services to which an eligible individual has been referred, including for foster care programs, services such as, but not limited to, the following:

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

(2) Assessing adoption placements.

(3) Recruiting or interviewing potential foster care parents.

(4) Serving legal papers.

(5) Home investigations.

(6) Providing transportation.

(7) Administering foster care subsidies.

(8) Making placement arrangements.

(d) After the State assesses whether the activities are within the scope of

the case management benefit (applying the limitations described above), in determining the allowable costs for case management (or targeted case management) services that are also furnished by another federally-funded program, the State must use cost allocation methodologies, consistent with OMB Circular A–87, CMS policies, or any subsequent guidance and reflected in an approved cost allocation plan.

[72 FR 68092, Dec. 4, 2007, as amended at 74 FR 31196, June 30, 2009]

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

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

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

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

(ii) The date the individual reaches 22; and

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

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

[66 FR 7160, Jan. 22, 2001, as amended at 75 FR 50418, Aug. 16, 2010]

§ 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:

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

Subpart J—Optional Self-Directed Personal Assistance Services Program

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

§ 441.450 Basis, scope, and definitions.

(a) *Basis.* This subpart implements section 1915(j) of the Act concerning the self-directed personal assistance services (PAS) option through a State Plan.

(b) *Scope.* A self-directed PAS option is designed to allow individuals, or their representatives, if applicable, to exercise decision-making authority in identifying, accessing, managing and purchasing their PAS. This authority includes, at a minimum, all of the following:

(1) The purchase of PAS and supports for PAS.

(2) Recruiting workers.

(3) Hiring and discharging workers.

(4) Training workers and accessing training provided by or through the State if additional worker training is required or desired by the participant, or participant's representative, if applicable.

(5) Specifying worker qualifications.

(6) Determining worker duties.

(7) Scheduling workers.

(8) Supervising workers.

(9) Evaluating worker performance.

(10) Determining the amount paid for a service, support or item.

(11) Scheduling when services are provided.

(12) Identifying service workers.

(13) Reviewing and approving invoices.

(c) *Definitions.* As used in this part—

Assessment of need means an evaluation of the needs, strengths, and preferences of participants for services. This includes one or more processes to obtain information about an individual, including health condition, personal goals and preferences, functional limitation, age, school, employment, household, and other factors that are relevant to the authorization and provision of services. Assessment information supports the development of the service plan and the subsequent service budget.

Individualized backup plan means a written plan that meets all of the following:

(1) Is sufficiently individualized to address each participant's critical contingencies or incidents that would pose a risk of harm to the participant's health or welfare;

(2) Must demonstrate an interface with the risk management provision at §441.476 which requires States to assess and identify the potential risks to the participant (such as any critical health needs), and ensure that the risks and how they will be managed are the result of discussion and negotiation among the persons involved in the service plan development;

(3) Must not include the 911 emergency system or other emergency system as the sole backup feature of the plan; and

(4) Must be incorporated into the participant's service plan.

Legally liable relatives means persons who have a duty under the provisions of State law to care for another person. Legally liable relatives may include any of the following:

(1) The parent (biological or adoptive) of a minor child or the guardian of a minor child who must provide care to the child.

(2) Legally-assigned caretaker relatives.

(3) A spouse.

Self-directed personal assistance services (PAS) means personal care and related services, or home and community-based services otherwise available under the State plan or a 1915(c) waiver program that are provided to an individual who has been determined eligible for the PAS option. Self-directed PAS also includes, at the State's option, items that increase the individual's independence or substitutes (such as a microwave oven or an accessibility ramp) for human assistance, to the extent the expenditures would otherwise be made for the human assistance.

Self-direction means the opportunity for participants or their representatives to exercise choice and control over the budget, planning, and purchase of self-directed PAS, including the amount, duration, scope, provider, and location of service provision.

Service budget means an amount of funds that is under the control and direction of a participant, or the participant's representative, if any, when the State has selected the State plan option for provision of self-directed PAS. It is developed using a person-centered and directed process and is individually tailored in accordance with the participant's needs and personal preferences as established in the service plan.

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to remain in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan builds upon the participant's capacity to engage in activities that promote community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends and professionals, as desired or required by the participant, will be involved in the service-planning process.

Support system means information, counseling, training, and assistance that support the participant (or the participant's family or representative, as appropriate) in identifying, accessing, managing, and directing their PAS and supports and in purchasing their PAS identified in the service plan and budget.

Supports broker or consultant means an individual who supports participants in directing their PAS and service budgets. The supports broker or consultant is an agent of the participants and takes direction from the participants, or their representatives, if applicable, about what information, counseling, training or assistance is needed or desired. The supports broker or consultant is primarily responsible for facilitating participants' development of a service budget and effective management of the participants' PAS and budgets in a manner that comports with the participants' preferences. States must develop a protocol to ensure that supports brokers or consultants: are accessible to participants; have regularly scheduled phone and in-person contacts with participants; monitor whether participants' health status has changed and whether expenditure of funds are being made in accordance with service budgets. States must also develop the training requirements and qualifications for

supports brokers or consultants that include, at a minimum, the following:

(1) An understanding of the philosophy of self-direction and person-centered and directed planning;

(2) The ability to facilitate participants' independence and participants' preferences in managing PAS and budgets, including any risks assumed by participants;

(3) The ability to develop service budgets and ensure appropriate documentation; and

(4) Knowledge of the PAS and resources available in the participant's community and how to access them.

The availability of a supports broker or consultant to each participant is a requirement of the support system.

§ 441.452 Self-direction: General.

(a) States must have in place, before electing the self-directed PAS option, personal care services through the State plan, or home and community-based services under a section 1915(c) waiver.

(b) The State must have both traditional service delivery and the self-directed PAS service delivery option available in the event that an individual voluntarily disenrolls or is involuntarily disenrolled, from the self-directed PAS service delivery option.

(c) The State's assessment of an individual's needs must form the basis of the level of services for which the individual is eligible.

(d) Nothing in this subpart will be construed as affecting an individual's Medicaid eligibility, including that of an individual whose Medicaid eligibility is attained through receipt of section 1915(c) waiver services.

§ 441.454 Use of cash.

(a) States have the option of disbursing cash prospectively to participants, or their representatives, as applicable, self-directing their PAS.

(b) States that choose to offer the cash option must ensure compliance with all applicable requirements of the Internal Revenue Service, including, but not limited to, retaining required forms and payment of FICA, FUTA and State unemployment taxes.

(c) States must permit participants, or their representatives, as applicable, using the cash option to choose to use the financial management entity for some or all of the functions described in § 441.484(c).

(d) States must make available a financial management entity to a participant, or the participant's representative, if applicable, who has demonstrated, after additional counseling, information, training, or assistance, that the participant cannot effectively manage the cash option described in paragraph (a) of this section.

§ 441.456 Voluntary disenrollment.

(a) States must permit a participant to voluntarily disenroll from the self-directed PAS option at any time and return to a traditional service delivery system.

(b) The State must specify in a section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§ 441.458 Involuntary disenrollment.

(a) States must specify the conditions under which a participant may be involuntarily disenrolled from the self-directed PAS option.

(b) CMS must approve the State's conditions under which a participant may be involuntarily disenrolled.

(c) The State must specify in the section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§ 441.460 Participant living arrangements.

(a) Self-directed PAS are not available to an individual who resides in a home or property that is owned, operated, or controlled by a PAS provider who is not related to the individual by blood or marriage.

(b) States may specify additional restrictions on a participant's living arrangements if they have been approved by CMS.

§ 441.462 Statewideness, comparability and limitations on number served.

A State may do the following:

(a) Provide self-directed PAS without regard to the requirements of statewideness.

(b) Limit the population eligible to receive these services without regard to comparability of amount, duration, and scope of services.

(c) Limit the number of persons served without regard to comparability of amount, duration, and scope of services.

§441.464 State assurances.

A State must assure that the following requirements are met:

(a) *Necessary safeguards.* Necessary safeguards have been taken to protect the health and welfare of individuals furnished services under the program and to assure the financial accountability for funds expended for self-directed services.

(1) Safeguards must prevent the premature depletion of the participant directed budget as well as identify potential service delivery problems that might be associated with budget underutilization.

(2) These safeguards may include the following:

(i) Requiring a case manager, support broker or other person to monitor the participant's expenditures.

(ii) Requiring the financial management entity to flag significant budget variances (over and under expenditures) and bring them to the attention of the participant, the participant's representative, if applicable, case manager, or support broker.

(iii) Allocating the budget on a monthly or quarterly basis.

(iv) Other appropriate safeguards as determined by the State.

(3) Safeguards must be designed so that budget problems are identified on a timely basis so that corrective action may be taken, if necessary.

(b) *Evaluation of need.* The State must perform an evaluation of the need for personal care under the State Plan or services under a section 1915(c) waiver program for individuals who meet the following requirements:

(1) Are entitled to medical assistance for personal care services under the State plan or receiving home and community based services under a section 1915(c) waiver program.

(2) May require self-directed PAS.

(3) May be eligible for self-directed PAS.

(c) *Notification of feasible alternatives.* Individuals who are likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program are informed of the feasible alternatives, if available, under the State's self-directed PAS State plan option, at the choice of these individuals, to the provision of personal care services under the State plan, or PAS under a section 1915(c) home and community-based services waiver program. Information on feasible alternatives must be communicated to the individual in a manner and language understandable by the individual. Such information includes, but is not limited to, the following:

(1) Information about self-direction opportunities that is sufficient to inform decision-making about the election of self-direction and provided on a timely basis to an individual or the representative which minimally includes the following:

(i) Elements of self-direction compared to non-self-directed PAS.

(ii) Individual responsibilities and potential liabilities under the self-direction service delivery model.

(iii) The choice to receive PAS through a waiver program administered under section 1915(c) of the Act, regardless of delivery system, if applicable.

(iv) The option, if available, to receive and manage the cash amount of their individual budget allocation.

(2) When and how this information is provided.

(d) *Support system.* States must provide, or arrange for the provision of, a support system that meets the following conditions:

(1) Appropriately assesses and counsels an individual, or the individual's representative, if applicable, before enrollment, including information about disenrollment.

(2) Provides appropriate information, counseling, training, and assistance to ensure that a participant is able to manage the services and budgets. Such information must be communicated to the participant in a manner and language understandable by the participant. The support activities must include at least the following:

(i) Person-centered planning and how it is applied.

(ii) Information about the services available for self-direction.

(iii) Range and scope of individual choices and options.

(iv) Process for changing the service plan and service budget.

(v) Grievance process.

(vi) Risks and responsibilities of self-direction.

(vii) The ability to freely choose from available PAS providers.

(viii) Individual rights.

(ix) Reassessment and review schedules.

(x) Defining goals, needs, and preferences.

(xi) Identifying and accessing services, supports, and resources.

(xii) Development of risk management agreements.

(xiii) Development of an individualized backup plan.

(xiv) Recognizing and reporting critical events.

(xv) Information about an advocate or advocacy systems available in the State and how a participant, or a participant's representative, if applicable, can access the advocate or advocacy systems.

(3) Offers additional information, counseling, training, or assistance, including financial management services under either of the following conditions:

(i) At the request of the participant, or participant's representative, if applicable, for any reason.

(ii) When the State has determined the participant, or participant's representative, if applicable, is not effectively managing the services identified in the service plan or budget.

(4) The State may mandate the use of additional assistance, including the use of a financial management entity, or may initiate an involuntary disenrollment in accordance with § 441.458, if, after additional information, counseling, training or assistance is provided to a participant (or participant's representative, if applicable), the participant (or participant's representative, if applicable) has continued to demonstrate an inability to effectively manage the services and budget.

(e) *Annual report.* The State must provide to CMS an annual report on the number of individuals served and the total expenditures on their behalf in the aggregate.

(f) *Three-year evaluation.* The State must provide to CMS an evaluation of the overall impact of the self-directed PAS option on the health and welfare of participating individuals compared to non-participants every 3 years.

§ 441.466 Assessment of need.

States must conduct an assessment of the participant's needs, strengths, and preferences in accordance with the following:

(a) States may use one or more processes and techniques to obtain information about an individual, including health condition, personal goals and preferences for the provision of services, functional limitations, age, school, employment, household, and other factors that are relevant to the need for and authorization and provision of services.

(b) Assessment information supports the determination that an individual requires PAS and also supports the development of the service plan and budget.

§ 441.468 Service plan elements.

(a) The service plan must include at least the following:

(1) The scope, amount, frequency, and duration of each service.

(2) The type of provider to furnish each service.

(3) Location of the service provision.

(4) The identification of risks that may pose harm to the participant along with a written individualized backup plan for mitigating those risks.

(b) A State must develop a service plan for each program participant using a person-centered and directed planning process to ensure the following:

(1) The identification of each program participant's preferences, choices, and abilities, and strategies to address those preferences, choices, and abilities.

(2) The option for the program participant, or participant's representative, if applicable, to exercise choice and

control over services and supports discussed in the plan.

(3) Assessment of, and planning for avoiding, risks that may pose harm to a participant.

(c) All of the State's applicable policies and procedures associated with service plan development must be carried out and include, but are not limited to, the following:

(1) Allow the participant, or participant's representative, if applicable, the opportunity to engage in, and direct, the process to the extent desired.

(2) Allow the participant, or participant's representative, if applicable, the opportunity to involve family, friends, and professionals (as desired or required) in the development and implementation of the service plan.

(3) Ensure the planning process is timely.

(4) Ensure the participant's needs are assessed and that the services meet the participant's needs.

(5) Ensure the responsibilities for service plan development are identified.

(6) Ensure the qualifications of the individuals who are responsible for service plan development reflect the nature of the program's target population(s).

(7) Ensure the State reviews the service plan annually, or whenever necessary due to a change in the participant's needs or health status.

(8) Ensure that a participant may request revisions to a service plan, based on a change in needs or health status.

(d) When an entity that is permitted to provide other State plan services is responsible for service plan development, the State must describe the safeguards that are in place to ensure that the service provider's role in the planning process is fully disclosed to the participant, or participant's representative, if applicable, and controls are in place to avoid any possible conflict of interest.

(e) An approved self-directed service plan conveys authority to the participant, or participant's representative, if applicable, to perform, at a minimum, the following tasks:

(1) Recruit and hire workers to provide self-directed services, including specifying worker qualifications.

(2) Fire workers.

(3) Supervise workers in the provision of self-directed services.

(4) Manage workers in the provision of self-directed services, which includes the following functions:

(i) Determining worker duties.

(ii) Scheduling workers.

(iii) Training workers in assigned tasks.

(iv) Evaluating workers performance.

(5) Determine the amount paid for a service, support, or item.

(6) Review and approve provider invoices.

§441.470 Service budget elements.

A service budget must be developed and approved by the State based on the assessment of need and service plan and must include the following:

(a) The specific dollar amount a participant may utilize for services and supports.

(b) How the participant is informed of the amount of the service budget before the service plan is finalized.

(c) The procedures for how the participant, or participant's representative, if applicable, may adjust the budget, including the following:

(1) How the participant, or participant's representative, if applicable, may freely make changes to the budget.

(2) The circumstances, if any, that may require prior approval before a budget adjustment is made.

(3) The circumstances, if any, that may require a change in the service plan.

(d) The procedure(s) that governs how a person, at the election of the State, may reserve funds to purchase items that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance, including additional goods, supports, services or supplies.

(e) The procedure(s) that governs how a person may use a discretionary amount, if applicable, to purchase items not otherwise delineated in the budget or reserved for permissible purchases.

(f) How participants, or their representative, if applicable, are afforded

the opportunity to request a fair hearing under § 441.300 if a participant's, or participant's representative, if applicable, request for a budget adjustment is denied or the amount of the budget is reduced.

§ 441.472 Budget methodology.

(a) The State shall set forth a budget methodology that ensures service authorization resides with the State and meets the following criteria:

(1) The State's method of determining the budget allocation is objective and evidence based utilizing valid, reliable cost data.

(2) The State's method is applied consistently to participants.

(3) The State's method is open for public inspection.

(4) The State's method includes a calculation of the expected cost of the self-directed PAS and supports, if those services and supports were not self-directed.

(5) The State has a process in place that describes the following:

(i) Any limits it places on self-directed services and supports, and the basis for the limits.

(ii) Any adjustments that will be allowed and the basis for the adjustments.

(b) The State must have procedures to safeguard participants when the budgeted service amount is insufficient to meet a participant's needs.

(c) The State must have a method of notifying participants, or their representative, if applicable, of the amount of any limit that applies to a participant's self-directed PAS and supports.

(d) The budget may not restrict access to other medically necessary care and services furnished under the plan and approved by the State but not included in the budget.

(e) The State must have a procedure to adjust a budget when a reassessment indicates a change in a participant's medical condition, functional status or living situation.

§ 441.474 Quality assurance and improvement plan.

(a) The State must provide a quality assurance and improvement plan that describes the State's system of how it will perform activities of discovery, remediation and quality improvement in order to learn of critical incidents or events that affect participants, correct shortcomings, and pursue opportunities for system improvement.

(b) The quality assurance and improvement plan shall also describe the system performance measures, outcome measures, and satisfaction measures that the State must use to monitor and evaluate the self-directed State plan option. Quality of care measures must be made available to CMS upon request and include indicators approved or prescribed by the Secretary.

§ 441.476 Risk management.

(a) The State must specify the risk assessment methods it uses to identify potential risks to the participant.

(b) The State must specify any tools or instruments it uses to mitigate identified risks.

(c) The State must ensure that each service plan includes the risks that an individual is willing and able to assume, and the plan for how identified risks will be mitigated.

(d) The State must ensure that the risk management plan is the result of discussion and negotiation among the persons designated by the State to develop the service plan, the participant, the participant's representative, if any, and others from whom the participant may seek guidance.

§ 441.478 Qualifications of providers of personal assistance.

(a) States have the option to permit participants, or their representatives, if applicable, to hire any individual capable of providing the assigned tasks, including legally liable relatives, as paid providers of the PAS identified in the service plan and budget.

(b) Participants, or their representatives, if applicable, retain the right to train their workers in the specific areas of personal assistance needed by the participant and to perform the needed assistance in a manner that comports with the participant's personal, cultural, and/or religious preferences. Participants, or their representatives, if applicable, also have

the right to access other training provided by or through the State so that their PAS providers can meet any additional qualifications required or desired by participants, or participants' representatives, if applicable.

(c) Participants, or their representatives, if applicable, retain the right to establish additional staff qualifications based on participants' needs and preferences.

§441.480 Use of a representative.

(a) States may permit participants to appoint a representative to direct the provision of self-directed PAS on their behalf. The following types of representatives are permissible:

(1) A minor child's parent or guardian.

(2) An individual recognized under State law to act on behalf of an incapacitated adult.

(3) A State-mandated representative, after approval by CMS of the State criteria, if the participant has demonstrated, after additional counseling, information, training or assistance, the inability to self-direct PAS.

(b) A person acting as a representative for a participant receiving self-directed PAS is prohibited from acting as a provider of self-directed PAS to the participant.

§441.482 Permissible purchases.

(a) Participants, or their representatives, if applicable, may, at the State's option, use their service budgets to pay for items that increase a participant's independence or substitute (such as a microwave oven or an accessibility ramp) for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

(b) The services, supports and items that are purchased with a service budget must be linked to an assessed participant need or goal established in the service plan.

§441.484 Financial management services.

(a) States may choose to provide financial management services to participants, or their representatives, as applicable, self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions, utilizing a financial management entity, through the following arrangements:

(1) States may use a reporting or subagent through its fiscal intermediary in accordance with section 3504 of the IRS Code and Revenue Procedure 80–4 and Notice 2003–70; or

(2) States may use a vendor organization that has the capabilities to perform the required tasks in accordance with Section 3504 of the IRS Code and Revenue Procedure 70–6. When private entities furnish financial management services, the procurement method must meet the requirements set forth in 45 CFR 74.40 through 74.48.

(b) States must provide oversight of financial management services by performing the following functions:

(1) Monitoring and assessing the performance of financial management entity, including assuring the integrity of financial transactions they perform.

(2) Designating a State entity or entities responsible for this monitoring.

(3) Determining how frequently financial management entity performance will be assessed.

(c) A financial management entity must provide functions including, but not limited to, the following:

(1) Collect and process timesheets of the participant's workers.

(2) Process payroll, withholding, filing and payment of applicable Federal, State and local employment-related taxes and insurance.

(3) Maintain a separate account for each participant's budget.

(4) Track and report disbursements and balances of participant funds.

(5) Process and pay invoices for goods and services approved in the service plan.

(6) Provide to participants periodic reports of expenditures and the status of the approved service budget.

(d) States not utilizing a financial management entity must perform the functions listed in paragraph (c) of this section on behalf of participants self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions.

(e) States will be reimbursed for the cost of financial management services, either provided directly or through a

financial management entity, at the administrative rate of 50 percent.

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

Subpart A—General Provisions

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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 these facilities and for certain survey agency responsibilities.

[43 FR 45233, Sept. 29, 1978, as amended at 47 FR 31533, July 20, 1982; 59 FR 56235, Nov. 10, 1994]

§ 442.2 Terms.

In this part—

Facility refers to a nursing facility, and an intermediate care facility for the mentally retarded or persons with related conditions (ICF/MR).

Facility, and any specific type of facility referred to, may include a distinct part of a facility as specified in § 440.40 or § 440.150 of this subchapter.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the provider's noncompliance with one or more requirements of participation or conditions of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to an individual receiving care in a facility.

New admission means the admission of a Medicaid recipient who has never

been in the facility or, if previously admitted, had been discharged or had voluntarily left the facility. The term does not include the following:

(a) Individuals who were in the facility before the effective date of denial of payment for new admissions, even if they become eligible for Medicaid after that date.

(b) If the approved State plan includes payments for reserved beds, individuals who, after a temporary absence from the facility, are readmitted to beds reserved for them in accordance with § 447.40(a) of this chapter.

[43 FR 45233, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986; 53 FR 1993, Jan. 25, 1988; 54 FR 5358, Feb. 2, 1989; 56 FR 48865, Sept. 26, 1991; 59 FR 56235, Nov. 10, 1994]

Subpart B—Provider Agreements

§ 442.10 State plan requirement.

A State plan must provide that requirements of this subpart are met.

§ 442.12 Provider agreement: General requirements.

(a) *Certification and recertification.* Except as provided in paragraph (b) of this section, a Medicaid agency may not execute a provider agreement with a facility for nursing facility services nor make Medicaid payments to a facility for those services unless the Secretary or the State survey agency has certified the facility under this part to provide those services. (See § 442.101 for certification by the Secretary or by the State survey agency).

(b) *Exception.* The certification requirement of paragraph (a) of this section does not apply with respect to religious nonmedical institutions as defined in § 440.170(b) of this chapter.

(c) *Conformance with certification condition.* An agreement must be in accordance with the certification provisions set by the Secretary or the survey agency under subpart C of this part for ICFs/MR or subpart E of part 488 of this chapter for NFs.

(d) *Denial for good cause.* (1) If the Medicaid agency has adequate documentation showing good cause, it may refuse to execute an agreement, or may cancel an agreement, with a certified facility.

(2) A provider agreement is not a valid agreement for purposes of this part even though certified by the State survey agency, if the facility fails to meet the civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

[45 FR 22936, Apr. 4, 1980, as amended at 56 FR 48865, Sept. 26, 1991; 59 FR 56235, Nov. 10, 1994; 64 FR 67052, Nov. 30, 1999]

§ 442.13 Effective date of provider agreement.

The effective date of a provider agreement with an NF or ICF/MR is determined in accordance with the rules set forth in § 431.108.

[62 FR 43936, Aug. 18, 1997]

§ 442.14 Effect of change of ownership.

(a) *Assignment of agreement.* When there is a change of ownership, the Medicaid agency must automatically assign the agreement to the new owner.

(b) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued, including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Any expiration date for ICFs/MR.

(3) Compliance with applicable health and safety requirements.

(4) Compliance with the ownership and financial interest disclosure requirements of §§ 455.104 and 455.105 of this chapter.

(5) Compliance with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

(6) Compliance with any additional requirements imposed by the Medicaid agency.

[45 FR 22936, Apr. 4, 1980, as amended at 53 FR 20495, June 3, 1988; 59 FR 56235, Nov. 10, 1994]

§ 442.15 Duration of agreement for ICFs/MR.

(a) Except as specified under § 442.16, the duration of an agreement may not exceed 12 months.

(b) The agreement must be for the same duration as the certification period set by the survey agency. However, if the Medicaid agency has adequate documentation showing good cause, it may make an agreement for less than this period.

(c) FFP is available for services provided by a facility for up to 30 days after its agreement expires or terminates under the conditions specified in § 441.11 of this subchapter.

[43 FR 45233, Sept. 29, 1978, as amended at 47 FR 31532, July 20, 1982; 59 FR 56235, Nov. 10, 1994]

§ 442.16 Extension of agreement for ICFs/MR.

A Medicaid agency may extend a provider agreement for a single period of up to 2 months beyond the original expiration date specified in the agreement if it receives written notice from the survey agency, before the expiration date of the agreement, that extension will not jeopardize the patients' health and safety, and—

(a) Is needed to prevent irreparable harm to the facility or hardship to the recipients in the facility; or

(b) Is needed because it is impracticable to determine, before the expiration date, whether the facility meets certification requirements.

[43 FR 45233, Sept. 29, 1978, as amended at 52 FR 32551, Aug. 28, 1987; 53 FR 20495, June 3, 1988; 59 FR 56235, Nov. 10, 1994]

§ 442.30 Agreement as evidence of certification.

(a) Under §§ 440.40(a) and 440.150 of this chapter, FFP is available in expenditures for NF and ICF/MR services only if the facility has been certified as meeting the requirements for Medicaid participation, as evidenced by a provider agreement executed under this part. An agreement is not valid evidence that a facility has met those requirements if CMS determines that—

(1) The survey agency failed to apply the applicable requirements under subpart B of part 483 of this chapter for NFs or subpart I of part 483 of this chapter, which set forth the conditions of participation for ICFs/MR.

(2) The survey agency failed to follow the rules and procedures for certification set forth in subpart C of this part, subpart E of part 488, and § 431.610 of this subchapter;

(3) The survey agency failed to perform any of the functions specified in § 431.610(g) of this subchapter relating to evaluating and acting on information about the facility and inspecting the facility;

(4) The agency failed to use the Federal standards, and the forms, methods and procedures prescribed by CMS as required under § 431.610(f)(1) or § 488.318(b) of this chapter, for determining the qualifications of providers; or

(5) The survey agency failed to adhere to the following principles in determining compliance:

(i) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(ii) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically, surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(iii) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

(iv) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(v) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(6) The survey agency failed to assess in a systematic manner a facility's actual provision of care and services to residents and effects of that care on residents.

(7) Required elements of the NF survey process fails to include all of the following:

(i) An entrance conference;

(ii) A resident-centered tour of facility;

(iii) An in-depth review of a sample of residents including observation, interview and record review;

(iv) Observation of the preparation and administration of drugs for a sample of residents;

(v) Evaluation of a facility's meals, dining areas and eating assistance procedures;

(vi) Formulation of a deficiency statement based on the incorporation of all appropriate findings onto the survey report form;

(vii) An exit conference; and

(viii) Follow-up surveys as appropriate.

(8) The agreement's terms and conditions do not meet the requirements of this subpart.

(b) The Administrator will make the determination under paragraph (a) of this section through onsite surveys, other Federal reviews, State certification records, or reports he may require from the Medicaid or survey agency.

(c) If the Administrator disallows a State's claim for FFP because of a determination under paragraph (a) of this section, the State is entitled upon request to reconsideration of the disallowance under 45 CFR part 16.

[43 FR 45233, Sept. 29, 1978, as amended at 51 FR 21558, June 13, 1986; 53 FR 20495, June 3, 1988; 53 FR 23101, June 17, 1988; 56 FR 48865, Sept. 26, 1991; 59 FR 56235, Nov. 10, 1994]

§ 442.40 Availability of FFP during appeals for ICFs/MR.

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

Effective date of expiration means the date of expiration originally specified in the provider agreement, or the later date specified if the agreement is extended under § 442.16; and

Effective date of termination means a date earlier than the expiration date, set by the Medicaid agency when continuing participation until the expiration date is not justified, because the facility no longer meets the requirements for participation.

(b) *Scope, applicability, and effective date*—(1) *Scope.* This section sets forth the extent of FFP in State Medicaid payments to an ICF/MR after its provider agreement has been terminated or has expired and not been renewed.

(2) *Applicability.* (i) This section and § 442.42 apply only when the Medicaid agency, of its own volition, terminates or does not a renew a provider agreement, and only when the survey agency certifies that there is no jeopardy to recipient health and safety. When the survey agency certifies that there is jeopardy to recipient health and safety, or when it fails to certify that there is no jeopardy, FFP ends on the effective date of termination or expiration.

(ii) When the State acts under instructions from CMS, FFP ends on the date specified by CMS (CMS instructs the State to terminate the Medicaid provider agreement when CMS in validating a State survey agency certification, determines that an ICF/MR does not meet the requirements for participation.)

(3) *Effective date.* This section and § 442.42 apply to terminations or expirations that are effective on or after September 28, 1987. For terminations or nonrenewals that were effective before that date, FFP may continue for up to 120 days from September 28, 1987, or 12 months from the effective date of termination or nonrenewal, whichever is earlier.

(c) *Basic rules.* (1) Except as provided in paragraphs (d) and (e) of this section, FFP in payments to an ICF/MR ends on the effective date of termination of the facility's provider agreement, or if the agreement is not terminated, on the effective date of expiration.

(2) If State law, or a Federal or State court order or injunction, requires the agency to extend the provider agreement or continue payments to a facility after the dates specified in paragraph (d) of this section, FFP is not available in those payments.

(d) *Exception: Continuation of FFP after termination or expiration of provider agreement*—(1) *Conditions for continuation.* FFP is available after the effective date of termination or expiration only if—

(i) The evidentiary hearing required under § 431.153 of this chapter is provided by the State agency after the effective date of termination or expiration (or, if begun before termination or expiration, is not completed until after that date); and

(ii) Termination or nonrenewal action is based on a survey agency certification that there is no jeopardy to recipients' health and safety.

(2) *Extent of continuation.* FFP is available only through the earlier of the following:

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

(ii) The 120th day after the effective date of termination of the facility's provider agreement or, if the agreement is not terminated, the 120th day after the effective date of expiration. (If a hearing decision that upholds the facility is issued after the end of the 120-day period, when FFP has already been discontinued, the rules of § 442.42 on retroactive agreements apply).

(e) *Applicability of § 441.11.* If FFP is continued during appeal under paragraph (d) of this section, the 30-day period provided by § 441.11 of this chapter would not begin to run until issuance of a hearing decision that upholds the agency's termination or nonrenewal action.

[52 FR 32551, Aug. 28, 1987, as amended at 56 FR 48865, Sept. 26, 1991; 59 FR 56236, Nov. 10, 1994]

§ 442.42 FFP under a retroactive provider agreement following appeal.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, if an NF or ICF/MR prevails on appeal from termination or, in the case of an ICF/MR, nonrenewal of a provider agreement, and the State issues a retroactive agreement, FFP is available beginning with the retroactive effective date, which must be determined in accordance with § 442.13.

(b) *Exception.* This rule does not apply if CMS determines, under § 442.30, that the agreement is not valid evidence that the facility meets the requirements for participation. This exclusion applies even if the State issues the new agreement as the result of an administrative hearing decision favorable to the facility or under a Federal or State court order.

[52 FR 32551, Aug. 28, 1987, as amended at 59 FR 56236, Nov. 10, 1994]

Subpart C—Certification of ICFs/MR

§ 442.100 State plan requirements.

A State plan must provide that the requirements of this subpart and part 483 are met.

[53 FR 20495, June 3, 1988]

§ 442.101 Obtaining certification.

(a) This section states the requirements for obtaining notice of an ICF/MR's certification before a Medicaid agency executes a provider agreement under § 442.12.

(b) The agency must obtain notice of certification from the Secretary for an ICF/MR located on an Indian reservation.

(c) The agency must obtain notice of certification from the survey agency for all other ICFs/MR.

(d) The notice must indicate that one of the following provisions pertains to the ICF/MR:

(1) An ICF/MR meets the conditions of participation set forth in subpart I of part 483 of this chapter.

(2) The ICF/MR has been granted a waiver or variance by CMS or the survey agency under subpart I of part 483 of this chapter.

(3) An ICF/MR has been certified with standard-level deficiencies and

(i) All conditions of participation are found met; and

(ii) The facility submits an acceptable plan of correction covering the remaining deficiencies, subject to other limitations specified in § 442.105.

(e) The failure to meet one or more of the applicable conditions of participation is cause for termination or non-renewal of the ICF/MR provider agreement.

[56 FR 48866, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 59 FR 56236, Nov. 10, 1994]

§ 442.105 Certification of ICFs/MR with deficiencies: General provisions.

If a survey agency finds a facility deficient in meeting the standards for ICFs/MR, as specified under subpart I of part 483 of this chapter, the agency may certify the facility for Medicaid purposes under the following conditions:

(a) The agency finds that the facility's deficiencies, individually or in combination, do not jeopardize the patient's health and safety, nor seriously limit the facility's capacity to give adequate care.

(b) The agency finds acceptable the facility's written plan for correcting the deficiencies.

(c) If a facility was previously certified with a deficiency and has a different deficiency at the time of the next survey, the agency documents that the facility—

(1) Was unable to stay in compliance with the standard for ICFs/MR for reasons beyond its control, or despite intensive efforts to comply; and

(2) Is making the best use of its resources to furnish adequate care.

(d) If a facility has the same deficiency it had under the prior certification, the agency documents that the facility—

(1) Did achieve compliance with the standard for ICFs/MR at some time during the prior certification period;

(2) Made a good faith effort, as judged by the survey agency, to stay in compliance; and

(3) Again became out of compliance for reasons beyond its control.

[56 FR 48866, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 57 FR 54712, Nov. 20, 1992; 59 FR 56236, Nov. 10, 1994]

§442.109 Certification period for ICFs/MR: General provisions.

(a) A survey agency may certify a facility that fully meets applicable requirements for up to 12 months.

(b) The survey agency may notify the Medicaid agency that the term of a provider agreement may be extended up to 2 months after the expiration date of the agreement under the conditions specified in §442.16.

[43 FR 45233, Sept. 29, 1978. Redesignated at 53 FR 1993, Jan. 25, 1988, and amended at 59 FR 56236, Nov. 10, 1994]

§442.110 Certification period for ICFs/MR with standard-level deficiencies.

(a) Facilities with deficiencies may be certified under §442.105 for the period specified in either paragraph (b) or (c) of this section.

(b) The survey agency may certify a facility for a period that ends no later than 60 days after the last day specified in the plan for correcting deficiencies. The certification period must not exceed 12 months, including the period allowed for corrections.

(c) The survey agency may certify a facility for up to 12 months with a condition that the certification will be automatically canceled on a specified date within the certification period unless—

(1) The survey agency finds that all deficiencies have been satisfactorily corrected; or

(2) The survey agency finds and notifies the Medicaid agency that the facility has made substantial progress in correcting the deficiencies and has a new plan for correction that is acceptable.

The automatic cancellation date must be no later than 60 days after the last day specified in the plan for correction of deficiencies under §442.105.

[43 FR 45233, Sept. 29, 1978. Redesignated and amended at 53 FR 1993, Jan. 25, 1988; 59 FR 56236, Nov. 10, 1994]

§442.117 Termination of certification for ICFs/MR whose deficiencies pose immediate jeopardy.

(a) A survey agency must terminate a facility's certification if it determines that—

(1) The facility no longer meets conditions of participation for ICFs/MR as specified in subpart I of part 483 of this chapter.

(2) The facility's deficiencies pose immediate jeopardy to residents' health and safety.

(b) Subsequent to a certification of a facility's noncompliance, the Medicaid agency must, in terminating the provider agreement, follow the appeals process specified in part 431, subpart D of this chapter.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

§442.118 Denial of payments for new admissions to an ICF/MR.

(a) *Basis for denial of payments.* The Medicaid agency may deny payment for new admissions to an ICF/MR that

no longer meets the applicable conditions of participation specified under subpart I of part 483 of this chapter.

(b) *Agency procedures.* Before denying payments for new admissions, the Medicaid agency must comply with the following requirements:

(1) Provide the facility up to 60 days to correct the cited deficiencies and comply with conditions of participation for ICFs/MR.

(2) If at the end of the specified period the facility has not achieved compliance, give the facility notice of intent to deny payment for new admissions, and opportunity for an informal hearing.

(3) If the facility requests a hearing, provide an informal hearing that includes—

(i) The opportunity for the facility to present, before a State Medicaid official who was not involved in making the initial determination, evidence or documentation, in writing or in person, to refute the decision that the facility is out of compliance with the conditions of participation for ICFs/MR.

(ii) A written decision setting forth the factual and legal bases pertinent to a resolution of the dispute.

(4) If the decision of the informal hearing is to deny payments for new admissions, provide the facility and the public, at least 15 days before the effective date of the sanction, with a notice that includes the effective date and the reasons for the denial of payments.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

§ 442.119 Duration of denial of payments and subsequent termination of an ICF/MR.

(a) *Period of denial.* The denial of payments for new admissions will continue for 11 months after the month it was imposed unless, before the end of that period, the Medicaid agency finds that—

(1) The facility has corrected the deficiencies or is making a good faith effort to achieve compliance with the conditions of participation for ICFs/MR; or

(2) The deficiencies are such that it is necessary to terminate the facility's provider agreement.

(b) *Subsequent termination.* The Medicaid agency must terminate a facility's provider agreement—

(1) Upon the agency's finding that the facility has been unable to achieve compliance with the conditions of participation for ICFs/MR during the period that payments for new admissions have been denied;

(2) Effective the day following the last day of the denial of payments period; and

(3) In accordance with the procedures for appeal of terminations set forth in subpart D of part 431 of this chapter.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

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PART 447—PAYMENTS FOR SERVICES

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

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted.

Subpart A—Payments: General Provisions

§ 447.1 Purpose.

This subpart prescribes State plan requirements, FFP limitations and procedures concerning payments made by State Medicaid agencies for Medicaid services.

§ 447.10 Prohibition against reassignment of provider claims.

(a) *Basis and purpose.* This section implements section 1902(a)(32) of the Act which prohibits State payments for Medicaid services to anyone other than a provider or recipient, except in specified circumstances.

(b) *Definitions.* For purposes of this section:

Facility means an institution that furnishes health care services to inpatients.

Factor means an individual or an organization, such as a collection agency or service bureau, that advances money to a provider for accounts receivable that the provider has assigned, sold or transferred to the individual organization for an added fee or a deduction of a portion of the accounts receivable. Factor does not include a business representative as described in paragraph (f) of this section.

Organized health care delivery system means a public or private organization for delivering health services. It includes, but is not limited to, a clinic, a group practice prepaid capitation plan, and a health maintenance organization.

(c) *State plan requirements.* A State plan must provide that the requirements of paragraphs (d) through (h) of this section are met.

(d) *Who may receive payment.* Payment may be made only—

(1) To the provider; or

(2) To the recipient if he is a noncash recipient eligible to receive the payment under § 447.25; or

(3) In accordance with paragraphs (e), (f), and (g) of this section.

(e) *Reassignments.* Payment may be made in accordance with a reassignment from the provider to a government agency or reassignment by a court order.

(f) *Business agents.* Payment may be made to a business agent, such as a billing service or an accounting firm, that furnishes statements and receives payments in the name of the provider, if the agent's compensation for this service is—

(1) Related to the cost of processing the billing;

(2) Not related on a percentage or other basis to the amount that is billed or collected; and

(3) Not dependent upon the collection of the payment.

(g) *Individual practitioners.* Payment may be made to—

(1) The employer of the practitioner, if the practitioner is required as a condition of employment to turn over his fees to the employer;

(2) The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or

(3) A foundation, plan, or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

(h) *Prohibition of payment to factors.* Payment for any service furnished to a recipient by a provider may not be made to or through a factor, either directly or by power of attorney.

[43 FR 45253, Sept. 29, 1978, as amended at 46 FR 42672, Aug. 24, 1981; 61 FR 38398, July 24, 1996]

§ 447.15 Acceptance of State payment as payment in full.

A State plan must provide that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual. However, the provider may not deny services to any eligible individual on account of the individual's inability to pay the cost sharing amount imposed by the plan in accordance with § 431.55(g) or § 447.53. The previous sentence does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the cost sharing charge.

[50 FR 23013, May 30, 1985]

§ 447.20 Provider restrictions: State plan requirements.

A State plan must provide for the following:

(a) In the case of an individual who is eligible for medical assistance under the plan for service(s) for which a third party or parties is liable for payment, if the total amount of the established liability of the third party or parties for the service is—

(1) Equal to or greater than the amount payable under the State plan (which includes, when applicable, cost-sharing payments provided for in §§ 447.53 through 447.56), the provider furnishing the service to the individual may not seek to collect from the individual (or any financially responsible relative or representative of that individual) any payment amount for that service; or

(2) Less than the amount payable under the State plan (including cost sharing payments set forth in §§ 447.53 through 447.56), the provider furnishing the service to that individual may collect from the individual (or any financially responsible relative or representative of the individual) an amount which is the lesser of—

(i) Any cost-sharing payment amount imposed upon the individual under §§ 447.53 through 447.56; or

(ii) An amount which represents the difference between the amount payable under the State plan (which includes, where applicable, cost-sharing payments provided for in §§ 447.53 through 447.56) and the total of the established third party liability for the services.

(b) A provider may not refuse to furnish services covered under the plan to an individual who is eligible for medical assistance under the plan on account of a third party's potential liability for the service(s).

[55 FR 1433, Jan. 16, 1990]

§ 447.21 Reduction of payments to providers.

If a provider seeks to collect from an individual (or any financially responsible relative or representative of that individual) an amount that exceeds an amount specified under § 447.20(a)—

(a) The Medicaid agency may provide for a reduction of any payment amount otherwise due to the provider in addition to any other sanction available to the agency; and

(b) The reduction may be equal to up to three times the amount that the provider sought to collect in violation of § 447.20(a).

[55 FR 1433, Jan. 16, 1990]

§ 447.25 Direct payments to certain recipients for physicians' or dentists' services.

(a) *Basis and purpose.* This section implements section 1905(a) of the Act by prescribing requirements applicable to States making direct payments to certain recipients for physicians' or dentists' services.

(b) *State plan requirements.* Except for groups specified in paragraph (c) of this section, a State may make direct payments to recipients for physicians' or dentists' services. If it does so, the State plan must—

(1) Provide for direct payments; and

(2) Specify the conditions under which payments are made.

(c) *Federal financial participation.* No FFP is available in expenditures for direct payment for physicians' or dentists' services to any recipient—

(1) Who is receiving assistance under the State's approved plan under title I, IV-A, X, XIV or XVI (AABD) of the Act; or

(2) To whom supplemental security benefits are being paid under title XVI of the Act; or

(3) Who is receiving or eligible for a State supplementary payment or would be eligible if he were not in a medical institution, and who is eligible for Medicaid as a categorically needy recipient.

(d) *Federal requirements.* (1) Direct payments to recipients under this section are an alternative to payments directly to providers and are subject to the same conditions; for example, the State's reasonable charge schedules are applicable.

(2) Direct payments must be supported by providers' bills for services.

§ 447.30 Withholding the Federal share of payments to Medicaid providers to recover Medicare overpayments.

(a) *Basis and purpose.* This section implements section 1914 of the Act, which provides for withholding the Federal share of Medicaid payments to a provider if the provider has not arranged to repay Medicare overpayments or has failed to provide information to determine the amount of the overpayments. The intent of the statute and regulations is to facilitate the recovery of Medicare overpayments. The provision enables recovery of overpayments when institutions have reduced participation in Medicare or when physicians and suppliers have submitted few or no claims under Medicare, thus not receiving enough in Medicare reimbursement to permit offset of the overpayment.

(b) *When withholding occurs.* The Federal share of Medicaid payments may be withheld from any provider specified in paragraph (c) of this section to recover Medicare overpayments that CMS has been unable to collect if the provider participates in Medicaid and—

(1) The provider has not made arrangements satisfactory to CMS to repay the Medicare overpayment; or

(2) CMS has been unable to collect information from the provider to determine the existence or amount of Medicare overpayment.

(c) The Federal share of Medicaid payments may be withheld with respect to the following providers:

(1) An institutional provider that has or previously had in effect a Medicare provider agreement under section 1866 of the Act; and

(2) A Medicaid provider who has previously accepted Medicare payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act; and during the 12 month period preceding the quarter in which the Federal share is to be withheld for a Medicare overpayment, submitted no claims under Medicare or submitted claims which total less than the amount of overpayment.

(d) *Order to reduce State payment.* (1) CMS may, at its discretion, issue an order to the Medicaid agency of any State that is using the provider's services, to reduce its payment to the provider by the amount specified in paragraph (f) of this section.

(2) The order to reduce payment to the provider will remain in effect until—

(i) The Medicaid agency determines that the overpayment has been completely recovered; or

(ii) CMS terminates the order.

(3) CMS may withhold FFP from any State that does not comply with the order specified in paragraph (d)(1) of this section to reduce payment to the provider and claims FFP for the expenditure on its quarterly expenditure report.

(e) *Notice of withholding.* (1) Before the Federal share of payments may be withheld under this section, CMS will notify the provider and the Medicaid agency of each State that CMS believes may use the overpaid provider's services under Medicaid.

(2) The notice will include the instruction to reduce State payments, as provided under paragraph (d) of this section.

(3) CMS will send the notice referred to in paragraph (e)(1) by certified mail, return receipt requested.

(4) Each Medicaid agency must identify the amount of payment due the

provider under Medicaid and give that information to CMS in the next quarterly expenditure report.

(5) The Medicaid agency may appeal any disallowance of FFP resulting from the withholding decision to the Grant Appeals Board, in accordance with 45 CFR part 16.

(f) Amount to be withheld. CMS may require the Medicaid agency to reduce the Federal share of its payment to the provider by the lesser of the following amounts.

(1) The Federal matching share of payments to the provider, or

(2) The total Medicare overpayment to the provider.

(g) *Effective date of withholding.* Withholding of payment will become effective no less than 60 days after the day on which the agency receives notice of withholding.

(h) *Duration of withholding.* No Federal funds are available in expenditures for services that are furnished by a provider specified in paragraph (c) of this section from the date on which the withholding becomes effective until the termination of withholding under paragraph (i) of this section.

(i) *Termination of withholding.* (1) CMS will terminate the order to reduce State payment if it determines that any of the following has occurred:

(i) The Medicare overpayment is completely recovered:

(ii) The institution or person makes an agreement satisfactory to CMS to repay the overpayment; or

(iii) CMS determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(2) CMS will notify each State that previously received a notice ordering the withholding that the withholding has been terminated.

(j) *Procedures for restoring excess withholding.* If an amount ultimately determined to be in excess of the Medicare overpayment is withheld, CMS will restore any excess funds withheld.

(k) *Recovery of funds from Medicaid agency.* A provider is not entitled to recover from the Medicaid agency the amount of payment withheld by the agency in accordance with a CMS order issued under paragraph (d) of this section.

[50 FR 19688, May 10, 1985; 50 FR 23307, June 3, 1985]

§ 447.31 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* Section 1885 of the Act provides authority for CMS to withhold Medicare payments to a Medicaid provider in order to recover Medicaid overpayments to the provider. Section 405.377 of this chapter sets forth the Medicare rules implementing section 1885, and specifies under what circumstances withholding will occur and the providers that are subject to withholding. This section establishes the procedures that the Medicaid agency must follow when requesting that CMS withhold Medicare payments.

(b) *Agency notice to providers.* (1) Before the agency requests recovery of a Medicaid overpayment through Medicare, the agency must send either or both of the following notices, in addition to that required under paragraph (b)(2) of this section, to the provider.

(i) Notice that—

(A) There has been an overpayment;

(B) Repayment is required; and

(C) The overpayment determination is subject to agency appeal procedures, but we may withhold Medicare payments while an appeal is in progress.

(ii) Notice that—

(A) Information is needed to determine the amount of overpayment if any; and

(B) The provider has at least 30 days in which to supply the information to the agency.

(2) Notice that, 30 days or later from the date of the notice, the agency intends to refer the case to CMS for withholding of Medicare payments.

(3) The agency must send all notices to providers by certified mail, return receipt requested.

(c) *Documentation to be submitted to CMS.* The agency must submit the following information or documentation to CMS (unless otherwise specified) with the request for withholding of Medicare payments.

(1) A statement of the reason that withholding is requested.

(2) The amount of overpayment, type of overpayment, date the overpayment was determined, and the closing date of the pertinent cost reporting period (if applicable).

(3) The quarter in which the overpayment was reported on the quarterly expenditure report (Form CMS 64).

(4) As needed, and upon request from CMS, the names and addresses of the provider's officers and owners for each period that there is an outstanding overpayment.

(5) A statement of assurance that the State agency has met the notice requirements under paragraph (b) of this section.

(6) As needed, and upon request for CMS, copies of notices (under paragraph (b) of this section), and reports of contact or attempted contact with the provider concerning the overpayment, including any reduction or suspension of Medicaid payments made with respect to that overpayment.

(7) A copy of the provider's agreement with the agency under § 431.107 of this chapter.

(d) *Notification to terminate withholding.* (1) If an agency has requested withholding under this section, it must notify CMS if any of the following occurs:

(i) The Medicaid provider makes an agreement satisfactory to the agency to repay the overpayment;

(ii) The Medicaid overpayment is completely recovered; or

(iii) The agency determines that there is no overpayment, based on newly acquired evidence or subsequent audit.

(2) Upon receipt of notification from the State agency, CMS will terminate withholding.

(e) *Accounting for returned overpayment.* The agency must treat as a recovered overpayment the amounts received from CMS to offset Medicaid overpayments.

(f) *Procedures for restoring excess withholding.* The agency must establish procedures satisfactory to CMS to assure the return to the provider of amounts withheld under this section that are ultimately determined to be in excess of overpayments. Those procedures are subject to CMS review.

[50 FR 19689, May 10, 1985, as amended at 61 FR 63749, Dec. 2, 1996]

§ 447.40 Payments for reserving beds in institutions.

(a) The Medicaid agency may make payments to reserve a bed during a recipient's temporary absence from an inpatient facility, if—

(1) The State plan provides for such payments and specifies any limitations on the policy; and

(2) Absences for purposes other than required hospitalization (which cannot be anticipated and planned) are included in the patient's plan of care.

(b) An agency that pays for reserved beds in an inpatient facility may pay less for a reserved bed than an occupied bed if there is a cost differential between the two beds. (Section 1102 of the Act.)

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986]

§ 447.45 Timely claims payment.

(a) *Basis and purpose.* This section implements section 1902(a)(37) of the Act by specifying—

(1) State plan requirements for—

(i) Timely processing of claims for payment;

(ii) Prepayment and postpayment claims reviews; and

(2) Conditions under which the Administrator may grant waivers of the time requirements.

(b) *Definitions. Claim* means (1) a bill for services, (2) a line item of service, or (3) all services for one recipient within a bill.

Clean claim means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a State's claims system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

A *shared health facility* means any arrangement in which—

(1) Two or more health care practitioners practice their professions at a common physical location;

(2) The practitioners share common waiting areas, examining rooms, treatment rooms, or other space, the services of supporting staff, or equipment;

(3) The practitioners have a person (who may himself be a practitioner)—

(i) Who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at the common physical location other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) Who makes available to the practitioners the services of supporting staff who are not employees of the practitioners; and

(iii) Who is compensated in whole or in part, for the use of the common physical location or related support services, on a basis related to amounts charged or collected for the services rendered or ordered at the location or on any basis clearly unrelated to the value of the services provided by the person; and

(4) At least one of the practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding $5,000 for any one month during the preceding 12 months or in an aggregate amount exceeding $40,000 during the preceding 12 months.

The term does not include a provider of services (as specified in § 489.2(b) of this chapter), a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.

Third party is defined in § 433.135 of this chapter.

(c) *State plan requirements.* A State plan must (1) provide that the requirements of paragraphs (d), (e)(2), (f) and (g) of this section are met; and

(2) Specify the definition of a claim, as provided in paragraph (b) of this section, to be used in meeting the requirements for timely claims payment. The definition may vary by type of service (e.g., physician service, hospital service).

(d) *Timely processing of claims.* (1) The Medicaid agency must require providers to submit all claims no later than 12 months from the date of service.

(2) The agency must pay 90 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 30 days of the date of receipt.

(3) The agency must pay 99 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 90 days of the date of receipt.

(4) The agency must pay all other claims within 12 months of the date of receipt, except in the following circumstances:

(i) This time limitation does not apply to retroactive adjustments paid to providers who are reimbursed under a retrospective payment system, as defined in § 447.272 of this part.

(ii) If a claim for payment under Medicare has been filed in a timely manner, the agency may pay a Medicaid claim relating to the same services within 6 months after the agency or the provider receives notice of the disposition of the Medicare claim.

(iii) The time limitation does not apply to claims from providers under investigation for fraud or abuse.

(iv) The agency may make payments at any time in accordance with a court order, to carry out hearing decisions or agency corrective actions taken to resolve a dispute, or to extend the benefits of a hearing decision, corrective action, or court order to others in the same situation as those directly affected by it.

(5) The date of receipt is the date the agency receives the claim, as indicated by its date stamp on the claim.

(6) The date of payment is the date of the check or other form of payment.

(e) *Waivers.* (1) The Administrator may waive the requirements of paragraphs (d) (2) and (3) of this section upon request by an agency if he finds that the agency has shown good faith in trying to meet them. In deciding whether the agency has shown good faith, the Administrator will consider whether the agency has received an unusually high volume of claims which are not clean claims, and whether the agency is making diligent efforts to

implement an automated claims processing and information retrieval system.

(2) The agency's request for a waiver must contain a written plan of correction specifying all steps it will take to meet the requirements of this section.

(3) The Administrator will review each case and if he approves a waiver, will specify its expiration date, based on the State's capability and efforts to meet the requirements of this section.

(f) *Prepayment and postpayment claims review.* (1) For all claims, the agency must conduct prepayment claims review consisting of—

(i) Verification that the recipient was included in the eligibility file and that the provider was authorized to furnish the service at the time the service was furnished;

(ii) Checks that the number of visits and services delivered are logically consistent with the recipient's characteristics and circumstances, such as type of illness, age, sex, service location;

(iii) Verification that the claim does not duplicate or conflict with one reviewed previously or currently being reviewed;

(iv) Verification that a payment does not exceed any reimbursement rates or limits in the State plan; and

(v) Checks for third party liability within the requirements of § 433.137 of this chapter.

(2) The agency must conduct postpayment claims review that meets the requirements of parts 455 and 456 of this chapter, dealing with fraud and utilization control.

(g) *Reports.* The agency must provide any reports and documentation on compliance with this section that the Administrator may require.

(Secs. 1102 and 1902(a)(37) of the Social Security Act (42 U.S.C. 1302, 1396a(a)(37)))

[44 FR 30344, May 25, 1979, as amended at 55 FR 1434, Jan. 16, 1990]

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* ''Claim'' and ''clean claim'' have the meaning given those terms in § 447.45.

(c) *Contract requirements*—(1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of §§ 447.45(d)(2) and (d)(3), and abide by the specifications of §§ 447.45(d)(5) and (d)(6).

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) *Alternative schedule.* Any alternative schedule must be stipulated in the contract.

[67 FR 41115, June 14, 2002]

COST SHARING

§ 447.50 Cost sharing: Basis and purpose.

(a) Section 1902(a)(14) of the Act permits States to require certain recipients to share some of the costs of Medicaid by imposing upon them such payments as enrollment fees, premiums, deductibles, coinsurance, co-payments, or similar cost sharing charges. For States that impose cost sharing payments, §§ 447.51 through 447.59 prescribe State plan requirements and options for cost sharing, specify the standards and conditions under which States may impose cost sharing, set forth minimum amounts and the methods for determining maximum amounts, and prescribe conditions for FFP that relate to cost sharing requirements.

(b) *Definitions.* For the purposes of this subpart:

(1) *Indian* means any individual defined at 25 USC 1603(c), 1603(f), or 1679(b), or who has been determined eligible as an Indian, pursuant to § 136.12 of this part. This means the individual:

(i) Is a member of a Federally-recognized Indian tribe;

(ii) Resides in an urban center and meets one or more of the following four criteria:

(A) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(D) Is determined to be an Indian under regulations promulgated by the Secretary;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(iv) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

(2) *Indian health care provider* means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

[43 FR 45253, Sept. 29, 1978, as amended at 75 FR 30261, May 28, 2010; 75 FR 38749, July 1, 2010]

ENROLLMENT FEE, PREMIUM OR SIMILAR COST SHARING CHARGE

§ 447.51 Requirements and options.

(a) The plan must provide that the Medicaid agency does not impose any enrollment fee, premium, or similar charge for any services available under the plan upon:

(1) Categorically needy individuals, as defined in § 435.4 and § 436.3 of this subchapter, except for the following populations in accordance with sections 1916(c), (d), (g), and (i) of the Act:

(i) A pregnant woman or an infant under one year of age described in subparagraph (A) or (B) of section 1902(l)(1) of the Act, who is receiving medical assistance on the basis of section 1902(a)(10)(A)(ii)(IX) of the Act and whose family income equals or exceeds 150 percent of the Federal poverty level (FPL) applicable to a family of the size involved;

(ii) A qualified disabled and working individual described in section 1905(s) of the Act whose income exceeds 150 percent of the FPL;

(iii) An individual provided medical assistance only under section 1902(a)(10)(A)(ii)(XV) or section 1902(a)(10)(A)(ii)(XVI) of the Act and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA); and

(iv) A disabled child provided medical assistance under section 1902(a)(10)(A)(ii)(XIX) of the Act in accordance with the Family Opportunity Act; and

(2) An Indian who either is eligible to receive or has received an item or service furnished by an Indian health care provider or through referral under contract health services.

(b) The plan may impose an enrollment fee, premium, or similar charge on medically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(c) For each charge imposed under paragraph (a) or (b) of this section, the plan must specify—

(1) The amount of the charge;

(2) The period of liability for the charge; and

(3) The consequences for an individual who does not pay.

(d) The plan must provide that any charge imposed under paragraph (b) of this section is related to total gross family income as set forth under § 447.52.

[43 FR 45253, Sept. 29, 1978, as amended at 75 FR 30261, May 28, 2010]

§ 447.52 Minimum and maximum income-related charges.

For the purpose of relating the amount of an enrollment fee, premium, or similar charge to total gross family income, as required under § 447.51(d), the following rules apply:

(a) *Minimum charge.* A charge of at least $1.00 per month is imposed on each—

(1) One- or two-person family with monthly gross income of $150 or less;

(2) Three- or four-person family with monthly gross income of $300 or less; and

(3) Five- or more-person family with monthly gross income of $350 or less.

(b) *Maximum charge.* Any charge related to gross family income that is above the minimum listed in paragraph

(a) of this section may not exceed the standards shown in the following table:

MAXIMUM MONTHLY CHARGE

Gross family income (per month)	Family size		
	1 or 2	3 or 4	5 or more
$150 or less	$1	$1	$1
$151 or $200	2	1	1
$201 to $250	3	1	1
$251 to $300	4	1	1
$301 to $350	5	2	1
$351 to $400	6	3	2
$401 to $450	7	4	3
$451 to $500	8	5	4
$501 to $550	9	6	5
$551 to $600	10	7	6
$601 to $650	11	8	7
$651 to $700	12	9	8
$701 to $750	13	10	9
$751 to $800	14	11	10
$801 to $850	15	12	11
$851 to $900	16	13	12
$901 to $950	17	14	13
$951 to $1,000	18	15	14
More than $1,000	19	16	15

(c) *Income-related charges.* The agency must impose an appropriately higher charge for each higher level of family income, within the maximum amounts specified in paragraph (b) of this section.

[43 FR 45253, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980]

DEDUCTIBLE, COINSURANCE, CO-PAYMENT OR SIMILAR COST-SHARING CHARGE

§ 447.53 Applicability; specification; multiple charges.

(a) *Basic requirements.* Except as specified in paragraph (b) of this section, the plan may impose a nominal deductible, coinsurance, copayment, or similar charge upon categorically and medically needy individuals for any service under the plan.

(b) *Exclusions from cost sharing.* The plan may not provide for impositions of a deductible, coinsurance, copayment, or similar charge upon categorically or medically needy individuals for the following:

(1) *Children.* Services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over but under 21) are excluded from cost sharing.

(2) *Pregnant women.* Services furnished to pregnant women if such services related to the pregnancy, or to any other medical condition which may complicate the pregnancy are excluded from cost sharing obligations. These services include routine prenatal care, labor and delivery, routine postpartum care, family planning services, complications of pregnancy or delivery likely to affect the pregnancy, such as hypertension, diabetes, urinary tract infection, and services furnished during the postpartum period for conditions or complications related to the pregnancy. The postpartum period is the immediate postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends. States may further exclude from cost sharing all services furnished to pregnant women if they desire.

(3) *Institutionalized individuals.* Services furnished to any individual who is an inpatient in a hospital, long-term care facility, or other medical institution if the individual is required (pursuant to § 435.725, § 435,733, § 435.832, or § 436.832), as a condition of receiving services in the institution, to spend all but a minimal amount of his income required for personal needs, for medical care costs are excluded from cost sharing.

(4) *Emergency services.* Services as defined at section 1932(b)(2) of the Act and § 438.114(a).

(5) *Family planning.* Family planning services and supplies furnished to individuals of child-bearing age are excluded from cost sharing.

(6) *Indians.* Items and services furnished to an Indian directly by an Indian health care provider or through referral under contract health services.

(c) *Prohibition against multiple charges.* For any service, the plan may not impose more than one type of charge referred to in paragraph (a) of this section.

(d) *State plan specifications.* For each charge imposed under this section, the plan must specify—

(1) The service for which the charge is made;

(2) The amount of the charge;

(3) The basis for determining the charge;

(4) The basis for determining whether an individual is unable to pay the charge and the means by which such an individual will be identified to providers; and

(5) The procedures for implementing and enforcing the exclusions from cost sharing found in paragraph (b) of this section.

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

[43 FR 45253, Sept. 29, 1978, as amended at 47 FR 21051, May 17, 1982; 48 FR 5736, Jan. 8, 1983; 50 FR 23013, May 30, 1985; 55 FR 48611, Nov. 21, 1990; 55 FR 52130, Dec. 19, 1990; 67 FR 41116, June 14, 2002; 75 FR 30261, May 28, 2010]

§ 447.54 Maximum allowable and nominal charges.

Except as provided at §§ 447.62 through 447.82 of this part, the following requirements must be met:

(a) *Non-institutional services.* Except as specified in paragraph (b) of this section, for non-institutional services, the plan must provide that the following requirements are met:

(1) For Federal FY 2009, any deductible it imposes does not exceed $2.30 per month per family for each period of Medicaid eligibility. For example, if Medicaid eligibility is certified for a 6-month period, the maximum deductible which may be imposed on a family for that period of eligibility is $13.80. In succeeding years, any deductible may not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year, and then rounded to the next higher 5-cent increment.

(2) Any coinsurance rate it imposes does not exceed 5 percent of the payment the agency makes for the services; and

(3)(i) For Federal FY 2009, any copayments it imposes under a fee-for-service delivery system do not exceed the amounts shown in the following table:

State payment for the service	Maximum copayment
$10 or less	$0.60
$10.01 to $25	1.15
$25.01 to $50	2.30
$50.01 or more	3.40

(ii) Thereafter, any copayments may not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(4) For Federal FY 2009, any copayment that the State imposes for services provided by a managed care organization (MCO) may not exceed the copayment permitted under paragraph (a)(3)(i) of this section for comparable services under a fee-for-service delivery system. When there is no fee-for-service delivery system, the copayment may not exceed $3.40 per visit. In succeeding years, any copayment may not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(b) *Waiver of the requirement that cost sharing amounts be nominal.* Upon approval from CMS, the requirement that cost sharing charges must be nominal may be waived, in accordance with sections 1916(a)(3) and 1916(b)(3) of the Act and § 431.57 of this chapter, for nonemergency services furnished in a hospital emergency department, if the State establishes to the satisfaction of the Secretary that alternative sources of nonemergency, outpatient services are actually available and accessible to Medicaid beneficiaries in a timely manner.

(b) *Waiver of the requirement that cost sharing amounts be nominal.* Upon approval from CMS, the requirement that cost sharing charges must be nominal may be waived, in accordance with section 431.55(g) for nonemergency services furnished in a hospital emergency room.

(c) *Institutional services.* For institutional services, the plan must provide that the maximum deductible, coinsurance or co-payment charge for each admission does not exceed 50 percent of

the payment the agency makes for the first day of care in the institution.

(d) *Cumulative maximum.* The plan may provide for a cumulative maximum amount for all deductible, coinsurance or co-payment charges that it imposes on any family during a specified period of time.

[48 FR 5736, Jan. 8, 1983, as amended at 73 FR 71851, Nov. 25, 2008; 75 FR 30262, May 28, 2010]

§ 447.55 Standard co-payment.

(a) The plan may provide for a standard, or fixed, co-payment amount for any service.

(b) This standard copayment amount for any service may be determined by applying the maximum copayment amounts specified in § 447.54(a) and (c) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is $4 to $5 per prescription, the agency might set a standard copayment of $.60 per prescription. This standard copayment may be adjusted based on updated copayments as permitted under § 447.54(a)(3).

[43 FR 45253, Sept. 29, 1978, as amended at 73 FR 71851, Nov. 25, 2008; 75 FR 30262, May 28, 2010]

§ 447.56 Income-related charges.

Subject to the maximum allowable charges specified in § 447.54 (a) and (b), the plan may provide for income-related deductible, coinsurance or co-payment charges. For example, an agency may impose a higher charge on medically needy recipients than it imposes upon categorically needy recipients.

§ 447.57 Restrictions on payments to providers.

(a) The plan must provide that the agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, coinsurance, copayments or similar charges that the provider has waived or are uncollectable, except as permitted under paragraph (b) of this section.

(b) For those providers that the agency reimburses under Medicare reasonable cost reimbursement principles, in accordance with subpart B of this part, an agency may increase its payment to offset uncollected deductible, coinsurance, copayment, or similar charges that are bad debts of providers.

(c) Payment under Medicaid due to an Indian health care provider or a health care provider through referral under contract health services for directly furnishing an item or service to an Indian may not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deductible, copayment, cost sharing, or similar charge that otherwise would be due from the Indian.

[43 FR 45253, Sept. 29, 1978, as amended at 75 FR 30262, May 28, 2010]

§ 447.58 Payments to prepaid capitation organizations.

If the agency contracts with a prepaid capitation organization that does not impose the agency's deductibles, coinsurance, co-payments or similar charges on its recipient members, the plan must provide that the agency calculates its payments to the organization as if those cost sharing charges were collected.

[48 FR 5736, Jan. 8, 1983, as amended at 67 FR 41116, June 14, 2002]

FEDERAL FINANCIAL PARTICIPATION

§ 447.59 FFP: Conditions relating to cost sharing.

No FFP in the State's expenditures for services is available for—

(a) Any cost sharing amounts that recipients should have paid as enrollment fees, premiums, deductibles, coinsurance, copayments, or similar charges under §§ 447.50 through 447.58 (except for amounts that the agency pays as bad debts of providers under § 447.57); and

(b) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium or enrollment fee.

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through

447.58 for cost-sharing charges imposed by the State agency.

[67 FR 41116, June 14, 2002]

ALTERNATIVE PREMIUMS AND COST SHARING UNDER SECTION 1916A

SOURCE: 73 FR 71851, Nov. 25, 2008, unless otherwise noted.

§ 447.62 Alternative premiums and cost sharing: Basis, purpose and scope.

(a) Section 1916A of the Act sets forth options for a State through a Medicaid State plan amendment to impose alternative premiums and cost sharing, which are premiums and cost sharing that are not subject to the limitations under section 1916 of the Act as described in §§ 447.51 through 447.56. For States that impose alternative premiums or cost sharing, § 447.64, § 447.66, § 447.68, § 447.70, § 447.71, § 447.72, § 447.74, § 447.76, § 447.78, § 447.80, and § 447.82 prescribe State plan requirements and options for alternative premiums and cost sharing for a group or groups of individuals (as specified by the State) for services or items (as specified by the State) and the standards and conditions under which States may impose them. The State may vary the premiums and cost sharing among groups of individuals or types of services or items, consistent with the limitations specified in this subpart and section 1916A(a)(1) of the Social Security Act. Otherwise, premiums and cost sharing must comply with the requirements described in § 447.50 through § 447.60.

(b) Waivers of the limitations described in this subpart on deductions, cost sharing, and similar charges may be granted only in accordance with the provisions of section 1916(f) of the Act.

[75 FR 30262, May 28, 2010]

§ 447.64 Alternative premiums, enrollment fees, or similar fees: State plan requirements.

When a State imposes alternative premiums, enrollment fees, or similar fees on individuals, the State plan must describe the following:

(a) The group or groups of individuals that may be subject to the premiums, enrollment fees, or similar charges.

(b) The schedule of the premiums, enrollment fees, or similar fees imposed.

(c) The methodology used to determine family income for purposes of the limitations on premiums related to family income level that are described in § 447.78(c) of this chapter, including the period and periodicity of those determinations.

(d) The methodology used by the State to:

(1) Identify beneficiaries who are subject to premiums or cost sharing for specific items or services; and

(2) If the State adopts cost sharing rules that could place families at risk of reaching the total aggregate limit for premiums and cost sharing under Medicaid, defined at § 447.78, track beneficiaries' incurred premiums and cost sharing through a mechanism developed by the State that does not rely on beneficiaries, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have incurred family out-of-pocket expenses up to that limit and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period.

(e) The process for informing the recipients, applicants, providers, and the public of the schedule of premiums, enrollment fees, or similar fees for a group or groups of individuals in accordance with § 447.76.

(f) The notice of, time frame for, and manner of required premium payments for a group or groups of individuals and the consequences for an individual who does not pay.

[73 FR 71851, Nov. 25, 2008, as amended at 75 FR 30262, May 28, 2010]

§ 447.66 General alternative premium protections.

(a) States may not impose alternative premiums upon the following individuals:

(1) Individuals under 18 years of age that are required to be provided medical assistance under section 1902(a)(10)(A)(i) of the Act, and including individuals with respect to whom child welfare services are made available under Part B of title IV of the Act on the basis of being a child in foster

care and individuals with respect to whom adoption or foster care assistance is made available under Part E of that title, without regard to age.

(2) Pregnant women.

(3) Any terminally ill individual receiving hospice care, as defined in section 1905(o) of the Act.

(4) Any individual who is an inpatient in a hospital, nursing facility, intermediate care facility, or other medical institution, if the individual is required, as a condition of receiving services in that institution under the State plan, to spend for costs of medical care all but a minimal amount of the individual's income required for personal needs.

(5) Women who are receiving Medicaid on the basis of the breast or cervical cancer eligibility group under sections 1902(a)(10)(A)(ii)(XVIII) and 1902(aa) of the Act.

(6) Disabled children who are receiving medical assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(7) An Indian who is eligible to receive or has received an item or service furnished by an Indian health care provider or through referral under contract health services.

(b) States may exempt additional classes of individuals from premiums.

(c) Nothing in this subsection shall be construed as restricting the application of any other limitations on the imposition of premiums that may apply to an individual receiving Medicaid who is an Indian.

[73 FR 71851, Nov. 25, 2008, as amended at 75 FR 30262, May 28, 2010]

§ 447.68 Alternative copayments, coinsurance, deductibles, or similar cost sharing charges: State plan requirements.

When a State imposes alternative copayments, coinsurance, deductibles, or similar cost sharing charges on individuals, the State plan must describe the following:

(a) The group or groups of individuals that may be subject to the cost sharing charge.

(b) The methodology used to determine family income, for purposes of the limitations on cost sharing related to family income level that are described in § 447.78(c) of this chapter, including the period and periodicity of those determinations.

(c) The schedule of the copayments, coinsurance, deductibles, or similar cost sharing charges imposed for each item or service for which a charge is imposed.

(d) The methodology used by the State to identify beneficiaries who are subject to premiums or cost sharing for specific items or services and, if families are at risk of reaching the total aggregate limit for premiums and cost sharing under Medicaid defined at § 447.78, track beneficiaries' incurred premiums and cost sharing through a mechanism developed by the State that does not rely on beneficiaries, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have incurred family out-of-pocket expenses up to that limit and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period.

(e) The process for informing recipients, applicants, providers, and the public of the schedule of cost sharing charges for specific items and services for a group or groups of individuals in accordance with § 447.76.

(f) The methodology used to ensure that:

(1) The aggregate amount of premiums and cost sharing imposed under section 1916 and section 1916A of the Act for all individuals in the family enrolled in Medicaid with family income above 100 percent of the Federal poverty level (FPL) does not exceed 5 percent of the family's income of the family involved.

(2) The aggregate amount of cost sharing imposed under section 1916 and section 1916A of the Act for all individuals in the family enrolled in Medicaid with family income at or below 100 percent of the FPL does not exceed 5 percent of the family's income of the family involved.

(g) The notice of, time frame for, and manner of required cost sharing and the consequences for failure to *pay*.

[73 FR 71851, Nov. 25, 2008, as amended at 75 FR 30262, May 28, 2010]

§ 447.70 General alternative cost sharing protections.

(a) States may not impose alternative cost sharing for the following items or services. Except as indicated, these limits do not apply to alternative cost sharing for prescription drugs identified by a State's Medicaid program as non-preferred within a class of such drugs or for non-emergency use of the emergency room.

(1) Services furnished to individuals under 18 years of age who are required to be provided Medicaid under section 1902(a)(10)(A)(i) of the Act, including services furnished to individuals with respect to whom child welfare services are being made available under Part B of title IV of the Act on the basis of being a child in foster care and individuals with respect to whom adoption or foster care assistance is made available under Part E of that title, without regard to age.

(2) Preventive services, at a minimum the services specified at § 457.520, provided to children under 18 years of age regardless of family income, which reflect the well baby and well child care and immunizations in the Bright Futures guidelines issued by the American Academy of Pediatrics.

(3) Services furnished to pregnant women, if those services relate to the pregnancy or to any other medical condition which may complicate the pregnancy.

(4) Services furnished to a terminally ill individual who is receiving hospice care (as defined in section 1905(o) of the Act).

(5) Services furnished to any individual who is an inpatient in a hospital, nursing facility, intermediate care facility for the mentally retarded, or other medical institution, if the individual is required, as a condition of receiving services in that institution under the State plan, to spend for costs of medical care all but a minimal amount of the individual's income required for personal needs.

(6) Emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a), except charges for services furnished after the hospital has determined, based on the screening and any other services required under § 489.24 of this chapter, that the individual does not need emergency services consistent with the requirements of paragraph (b) of this section.

(7) Family planning services and supplies described in section 1905(a)(4)(C) of the Act, including contraceptives and other pharmaceuticals for which the State claims or could claim Federal match at the enhanced rate under section 1903(a)(5) of the Act for family planning services and supplies.

(8) Services furnished to women who are receiving medical assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XVIII) and 1902(aa) of the Act (breast or cervical cancer provisions).

(9) Services furnished to disabled children who are receiving medical assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act, in accordance with the Family Opportunity Act.

(10) Items and services furnished to an Indian directly by an Indian health care provider or through referral under contract health services.

(11) Preferred drugs within a class, or drugs not identified by the State's Medicaid program as a non-preferred drug within a class, for individuals for whom cost sharing may not otherwise be imposed as described in paragraphs (a)(1) through (10) of this section.

(b) For the exempt populations specified in paragraph (a) of this section, a State may impose nominal cost sharing as defined in § 447.54 of this chapter for services furnished in a hospital emergency department, other than those required under § 489.24, if the hospital has determined based on the medical screening required under § 489.24 that the individual does not need emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a), the requirements of § 447.80(b)(1) are met, and the services are available in a timely manner without cost sharing through an outpatient department or another alternative non-emergency health care provider in the geographic area of the hospital emergency department involved.

(c) In the case of a drug that a State's Medicaid program either has identified as a preferred drug within a class or has not otherwise identified as a non-preferred drug within a class,

cost sharing may not exceed the nominal levels permitted under section 1916 of the Act as specified in § 447.54 of this chapter. Cost sharing can be imposed that exceeds the nominal levels permitted under section 1916 of the Act for drugs that are identified by a State's Medicaid program as non-preferred drugs within a class in accordance with section 1916A(c) of the Act.

(d) In the case of a drug that is identified by a State's Medicaid program as a non-preferred drug within a class, the cost sharing is limited to the amount imposed for a preferred drug if the individual's prescribing physician determines that the preferred drug for treatment of the same condition either would be less effective for the individual or would have adverse effects for the individual or both.

(e) States may exempt additional individuals, items, or services from cost sharing.

[75 FR 30263, May 28, 2010]

§ 447.71 Alternative premium and cost sharing exemptions and protections for individuals with family incomes at or below 100 percent of the FPL.

(a) The State may not impose premiums under the State plan on individuals whose family income is at or below 100 percent of the FPL.

(b) The State may not impose cost sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL, with the following exceptions:

(1) The State may impose cost sharing under authority provided under section 1916 of the Act and consistent with the levels described in such section and § 447.54.

(2) The State may impose cost sharing for non-preferred drugs that does not exceed the nominal amount as defined in § 447.54.

(3) The State may impose cost sharing for non-emergency services furnished in a hospital emergency department that does not exceed the nominal amount as defined in § 447.54 as long as the services are available in a timely manner without cost sharing through an outpatient department or other alternative non-emergency services health care provider in the geographic area of the hospital emergency department involved.

(c) Aggregate cost sharing under sections 1916 and 1916A of the Act for all individuals in the family enrolled in Medicaid may not exceed the maximum permitted under § 447.78(b).

(d) The State may not impose alternative premiums and cost sharing in accordance with section 1916A of the Act on individuals whose family income is at or below 100 percent of the FPL, but may impose cost sharing that does not exceed the nominal amount as defined at § 447.54 and section 1916 of the Act.

[73 FR 71851, Nov. 25, 2008, as amended at 75 FR 30264, May 28, 2010]

§ 447.72 Alternative premium and cost sharing exemptions and protections for individuals with family incomes above 100 percent but at or below 150 percent of the FPL.

(a) The State may not impose premiums under the State plan on individuals whose family income exceeds 100 percent, but does not exceed 150 percent, of the FPL.

(b) Cost sharing may be imposed under the State plan for individuals whose family income exceeds 100 percent, but does not exceed 150 percent, of the FPL if the cost sharing does not exceed 10 percent of the payment the agency makes for the item or service, with the following exceptions:

(1) Cost sharing for non-preferred drugs cannot exceed the nominal amount as defined in § 447.54.

(2) Cost sharing for non-emergency services furnished in the hospital emergency department cannot exceed twice the nominal amount as defined in § 447.54. A hospital must meet the requirements described at § 447.80(b)(2) before the cost sharing can be imposed.

(3) In the case of States that do not have fee-for-service payment rates, any copayment that the State imposes for services provided by an MCO to a Medicaid beneficiary, including a child covered under a Medicaid expansion program for whom enhanced match is claimed under title XXI of the Act, may not exceed $3.40 per visit for Federal FY 2009. Thereafter, any copayment may not exceed this amount as

updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 5-cent increment.

(c) Aggregate cost sharing under sections 1916 and 1916A of the Act for all individuals in the family enrolled in Medicaid may not exceed the maximum permitted under § 447.78(a).

[73 FR 71851, Nov. 25, 2008, as amended at 75 FR 30264, May 28, 2010]

§ 447.74 Alternative premium and cost sharing protections for individuals with family incomes above 150 percent of the FPL.

(a) States may impose premiums under the State plan consistent with the aggregate limits set forth in § 447.78(a) on individuals whose family income exceeds 150 percent of the FPL.

(b) Cost sharing may be imposed under the State plan on individuals whose family income exceeds 150 percent of the FPL if the cost sharing does not exceed 20 percent of the payment the agency makes for the item or service (including a non-preferred drug but not including non-emergency services furnished in a hospital emergency department), with the following exception: In the case of States that do not have fee-for-service payment rates, any copayment that the State imposes for services provided by an MCO to a Medicaid beneficiary, including a child covered under a Medicaid expansion program for whom enhanced match is claimed under title XXI of the Act, may not exceed $3.40 per visit for Federal FY 2009. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 5-cent increment.

(c) Aggregate premiums and cost sharing under sections 1916 and 1916A of the Act for all individuals in the family enrolled in Medicaid may not exceed the maximum permitted under § 447.78(a).

[75 FR 30264, May 28, 2010, as amended at 75 FR 38749, July 1, 2010]

§ 447.76 Public schedule.

(a) The State must make available to the groups in paragraph (b) of this section a public schedule that contains the following information:

(1) Current premiums, enrollment fees, or similar fees.

(2) Current cost sharing charges.

(3) The aggregate limit on premiums and cost sharing or just cost sharing.

(4) Mechanisms for making payments for required premiums and charges.

(5) The consequences for an applicant or recipient who does not pay a premium or charge.

(6) A list of hospitals charging alternative cost sharing for non-emergency use of the emergency department.

(7) Either a list of preferred drugs or a method to obtain such a list upon request.

(b) The State must make the public schedule available to the following:

(1) Beneficiaries, at the time of their enrollment and reenrollment after a redetermination of eligibility, and when premiums, cost sharing charges, or aggregate limits are revised.

(2) Applicants, at the time of application.

(3) All participating providers.

(4) The general public.

(c) Prior to submitting to the Centers for Medicare & Medicaid Services for approval a State plan amendment (SPA) to establish alternative premiums or cost sharing under section 1916A of the Act or an amendment to modify substantially an existing plan for alternative premiums or cost sharing, the State must provide the public with advance notice of the amendment and reasonable opportunity to comment with respect to such amendment in a form and manner provided under applicable State law, and must submit documentation with the SPA to demonstrate that this requirement was met.

[73 FR 71851, Nov. 25, 2008, as amended at 75 FR 30264, May 28, 2010]

§ 447.78 Aggregate limits on alternative premiums and cost sharing.

(a) The total aggregate amount of premiums and cost sharing imposed under sections 1916 and 1916A of the Act for all individuals in a family enrolled in Medicaid with family income above 100 percent of the FPL may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified by the State in the State plan.

(b) The total aggregate amount of cost sharing imposed under sections 1916 and 1916A of the Act for all individuals in a family enrolled in Medicaid with family income at or below 100 percent of the FPL may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified by the State in the State plan.

(c) Family income shall be determined in a manner, for such period, and at such periodicity as specified by the State in the State plan, including the use of such disregards as the State may provide and the process for individuals to request a reassessment of the family's aggregate limit if the family's income is reduced or if eligibility is being terminated due to nonpayment of a premium.

(1) States may use gross income or any other methodology.

(2) States may use a different methodology for determining the family's income to which the 5 percent aggregate limit is applied than is used for determining income eligibility.

[75 FR 30264, May 28, 2010]

§ 447.80 Enforceability of alternative premiums and cost sharing.

(a) With respect to alternative premiums, a State may do the following:

(1) Require a group or groups of individuals to prepay.

(2) Terminate an individual from medical assistance on the basis of failure to pay for 60 days or more.

(3) Waive payment of a premium in any case where the State determines that requiring the payment would create an undue hardship for the individual.

(b) With respect to alternative cost sharing, a State may amend its Medicaid State plan to permit a provider, including a pharmacy or hospital, to require an individual, as a condition for receiving the item or service, to pay the cost sharing charge, except as specified in paragraphs (b)(1) through (3) of this section.

(1) A provider, including a pharmacy and a hospital, may not require an individual whose family income is at or below 100 percent of the FPL to pay the cost sharing charge as a condition of receiving the service.

(2) A hospital that has determined after an appropriate medical screening pursuant to § 489.24 of this chapter, that an individual does not need emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a), before providing treatment and imposing alternative cost sharing on an individual in accordance with § 447.72(b)(2) and § 447.74(b) of this chapter for non-emergency services as defined in section 1916A(e)(4)(A) of the Act, must provide:

(i) The name and location of an available and accessible alternate non-emergency services provider, as defined in section 1916A(e)(4)(B) of the Act.

(ii) Information that the alternate provider can provide the services in a timely manner with the imposition of a lesser cost sharing amount or no cost sharing.

(iii) A referral to coordinate scheduling of treatment by this provider.

(3) The provider is not prohibited by this authority from choosing to reduce or waive cost sharing on a case-by-case basis.

(c) Nothing in paragraph (b)(2) of this section shall be construed to:

(1) Limit a hospital's obligations with respect to screening and stabilizing treatment of an emergency medical condition under section 1867 of the Act; or

(2) Modify any obligations under either State or Federal standards relating to the application of a prudent-layperson standard with respect to payment or coverage of emergency medical services by any managed care organization.

[73 FR 71851, Nov. 25, 2008, as amended at 75 FR 30265, May 28, 2010]

§ 447.82 Restrictions on payments to providers.

(a) The plan must provide that the State Medicaid agency reduces the

payment it makes to a provider by the amount of a beneficiary's cost sharing obligation, regardless of whether the provider successfully collects the cost sharing.

(b) Payment that is due under Medicaid to an Indian health care provider or a health care provider through referral under contract health services for directly furnishing an item or service to an Indian may not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deductible, copayment, cost sharing, or similar charge that otherwise would be due.

(c) The plan must describe how the State identifies for providers, ideally through the use of the automated systems, whether cost sharing for a specific item or service may be imposed on an individual beneficiary and whether the provider may require the beneficiary, as a condition for receiving the item or service, to pay the cost sharing charge.

[75 FR 30265, May 28, 2010]

ALTERNATIVE PREMIUMS AND COST SHARING UNDER SECTION 1916A

§ 447.88 Options for claiming FFP payment for section 1920A presumptive eligibility medical assistance payments.

(a) The FMAP rate for medical assistance payments made available to a child during a presumptive eligibility period under section 1920A of the Act is the regular FMAP under title XIX, based on the category of medical assistance; that is, the enhanced FMAP is not available for section 1920A presumptive eligibility expenditures.

(b) States have the following 3 options for identifying Medicaid section 1920A presumptive eligibility expenditures and the application of payments for those expenditures:

(1) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended with no further adjustment based on the results of a subsequent actual eligibility determination (if any).

(2) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended but may adjust reported expenditures based on results of the actual eligibility determination (if any) to reflect the actual eligibility status of the individual, if other than presumptively eligible.

(3) A State may elect to delay submission of claims for payments of section 1920A presumptive eligibility expenditures until after the actual eligibility determination (if any) is made and, at that time identify such expenditures based on the actual eligibility status of individuals if other than presumptively eligible. At that time, the State would, as appropriate, recategorize the medical assistance expenditures made during the section 1920A presumptive eligibility period based on the results of the actual eligibility determination, and claim them appropriately.

[65 FR 33622, May 24, 2000]

Subpart B—Payment Methods: General Provisions

§ 447.200 Basis and purpose.

This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the Act, which requires that payments for services be consistent with efficiency, economy, and quality of care.

[46 FR 48560, Oct. 1, 1981]

§ 447.201 State plan requirements.

(a) A State plan must provide that the requirements in this subpart are met.

(b) The plan must describe the policy and the methods to be used in setting payment rates for each type of service included in the State's Medicaid program.

§ 447.202 Audits.

The Medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials.

§ 447.203 Documentation of payment rates.

(a) The agency must maintain documentation of payment rates and make it available to HHS upon request.

(b) The agency must record, in State manuals or other official files, the following information for increases in payment rates for individual practitioner services:

(1) An estimate of the percentile of the range of customary charges to which the revised payment structure equates and a description of the methods used to make the estimate.

(2) An estimate of the composite average percentage increase of the revised payment rates over the preceding rates.

§ 447.204 Encouragement of provider participation.

The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.

§ 447.205 Public notice of changes in Statewide methods and standards for setting payment rates.

(a) *When notice is required.* Except as specified in paragraph (b) of this section, the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services.

(b) *When notice is not required.* Notice is not required if—

(1) The change is being made to conform to Medicare methods or levels of reimbursement;

(2) The change is required by court order; or

(3) The change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost plus a professional fee.

(c) *Content of notice.* The notice must—

(1) Describe the proposed change in methods and standards;

(2) Give an estimate of any expected increase or decrease in annual aggregate expenditures;

(3) Explain why the agency is changing its methods and standards;

(4) Identify a local agency in each county (such as the social services agency or health department) where copies of the proposed changes are available for public review;

(5) Give an address where written comments may be sent and reviewed by the public; and

(6) If there are public hearings, give the location, date and time for hearings or tell how this information may be obtained.

(d) *Publication of notice.* The notice must—

(1) Be published before the proposed effective date of the change; and

(2) Appear as a public announcement in one of the following publications:

(i) A State register similar to the FEDERAL REGISTER.

(ii) The newspaper of widest circulation in each city with a population of 50,000 or more.

(iii) The newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more.

[46 FR 58680, Dec. 3, 1981; 47 FR 8567, Mar. 1, 1982, as amended at 48 FR 56057, Dec. 19, 1983]

§ 447.206 Cost limit for providers operated by units of government.

(a) *Scope.* This section applies to payments made to health care providers that are operated by units of government as defined in § 433.50(a)(1) of this chapter.

(b) *Exceptions.* The limitation in paragraph (c) of this section does not apply to:

(1) Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638);

(2) Managed Care Organizations (MCOs), Prepaid Inpatient

Health Plans (PIHPs), and Prepaid Ambulatory Health Plans (PAHPs) which are organized and operating in accordance with the provisions of 42 CFR 438;

(3) Federally Qualified Health Centers (FQHCs) and Rural

Health Clinics (RHCs) reimbursed in accordance with Section 1902(bb) of the Act; and

(4) *Disproportionate share hospital payments.* The limitation in paragraph (c) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided

in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(a) *General rules.* (1) All health care providers that are operated by units of government are limited to reimbursement not in excess of the individual health care provider's cost of providing covered Medicaid services to eligible Medicaid recipients.

(2) Reasonable methods of identifying and allocating costs to Medicaid will be determined by the Secretary in accordance with sections 1902, 1903, and 1905 of the Act, as well as 45 CFR 92.22 and Medicare cost principles when applicable.

(3) Institutional governmentally-operated health care providers (i.e., hospitals, nursing facilities, and ICFs/MR) are required to provide the State with data extracted from primary source documents as well as copies of the source documents. These source documents would include the health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles, and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information System (MMIS).

(4) Medicaid costs for non-institutional governmentally-operated health care providers must be supported by auditable documentation in a form approved by the Secretary that is consistent with § 433.51(b)(1) through (b)(4) of this chapter.

(d) *Use of certified public expenditures.* This paragraph applies when States use a cost reimbursement methodology funded by certified public expenditures.

(1) In accordance with paragraph (c) of this section, each provider must submit annually a cost report to the Medicaid agency that reflects the individual provider's cost of serving Medicaid recipients during the year.

(2) States may utilize most recently filed cost reports to develop interim rates and may trend those interim rates by an applicable health care-related index. Interim reconciliations must be performed by reconciling the interim Medicaid payment rates to the filed cost report for the spending year in which interim payment rates were made.

(3) Final reconciliation must be performed annually by reconciling any interim payments to the finalized cost report for the spending year in which any interim payment rates were made.

(4) Non-institutional governmentally-operated health care providers must utilize a cost report, approved by the Secretary, beginning in their Medicaid State plan rate year 2009. Interim rates set by States for purposes of Medicaid payments funded by certified public expenditures in Medicaid State plan rate year 2009 must be calculated based on cost data from at least one quarter of their Medicaid State plan rate year 2008 documented in accordance with the cost report approved by the Secretary. Existing certified public expenditure methodologies can be used to make Medicaid payments during Medicaid State plan rate year 2008.

(e) *Payments not funded by certified public expenditures.* This paragraph applies to payments made to providers operated by units of government that are not funded by certified public expenditures. In accordance with paragraph (c) of this section, each provider must submit annually a cost report to the Medicaid agency that reflects the individual provider's cost of serving Medicaid recipients during the year. The Medicaid agency must review the cost report to determine that costs on the report were properly allocated to Medicaid and verify that Medicaid payments to the provider during the year did not exceed the provider's cost.

(f) *Overpayments.* If, under paragraph (d) or (e) of this section, it is determined that a governmentally-operated health care provider received an overpayment, amounts related to the overpayment will be properly credited to

the Federal government, in accordance with part 433, subpart F of this chapter.

(g) *Compliance dates.* Initial compliance dates have been separately established for institutional and non-institutional Medicaid providers operated by units of government. Following initial compliance dates, ongoing compliance will be consistent for all providers operated by units of government. A State must comply with the Medicaid cost limit described in paragraph (c) of this section in accordance with the timeframes and requirements in paragraphs (g)(1) through (g)(3) of this section.

(1) *Initial Compliance for Institutional Govermentally-Operated Health Care Providers.* For each State, compliance with the Medicaid cost limit described in paragraph (c) of this section applicable to institutional governmentally-operated health care providers begins with the Medicaid State plan rate year 2008. A State's review of Medicaid payments made to institutional governmentally-operated health care providers to ensure compliance with the Medicaid cost limit during Medicaid State plan rate year 2008 must be completed no later than the last day of federal fiscal year 2010 (September 30, 2010). The State must submit to CMS a summary report of the findings of this review by the last day of calendar year of 2010 (December 31, 2010). For any cost reports that are not finalized, the State should use the ''as filed'' cost report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

(2) *Initial Compliance for Non-Institutional Governmentally-Operated Health Care Providers.* For each State, compliance with the cost limit described in paragraph (c) of this section applicable to non-institutional governmentally-operated health care providers begins with the Medicaid State plan rate year 2009. A State's review of Medicaid payments made to non-institutional governmentally-operated health care providers to ensure compliance with the Medicaid cost limit during Medicaid State plan rate year 2009 must be completed no later than the last day of federal fiscal year 2011 (September 30, 2011). The State must submit to CMS a summary report of the findings of this review by the last day of calendar year of 2011 (December 31, 2011).

(3) *Ongoing Compliance for Institutional and Non-Institutional Governmentally-Operated Health Care Providers.* Each subsequent State review of Medicaid payments made to governmentally-operated health care providers, after the Medicaid State plan rate years identified in paragraphs (g)(1) and (g)(2) of this section, must be performed annually and completed by the last day of the federal fiscal year ending two years from the Medicaid State plan rate year under review. Each State must submit a summary report to CMS demonstrating the results of the State's review of Medicaid payments to ensure compliance with the Medicaid cost limit applicable to governmentally-operated health care providers by the last day of the calendar year ending two years from the Medicaid State Plan rate year under review.

(i) For any cost reports that are not finalized at the time the State performs the review of Medicaid payments to institutional governmentally-operated health care providers, the State should use the ''as filed'' cost report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

[72 FR 29833, May 29, 2007]

§ 447.207 Retention of payments.

(a) Payment methodologies must permit the provider to receive and retain the full amount of the total computable payment for services furnished under the approved State plan (or the approved provisions of a waiver or demonstration if applicable). The Secretary will determine compliance with this provision by examining any associated transactions that are related to the provider's total computable payment to ensure that the State's claimed expenditure, which serves as the basis for Federal Financial Participation, is equal to the State's net expenditure, and that the full amount of the non-Federal share of the payment has been satisfied.

(b) *Exceptions.* Provisions of paragraph (a) of this section specifically do not pertain to:

(1) Use of Medicaid revenues to fund payments that are normal operating expenses of conducting business, such as payments related to taxes (including permissible health-care related taxes), fees, or business relationships with governments unrelated to Medicaid in which there is no connection to Medicaid payment.

(2) Payments authorized by Sections 701(d) and 705 of the Benefits Improvement Act of 2000 (BIPA).

[72 FR 29834, May 29, 2007]

Subpart C—Payment for Inpatient Hospital and Long-Term Care Facility Services

SOURCE: 46 FR 47971, Sept. 30, 1981, unless otherwise noted.

§ 447.250 Basis and purpose.

(a) This subpart implements section 1902(a)(13)(A) of the Act, which requires that the State plan provide for payment for hospital and long-term care facility services through the use of rates that the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated facilities to provide services in conformity with State and Federal laws, regulations, and quality and safety standards.

(b) Section 447.253(a)(2) implements section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care;

(c) Sections 447.253 (c) and (d) implement sections 1902(a)(13)(B) and 1902(a)(13)(C) of the Act, which require a State Medicaid agency to make certain assurances to the Secretary regarding increases in payments resulting solely from changes in ownerships of hospitals, NFs, and ICFs/MR.

(d) Section 447.271 implements section 1903(i)(3) of the Act, which requires that payments for inpatient hospital services not exceed the hospital's customary charges.

(e) Section 447.280 implements section 1913(b) of the Act, which concerns reimbursement for long-term care services furnished by swing-bed hospitals.

[48 FR 56057, Dec. 19, 1983, as amended at 57 FR 43921, Sept. 23, 1992]

PAYMENT RATES

§ 447.251 Definitions.

For the purposes of this subpart—

Long-term care facility services means intermediate care facility services for the mentally retarded (ICF/MR) and nursing facility (NF) services.

Provider means an institution that furnishes inpatient hospital services or an institution that furnishes long-term care facility services.

[46 FR 47971, Sept. 30, 1981, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991]

§ 447.252 State plan requirements.

(a) The plan must provide that the requirements of this subpart are met.

(b) The plan must specify comprehensively the methods and standards used by the agency to set payment rates in a manner consistent with § 430.10 of this chapter.

(c) If the agency chooses to apply the cost limits established under Medicare (see § 413.30 of this chapter) on an individual provider basis, the plan must specify this requirement.

(Approved by the Office of Management and Budget under control number 0938–0193)

[48 FR 56058, Dec. 19, 1983, as amended at 51 FR 34833, Sept. 30, 1986]

§ 447.253 Other requirements.

(a) *State assurances.* In order to receive CMS approval of a State plan change in payment methods and standards, the Medicaid agency must make assurances satisfactory to CMS that the requirements set forth in paragraphs (b) through (i) of this section are being met, must submit the related information required by § 447.255 of this subpart, and must comply with all other requirements of this subpart.

(b) *Findings.* Whenever the Medicaid agency makes a change in its methods and standards, but not less often than annually, the agency must make the following findings:

(1) *Payment rates.* (i) The Medicaid agency pays for inpatient hospital services and long-term care facility services through the use of rates that are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations, and quality and safety standards.

(ii) With respect to inpatient hospital services—

(A) The methods and standards used to determine payment rates take into account the situation of hospitals which serve a disproportionate number of low income patients with special needs;

(B) If a State elects in its State plan to cover inappropriate level of care services (that is, services furnished to hospital inpatients who require a lower covered level of care such as skilled nursing or intermediate care services) under conditions similar to those described in section 1861(v)(1)(G) of the Act, the methods and standards used to determine payment rates must specify that the payments for this type of care must be made at rates lower than those for inpatient hospital level of care services, reflecting the level of care actually received, in a manner consistent with section 1861(v)(1)(G) of the Act; and

(C) The payment rates are adequate to assure that recipients have reasonable access, taking into account geographic location and reasonable travel time, to inpatient hospital services of adequate quality.

(iii) With respect to nursing facility services—

(A) Except for preadmission screening for individuals with mental illness and mental retardation under § 483.20(f) of this Chapter, the methods and standards used to determine payment rates take into account the costs of complying with the requirements of part 483 subpart B of this chapter;

(B) The methods and standards used to determine payment rates provide for an appropriate reduction to take into account the lower costs (if any) of the facility for nursing care under a waiver of the requirement in § 483.30(c) of this Chapter to provide licensed nurses on a 24-hour basis;

(C) The State establishes procedures under which the data and methodology used in establishing payment rates are made available to the public.

(2) *Upper payment limits.* The agency's proposed payment rate will not exceed the upper payment limits as specified in § 447.272.

(c) *Changes in ownership of hospitals.* In determining payment when there has been a sale or transfer of the assets of a hospital, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate solely as a result of changes of ownership, more than the payments would increase under Medicare under §§ 413.130, 413.134, 413.153, and 413.157 of this chapter, insofar as these sections affect payments for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(d) *Changes in ownership of NFs and ICFs/MR.* In determining payment when there has been a sale or transfer of assets of an NF or ICF/MR, the State's methods and standards must provide the following depending upon the date of the transfer.

(1) For transfers on or after July 18, 1984 but before October 1, 1985, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate, solely as the result of a change in ownership, more than payments would increase under Medicare under §§ 413.130, 413.134, 413.153 and 413.157 of this chapter, insofar as these sections affect payment for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(2) For transfers on or after October 1, 1985, the State's methods and standards must provide that the valuation of capital assets for purposes of determining payment rates for NFs and ICFs/MR is not to increase (as measured from the date of acquisition by the seller to the date of the change of

ownership) solely as a result of a change of ownership, by more than the lesser of—

(i) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership, or, if necessary, as extrapolated retrospectively by the Secretary) in the Dodge construction index applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year; or

(ii) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership) in the Consumer Price Index for All Urban Consumers (CPI-U) (United States city average) applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year.

(e) *Provider appeals.* The Medicaid agency must provide an appeals or exception procedure that allows individual providers an opportunity to submit additional evidence and receive prompt administrative review, with respect to such issues as the agency determines appropriate, of payment rates.

(f) *Uniform cost reporting.* The Medicaid agency must provide for the filing of uniform cost reports by each participating provider.

(g) *Audit requirements.* The Medicaid agency must provide for periodic audits of the financial and statistical records of participating providers.

(h) *Public notice.* The Medicaid agency must provide that it has complied with the public notice requirements in § 447.205 of this part when it is proposing significant changes to its methods or standards for setting payment rates for inpatient hospital or LTC facility services.

(i) *Rates paid.* The Medicaid agency must pay for inpatient hospital and long term care services using rates determined in accordance with methods and standards specified in an approved State plan.

[48 FR 56057, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987; 54 FR 5359, Feb. 2, 1989; 57 FR 43921, Sept. 23, 1992]

§ 447.255 Related information.

The Medicaid agency must submit, with the assurances described in § 447.253(a), the following information:

(a) The amount of the estimated average proposed payment rate for each type of provider (hospital, ICF/MR, or nursing facility), and the amount by which that estimated average rate increased or decreased relative to the average payment rate in effect for each type or provider for the immediately preceding rate period;

(b) An estimate of the short-term and, to the extent feasible, long-term effect the change in the estimated average rate will have on—

(1) The availability of services on a Statewide and geographic area basis;

(2) The type of care furnished;

(3) The extent of provider participation; and

(4) The degree to which costs are covered in hospitals that serve a disproportionate number of low income patients with special needs.

[48 FR 56058, Dec. 19, 1983, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991; 57 FR 43924, Sept. 23, 1992; 57 FR 46431, Oct. 8, 1992]

§ 447.256 Procedures for CMS action on assurances and State plan amendments.

(a) *Criteria for approval.* (1) CMS approval action on State plans and State plan amendments, is taken in accordance with subpart B of part 430 of this chapter and sections 1116, 1902(b) and 1915(f) of the Act.

(2) In the case of State plan and plan amendment changes in payment methods and standards, CMS bases its approval on the acceptability of the Medicaid agency's assurances that the requirements of § 447.253 have been met, and the State's compliance with the other requirements of this subpart.

(b) *Time limit.* CMS will send a notice to the agency of its determination as to whether the assurances regarding a State plan amendment are acceptable within 90 days of the date CMS receives the assurances described in § 447.253, and the related information described in § 447.255 of this subpart. If CMS does not send a notice to the agency of its determination within this time limit and the provisions in paragraph (a) of

this section are met, the assurances and/or the State plan amendment will be deemed accepted and approved.

(c) *Effective date.* A State plan amendment that is approved will become effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted in accordance with § 430.20 of this chapter and 447.253.

[48 FR 56058, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987]

FEDERAL FINANCIAL PARTICIPATION

§ 447.257 FFP: Conditions relating to institutional reimbursement.

FFP is not available for a State's expenditures for hospital inpatient or long-term care facility services that are in excess of the amounts allowable under this subpart.

[52 FR 28147, July 28, 1987]

UPPER LIMITS

§ 447.271 Upper limits based on customary charges.

(a) The agency may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(b) [Reserved]

[72 FR 29834, May 29, 2007]

§ 447.272 Inpatient services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for inpatient services furnished by hospitals, nursing facilities, and ICFs/MR within one of the following categories:

(1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities, that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) *General rules.* (1) For privately operated facilities, upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) For State government operated facilities and for non-State government operated facilities, upper payment limit refers to the individual health care provider's Medicaid cost as defined at § 447.206.

(3) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to the group of privately operated facilities described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(4) Except as provided in paragraph (c) of this section, Medicaid payments to State government operated facilities and non-State government operated facilities must not exceed the individual health care provider's Medicaid cost as documented in accordance with § 447.206.

(c) *Exceptions—(1) Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(3) The limitation in paragraph (b) of this section does not apply to payments authorized by Sections 701(d) and 705 of the Benefits Improvement Protection Act of 2000 (BIPA).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For State government operated and non-State government operated hospitals, nursing facilities and ICFs/MR '' Medicaid State plan rate year 2008.

(2) For all other facilities—March 13, 2001.

(e) *Transition periods*—(1) *Definitions.* For purposes of this paragraph, the following definitions apply:

(i) *Transition period* refers to the period of time beginning March 13, 2001 through the end of one of the schedules permitted under paragraph (e)(2)(ii) of this section.

(ii) *UPL* stands for the upper payment limit described in paragraph (b)(1) of this section for the referenced year.

(iii) *X* stands for the payments to a specific group of providers described in paragraphs (a)(2) and (a)(3) of this section in State FY 2000 that exceeded the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) *General rules.* (i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraphs (a)(2) and (a)(3) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following—

(*1*) For State FY 2003: State FY 2003 UPL + .75X.

(*2*) For State FY 2004: State FY 2004 UPL + .50X.

(*3*) For State FY 2005: State FY 2005 UPL + .25X.

(*4*) For State FY 2006; State FY 2006 UPL.

(C) For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:

(*1*) For State FY 2004: State FY 2004 UPL + .85X.

(*2*) For State FY 2005: State FY 2005 UPL + .70X.

(*3*) For State FY 2006: State FY 2006 UPL + .55X.

(*4*) For State FY 2007: State FY 2007 UPL + .40X.

(*5*) For State FY 2008: State FY 2008 UPL + .25X.

(*6*) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(*7*) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999, submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(*1*) through (e)(2)(ii)(C)(*7*) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(f) *Reporting requirements for payments during the transition periods.* States that

are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the upper payment limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

[66 FR 3175, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2610, Jan. 18, 2002; 72 FR 29834, May 29, 2007]

SWING-BED HOSPITALS

§ 447.280 Hospital providers of NF services (swing-bed hospitals).

(a) *General rule.* If the State plan provides for NF services furnished by a swing-bed hospital, as specified in §§ 440.40(a) and 440.150(f) of this chapter, the methods and standards used to determine payment rates for routine NF services must—

(1) Provide for payment at the average rate per patient day paid to NFs, as applicable, for routine services furnished during the previous calendar year; or

(2) Meet the State plan and payment requirements described in this subpart, as applicable.

(b) *Application of the rule.* The payment methodology used by a State to set payment rates for routine NF services must apply to all swing-bed hospitals in the State.

[59 FR 56237, Nov. 10, 1994]

Subpart D [Reserved]

Subpart E—Payment Adjustments for Hospitals That Serve a Disproportionate Number of Low-Income Patients

SOURCE: 57 FR 55143, Nov. 24, 1992, unless otherwise noted.

§ 447.296 Limitations on aggregate payments for disproportionate share hospitals for the period January 1, 1992 through September 30, 1992.

(a) The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) For the period January 1, 1992 through September 30, 1992, FFP is available for aggregate payments to hospitals that serve a disproprotionate number of low-income patients with special needs only if the payments are made in accordance with sections 1902(a)(13)(A) and 1923 of the Act, and with one of the following:

(1) An approved State plan in effect as of September 30, 1991.

(2) A State plan amendment submitted to CMS by September 30, 1991.

(3) A State plan amendment, or modification thereof, submitted to CMS between October 1, 1991 and November 26, 1991, if the amendment, or modification thereof, was intended to limit the State's definition of disproportionate share hospitals to those hospitals with Medicaid inpatient utilization rates or low-income utilization rates (as defined in section 1923 (b) of the Act) at or above the statewide arithmetic mean.

(4) A methodology for disproportionate share hospital payments that was established and in effect as of September 30, 1991, or in accordance with a State law enacted or State regulation adopted as of September 30, 1991.

(5) A State plan amendment submitted to CMS by September 30, 1992 that increases aggregate disproportionate share hospitals payments in order to meet the minimum payment adjustments required by section 1923(c)(1) of the Act. The minimum payment adjustment is the amount required by the Medicare methodology described in section 1923(c)(1) of the Act for those hospitals that satisfy the minimum Federal definition of a disproportionate share hospital in section 1923(b) of the Act.

(6) A State plan amendment submitted to CMS by September 30, 1992 that provides for a redistribution of

disproportionate share hospital payments within the State without raising total payments compared to the previously approved State plan. CMS will approve the amendment only if the State submits written documentation that demonstrates to CMS that the aggregate payments that will be made after the redistribution are no greater than those payments made before the redistribution.

(7) A State plan amendment submitted to CMS by September 30, 1992 that provides for a reduction in disproportionate share hospital payments.

§447.297 Limitations on aggregate payments for disproportionate share hospitals beginning October 1, 1992.

(a) *Applicability.* The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) *National payment target.* The national payment target for disproportionate share hospital (DSH) payments for any Federal fiscal year is equal to 12 percent of the total medical assistance expenditures that will be made during the Federal fiscal year under State plans, excluding administrative costs. A preliminary national expenditure target will be published by CMS prior to October 1 of each year. This preliminary national expenditure target will be superseded by a final national expenditure target published by April 1 of each Federal fiscal year, as specified in paragraph (d) of this section.

(c) *State disproportionate share hospital allotments.* Prior to October 1 of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER preliminary State DSH allotments for each State. These preliminary State DSH allotments will be determined using the most current applicable actual and estimated State expenditure information as reported to CMS and adjusted by CMS as may be necessary using the methodology described in §447.298. CMS will publish final State DSH allotments by April 1 of each Federal fiscal year, as described in paragraph (d) of this section.

(d) *Final national disproportionate share hospitals expenditure target and State disproportionate share hospitals allotments.* (1) CMS will revise the preliminary national expenditure target and the preliminary State DSH allotments by April 1 of each Federal fiscal year. The final national DSH expenditure target and State DSH allotments will be based on the most current applicable actual and estimated expenditure information reported to CMS and adjusted by CMS as may be necessary immediately prior to the April 1 publication date. The final national expenditure target and State DSH allotments will not be recalculated for that Federal fiscal year based upon any subsequent actual or estimated expenditure information reported to CMS.

(2) If CMS determines that at any time a State has exceeded its final DSH allotment for a Federal fiscal year, FFP attributable to the excess DSH expenditures will be disallowed.

(3) If a State's actual DSH expenditures applicable to a Federal fiscal year are less than its final State DSH allotment for that Federal fiscal year, the State is permitted, to the extent allowed by its approved State plan, to make additional DSH expenditures applicable to that Federal fiscal year up to the amount of its final DSH allotment for that Federal fiscal year.

(e) *Publication of limits.* (1) Before the beginning of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER—

(i) A preliminary national DSH expenditure target for the Federal fiscal year; and

(ii) A preliminary DSH allotment for each State for the Federal fiscal year.

(2) The final national DSH expenditure target and State DSH allotments will be published in the FEDERAL REGISTER by April 1 of each Federal fiscal year.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§447.298 State disproportionate share hospital allotments.

(a) *Calculation of State's base allotment for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate for each State a DSH allotment, using the State's ''base allotment.'' The

State's base allotment is the greater of:

(i) The total amount of the State's projected DSH payments for Federal fiscal year 1992 under the State plan applicable to Federal fiscal year 1992, calculated in accordance with paragraph (a)(2) of this section; or

(ii) $1,000,000.

(2) In calculating the State's DSH payments applicable to Federal fiscal year 1992, CMS will derive amounts from payments applicable to the period of October 1, 1991, through September 30, 1992, under State plans or plan amendments that meet the requirements specified in § 447.296(b). The calculation will not include—

(i) DSH payment adjustments made by the State applicable to the period October 1, 1991 through December 31, 1991 under State plans or plan amendments that do not meet the criteria described in § 447.296; and

(ii) Retroactive DSH payments made in 1992 that are not applicable to Federal fiscal year 1992.

(3) CMS will calculate a percentage for each State by dividing the DSH base allotment by the total unadjusted medical assistance expenditures, excluding administrative costs, made during Federal fiscal year 1992. On the basis of this percentage, CMS will classify each State as a ''high-DSH'' or ''low-DSH'' State.

(i) If the State's base allotment exceeded 12 percent of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a ''high-DSH'' State.

(ii) If the State's base allotment was 12 percent or less of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a ''low-DSH'' State.

(b) *State disproportionate share hospital allotments for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate a DSH allotment for each low-DSH State that equals the State's base allotment described under paragraph (a) of this section, increased by State growth, as specified in paragraph (d) of this section.

(2) For high-DSH States, the dollar amount of DSH payments in Federal fiscal year 1993 may not exceed the dollar amount of DSH payments applicable to Federal fiscal year 1992 (that is, the State base allotment).

(c) *State disproportionate share hospital allotment for Federal fiscal years 1994 and after.* For Federal fiscal years 1994 and after—

(1) For low-DSH States, CMS will calculate the DSH allotment for each Federal fiscal year by increasing the prior year's State DSHs allotment by—

(i) State growth, as specified in paragraph (d) of this section; and

(ii) A supplemental amount, if applicable, as described in paragraph (e) of this section.

(2) For high-DSH States, the dollar amount of DSH payments applicable to any Federal fiscal year may not exceed the dollar amount of payments applicable to Federal fiscal year 1992 (that is, the State base allotment). This payment limitation will apply until the Federal fiscal year in which the State's DSH payments applicable to that Federal fiscal year, expressed as a percentage of the State's total unadjusted medical assistance expenditures in that Federal fiscal year, equal 12 percent or less. When a high-DSH State's percentage equals 12 percent or less, the State will be reclassified as a low-DSH State.

(d) *State growth.* (1) The State growth for a State in a Federal fiscal year is equal to the product of—

(i) The growth factor that is CMS's projected percentage increase in the State's total unadjusted medical assistance expenditures (including administrative costs) relative to the corresponding amount in the previous year; and

(ii) The State's prior year DSH allotment.

(2) If the growth factor is zero or is negative, the State growth is zero.

(3) If a low-DSH State experiences a level of negative growth to the extent that its previous Federal fiscal year's DSH allotment would be more than 12 percent of its current Federal fiscal year's total unadjusted medical assistance expenditures (excluding administrative costs), the low-DSH State's previous year's DSH allotment will be reduced to the extent necessary to maintain the individual low-DSH State's 12-

percent limit and that amount will become the low-DSH State's DSH allotment for the current Federal fiscal year. In no Federal fiscal year will a low-DSH State's DSH allotment be allowed to exceed its individual State 12-percent limit.

(e) *Supplemental amount available for low-DSH States.*

(1) A supplemental amount is the State's share of a pool of money (referred to as a redistribution pool).

(2) CMS will calculate the redistribution pool for the appropriate Federal fiscal year by subtracting from the projected national DSH expenditure target the following:

(i) The total of the State DSH base allotments for all high-DSH States;

(ii) The total of the previous year's State DSH allotments for all low-DSH States;

(iii) The State growth amount for all low-DSH States; and

(iv) The total amount of additional DSH payment adjustments made in order to meet the minimum payment adjustments required under section 1923(c)(l) of the Act, which are made in accordance with §447.296(b)(5).

(3) CMS will determine the percent of the redistribution pool for each low-DSH State on the basis of each State's relative share of the total unadjusted medical assistance expenditures for the Federal fiscal year compared to the total unadjusted medical assistance expenditures for the Federal fiscal year projected to be made by all low-DSH States. The percent of the redistribution pool that each State will receive is equal to the State's total unadjusted medical assistance expenditures divided by the total unadjusted medical assistance expenditures for all low-DSH States.

(4) CMS will not provide any low-DSH State a supplemental amount that would result in the State's total DSH allotment exceeding 12 percent of its projected total unadjusted medical assistance expenditures. CMS will reallocate any supplemental amounts not allocated to States because of this 12-percent limitation to other low-DSH States in accordance with the percentage determined in paragraph (e)(3) of this section.

(5) CMS will not reallocate to low-DSH States the difference between any State's actual DSH expenditures applicable to a Federal fiscal year and its State DSH allotment applicable to that Federal fiscal year. Thus, any unspent DSH allotment may not be reallocated.

(f) *Special provision.* Any increases in a State's aggregate disproportionate payments, that are made to meet the minimum payment requirements specified in §447.296(b)(5), may exceed the State base allotment to the extent such increases are made to satisfy the minimum payment requirement. In such cases, CMS will adjust the State's base allotment in the subsequent Federal fiscal year to include the increased minimum payments.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§447.299 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993, each State must submit to CMS the quarterly aggregate amount of its disproportionate share hospital payments made to each individual public and private provider or facility. States' reports must present a complete, accurate, and full disclosure of all of their DSH programs and expenditures.

(b) Each State must report the aggregate information specified under paragraph (a) of this section on a quarterly basis in accordance with procedures established by CMS.

(c) Beginning with each State's Medicaid State plan rate year 2005, for each Medicaid State plan rate year, the State must submit to CMS, at the same time as it submits the completed audit required under §455.204, the following information for each DSH hospital to which the State made a DSH payment in order to permit verification of the appropriateness of such payments:

(1) *Hospital name.* The name of the hospital that received a DSH payment from the State, identifying facilities that are institutes for mental disease (IMDs) and facilities that are located out-of-state.

(2) *Estimate of hospital-specific DSH limit.* The State's estimate of eligible uncompensated care for the hospital receiving a DSH payment for the year

under audit based on the State's methodology for determining such limit.

(3) *Medicaid inpatient utilization rate.* The hospital's Medicaid inpatient utilization rate, as defined in Section 1923(b)(2) of the Act, if the State does not use alternative qualification criteria described in paragraph (c)(5) of this section.

(4) *Low income utilization rate.* The hospital's low income utilization rate, as defined in Section 1923(b)(3) of the Act if the State does not use alternative qualification criteria described in paragraph (c)(5) of this section.

(5) *State defined DSH qualification criteria.* If the State uses an alternate broader DSH qualification methodology as authorized in Section 1923(b)(4) of the Act, the value of the statistic and the methodology used to determine that statistic.

(6) *IP/OP Medicaid fee-for-service (FFS) basic rate payments.* The total annual amount paid to the hospital under the State plan, including Medicaid FFS rate adjustments, but not including DSH payments or supplemental/enhanced Medicaid payments, for inpatient and outpatient services furnished to Medicaid eligible individuals.

(7) *IP/OP Medicaid managed care organization payments.* The total annual amount paid to the hospital by Medicaid managed care organizations for inpatient hospital and outpatient hospital services furnished to Medicaid eligible individuals.

(8) *Supplemental/enhanced Medicaid IP/OP payments.* Indicate the total annual amount of supplemental/enhanced Medicaid payments made to the hospital under the State plan. These amounts do not include DSH payments, regular Medicaid FFS rate payments, and Medicaid managed care organization payments.

(9) *Total Medicaid IP/OP Payments.* Provide the total sum of items identified in § 447.299(c)(6), (7) and (8).

(10) *Total Cost of Care for Medicaid IP/OP Services.* The total annual costs incurred by each hospital for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals.

(11) *Total Medicaid Uncompensated Care.* The total amount of uncompensated care attributable to Medicaid inpatient and outpatient services. The amount should be the result of subtracting the amount identified in § 447.299(c)(9) from the amount identified in § 447.299(c)(10). The uncompensated care costs of providing Medicaid physician services cannot be included in this amount.

(12) *Uninsured IP/OP revenue.* Total annual payments received by the hospital by or on behalf of individuals with no source of third party coverage for inpatient and outpatient hospital services they receive. This amount does not include payments made by a State or units of local government, for services furnished to indigent patients.

(13) *Total Applicable Section 1011 Payments.* Federal Section 1011 payments for uncompensated inpatient and outpatient hospital services provided to Section 1011 eligible aliens with no source of third party coverage for the inpatient and outpatient hospital services they receive.

(14) *Total cost of IP/OP care for the uninsured.* Indicate the total costs incurred for furnishing inpatient hospital and outpatient hospital services to individuals with no source of third party coverage for the hospital services they receive.

(15) *Total uninsured IP/OP uncompensated care costs.* Total annual amount of uncompensated IP/OP care for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals and to individuals with no source of third party coverage for the hospital services they receive. The amount should be the result of subtracting paragraphs (c)(12) and (c)(13), from paragraph (c)(14) of this section. The uncompensated care costs of providing physician services to the uninsured cannot be included in this amount. The uninsured uncompensated amount also cannot include amounts associated with unpaid co-pays or deductibles for individuals with third party coverage for the inpatient and/or outpatient hospital services they receive or any other unreimbursed costs associated with inpatient and/or outpatient hospital services provided to individuals with those services in their third party coverage benefit package.

Nor does uncompensated care costs include bad debt or payer discounts related to services furnished to individuals who have health insurance or other third party payer.

(16) *Total annual uncompensated care costs.* The total annual uncompensated care cost equals the total cost of care for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals and to individuals with no source of third party coverage for the hospital services they receive less the sum of regular Medicaid FFS rate payments, Medicaid managed care organization payments, supplemental/enhanced Medicaid payments, uninsured revenues, and Section 1011 payments for inpatient and outpatient hospital services. This should equal the sum of paragraphs (c)(9),(c)(12), and (c)(13) subtracted from the sum of paragraphs (c)(10) and (c)(14) of this section.

(17) *Disproportionate share hospital payments.* Indicate total annual payment adjustments made to the hospital under Section 1923 of the Act.

(18) States must report DSH payments made to all hospitals under the authority of the approved Medicaid State plan. This includes both in-State and out-of-State hospitals. For out-of-State hospitals, States must report, at a minimum, the information identified in §447.299(c)(1) through (c)(6), (c)(8), (c)(9) and (c)(17).

(d) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description of each DSH program, the legal basis of each DSH program, and the amount of DSH payments made to each individual public and private provider or facility each quarter. This information must be made available to Federal reviewers upon request.

(e) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP CMS estimates is attributable to the expenditures made to the disproportionate share hospitals as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released when the State complies with all reporting requirements.

[46 FR 47971, Sept. 30, 1981, as amended at 73 FR 77950, Dec. 19, 2008; 74 FR 18657, Apr. 24, 2009]

Subpart F—Payment Methods for Other Institutional and Noninstitutional Services

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted. Redesignated at 46 FR 47973, Sept. 30, 1981, and further redesignated at 58 FR 6095, Jan. 26, 1993.

§447.300 Basis and purpose.

In this subpart, §447.302 through §447.325 and §447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(15) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

[72 FR 39239, July 17, 2007]

§447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

[46 FR 48560, Oct. 1, 1981]

§447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is not available for a State's expenditures for services that are in excess of the amounts allowable under this subpart.

NOTE: The Secretary may waive any limitation on reimbursement imposed by subpart F of this part for experiments conducted under section 402 of Pub. L. 90–428, Incentives

for Economy Experimentation, as amended by section 222(b) of Pub. L. 92–603, and under section 222(a) of Pub. L. 92–603.

[46 FR 48560, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 66 FR 3176, Jan. 12, 2001]

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:

(1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) *General rules.* (1) For privately operated facilities, upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) For State government operated facilities and for non-State government operated facilities, upper payment limit refers to the individual health care provider's Medicaid cost as defined at § 447.206.

(3) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to the group of privately operated facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(4) Except as provided in paragraph (c) of this section, Medicaid payments to State government operated facilities and non-State government operated facilities must not exceed the individual health care provider's Medicaid cost as documented in accordance with § 447.206.

(c) *Exceptions—(1) Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(3) The limitation in paragraph (b) of this section does not apply to payments authorized by Sections 701(d) and 705 of the Benefits Improvement Protection Act of 2000 (BIPA).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For State government operated and non-State government operated hospitals—Medicaid State plan rate year 2008.

(2) For State government operated and non-State government operated clinics—Medicaid State plan rate year 2009.

(3) For all other facilities—March 13, 2001.

(e) *Transition periods*—(1) *Definitions.* For purposes of this paragraph, the following definitions apply:

(i) *Transition period* refers to the period of time beginning March 13, 2001 through the end of one of the schedules permitted under paragraph (e)(2)(ii) of this section.

(ii) *UPL* stands for the upper payment limit described in paragraph

(b)(1) of this section for the referenced year.

(iii) *X* stands for the payments to a specific group of providers described in paragraph (a) of this section in State FY 2000 that exceeded the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) *General rules.* (i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraph (a) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) *For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following—*

(*1*) For State FY 2003: State FY 2003 UPL + .75X.

(*2*) For State FY 2004: State FY 2004 UPL + .50X.

(*3*) For State FY 2005: State FY 2005 UPL + .25X.

(*4*) For State FY 2006; State FY 2006 UPL.

(C) *For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:*

(*1*) For State FY 2004: State FY 2004 UPL + .85X.

(*2*) For State FY 2005: State FY 2005 UPL + .70X.

(*3*) For State FY 2006: State FY 2006 UPL + .55X.

(*4*) For State FY 2007: State FY 2007 UPL + .40X.

(*5*) For State FY 2008: State FY 2008 UPL + .25X.

(*6*) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(*7*) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999, submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(1) through (e)(2)(ii)(C)(7) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(f) *Reporting requirements for payments during the transition periods.* States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

[66 FR 3176, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2611, Jan. 18, 2002; 72 FR 29835, May 29, 2007]

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

§ 447.342 [Reserved]

PREPAID CAPITATION PLANS

§ 447.362 Upper limits of payment: Nonrisk contract.

Under a nonrisk contract, Medicaid payments to the contractor may not exceed—

(a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to recipients: plus

(b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

RURAL HEALTH CLINIC SERVICES

§ 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in § 405.2426 of this chapter.

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.

(d) For purposes of paragraph (c) (1) and (3) of this section, ''visit'' means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 34833, Sept. 30, 1986]

Subparts G–H [Reserved]

Subpart I—Payment for Drugs

SOURCE: 72 FR 39239, July 17, 2007, unless otherwise noted.

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

Bona fide service fees mean fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.

Consumer Price Index—Urban (CPI–U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Dispensing fee means the fee which—

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Estimated acquisition cost (EAC) means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic

drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA).

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Manufacturer means any entity that possesses legal title to the NDC for a covered drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) With respect to authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(4) With respect to drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity that does not possess legal title to the NDC.

Multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the State during the rebate period as follows:

(i) A drug product is considered sold or marketed in a State if it appears in a published national listing of average wholesale prices, selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(ii) A covered outpatient drug is not subject to the FUL for a rebate period if it is not a multiple source drug in the State for that rebate period.

National drug code (NDC) means the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in this part as being without respect to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means (1) a multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application, or (3) a drug that entered the market before 1962 that was not originally marketed under an original NDA.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application, PLA, ELA, or ADA.

States means the 50 States and the District of Columbia.

[72 FR 39239, July 17, 2007, as amended at 73 FR 13788, Mar. 14, 2008; 73 FR 58497, Oct. 7, 2008]

§447.504 Determination of AMP.

(a) *AMP* means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

(b) *Average unit price* means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

(c) *Customary prompt pay discount* means any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

(d) *Net sales* means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

(e) *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

(g) *Sales, rebates, discounts, or other price concessions included in AMP.* Except with respect to those sales identified in paragraph (h) of this section, AMP for covered outpatient drugs shall include the following sales and associated rebates, discounts, or other price concessions—

(1) Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section;

(2) Sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements;

(3) Direct and indirect sales to hospitals, where the drug is used in the outpatient pharmacy, except those sales that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use (for example hospital outpatient department, clinic, or affiliated entity);

(4) Sales at nominal prices to any entity except a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR) providing services as set forth in §440.150 of this chapter, or a State-owned or operated nursing facility providing services as set forth in §440.155 of this chapter;

(5) Sales to retail pharmacies including discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs to the retail pharmacy class of trade;

(6) Sales including discounts, rebates, or other price concessions provided to pharmacy benefit managers (PBMs) for their mail order pharmacy purchases;

(7) Sales directly to patients;

(8) Sales to outpatient facilities (for example, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers);

(9) Sales to mail order pharmacies;

(10) Sales to home infusion providers;

(11) Sales to specialty pharmacies;

(12) Sales to home health care providers;

(13) Sales to physicians;

(14) Rebates, discounts, or other price concessions (other than rebates under section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade; and

(15) Sales of drugs reimbursed by third party payers including the Medicare Part D Program, a Medicare Advantage prescription drug plan (MA–PD), a Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, Children's Health Insurance Program (CHIP), State pharmaceutical assistance programs (SPAPs), health maintenance organizations (HMOs) (including managed care organizations (MCOs)) that do not purchase or take possession of drugs, TRICARE Retail Pharmacy Program (TRRx), and Medicaid Programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under section 1927 of the Act or as otherwise specified in the statute or regulations).

(h) *Sales, rebates, discounts, or other price concessions excluded from AMP.* AMP excludes—

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA);

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(4) Direct and indirect sales to hospitals, where the drug is used in the inpatient setting or in the outpatient pharmacy for outpatient use where the sales cannot be identified with adequate documentation;

(5) Sales to HMOs (including MCOs, and HMO/MCO-operated pharmacies) that purchase or take possession of drugs;

(6) Sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities;

(7) Sales to hospices (inpatient and outpatient);

(8) Sales to veterinarians;

(9) Sales to prisons;

(10) Sales outside the 50 States and the District of Columbia;

(11) Sales to State, county, and municipal entities;

(12) Sales to patient assistance programs;

(13) Sales to wholesalers where the drug is distributed to the non-retail pharmacy class of trade;

(14) Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number;

(15) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(16) Manufacturer vouchers;

(17) Manufacturer-sponsored drug discount card programs;

(18) Free goods, not contingent upon any purchase requirement;

(19) Bona fide service fees;

(20) Customary prompt pay discounts extended to wholesalers;

(21) Returned or replaced goods when accepted or replaced in good faith;

(22) Discounts, rebates, or other price concessions to PBMs, except for their mail order pharmacy's purchases.

(23) Associated rebates, discounts, or other price concessions to third party payers including the Medicare Part D Program, an MA–PD, Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, CHIP, SPAPs, HMOs (including MCOs that do not take possession of drugs) the TRICARE Retail Pharmacy Program, and Medicaid Programs; and

(24) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(i) *Further clarification of AMP calculation.* (1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees, (except bona fide service fees), and any other rebates, discounts or other price concessions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in the quarter.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

[72 FR 39239, July 17, 2007, as amended at 75 FR 48852, Aug. 11, 2010]

§447.505 Determination of best price.

(a) *Best price* means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.

(b) For purposes of this section, *provider* means a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section, best price for covered outpatient drugs includes the following prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly—

(1) Prices to wholesalers;

(2) Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs;

(3) Prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies);

(4) Prices available to non-profit entities;

(5) Prices available to governmental entities within the United States;

(6) Prices of authorized generic drugs, sold by the primary manufacturer in accordance with §447.506(d) of this subpart;

(7) Prices of sales directly to patients;

(8) Prices available to mail order pharmacies;

(9) Prices available to outpatient clinics;

(10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements; and

(11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity.

(d) *Prices excluded from best price.* Best price excludes:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the FSS of the GSA;

(3) Any prices provided to a designated SPAP;

(4) Any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(5) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA–PD plan under Part C of such title with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare;

(6) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer-sponsored drug discount card program;

(8) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(9) Goods provided free of charge under a manufacturer's patient assistance programs;

(10) Free goods, not contingent upon any purchase requirement;

(11) Nominal prices to certain entities as set forth in § 447.508 of this subpart;

(12) Bona fide service fees; and

(13) PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level.

(e) *Further clarification of best price.* (1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount as described in § 447.508 of this subpart.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Authorized generic drug defined.* For the purposes of this subpart, an authorized generic drug means any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug.

(b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity described in section 340B(a)(4) of the PHSA;

(2) An ICF/MR providing services as set forth in §440.150 of this chapter; or

(3) A State-owned or operated nursing facility providing services as set forth in §440.155 of this chapter.

(b) *Nonapplication.* This restriction shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38, U.S.C. 8126.

§447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with §447.504 of this subpart;

(2) Best price, calculated in accordance with §447.505 of this subpart;

(3) Customary prompt pay discounts, which shall be reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period; and

(4) Prices that fall within the nominal price exclusion, which shall be reported as an aggregate dollar amount and shall include all sales of single source and innovator multiple source drugs to the entities listed in §447.508(a) of this subpart for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.

(2) A manufacturer must report revisions to AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.* (1) A manufacturer may report a revised base date AMP to CMS within the first four full calendar quarters following [OFR: insert publication date of the final rule].

(2) *Recalculation of base date AMP.* (i) A manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in §447.504 of this subpart.

(ii) A manufacturer may choose to recalculate base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating base date AMP.

(d) *Monthly AMP*—(1) *Definition of Monthly AMP.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP should be calculated based on the methodology in section 447.504 of this subpart, except the period covered should be based on monthly, as opposed to quarterly, sales. The monthly AMP should be calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units sold, excluding goods or any other items given away unless contingent on any purchase requirements. Monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission. In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due.

(4) *Exception.* A manufacturer must report revisions to monthly AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO);

(2) The manufacturer's chief financial officer (CFO);

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for ''other drugs'' set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like ''brand necessary'' is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in its most current edition of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

(ii) At least two suppliers meet the criteria in paragraph (a)(1)(i) of this section.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

(c) *Ensuring a drug is for sale nationally.* To assure that a drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.

(2) Except as set forth in paragraph (c)(3) of this section, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 40 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the brand name drug and the first new generic or authorized generic drug which has entered the market, the criteria in paragraph (c)(2) of this section will not apply.

§447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§447.518 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with §447.514(a) of this subpart, are in accordance with the upper limits specified in §447.514(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with §447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§447.512 and 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest

dollar value under the Medicaid Program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

PART 455—PROGRAM INTEGRITY: MEDICAID

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

SOURCE: 43 FR 45262, Sept. 29, 1978, unless otherwise noted.

§ 455.1 Basis and scope.

This part sets forth requirements for a State fraud detection and investigation program, and for disclosure of information on ownership and control.

(a) Under the authority of sections 1902(a)(4), 1903(i)(2), and 1909 of the Social Security Act, Subpart A provides State plan requirements for the identification, investigation, and referral of suspected fraud and abuse cases. In addition, the subpart requires that the State—

(1) Report fraud and abuse information to the Department; and

(2) Have a method to verify whether services reimbursed by Medicaid were actually furnished to recipients.

(b) Subpart B implements sections 1124, 1126, 1902(a)(36), 1903(i)(2), and 1903(n) of the Act. It requires that providers and fiscal agents must agree to disclose ownership and control information to the Medicaid State agency.

(c) Subpart C implements section 1936 of the Act. It establishes the Medicaid Integrity Program under which the Secretary will promote the integrity of the program by entering into contracts with eligible entities to carry out the activities of subpart C.

[51 FR 34787, Sept. 30, 1986, as amended at 72 FR 67655, Nov. 30, 2007]

§ 455.2 Definitions.

As used in this part unless the context indicates otherwise—

Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for

services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Conviction or *Convicted* means that a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending.

Exclusion means that items or services furnished by a specific provider who has defrauded or abused the Medicaid program will not be reimbursed under Medicaid.

Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual (either as an employee or in his or her own capacity), a provider, or other supplier of services. (For purposes of denial of reimbursement within this part, it does not refer to services ordered by one party but billed for and provided by or under the supervision of another.)

Practitioner means a physician or other individual licensed under State law to practice his or her profession.

Suspension means that items or services furnished by a specified provider who has been convicted of a program-related offense in a Federal, State, or local court will not be reimbursed under Medicaid.

[48 FR 3755, Jan. 27, 1983, as amended at 50 FR 37375, Sept. 13, 1985; 51 FR 34788, Sept. 30, 1986]

§ 455.3 Other applicable regulations.

Part 1002 of this title sets forth the following:

(a) State plan requirements for excluding providers for fraud and abuse, and suspending practitioners convicted of program-related crimes.

(b) The limitations on FFP for services furnished by excluded providers or suspended practitioners.

(c) The requirements and procedures for reinstatement after exclusion or suspension.

(d) Requirements for the establishment and operation of State Medicaid fraud control units and the rates of FFP for their fraud control activities.

[51 FR 34788, Sept. 30, 1986]

Subpart A—Medicaid Agency Fraud Detection and Investigation Program

§ 455.12 State plan requirement.

A State plan must meet the requirements of §§ 455.13 through 455.23.

[52 FR 48817, Dec. 28, 1987]

§ 455.13 Methods for identification, investigation, and referral.

The Medicaid agency must have—

(a) Methods and criteria for identifying suspected fraud cases;

(b) Methods for investigating these cases that—

(1) Do not infringe on the legal rights of persons involved; and

(2) Afford due process of law; and

(c) Procedures, developed in cooperation with State legal authorities, for referring suspected fraud cases to law enforcement officials.

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3755, Jan. 27, 1983]

§ 455.14 Preliminary investigation.

If the agency receives a complaint of Medicaid fraud or abuse from any source or identifies any questionable practices, it must conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation.

[48 FR 3756, Jan. 27, 1983]

§ 455.15 Full investigation.

If the findings of a preliminary investigation give the agency reason to believe that an incident of fraud or abuse has occurred in the Medicaid program, the agency must take the following action, as appropriate:

(a) If a provider is suspected of fraud or abuse, the agency must—

(1) In States with a State Medicaid fraud control unit certified under subpart C of part 1002 of this title, refer

the case to the unit under the terms of its agreement with the unit entered into under § 1002.309 of this title; or

(2) In States with no certified Medicaid fraud control unit, or in cases where no referral to the State Medicaid fraud control unit is required under paragraph (a)(1) of this section, conduct a full investigation or refer the case to the appropriate law enforcement agency.

(b) If there is reason to believe that a recipient has defrauded the Medicaid program, the agency must refer the case to an appropriate law enforcement agency.

(c) If there is reason to believe that a recipient has abused the Medicaid program, the agency must conduct a full investigation of the abuse.

[48 FR 3756, Jan. 27, 1983, as amended at 51 FR 34788, Sept. 30, 1986]

§ 455.16 Resolution of full investigation.

A full investigation must continue until—

(a) Appropriate legal action is initiated;

(b) The case is closed or dropped because of insufficient evidence to support the allegations of fraud or abuse; or

(c) The matter is resolved between the agency and the provider or recipient. This resolution may include but is not limited to—

(1) Sending a warning letter to the provider or recipient, giving notice that continuation of the activity in question will result in further action;

(2) Suspending or terminating the provider from participation in the Medicaid program;

(3) Seeking recovery of payments made to the provider; or

(4) Imposing other sanctions provided under the State plan.

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3756, Jan. 27, 1983]

§ 455.17 Reporting requirements.

The agency must report the following fraud or abuse information to the appropriate Department officials at intervals prescribed in instructions.

(a) The number of complaints of fraud and abuse made to the agency that warrant preliminary investigation.

(b) For each case of suspected provider fraud and abuse that warrants a full investigation—

(1) The provider's name and number;

(2) The source of the complaint;

(3) The type of provider;

(4) The nature of the complaint;

(5) The approximate range of dollars involved; and

(6) The legal and administrative disposition of the case, including actions taken by law enforcement officials to whom the case has been referred.

(Approved by the Office of Management and Budget under control number 0938–0076)

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3756, Jan. 27, 1983]

§ 455.18 Provider's statements on claims forms.

(a) Except as provided in § 455.19, the agency must provide that all provider claims forms be imprinted in boldface type with the following statements, or with alternate wording that is approved by the Regional CMS Administrator:

(1) ''This is to certify that the foregoing information is true, accurate, and complete.''

(2) ''I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws.''

(b) The statements may be printed above the claimant's signature or, if they are printed on the reverse of the form, a reference to the statements must appear immediately preceding the claimant's signature.

§ 455.19 Provider's statement on check.

As an alternative to the statements required in § 455.18, the agency may print the following wording above the claimant's endorsement on the reverse of checks or warrants payable to each provider: ''I understand in endorsing or depositing this check that payment will be from Federal and State funds and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws.''

§455.20 Recipient verification procedure.

(a) The agency must have a method for verifying with recipients whether services billed by providers were received.

(b) In States receiving Federal matching funds for a mechanized claims processing and information retrieval system under part 433, subpart C, of this subchapter, the agency must provide prompt written notice as required by §433.116 (e) and (f).

[48 FR 3756, Jan. 27, 1983, as amended at 56 FR 8854, Mar. 1, 1991]

§455.21 Cooperation with State Medicaid fraud control units.

In a State with a Medicaid fraud control unit established and certified under subpart C of this part,

(a) The agency must—

(1) Refer all cases of suspected provider fraud to the unit;

(2) If the unit determines that it may be useful in carrying out the unit's responsibilities, promptly comply with a request from the unit for—

(i) Access to, and free copies of, any records or information kept by the agency or its contractors;

(ii) Computerized data stored by the agency or its contractors. These data must be supplied without charge and in the form requested by the unit; and

(iii) Access to any information kept by providers to which the agency is authorized access by section 1902(a)(27) of the Act and §431.107 of this subchapter. In using this information, the unit must protect the privacy rights of recipients; and

(3) On referral from the unit, initiate any available administrative or judicial action to recover improper payments to a provider.

(b) The agency need not comply with specific requirements under this subpart that are the same as the responsibilities placed on the unit under subpart D of this part.

§455.23 Withholding of payments in cases of fraud or willful misrepresentation.

(a) *Basis for withholding.* The State Medicaid agency may withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud or willful misrepresentation under the Medicaid program. The State Medicaid agency may withhold payments without first notifying the provider of its intention to withhold such payments. A provider may request, and must be granted, administrative review where State law so requires.

(b) *Notice of withholding.* The State agency must send notice of its withholding of program payments within 5 days of taking such action. The notice must set forth the general allegations as to the nature of the withholding action, but need not disclose any specific information concerning its ongoing investigation. The notice must:

(1) State that payments are being withheld in accordance with this provision;

(2) State that the withholding is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which withholding will be terminated;

(3) Specify, when appropriate, to which type or types of Medicaid claims withholding is effective; and

(4) Inform the provider of the right to submit written evidence for consideration by the agency.

(c) *Duration of withholding.* All withholding of payment actions under this section will be temporary and will not continue after:

(1) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud or willful misrepresentation by the provider; or

(2) Legal proceedings related to the provider's alleged fraud or willful misrepresentation are completed.

[52 FR 48817, Dec. 28, 1987]

Subpart B—Disclosure of Information by Providers and Fiscal Agents

SOURCE: 44 FR 41644, July 17, 1979, unless otherwise noted.

§455.100 Purpose.

This subpart implements sections 1124, 1126, 1902(a)(38), 1903(i)(2), and 1903(n) of the Social Security Act. It

sets forth State plan requirements regarding—

(a) Disclosure by providers and fiscal agents of ownership and control information; and

(b) Disclosure of information on a provider's owners and other persons convicted of criminal offenses against Medicare, Medicaid, or the title XX services program.

The subpart also specifies conditions under which the Administrator will deny Federal financial participation for services furnished by providers or fiscal agents who fail to comply with the disclosure requirements.

§ 455.101 Definitions.

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent.

Other disclosing entity means any other Medicaid disclosing entity and any entity that does not participate in Medicaid, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XVIII, or XX of the Act. This includes:

(a) Any hospital, skilled nursing facility, home health agency, independent clinical laboratory, renal disease facility, rural health clinic, or health maintenance organization that participates in Medicare (title XVIII);

(b) Any Medicare intermediary or carrier; and

(c) Any entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which it claims payment under any plan or program established under title V or title XX of the Act.

Fiscal agent means a contractor that processes or pays vendor claims on behalf of the Medicaid agency.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means an ownership interest in an entity that has an ownership interest in the disclosing entity. This term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operation of an institution, organization, or agency.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(a) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(b) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(c) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(d) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(e) Is an officer or director of a disclosing entity that is organized as a corporation; or

(f) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of $25,000 and 5 percent of a provider's total operating expenses.

Subcontractor means—

(a) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(b) An individual, agency, or organization with which a fiscal agent has entered into a contract, agreement, purchase order, or lease (or leases of real property) to obtain space, supplies,

equipment, or services provided under the Medicaid agreeement.

Supplier means an individual, agency, or organization from which a provider purchases goods and services used in carrying out its responsibilities under Medicaid (e.g., a commercial laundry, a manufacturer of hospital beds, or a pharmaceutical firm).

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41644, July 17, 1979, as amended at 51 FR 34788, Sept. 30, 1986]

§ 455.102 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation which owns 80 percent of the stock of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation which owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine percentage of ownership, mortgage, deed of trust, note, or other obligation, the percentage of interest owned in the obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 455.103 State plan requirement.

A State plan must provide that the requirements of §§ 455.104 through 455.106 are met.

§ 455.104 Disclosure by providers and fiscal agents: Information on ownership and control.

(a) *Information that must be disclosed.* The Medicaid agency must require each disclosing entity to disclose the following information in accordance with paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the disclosing entity or in any subcontractor in which the disclosing entity has direct or indirect ownership of 5 percent or more;

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which a person with an ownership or control interest in the disclosing entity also has an ownership or control interest. This requirement applies to the extent that the disclosing entity can obtain this information by requesting it in writing from the person. The disclosing entity must—

(i) Keep copies of all these requests and the responses to them;

(ii) Make them available to the Secretary or the Medicaid agency upon request; and

(iii) Advise the Medicaid agency when there is no response to a request.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicaid standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency must promptly furnish the information to the Secretary and the Medicaid agency.

(2) Any disclosing entity that is not subject to periodic survey and certification and has not supplied the information specified in paragraph (a) of this section to the Secretary within the prior 12-month period, must submit the information to the Medicaid agency before entering into a contract or agreement to participate in the program. The Medicaid agency must promptly furnish the information to the Secretary.

(3) Updated information must be furnished to the Secretary or the State

survey or Medicaid agency at intervals between recertification or contract renewals, within 35 days of a written request.

(c) *Provider agreements and fiscal agent contracts.* A Medicaid agency shall not approve a provider agreement or a contract with a fiscal agent, and must terminate an existing agreement or contract, if the provider or fiscal agent fails to disclose ownership or control information as required by this section.

(d) *Denial of Federal financial participation (FFP).* FFP is not available in payments made to a provider or fiscal agent that fails to disclose ownership or control information as required by this section.

§ 455.105 Disclosure by providers: Information related to business transactions.

(a) *Provider agreements.* A Medicaid agency must enter into an agreement with each provider under which the provider agrees to furnish to it or to the Secretary on request, information related to business transactions in accordance with paragraph (b) of this section.

(b) *Information that must be submitted.* A provider must submit, within 35 days of the date on a request by the Secretary or the Medicaid agency, full and complete information about—

(1) The ownership of any subcontractor with whom the provider has had business transactions totaling more than $25,000 during the 12-month period ending on the date of the request; and

(2) Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request.

(c) *Denial of Federal financial participation (FFP).* (1) FFP is not available in expenditures for services furnished by providers who fail to comply with a request made by the Secretary or the Medicaid agency under paragraph (b) of this section or under § 420.205 of this chapter (Medicare requirements for disclosure).

(2) FFP will be denied in expenditures for services furnished during the period beginning on the day following the date the information was due to the Secretary or the Medicaid agency and ending on the day before the date on which the information was supplied.

§ 455.106 Disclosure by providers: Information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who:

(1) Has ownership or control interest in the provider, or is an agent or managing employee of the provider; and

(2) Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or the title XX services program since the inception of those programs.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of the Department of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must also promptly notify the Inspector General of the Department of any action it takes on the provider's application for participation in the program.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services Program.

(2) The Medicaid agency may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

Subpart C—Medicaid Integrity Program

SOURCE: 72 FR 67655, Nov. 30, 2007, unless otherwise noted.

§455.200 Basis and scope.

(a) *Statutory basis.* This subpart implements section 1936 of the Social Security Act that establishes the Medicaid Integrity Program, under which the Secretary will promote the integrity of the program by entering into contracts with eligible entities to carry out the activities under this subpart C.

(b) *Scope.* This subpart provides for the limitation on a contractor's liability to carry out a contract under the Medicaid Integrity Program and to carry out the Medicaid integrity audit program functions.

[73 FR 55771, Sept. 26, 2008]

§455.202 Limitation on contractor liability.

(a) A program contractor, a person, or an entity employed by, or having a fiduciary relationship with, or who furnishes professional services to a program contractor will not be held to have violated any criminal law and will not be held liable in any civil action, under any law of the United States or of any State (or political subdivision thereof), by reason of the performance of any duty, function, or activity required or authorized under this subpart or under a valid contract entered into under this subpart, provided due care was exercised in that performance and the contractor has a contract with CMS under this subpart.

(b) CMS pays a contractor, a person, or an entity described in paragraph (a) of this section, or anyone who furnishes legal counsel or services to a contractor or person, a sum equal to the reasonable amount of the expenses, as determined by CMS, incurred in connection with the defense of a suit, action, or proceeding, if the following conditions are met:

(1) The suit, action, or proceeding was brought against the contractor, person or entity by a third party and relates to the contractor's, person's or entity's performance of any duty, function, or activity under a contract entered into with CMS under this subpart.

(2) The funds are available.

(3) The expenses are otherwise allowable under the terms of the contract.

§455.230 Eligibility requirements.

CMS may enter into a contract with an entity to perform the activities described at §455.232, if it meets the following conditions:

(a) The entity has demonstrated capability to carry out the activities described below.

(b) In carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to Title XIX of the Social Security Act and in other cases arising out of such activities.

(c) Maintains an appropriate written code of conduct and compliance policies that include, without limitation, an enforced policy on employee conflicts of interest.

(d) The entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement.

(e) The entity meets such other requirements the Secretary may impose.

[73 FR 55771, Sept. 26, 2008]

§455.232 Medicaid integrity audit program contractor functions.

The contract between CMS and a Medicaid integrity audit program contractor specifies the functions the contractor will perform. The contract may include any or all of the following functions:

(a) Review of the actions of individuals or entities furnishing items or services (whether on a fee-for-service, risk, or other basis) for which payment may be made under a State Plan approved under title XIX of the Act (or under any waiver of such plan approved under section 1115 of the Act) to determine whether fraud, waste, or abuse has occurred, is likely to occur, or whether such actions have the potential for resulting in an expenditure of funds under title XIX in a manner

which is not intended under the provisions of title XIX.

(b) Auditing of claims for payment for items or services furnished, or administrative services rendered, under a State Plan under title XIX to ensure proper payments were made. This includes: cost reports, consulting contracts, and risk contracts under section 1903(m) of the Act.

(c) Identifying if overpayments have been made to individuals or entities receiving Federal funds under title XIX.

(d) Educating providers of service, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care.

[73 FR 55771, Sept. 26, 2008]

§ 455.234 Awarding of a contract.

(a) CMS awards and administers Medicaid integrity audit program contracts in accordance with acquisition regulations set forth at 48 CFR chapters 1 and 3, this subpart, and all other applicable laws and regulations. These competitive procedures and requirements for awarding Medicaid integrity audit program contracts are to be used as follows:

(1) When entering into new contracts under this section.

(2) At any other time considered appropriate by the Secretary.

(b) An entity is eligible to be awarded a Medicaid integrity audit program contract only if meets the eligibility requirements established in § 455.202, 48 CFR chapter 3, and all other applicable laws and requirements.

[73 FR 55771, Sept. 26, 2008]

§ 455.236 Renewal of a contract.

(a) CMS specifies the initial contract term in the Medicaid integrity audit program contract. CMS may, but is not required to, renew a Medicaid integrity audit program contract without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

(b) CMS may renew a Medicaid integrity audit program contract without competition if all of the following conditions are met:

(1) The Medicaid integrity audit program contractor continues to meet the requirements established in this subpart.

(2) The Medicaid integrity audit program contractor meets or exceeds the performance requirements established in its current contract.

(3) It is in the best interest of the government.

(c) If CMS does not renew a contract, the contract will end in accordance with its terms. The contractor will not have a right to a hearing or judicial review regarding CMS's renewal or nonrenewal decision.

[73 FR 55771, Sept. 26, 2008]

§ 455.238 Conflict of interest.

(a) Offerors for Medicaid integrity audit program contracts, and Medicaid integrity audit program contractors, are subject to the following requirements:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation organizational conflict of interest guidance, found under 48 CFR subpart 9.5.

(2) The standards and requirements that are contained in each individual contract awarded to perform activities described under section 1936 of the Act.

(b) Post-award conflicts of interest: CMS considers that a post-award conflict of interest has developed if, during the term of the contract, one of the following occurs:

(1) The contractor or any of its employees, agents, or subcontractors received, solicited, or arranged to receive any fee, compensation, gift (defined at 5 CFR 2635.203(b)), payment of expenses, offer of employment, or any other thing of value from any entity that is reviewed, audited, investigated, or contacted during the normal course of performing activities under the Medicaid integrity audit program contract.

(2) CMS determines that the contractor's activities are creating a conflict of interest.

(c) If CMS determines that a conflict of interest exists during the term of the contract, among other actions, CMS may:

(1) Not renew the contract for an additional term.

(2) Modify the contract.

(3) Terminate the contract.

[73 FR 55771, Sept. 26, 2008]

§ 455.240 Conflict of interest resolution.

(a) Review Board: CMS may establish a Conflicts of Interest Review Board to assist in resolving organizational conflicts of interest.

(b) Resolution: Resolution of an organizational conflict of interest is a determination by the contracting officer that:

(1) The conflict is mitigated.

(2) The conflict precludes award of a contract to the offeror.

(3) The conflict requires that CMS modify an existing contract.

(4) The conflict requires that CMS terminate an existing contract.

(5) It is in the best interest of the government to contract with the offeror or contractor even though the conflict of interest exists and a request for waiver is approved in accordance with 48 CFR 9.503.

[73 FR 55771, Sept. 26, 2008]

Subpart D—Independent Certified Audit of State Disproportionate Share Hospital Payment Adjustments

SOURCE: 73 FR 77951, Dec. 19, 2008, unless otherwise noted.

§ 455.300 Purpose.

This subpart implements Section 1923(j)(2) of the Act.

§ 455.301 Definitions.

For the purposes of this subpart—

Independent certified audit means an audit that is conducted by an auditor that operates independently from the Medicaid agency or subject hospitals and is eligible to perform the DSH audit. Certification means that the independent auditor engaged by the State reviews the criteria of the Federal audit regulation and completes the verification, calculations and report under the professional rules and generally accepted standards of audit practice. This certification would include a review of the State's audit protocol to ensure that the Federal regulation is satisfied, an opinion for each verification detailed in the regulation, and a determination of whether or not the State made DSH payments that exceeded any hospital's specific DSH limit in the Medicaid State plan rate year under audit. The certification should also identify any data issues or other caveats that the auditor identified as impacting the results of the audit.

Medicaid State Plan Rate Year means the 12-month period defined by a State's approved Medicaid State plan in which the State estimates eligible uncompensated care costs and determines corresponding disproportionate share hospital payments as well as all other Medicaid payment rates. The period usually corresponds with the State's fiscal year or the Federal fiscal year but can correspond to any 12-month period defined by the State as the Medicaid State plan rate year.

§ 455.304 Condition for Federal financial participation (FFP).

(a) *General rule.* (1) The State must submit an independent certified audit to CMS for each completed Medicaid State plan rate year, consistent with the requirements in this subpart, to receive Federal payments under Section 1903(a)(1) of the Act based on State expenditures for disproportionate share hospital (DSH) payments for Medicaid State plan rate years subsequent to the date the audit is due, except as provided in paragraph (e) of this section.

(2) FFP is not available in expenditures for DSH payments that are found in the independent certified audit to exceed the hospital-specific eligible uncompensated care cost limit, except as provided in paragraph (e) of this section.

(b) *Timing.* For Medicaid State plan rate years 2005 and 2006, a State must submit to CMS an independent certified audit report no later than the last day of calendar year 2009. Each subsequent audit beginning with Medicaid State plan rate year 2007 must be completed by the last day of the Federal fiscal year ending three years from the end of the Medicaid State plan rate year under audit. Completed audit reports must be submitted to CMS no later than 90 days after completion.

Post-audit adjustments based on claims for the Medicaid State plan rate year paid subsequent to the audit date, if any, must be submitted in the quarter the claim was paid.

(c) *Documentation.* In order to complete the independent certified audit, States must use the following data sources:

(1) Approved Medicaid State plan for the Medicaid State plan rate year under audit.

(2) Payment and utilization information from the State's Medicaid Management Information System.

(3) The Medicare 2552–96 hospital cost report(s) applicable to the Medicaid State plan rate year under audit. If the Medicare 2552–96 is superseded by an alternate Medicare developed cost reporting tool during an audit year, that tool must be used for the Medicaid State plan rate year under audit.

(4) Audited hospital financial statements and hospital accounting records.

(d) *Specific requirements.* The independent certified audit report must verify the following:

(1) *Verification 1:* Each hospital that qualifies for a DSH payment in the State is allowed to retain that payment so that the payment is available to offset its uncompensated care costs for furnishing inpatient hospital and outpatient hospital services during the Medicaid State plan rate year to Medicaid eligible individuals and individuals with no source of third party coverage for the services in order to reflect the total amount of claimed DSH expenditures.

(2) *Verification 2:* DSH payments made to each qualifying hospital comply with the hospital-specific DSH payment limit. For each audited Medicaid State plan rate year, the DSH payments made in that audited Medicaid State plan rate year must be measured against the actual uncompensated care cost in that same audited Medicaid State plan rate year.

(3) *Verification 3:* Only uncompensated care costs of furnishing inpatient and outpatient hospital services to Medicaid eligible individuals and individuals with no third party coverage for the inpatient and outpatient hospital services they received as described in Section 1923(g)(1)(A) of the Act are eligible for inclusion in the calculation of the hospital-specific disproportionate share limit payment limit, as described in Section 1923(g)(1)(A) of the Act.

(4) *Verification 4:* For purposes of this hospital-specific limit calculation, any Medicaid payments (including regular Medicaid fee-for-service rate payments, supplemental/enhanced Medicaid payments, and Medicaid managed care organization payments) made to a disproportionate share hospital for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals, which are in excess of the Medicaid incurred costs of such services, are applied against the uncompensated care costs of furnishing inpatient hospital and outpatient hospital services to individuals with no source of third party coverage for such services.

(5) *Verification 5:* Any information and records of all of its inpatient and outpatient hospital service costs under the Medicaid program; claimed expenditures under the Medicaid program; uninsured inpatient and outpatient hospital service costs in determining payment adjustments under this Section; and any payments made on behalf of the uninsured from payment adjustments under this Section has been separately documented and retained by the State.

(6) *Verification 6:* The information specified in paragraph (d)(5) of this Section includes a description of the methodology for calculating each hospital's payment limit under Section 1923(g)(1) of the Act. Included in the description of the methodology, the audit report must specify how the State defines incurred inpatient hospital and outpatient hospital costs for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals and individuals with no source of third party coverage for the inpatient hospital and outpatient hospital services they received.

(e) *Transition Provisions:* To ensure a period for developing and refining reporting and auditing techniques, findings of State reports and audits for Medicaid State Plan years 2005–2010 will not be given weight except to the extent that the findings draw into question the reasonableness of State

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

SOURCE: 43 FR 45266, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of Medicaid services including—

(1) A statewide program of control of the utilization of all Medicaid services; and

(2) Specific requirements for the control of the utilization of Medicaid services in institutions.

(3) Specific requirements for an outpatient drug use review program.

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship between these sections of the Act and the requirements in this part.

(1) *Methods and procedures to safeguard against unnecessary utilization of care and services.* Section 1902(a)(30) requires that the State plan provide methods and procedures to safeguard against unnecessary utilization of care and services.

(2) *Penalty for failure to have an effective program to control utilization of institutional services.* Section 1903(g)(1) provides for a reduction in the amount of Federal Medicaid funds paid to a State for long-stay inpatient services if the State does not make a showing satisfactory to the Secretary that it has an effective program of control over utilization of those services. This penalty provision applies to inpatient services in hospitals, mental hospitals, and intermediate care facilities (ICF's). Specific requirements are:

(i) Under section 1903(g)(1)(A), a physician must certify at admission, and a physician (or physician assistant or nurse practitioner under the supervision of a physician) must periodically recertify, the individual's need for inpatient care.

(ii) Under section 1903(g)(1)(B), services must be furnished under a plan established and periodically evaluated by a physician.

(iii) Under section 1903(g)(1)(C), the State must have in effect a continuous program of review of utilization of care and services under section 1902(a)(30) whereby each admission is reviewed or screened in accordance with criteria established by medical and other professional personnel.

(iv) Under section 1903(g)(1)(D), the State must have an effective program under sections 1902(a) (26) and (31) of review of care in intermediate care facilities and mental hospitals. This must include evaluation at least annually of the professional management of each case.

(3) *Medical review in mental hospitals.* Section 1902(a)(26)(A) requires that the plan provide for a program of medical review that includes a medical evaluation of each individual's need for care in a mental hospital, a plan of care, and, where applicable, a plan of rehabilitation.

(4) *Independent professional review in intermediate care facilities.* Section 1902(a)(31)(A) requires that the plan provide for a program of independent professional review that includes a medical evaluation of each individual's need for intermediate care and a written plan of service.

(5) *Inspection of care and services in institutions.* Sections 1902(a)(26) (B) and (C) and 1902(a)(31) (B) and (C) require that the plan provide for periodic inspections and reports, by a team of professional persons, of the care being provided to each recipient in institutions for mental diseases (IMD's), and ICF's participating in Medicaid.

(6) *Denial of FFP for failure to have specified utilization review procedures.* Section 1903(i)(4) provides that FFP is not available in a State's expenditures for hospital or mental hospital services unless the institution has in effect a utilization review plan that meets Medicare requirements. However, the Secretary may waive this requirement if the Medicaid agency demonstrates to his satisfaction that it has utilization review procedures superior in effectiveness to the Medicare procedures.

(7) *State health agency guidance on quality and appropriateness of care and services.* Section 1902(a)(33)(A) requires that the plan provide that the State health or other appropriate medical agency establish a plan for review, by professional health personnel, of the appropriateness and quality of Medicaid services to provide guidance to the Medicaid agency and the State licensing agency in administering the Medicaid program.

(8) *Drug use review program.* Section 1927(g) of the Act provides that, for payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a drug use review (DUR) program. It also requires that each State provide, either directly or through a contract with a private organization, for the establishment of a DUR Board.

TABLE 1

[This table relates the regulations in this part to the sections of the Act on which they are based.]

Subpart A—General	1902(a)(30) 1902(a)(33)(A)
Subpart B—Utilization Control: All Medicaid Services.	1902(a)(30)
Subpart C—Utilization Control: Hospitals	
Certification of need for care	1903(g)(1)(A)
Plan of care	1903(g)(1)(B)
Utilization review plan (including admission review).	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart D—Utilization Control: Mental Hospitals	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(26)(A) 1903(g)(1)(C)
Plan of care	1902(a)(26)(A) 1903(g)(1)(B)
Admission and plan of care requirements for individuals under 21.	1902(a)(26)(A) 1903(g)(1) (B), (C)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart F—Utilization Control: Intermediate Care Facilities	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(31)(A) 1903(g)(1)(C)
Plan of care	1902(a)(31)(A) 1903(g)(1)(B)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements.	1905 (a)(16) and (h)
Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals and Mental Hospitals.	
Subpart I—Inspections of Care in Intermediate Care Facilities and Institutions for Mental Diseases.	
Subpart J—Penalty for Failure To Make a Satisfactory Showing of An Effective Institutional Utilization Control Program.	1903(g)
Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims.	1927(g) and (h)

[43 FR 45266, Sept. 29, 1978, as amended at 46 FR 48561, Oct. 1, 1981; 57 FR 49408, Nov. 2, 1992; 61 FR 38398, July 24, 1996]

§ 456.2 State plan requirements.

(a) A State plan must provide that the requirements of this part are met.

(b) These requirements may be met by the agency by:

(1) Assuming direct responsibility for assuring that the requirements of this part are met; or

(2) Deeming of medical and utilization review requirements if the agency contracts with a QIO to perform that review, which in the case of inpatient acute care review will also serve as the initial determination for QIO medical necessity and appropriateness review for patients who are dually entitled to benefits under Medicare and Medicaid.

(c) In accordance with § 431.15 of this subchapter, FFP will be available for expenses incurred in meeting the requirements of this part.

[46 FR 48566, Oct. 1, 1981, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.3 Statewide surveillance and utilization control program.

The Medicaid agency must implement a statewide surveillance and utilization control program that—

(a) Safeguards against unnecessary or inappropriate use of Medicaid services and against excess payments;

(b) Assesses the quality of those services;

(c) Provides for the control of the utilization of all services provided under the plan in accordance with subpart B of this part; and

(d) Provides for the control of the utilization of inpatient services in accordance with subparts C through I of this part.

§ 456.4 Responsibility for monitoring the utilization control program.

(a) The agency must—

(1) Monitor the statewide utilization control program;

(2) Take all necessary corrective action to ensure the effectiveness of the program;

(3) Establish methods and procedures to implement this section;

(4) Keep copies of these methods and procedures on file; and

(5) Give copies of these methods and procedures to all staff involved in carrying out the utilization control program.

§ 456.5 Evaluation criteria.

The agency must establish and use written criteria for evaluating the appropriateness and quality of Medicaid services. This section does not apply to services in hospitals and mental hospitals. For these facilities, see the following sections: §§ 456.122 and 456.132 of subpart C; and § 456.232 of subpart D.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.6 Review by State medical agency of appropriateness and quality of services.

(a) The Medicaid agency must have an agreement with the State health agency or other appropriate State medical agency, under which the health or medical agency is responsible for establishing a plan for the review by professional health personnel of the appropriateness and quality of Medicaid services.

(b) The purpose of this review plan is to provide guidance to the Medicaid agency in the administration of the State plan and, where applicable, to the State licensing agency described in § 431.610.

Subpart B—Utilization Control: All Medicaid Services

§ 456.21 Scope.

This subpart prescribes utilization control requirements applicable to all services provided under a State plan.

§ 456.22 Sample basis evaluation of services.

To promote the most effective and appropriate use of available services and facilities the Medicaid agency must have procedures for the on-going evaluation, on a sample basis, of the need for and the quality and timeliness of Medicaid services.

§ 456.23 Post-payment review process.

The agency must have a post-payment review process that—

(a) Allows State personnel to develop and review—

(1) Recipient utilization profiles;

(2) Provider service profiles; and

(3) Exceptions criteria; and

(b) Identifies exceptions so that the agency can correct misutilization practices of recipients and providers.

Subpart C—Utilization Control: Hospitals

§ 456.50 Scope.

This subpart prescribes requirements for control of utilization of inpatient hospital services, including requirements concerning—

(a) Certification of need for care;

(b) Plan of care; and

(c) Utilization review plans.

§ 456.51 Definitions.

As used in this subpart:

Inpatient hospital services—

(a) Include—

(1) Services provided in an institution other than an institution for mental disease, as defined in § 440.10;

(2) [Reserved]

(3) Services provided in specialty hospitals and

(b) Exclude services provided in mental hospitals. Utilization control requirements for mental hospitals appear in subpart D.

Medical care appraisal norms or *norms* means numerical or statistical measures of usually observed performance.

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

CERTIFICATION OF NEED FOR CARE

§ 456.60 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that inpatient services in a hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a hospital are needed.

(2) Recertifications must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981]

PLAN OF CARE

§ 456.80 Individual written plan of care.

(a) Before admission to a hospital or before authorization for payment, a physician and other personnel involved in the care of the individual must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Social services;

(vi) Diet;

(4) Plans for continuing care, as appropriate; and

(5) Plans for discharge, as appropriate.

(c) Orders and activities must be developed in accordance with physician's instructions.

(d) Orders and activities must be reviewed and revised as appropriate by all personnel involved in the care of an individual.

(e) A physician and other personnel involved in the recipient's case must review each plan of care at least every 60 days.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.100 Scope.

Sections 456.101 through 456.145 of this subpart prescribe requirements for a written utilization review (UR) plan for each hospital providing Medicaid services. Sections 456.105 and 456.106

prescribe administrative requirements: §§456.111 through 456.113 prescribe informational requirements; §§456.121 through 456.129 prescribe requirements for admission review; §§456.131 through 456.137 prescribe requirements for continued stay review; and §§456.141 through 456.145 prescribe requirements for medical care evaluation studies.

§456.101 UR plan required for inpatient hospital services.

(a) A State plan must provide that each hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the hospital furnishes him.

(b) Each written hospital UR plan must meet the requirements under §§456.101 through 456.145.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§456.105 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§456.106 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, ''UR committee'' includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the hospital staff;

(2) A group outside the hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality;

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of the patient whose care is being reviewed; or

(2) Has a financial interest in any hospital.

UR PLAN: INFORMATIONAL REQUIREMENTS

§456.111 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed for the UR committee to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under §456.70.

(e) Initial and subsequent continued stay review dates described under §§456.128 and 456.133.

(f) Date of operating room reservation, if applicable.

(g) Justification of emergency admission, if applicable.

(h) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(i) Other supporting material that the committee believes appropriate to be included in the record.

§456.112 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§456.113 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR ADMISSION[1]

§ 456.121 Admission review required.

The UR plan must provide for a review of each recipient's admission to the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.122 through 456.129.

§ 456.122 Evaluation criteria for admission review.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for admission; and

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.123 Admission review process.

The UR plan must provide that—

(a) Admission review is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup, or designee evaluates the admission against the criteria developed under § 456.122 and applies close professional scrutiny to cases selected under § 456.129(b);

(c) If the committee, subgroup, or designee finds that the admission is needed, the committee assigns an initial continued stay review date in accordance with § 456.128;

(d) If the committee, subgroup, or designee finds that the admission does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for admission;

(e) If the committee or subgroup making the review under paragraph (d) of this section finds that the admission is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(f) If the attending physician does not present additional information or clarification of the need for the admission, the decision of the committee or subgroup is final; and

(g) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the admission. If they find that the admission is not needed, their decision if final.

§ 456.124 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for admission under § 456.123 (e) through (g) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.125 Time limits for admission review.

Except as required under § 456.127, the UR plan must provide that review of each recipient's admission to the hospital is conducted—

(a) Within one working day after admission, for an individual who is receiving Medicaid at that time; or

(b) Within one working day after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.126 Time limits for final decision and notification of adverse decision.

Except as required under § 456.127, the UR plan must provide that the committee makes a final decision on a recipient's need for admission and gives notice of an adverse final decision—

[1] The Department was enjoined in 1975 in the case of American Medical Assn. et al. v. Weinberger, 395 F. Supp. 515 (N.D. Ill., 1975), aff'd., 522 F2d 921 (7th cir., 1975) from implementing the admission review requirements contained in §§ 456.121–456.127. This case was dismissed on the condition that these requirements be revised. They are presently being revised, and will not be in force until that revision is completed.

(a) Within two working days after admission, for an individual who is receiving Medicaid at that time; or

(b) Within two working days after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§456.127 Pre-admission review.

The UR plan must provide for review and final decision prior to admission for certain providers or categories of admissions that the UR committee designates under §456.142(b) (4)(iii) to receive pre-admission review.

§456.128 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the hospital under the admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under §456.129;

(2) The individual's condition; and

(3) The individual's projected discharge date;

(c)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These regional norms are based on current and statistically valid data on duration of stay in hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose case is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate; and

(d) The committee ensures that the initial continued stay review date is recorded in the individual's record.

§456.129 Description of methods and criteria: Initial continued stay review date; close professional scrutiny; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign the initial continued stay review date under §456.128.

(b) The methods that the committee uses to select categories of admission to receive close professional scrutiny under §456.123(b); and

(c) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§456.131 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the hospital to decide whether it is needed, in accordance with the requirements of §§456.132 through 456.137.

§456.132 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§456.133 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§456.128 and 456.134(a);

(b) The committee assigns a subsequent review date each time it decides under §456.135 that the continued stay is needed; and

(c) The committee ensures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.134 Description of methods and criteria: Subsequent continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign subsequent continued stay review dates under § 456.133; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.135 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.111 against the criteria developed under § 456.132 and applies close professional scrutiny to cases selected under § 456.129(b);

(d) If the committee, subgroup, or designee finds that a recipient's continued stay in the hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.133;

(e) If the committee, subgroup, or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his reviews before it makes a final decision on the need for the continued stay;

(g) If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. If they find that the recipient no longer needs inpatient hospital services, their decision is final.

§ 456.136 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.135 (f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.137 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.136 of an adverse final decision within 2 working days after the assigned continued stay review dates, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.136 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.141 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.142 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process for admissions or continued stay cases;

(ii) Recommend more effective and efficient hospital care procedures; or

(iii) Designate certain providers or categories of admissions for review prior to admission.

§ 456.143 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions;

(2) Durations of stay;

(3) Ancillary services furnished, including drugs and biologicals;

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for changes beneficial to patients, staff, the hospital, and the community.

§ 456.144 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data;

(b) External organizations that compile statistics, design profiles, and produce other comparative data;

(c) Cooperative endeavors with—

(1) QIOs;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.145 Number of studies required to be performed.

The hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart D—Utilization Control: Mental Hospitals

§ 456.150 Scope.

This subpart prescribes requirements for control of utilization of inpatient services in mental hospitals, including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.151 Definitions.

As used in this subpart:

Medical care appraisal norms or *norms* means numerical or statistical measures of usually observed performance.

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

CERTIFICATION OF NEED FOR CARE

§ 456.160 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that inpatient services in a mental hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a mental hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a mental hospital are needed.

(2) Recertification must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981]

MEDICAL, PSYCHIATRIC, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.170 Medical, psychiatric, and social evaluations.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must make a medical evaluation of each applicant's or recipient's need for care in the hospital; and appropriate professional personnel must make a psychiatric and social evaluation.

(b) Each medical evaluation must include—

(1) Diagnoses;

(2) Summary of present medical findings;

(3) Medical history;

(4) Mental and physical functional capacity;

(5) Prognoses; and

(6) A recommendation by a physician concerning—

(i) Admission to the mental hospital; or

(ii) Continued care in the mental hospital for individuals who apply for Medicaid while in the mental hospital.

§ 456.171 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.170.

PLAN OF CARE

§ 456.180 Individual written plan of care.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures recommended for the health and safety of the patient;

(5) Plans for continuing care, including review and modification to the plan of care; and

(6) Plans for discharge.

(c) The attending or staff physician and other personnel involved in the recipient's care must review each plan of care at least every 90 days.

§ 456.181 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the facility, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENTS

§ 456.200 Scope.

Sections 456.201 through 456.245 of this subpart prescribe requirements for a written utilization review (UR) plan for each mental hospital providing Medicaid services. Sections 456.205 and 456.206 prescribe administrative requirements; §§ 456.211 through 456.213 prescribe informational requirements;

§§456.231 through 456.238 prescribe requirements for continued stay review; and §§456.241 through 456.245 prescribe requirements for medical care evaluation studies.

§456.201 UR plan required for inpatient mental hospital services.

(a) The State plan must provide that each mental hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the mental hospital furnishes him.

(b) Each written mental hospital UR plan must meet the requirements under §§456.201 through 456.245.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§456.205 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§456.206 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, ''UR committee'' includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, one of whom is knowledgeable in the diagnosis and treatment of mental diseases, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the mental hospital staff;

(2) A group outside the mental hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of patients whose care is being reviewed; or

(2) Has a financial interest in any mental hospital.

UR PLAN: INFORMATIONAL REQUIREMENTS

§456.211 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under §456.172.

(e) Initial and subsequent continued stay review dates described under §§456.233 and 456.234.

(f) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§456.212 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§456.213 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§456.231 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay

in the mental hospital to decide whether it is needed, in accordance with the requirements of §§ 456.232 through 456.238.

§ 456.232 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.233 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the mental hospital under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) If an individual applies for Medicaid while in the mental hospital, the committee assigns the initial continued stay review date within 1 working day after the mental hospital is notified of the application for Medicaid;

(c) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.235(a);

(2) The individual's condition; and

(3) The individual's projected discharge date;

(d)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These norms are based on current and statistically valid data on duration of stay in mental hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose need for continued stay is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate;

(e) The initial continued stay review date is not in any case later than 30 days after admission of the individual or notice to the mental hospital of his application for Medicaid; and

(f) The committee insures that the initial continued stay review date is recorded in the individual's record.

§ 456.234 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.235(a) and 456.233;

(b) The committee assigns a subsequent continued stay review date at least every 90 days each time it decides under § 456.236 that the continued stay is needed; and

(c) The committee insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.235 Description of methods and criteria: Continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign initial and subsequent continued stay review dates under §§ 456.233 and 456.234 of this subpart; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.236 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued

stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the mental hospital, the committee, subgroup or designee reviews and evaluates the documentation described under §456.211 against the criteria developed under §456.232 and applies close professional scrutiny to cases described under §456.232(b).

(d) If the committee, subgroup or designee finds that a recipient's continued stay in the mental hospital is needed, the committee assigns a new continued stay review date in accordance with §456.234;

(e) If the committee, subgroup or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending or staff physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending or staff physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

(h) If the attending or staff physician presents additional information or clarification, at least two physician members of the committee, one of whom is knowledgeable in the treatment of mental diseases, review the need for the continued stay. If they find that the recipient no longer needs inpatient mental hospital services, their decision is final.

§456.237 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under §456.236 (f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending or staff physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§456.238 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under §456.237 of an adverse decision within 2 working days after the assigned continued stay review date, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under §456.237 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§456.241 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§456.242 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the mental hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient hospital care procedures.

§ 456.243 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the mental hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions.

(2) Durations of stay.

(3) Ancillary services furnished, including drugs and biologicals.

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for change beneficial to patients, staff, the hospital, and the community.

§ 456.244 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data.

(b) External organizations that compile statistics, design profiles, and produce other comparative data.

(c) Cooperative endeavors with—

(1) QIOs;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.245 Number of studies required to be performed.

The mental hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart E [Reserved]

Subpart F—Utilization Control: Intermediate Care Facilities

§ 456.350 Scope.

This subpart prescribes requirements for control of utilization of intermediate care facility (ICF) services including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.351 Definition.

As used in this subpart:

Intermediate care facility services means those items and services furnished in an intermediate care facility as defined in §§ 440.140 and 440.150 of this subchapter, but excludes those services if they are provided in religious nonmedical institutions as defined in § 440.170(b) of this chapter.

[43 FR 45266, Sept. 29, 1978, as amended at 64 FR 67052, Nov. 30, 1999]

CERTIFICATION OF NEED FOR CARE

§ 456.360 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that ICF services are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in an ICF, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that ICF services are needed.

(2) Recertification must be made at least—

(i) Every 12 months after certification in an institution for the mentally retarded or persons with related conditions; and

(ii) Every 60 days after certification in an ICF other than an institution for

the mentally retarded or persons with related conditions.

[46 FR 48561, Oct. 1, 1981, as amended at 50 FR 33034, Aug. 16, 1985]

MEDICAL, PSYCHOLOGICAL, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.370 Medical, psychological, and social evaluations.

(a) Before admission to an ICF or before authorization for payment, an interdisciplinary team of health professionals must make a comprehensive medical and social evaluation and, where appropriate, a psychological evaluation of each applicant's or recipient's need for care in the ICF.

(b) In an institution for the mentally retarded or persons with related conditions, the team must also make a psychological evaluation of need for care. The psychological evaluation must be made before admission or authorization of payment, but not more than three months before admission.

(c) Each evaluation must include—

(1) Diagnoses;

(2) Summary of present medical, social, and where appropriate, developmental findings;

(3) Medical and social family history;

(4) Mental and physical functional capacity;

(5) Prognoses;

(6) Kinds of services needed;

(7) Evaluation by an agency worker of the resources available in the home, family and community; and

(8) A recommendation concerning—

(i) Admission to the ICF; or

(ii) Continued care in the ICF for individuals who apply for Medicaid while in the ICF.

§ 456.371 Exploration of alternative services.

If the comprehensive evaluation recommends ICF services for an applicant or recipient whose needs could be met by alternative services that are currently unavailable, the facility must enter this fact in the recipient's record and begin to look for alternative services.

§ 456.372 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.370.

PLAN OF CARE

§ 456.380 Individual written plan of care.

(a) Before admission to an ICF or before authorization for payment, a physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures designed to meet the objectives of the plan of care;

(5) Plans for continuing care, including review and modification of the plan of care; and

(6) Plans for discharge.

(c) The team must review each plan of care at least every 90 days.

§ 456.381 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the ICF, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.400 Scope.

Sections 456.401 through 456.438 of this subpart prescribe requirements for a written utilization review (UR) plan

for each ICF providing Medicaid services. Sections 456.405 through 456.407 prescribe administrative requirements; §§ 456.411 through 456.413 prescribe informational requirements; and §§ 456.431 through 456.438 prescribe requirements for continued stay review.

§ 456.401 State plan UR requirements and options; UR plan required for intermediate care facility services.

(a) The State plan must provide that—

(1) UR is performed for each ICF that furnishes inpatient services under the plan;

(2) Each ICF has on file a written UR plan that provides for review of each recipient's need for the services that the ICF furnishes him; and

(3) Each written ICF UR plan meets requirements under §§ 456.401 through 456.438.

(b) The State plan must specify the method used to perform UR, which may be—

(1) Review conducted by the facility;

(2) Direct review in the facility by individuals—

(i) Employed by the medical assistance unit of the Medicaid agency; or

(ii) Under contract to the Medicaid agency; or

(3) Any other method.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.405 Description of UR review function: How and when.

The UR plan must include a written description of—

(a) How UR is performed in the ICF; and

(b) When UR is performed.

§ 456.406 Description of UR review function: Who performs UR; disqualification from performing UR.

(a) The UR plan must include a written description of who performs UR in the ICF.

(b) UR must be performed using a method specified under § 456.401(b) by a group of professional personnel that includes—

(1) At least one physician;

(2) In an ICF that cares primarily for mental patients, at least one individual knowledgeable in the treatment of mental diseases; and

(3) In an institution for the mentally retarded, a least one individual knowledgeable in the treatment of mental retardation.

(c) The group performing UR may not include any individual who—

(1) Is directly responsible for the care of the recipient whose care is being reviewed;

(2) Is employed by the ICF; or

(3) Has a financial interest in any ICF.

§ 456.407 UR responsibilities of administrative staff.

The UR plan must describe—

(a) The UR support responsibilities of the ICF's administrative staff; and

(b) Procedures used by the staff for taking needed corrective action.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.411 Recipient information required for UR.

The UR plan must provide that each recipient's record include information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) The name of the qualified mental retardation professional (as defined under § 442.401 of this subchapter), if applicable.

(d) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(e) The plan of care required under § 456.372;

(f) Initial and subsequent continued stay review dates described under §§ 456.433 and 456.434.

(g) Reasons and plan for continued stay, if the attending physician or qualified mental retardation professional believes continued stay is necessary.

(h) Other supporting material that the UR group believes appropriate to be included in the record.

§ 456.412 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the group performing UR; and

(b) The type and frequency of reports made by the UR group, and arrangements for distribution of the reports to appropriate individuals.

§ 456.413 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.431 Continued stay review required.

(a) The UR plan must provide for a review of each recipients continued stay in the ICF at least every 6 months to decide whether it is needed.

(b) The UR plan requirement for continued stay review may be met by—

(1) Reviews that are performed in accordance with the requirements of §§ 456.432 through 456.437; or

(2) Reviews that meet on-site inspection requirements under subpart I if—

(i) The composition of the independent professional review team under subpart I meets the requirements of § 456.406; and

(ii) Reviews are conducted as frequently as required under §§ 456.433 and 456.434.

§ 456.432 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The group performing UR develops written criteria to assess the need for continued stay.

(b) The group develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.433 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the ICF under admission review requirements of this subpart, the group performing UR assigns a specified date by which the need for his continued stay will be reviewed;

(b) The group performing UR bases its assignment of the initial continued stay review date on the methods and criteria required to be described under § 456.435(a);

(c) The initial continued stay review date is—

(1) Not later than 6 months after admission; or

(2) Earlier than 6 months after admission, if indicated at the time of admission; and

(d) The group performing UR insures that the initial continued stay review date is recorded in the recipient's record.

§ 456.434 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The group performing UR assigns subsequent continued stay review dates in accordance with § 456.435.

(b) The group assigns a subsequent continued stay review date each time it decides under § 456.436 that the continued stay is needed—

(1) At least every 6 months; or

(2) More frequently than every six months if indicated at the time of continued stay review; and

(c) The group insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.435 Description of methods and criteria: Continued stay review dates.

The UR plan must describe the methods and criteria that the group performing UR uses to assign initial and subsequent continued stay review dates under §§ 456.433 and 456.434.

§ 456.436 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The group performing UR; or

(2) A designee of the UR group;

(b) The group or its designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date.

(c) For each continued stay of a recipient in the ICF, the group or its designee reviews and evaluates the documentation described under § 456.411 against the criteria developed under § 456.432 and applies close professional scrutiny to cases described under § 456.432(b);

(d) If the group or its designee finds that a recipient's continued stay in the ICF is needed, the group assigns a new continued stay review date in accordance with § 456.434;

(e) If the group or its designee finds that a continued stay case does not meet the criteria, the group or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the group or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician or, in institutions for the mentally retarded, the recipient's qualified mental retardation professional, within 1 working day of its decision, and gives him 2 working days from the notification date to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending physician or qualified mental retardation professional does not present additional information or clarification of the need for the continued stay, the decision of the UR group is final;

(h) If the attending physician or qualified mental retardation professional presents additional information or clarification, the need for continued stay is reviewed by—

(1) The physician member(s) of the UR group, in cases involving a medical determination; or

(2) The UR group, in cases not involving a medical determination; and

(i) If the individuals performing the review under paragraph (h) of this section find that the recipient no longer needs ICF services, their decision is final.

§ 456.437 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.436 (g) through (i) is sent to—

(a) The ICF administrator;

(b) The attending physician;

(c) The qualified mental retardation professional, if applicable;

(d) The Medicaid agency;

(e) The recipient; and

(f) If possible, the next of kin or sponsor.

§ 456.438 Time limits for notification of adverse decision.

The UR plan must provide that the group gives notice under § 456.437 of an adverse decision not later than 2 days after the date of the final decision.

Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements

§ 456.480 Scope.

This subpart concerns admission and plan of care requirements that apply to inpatient psychiatric services for individuals under age 21 in hospitals, mental hospitals, and intermediate care facilities.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.481 Admission certification and plan of care.

If a facility provides inpatient psychiatric services to a recipient under age 21—

(a) The admission certification by the review team required in § 441.152 satisfies the requirement for physician certification of need for care in §§ 456.60, 456.160, and 456.360; and

(b) The development and review of the plan of care required in § 441.154 satisfies the requirement for physician recertification of need for care in the sections cited in paragraph (a) and the requirement for establishment and periodic review of the plan of care in §§ 456.80, 456.180, and 456.380.

(c) The plan of care must be established by the team described in § 441.156.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.482 Medical, psychiatric, and social evaluations.

If a facility provides inpatient psychiatric services to a recipient under age 21, the medical, psychiatric, and social evaluations required by §§ 456.170, and 456.370 must be made by the team described in § 441.153.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals and Mental Hospitals

§ 456.500 Purpose.

For hospitals and mental hospitals, this subpart—

(a) Prescribes conditions for the availability of FFP relating to UR plans;

(b) Prescribes conditions for granting a waiver of UR plan requirements; and

(c) Prescribes conditions for granting a variance in UR plan requirements for remote facilities.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.501 UR plans as a condition for FFP.

(a) Except when waived under §§ 456.505 through 456.508, FFP is not available in expenditures for Medicaid services furnished by a hospital or mental hospital unless the facility has in effect a UR plan that meets the utilization review requirements for Medicare under section 1861(k) of the Act.

(b) A facility that participates in Medicare and Medicaid must use the same UR standards and procedures and review committee for Medicaid as it uses for Medicare.

(c) A facility that does not participate in Medicare must meet the UR plan requirements in subpart C or D of this part, which are equivalent to the Medicare UR plan requirements in §§ 405.1137, 482.30, and 482.60 of this chapter.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22042, June 17, 1986; 61 FR 38399, July 24, 1996]

UR PLAN: WAIVER OF REQUIREMENTS

§ 456.505 Applicability of waiver.

The Administrator may waive the UR plan requirements of subparts C or D of this part, except for provisions relating to disqualification of UR committee members under § 456.106 of subpart C, and § 456.206 of subpart D, if the Medicaid agency—

(a) Applies for a waiver; and

(b) Demonstrates to the Administrator's satisfaction that it has in operation specific UR procedures that are superior in their effectiveness to the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.506 Waiver options for Medicaid agency.

(a) The agency may apply for a waiver at any time it has the procedures referred to under § 456.505(b) in operation at least—

(1) On a demonstration basis; or

(2) In any part of the State.

(b) Any hospital or mental hospital participating under the plan that is not covered by a waiver must continue to meet all the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.507 Review and granting of waiver requests.

(a) When the agency applies for a waiver, the Administrator will assess the agency's UR procedures and grant the waiver if he determines that the procedures meet criteria he establishes.

(b) The Administrator will review and evaluate each waiver between 1 and 2 years after he has granted it and between 1 and 2 years periodically thereafter.

§ 456.508 Withdrawal of waiver.

(a) The Administrator will withdraw a waiver if he determines that State procedures are no longer superior in their effectiveness to the procedures required for UR plans under subpart C or D of this part.

(b) If a waiver is withdrawn by the Administrator, each hospital or mental hospital covered by the waiver must meet all the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

UR PLAN: REMOTE FACILITY VARIANCES FROM TIME REQUIREMENTS

§ 456.520 Definitions.

As used in §§ 456.521 through 456.525 of this subpart:

Available physician or other professional personnel means an individual who—

(a) Is professionally qualified;

(b) Is not precluded from participating in UR under § 456.107 of subpart C; or § 456.207 of subpart D; and

(c) Is not precluded from effective participation in UR because he requires more than approximately 1 hour to travel between the remote facility and his place of work.

Remote facility means a facility located in an area that does not have enough available physicians or other professional personnel to perform UR as required under subparts C or D of this part, and for which the State requests a variance.

Variance means permission granted by the Administrator to the Medicaid agency for a specific remote facility to use time periods different from those specified for the start and completion of reviews of all cases under the following sections: §§ 456.125, 456.126, 456.136, and 456.137 of subpart C; and § 456.238 of subpart D.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.521 Conditions for granting variance requests.

(a) Except as described under paragraph (b) of this section, the administrator may grant a variance for a specific remote facility if the agency submits concurrently—

(1) A request for the variance that documents to his satisfaction that the facility is unable to meet the time requirements for which the variance is requested; and

(2) A revised UR plan for the facility.

(b) The Administrator will not grant a variance if the remote facility is operating under a UR plan waiver that the Secretary has granted or is considering under §§ 456.505 through 456.508.

§ 456.522 Content of request for variance.

The agency's request for a variance must include—

(a) The name, location, and type of the remote facility;

(b) The number of total patient admissions and the average daily patient census at the facility in the 6 months preceding the request;

(c) The number of Medicare and Medicaid patient admissions and the average daily Medicare and Medicaid patient census at the facility in the 6 months preceding the request;

(d) The name and location of each hospital, mental hospital, and ICF located within a 50-mile radius of the facility;

(e) The distance and average travel time between the remote facility and each facility listed in paragraph (e) of this section;

(f) Documentation by the facility of its attempts to obtain the services of available physicians or other professional personnel, or both;

(g) The names of all physicians on the active staff, and the names of all other professional personnel on the staff whose availability is relevant to the request;

(h) The practice locations of available physicians and the estimated number of available professional personnel whose availability is relevant to the request;

(i) Documentation by the facility of its inability to perform UR within the time requirements for which the variance is requested and its good faith efforts to comply with the UR plan requirements of subpart C or D of this part;

(j) An assurance by the facility that it will continue its good faith efforts to meet the UR plan requirements of subpart C or D of this part; and

(k) A statement of whether a planning or conditional PSRO exists in the area where the facility is located.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§456.523 Revised UR plan.

(a) The revised UR plan for the remote facility must specify the methods and procedures that the facility will use if a variance is granted to insure that it—

(1) Maintains effective and timely control over the utilization of services; and

(2) Conducts reviews in a way that improves the quality of care provided to patients.

(b) The revised UR plan for the remote facility is the basis for validation of UR under sec. 1903(g)(2) of the Act for the period when a variance is in effect.

§456.524 Notification of Administrator's action and duration of variance.

(a) The Administrator—

(1) Will notify the agency of the action he takes on its request for a variance; and

(2) Will specify the period of time, not to exceed 1 year, for which the variance may be granted.

(b) When it receives the Administrator's notification, the agency must promptly notify the remote facility of his action.

§456.525 Request for renewal of variance.

(a) The agency must submit a request for renewal of a variance to the Administrator at least 30 days before the variance expires.

(b) The renewal request must contain the information required under §456.522.

(c) The renewal request must show, to the Administrator's satisfaction, that the remote facility continues to meet the requirements of §§456.521 through 456.523.

Subpart I—Inspections of Care in Intermediate Care Facilities and Institutions for Mental Diseases

§456.600 Purpose.

This subpart prescribes requirements for periodic inspections of care and services intermediate care facilities (ICF's), and institutions for mental diseases (IMD's).

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§456.601 Definitions.

For purposes of this subpart—

Facility means an institution for mental diseases, or an intermediate care facility.

Intermediate care facility includes institutions for the mentally retarded or persons with related conditions but excludes religious nonmedical institutions as defined in §440.170(b) of this chapter.

Institution for mental diseases includes a mental hospital, a psychiatric facility, and an intermediate care facility that primarily cares for mental patients.

Psychiatric facility includes a facility or program that provides inpatient psychiatric services for individuals under 21, as specified in §441.151 of this chapter, but does not include psychiatric wards in acute care hospitals.

[44 FR 56337, Oct. 1, 1979, as amended at 61 FR 38399, July 24, 1996; 64 FR 67052, Nov. 30, 1999]

§456.602 Inspection team.

(a) A team, as described in this section and §456.603 must periodically inspect the care and services provided to recipients in each facility.

(b) Each team conducting periodic inspections must have a least one member who is at physician or registered nurse and other appropriate health and social service personnel.

(c) For an IMD other than an ICF, each team must have a psychiatrist or physician knowledgeable about mental institutions and other appropriate mental health and social service personnel.

(d) For an ICF that primarily cares for mental patients, each team must have at least one member who knows

the problems and needs of mentally retarded individuals.

(e) For an institution for the mentally retarded or persons with related conditions, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(f) For ICFs primarily serving individuals 65 years of age or older, each team must have at least one member who knows the problems and needs of those individuals.

(g) If there is no physician on the team, the Medicaid agency must insure that a physician is available to provide consultation to the team.

(h) If a team has one or more physicians, it must be supervised by a physician.

§ 456.603 Financial interests and employment of team members.

(a) Except as provided in paragraph (b) of this section—

(1) [Reserved]

(2) No member of a team that reviews care in an ICF may have a financial interest in or be employed by any ICF.

(b) A member of a team that reviews care in an IMD or an institution for the mentally retarded or persons with related conditions—

(1) May not have a financial interest in any institution of that same type but may have a financial interest in other facilities or institutions; and

(2) May not review care in an institution where he is employed but may review care in any other facility or institution.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.604 Physician team member inspecting care of recipients.

No physician member of a team may inspect the care of a recipient for whom he is the attending physician.

§ 456.605 Number and location of teams.

There must be a sufficient number of teams so located within the State that onsite inspections can be made at appropriate intervals in each facility caring for recipients.

§ 456.606 Frequency of inspections.

The team and the agency must determine, based on the quality of care and services being provided in a facility and the condition of recipients in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each recipient in the facility at least annually.

§ 456.607 Notification before inspection.

No facility may be notified of the time of inspection more than 48 hours before the scheduled arrival of the team.

§ 456.608 Personal contact with and observation of recipients and review of records.

(a) For recipients under age 21 in psychiatric facilities and recipients in ICFs, other than those described in paragraph (b) of this section, the team's inspection must include—

(1) Personal contact with and observation of each recipient; and

(2) Review of each recipient's medical record.

(b) For recipients age 65 or older in IMDs, the team's inspection must include—

(1) Review of each recipient's medical record; and

(2) If the record does not contain complete reports of periodic assessments required by § 441.102 of this subchapter or, if such reports are inadequate, personal contact with and observation of each recipient

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 17940, Mar. 23, 1979; 61 FR 38399, July 24, 1996]

§ 456.609 Determinations by team.

The team must determine in its inspection whether—

(a) The services available in the facility are adequate to—

(1) Meet the health needs of each recipient, and the rehabilitative and social needs of each recipient in an ICF; and

(2) Promote his maximum physical, mental, and psychosocial functioning.

(b) It is necessary and desirable for the recipient to remain in the facility;

(c) It is feasible to meet the recipient's health needs and, in an ICF, the recipient's rehabilitative needs, through alternative institutional or noninstitutional services; and

(d) Each recipient under age 21 in a psychiatric facility and each recipient in an institution for the mentally retarded or persons with related conditions is receiving active treatment as defined in §441.154 of this subchapter.

§456.610 Basis for determinations.

In making the determinations on adequacy of services and related matters under §456.609 for each recipient, the team may consider such items as whether—

(a) The medical evaluation, any required social and psychological evaluations, and the plan of care are complete and current; the plan of care and, where required, the plan of rehabilitation are followed; and all ordered services, including dietary orders, are provided and properly recorded;

(b) The attending physician reviews prescribed medications—

(1) At least every 30 days in psychiatric facilities, and mental hospitals; and

(2) At least quarterly in ICFs;

(c) Tests or observations of each recipient indicated by his medication regimen are made at appropriate times and properly recorded;

(d) Physician, nurse, and other professional progress notes are made as required and appear to be consistent with the observed condition of the recipient;

(e) The recipient receives adequate services, based on such observations as—

(1) Cleanliness;

(2) Absence of bedsores;

(3) Absence of signs of malnutrition or dehydration; and

(4) Apparent maintenance of maximum physical, mental, and psychosocial funtion;

(f) In an ICF, the recipient receives adequate rehabilitative services, as evidenced by—

(1) A planned program of activities to prevent regression; and

(2) Progress toward meeting objectives of the plan of care;

(g) The recipient needs any service that is not furnished by the facility or through arrangements with others; and

(h) The recipient needs continued placement in the facility or there is an appropriate plan to transfer the recipient to an alternate method of care.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§456.611 Reports on inspections.

(a) The team must submit a report promptly to the agency on each inspection.

(b) The report must contain the observations, conclusions, and recommendations of the team concerning—

(1) The adequacy, appropriateness, and quality of all services provided in the facility or through other arrangements, including physician services to recipients; and

(2) Specific findings about individual recipients in the facility.

(c) The report must include the dates of the inspection and the names and qualifications of the members of the team.

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 56337, Oct. 1, 1979]

§456.612 Copies of reports.

The agency must send a copy of each inspection report to—

(a) The facility inspected;

(b) The facility's utilization review committee;

(c) The agency responsible for licensing, certification, or approval of the facility for purposes of Medicare and Medicaid; and

(d) Other State agencies that use the information in the reports to perform their official function, including, if inspection reports concern IMD's, the appropriate State mental health authorities.

§456.613 Action on reports.

The agency must take corrective action as needed based on the report and recommendations of the team submitted under this subpart.

§ 456.614 Inspections by utilization review committee.

A utilization review committee under subparts C through F of this part may conduct the periodic inspections required by this subpart if—

(a) The committee is not based in the facility being reviewed; and

(b) The composition of the committee meets the requirements of this subpart.

Subpart J—Penalty for Failure To Make a Satisfactory Showing of an Effective Institutional Utilization Control Program

AUTHORITY: Secs. 1102 and 1903(g) of the Social Security Act (42 U.S.C. 1302 and 1396 b(g)).

SOURCE: 44 FR 56338, Oct. 1, 1979, unless otherwise noted.

§ 456.650 Basis, purpose and scope.

(a) *Basis.* Section 1903(g) of the Act requires that FFP for long-stay inpatient services at a level of care be reduced, by a specified formula, for any quarter in which a State fails to make a satisfactory showing that it has an effective program of utilization control for that level of care.

(b) *Purpose.* This subpart specifies—

(1) What States must do to make a satisfactory showing;

(2) How the Administrator will determine whether reductions will be imposed; and

(3) How the required reductions will be implemented.

(c) *Scope.* The reductions required by this subpart do not apply to—

(1) Services provided under a contract with a health maintenance organization; or

(2) Facilities in which a QIO is performing medical and utilization reviews under contract with the Medicaid agency in accordance with § 431.630 of this chapter.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.651 Definitions.

For purposes of this subpart—

Facility, with respect to inpatient psychiatric services for individuals under 21, includes a psychiatric program as specified in § 441.151 of this chapter.

Level of care means one of the following types of inpatient services: hospital, mental hospital, intermediate care facility, or psychiatric services for individuals under 21.

Long-stay services means services provided to a recipient after a total of 60 days of inpatient stay (90 in the case of mental hospital services) during a 12-month period beginning July 1, not counting days of stay paid for wholly or in part by Medicare.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.652 Requirements for an effective utilization control program.

(a) *General requirements.* In order to avoid a reduction in FFP, the Medicaid agency must make a satisfactory showing to the Administrator, in each quarter, that it has met the following requirements for each recipient:

(1) Certification and recertification of the need for inpatient care, as specified in §§ 456.60, 456.160, 456.360 and 456.481.

(2) A plan of care established and periodically reviewed and evaluated by a physician, as specified in §§ 456.80, 456.180, and 456.481.

(3) A continuous program of utilization review under which the admission of each recipient is reviewed or screened in accordance with section 1903(g)(1)(C) of the Act; and

(4) A regular program of reviews, including medical evaluations, and annual on-site reviews of the care of each recipient, as specified in §§ 456.170, and 456.482 and subpart I of this part.

(b) *Annual on-site review requirements.* (1) An agency meets the quarterly on-site review requirements of paragraph (a)(4) of this section for a quarter if it completes on-site reviews of each recipient in every facility in the State, and in every State-owned facility regardless of location, by the end of the quarter in which a review is required under paragraph (b)(2) of this section.

(2) An on-site review is required in a facility by the end of a quarter if the facility entered the Medicaid program during the same calendar quarter 1 year earlier or has not been reviewed since the same calendar quarter 1 year

earlier. If there is no Medicaid recipient in the facility on the day a review is scheduled, the review is not required until the next quarter in which there is a Medicaid recipient in the facility.

(3) If a facility is not reviewed in the quarter in which it is required to be reviewed under paragraph (b)(2) of this section, it will continue to require a review in each subsequent quarter until the review is performed.

(4) The requirement for an on-site review in a given quarter is not affected by the addition or deletion of a level of care in a facility's provider agreement.

(c) *Facilities without valid provider agreements.* The requirements of paragraphs (a) and (b) of this section apply with respect to recipients for whose care the agency intends to claim FFP even if the recipients receive care in a facility whose provider agreement has expired or been terminated.

[44 FR 56338, Oct. 1, 1979, as amended at 46 FR 48561, Oct. 1, 1981; 61 FR 38399, July 24, 1996]

§ 456.653 Acceptable reasons for not meeting requirements for annual on-site review.

The Administrator will find an agency's showing satisfactory, even if it failed to meet the annual review requirements of § 456.652(a)(4), if—

(a) The agency demonstrates that—

(1) It completed reviews by the end of the quarter in at least 98 percent of all facilities requiring review by the end of the quarter;

(2) It completed reviews by the end of the quarter in all facilities with 200 or more certified Medicaid beds requiring review by the end of the quarter; and

(3) With respect to all unreviewed facilities, the agency exercised good faith and due diligence by attempting to review those facilities and would have succeeded but for events beyond its control which it could not have reasonably anticipated; or

(b) The agency demonstrates that it failed to meet the standard in paragraph (a) (1) and (2) of this section by the close of the quarter for technical reasons, but met the standard within 30 days after the close of the quarter. Technical reasons are circumstances within the agency's control.

(c) Facilities that are reviewed under paragraph (b) of this section, after the quarter in which they were due for review, retain their original anniversary quarter due date for purposes of subsequent reviews.

§ 456.654 Requirements for content of showings and procedures for submittal.

(a) An agency's showing for a quarter must—

(1) Include a certification by the agency that the requirements of § 456.652(a) (1) through (4) were met during the quarter for each level of care or, if applicable, a certification of the reasons the annual on-site review requirements of § 456.652(a)(4) were not met in any facilities;

(2) For all mental hospitals, intermediate care facilities, and facilities providing inpatient psychiatric services for individuals under 21, participating in Medicaid any time during the 12–month period ending on the last day of the quarter, list each facility by level of care, name, address and provider number;

(3) For each facility entering or leaving the program during the 12–month period ending on the last day of the quarter, list the beginning or ending dates of the provider agreement and supply a copy of the provider agreement;

(4) If review has been contracted to a QIO under § 431.630 of this chapter, list the date the QIO contracted for review.

(5) List all dates of on-site reviews completed by review teams anytime during the 12–month period ending on the last day of the quarter;

(6) For all facilities in which an on-site review was required but not conducted, list the facility by name, address and provider number;

(7) For each on-site review in a mental hospital, intermediate care facility that primarily cares for mental patients, or inpatient psychiatric facility, list the name and qualifications of one team member who is a physician; and

(8) For each on-site review in an intermediate care facility that does not primarily care for mental patients, list the name and qualifications of one team member who is either a physician or registered nurse.

(b) The quarterly showing must be in the form prescribed by the Administrator.

(c) The quarterly showing must be postmarked or received within 30 days after the close of the quarter for which it is made, unless the agency demonstrates good cause for later submittal and the showing is postmarked or received within 45 days after the close of the quarter. Good cause means unanticipated circumstances beyond the agency's control.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986; 61 FR 38399, July 24, 1996]

§ 456.655 Validation of showings.

(a) The Administrator will periodically validate showings submitted under § 456.654. Validation procedures will include on-site sample surveys of institutions and surveys at the Medicaid agencies.

(b) The Administrator will not find an agency's showing satisfactory if the information obtained through his validation procedures demonstrates, that any of the requirements of § 456.652(a)(1) through (4) were not met during the quarter for which the showing was made.

§ 456.656 Reductions in FFP.

(a) If the Administrator determines an agency's showing does not meet each of the requirements of this subpart, he will give the agency 30 days notice before making the required reduction.

(b) If the Administrator determines that a showing for any quarter is unsatisfactory on its face, he will make the required reduction in the grant award based on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program for that quarter. (This form CMS–64 is described in § 430.30(c) of this chapter.)

(c) If the Administrator finds a showing satisfactory on its face, but after validation determines the showing to be unsatisfactory, he will notify the agency of any required reduction in FFP no later than the first day of the fourth calendar quarter following the calendar quarter for which the showing was made. Any required reduction will be made by amending or adjusting the agency's grant award.

(d) The agency may request reconsideration of a reduction in accordance with the procedures specified in 45 CFR part 16.

§ 456.657 Computation of reductions in FFP.

(a) For each level of care specified in a provider agreement, and for each quarter for which a satisfactory showing is not made, the amount of the reduction in FFP is computed as follows:

(1) For each level of care, the number of recipients who received services in facilities that did not meet the requirements of this subpart is divided by the total number of recipients who received services in facilities for which a showing was required under this subpart. If any of the requirements specified in § 456.652(a)(1) through (4) were not met for any recipient in a facility, the reduction will be computed on the total number of recipients in that facility at the level of care in question.

(2) The fraction obtained in paragraph (a)(1) of this section is multiplied by one-third.

(3) The product obtained in paragraph (a)(2) of this section is multiplied by the Federal Medical Assistance Percentage (FMAP).

(4) The product obtained in paragraph (a)(3) of this section is multiplied by the agency payments for longstay services furnished during the quarter at that level of care.

(b) If any of the data required to compute the amount of the reduction in FFP are unavailable, the Administrator will substitute an estimate. If the agency determines the exact data to the satisfaction of the Administrator, the estimate may later be adjusted. If the number of recipients in individual facilities is not available, the fraction specified in paragraph (a)(1) of this section will be estimated, for each level of care, by dividing the number of facilities in which the requirements were not met by the total number of facilities for which a showing is required under this subpart.

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

SOURCE: 57 FR 49408, Nov. 2, 1992, unless otherwise noted.

§456.700 Scope.

This subpart prescribes requirements for—

(a) An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;

(b) The establishment, composition, and functions of a State DUR Board; and

(c) An optional point-of-sale electronic claims management system for processing claims for covered outpatient drugs.

§456.702 Definitions.

For purposes of this subpart—

Abuse is defined as in §455.2 of this chapter.

Adverse medical result means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.

Appropriate and medically necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with §456.703.

Criteria is defined as in §466.1 of this chapter.

Fraud is defined as in §455.2 of this chapter.

Gross overuse means repetitive overutilization without therapeutic benefit.

Inappropriate and medically unnecessary means drug prescribing and dispensing not in conformity with the definition of *appropriate and medically necessary*.

Overutilization means use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesirable effect, or both.

Predetermined standards means criteria and standards that have been established in accordance with the requirements of §456.703.

Standards is defined as in §466.1 of this chapter.

Underutilization means use of a drug by a recipient in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesired effect, or both.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§456.703 Drug use review program.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in order for FFP to be paid or made available under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of this subpart. The goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy.

(b) *Exception for drugs dispensed to certain nursing facility residents.* Prospective drug review and retrospective drug use review (including interventions and education) under the DUR program are not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in part 483 of this chapter. This does not preclude the State agency from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State agency makes the drugs subject to all the requirements of this subpart applicable to the respective review.

(c) *Exemption for certain covered outpatient drugs dispensed by hospitals and health maintenance organizations.* (1) The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart. Individual hospitals requesting this exemption must provide assurances to the State agency that they meet the requirements specified in section 1927(j)(2) of the Act.

(2) The State plan must provide that covered outpatient drugs dispensed by health maintenance organizations are not subject to the requirements of this subpart.

(d) *Use of predetermined standards.* A DUR program must assess drug use information against predetermined standards.

(e) *Source of predetermined standards.* The predetermined standards must be—

(1) Developed directly by the State or its contractor;

(2) Obtained by the State through contracts with commercial vendors of DUR services;

(3) Obtained by the State from independent organizations, such as the United States Pharmacopeial Convention, or entities receiving funding from the Public Health Service, CMS, or State agencies; or

(4) Any combination of paragraphs (e)(1) through (e)(3) of this section.

(f) *Requirements for predetermined standards.* The predetermined standards used in the DUR program must meet the following requirements:

(1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts) and the following compendia:

(i) American Hospital Formulary Service Drug Information;

(ii) United States Pharmacopeia-Drug Information;

(iii) American Medical Association Drug Evaluations.

(2) Differences between source materials were resolved by physicians and pharmacists developing consensus solutions. The consensus process means the reliance, by the criteria developers, on the expertise of physicians and pharmacists to evaluate differences in criteria source materials and to come to agreement on how differences should be resolved.

(3) They are non-proprietary and readily available to providers of services. Systems and algorithms using the predetermined standards may remain proprietary.

(4) They are clinically-based and scientifically valid.

(5) The review based on clinical criteria uses predetermined standards to determine the population at risk of a clinically significant adverse medical result and applies standards, appropriate to this population, across providers and patients to determine the provider outliers whose prescribing, dispensing, or consumption practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these data. Standards may be considered in deciding if an in-depth review is needed to determine whether to intervene once the potential therapeutic problems have been identified through the use of clinical criteria.

(6) They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems without undue levels of false positives.

(7) The predetermined standards for prospective and retrospective DUR are compatible.

(8) They are subjected to ongoing evaluation and modification either as a result of actions by their developer or as a result of recommendations by the DUR Board.

(g) *Access to predetermined standards.* Upon their adoption, predetermined standards must be available to the public. Pharmacists and physicians must be informed of the existence of predetermined standards and of how they can obtain copies of them.

(h) *Confidentiality of patient related data.* In implementing the DUR program, the agency must establish, in regulations or through other means, policies concerning confidentiality of patient related data that are consistent with applicable Federal confidentiality requirements at part 431, subpart F of this chapter; the State Pharmacy Practice Act; and the guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§456.705 Prospective drug review.

(a) *General.* Except as provided in §§456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient, and applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient's caregiver. The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements, including guidelines on counseling, profiling, and documentation of prospective DUR activities by the pharmacists. The pharmacies, in turn, must provide this information to their pharmacists. This information is to be based on guidelines provided by this subpart and by other sources that the State may specify.

(b) *Point-of-sale or point-of-distribution review.* Except as provided in §§456.703 (b) and (c), the State plan must provide for point-of-sale or point-of-distribution review of drug therapy using predetermined standards before each prescription is filled or delivered to the recipient or the recipient's caregiver. The review must include screening to identify potential drug therapy problems of the following types:

(1) Therapeutic duplication, that is, the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.

(2) Drug-disease contraindication, that is, the potential for, or the occurrence of—

(i) An undesirable alteration of the therapeutic effect of a given drug because of the presence, in the patient for whom it is prescribed, of a disease condition; or

(ii) An adverse effect of the drug on the patient's disease condition.

(3) Adverse drug-drug interaction, that is, the potential for, or occurrence of, a clinically significant adverse medical effect as a result of the recipient using two or more drugs together.

(4) Incorrect drug dosage, that is, the dosage lies outside the daily dosage specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage is the strength multiplied by the quantity dispensed divided by day's supply.

(5) Incorrect duration of drug treatment, that is, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

(6) Drug-allergy interactions, that is, the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

(7) Clinical abuse/misuse, that is, the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in §456.702, and incorrect dosage and incorrect duration, as defined in paragraphs (b)(4) and (b)(5) of this section, respectively.

(c) *Drug counseling.* (1) As part of the prospective drug review program, standards for counseling by pharmacists of recipients or the recipients' caregivers must be established by State law or other method that is satisfactory to the State agency. A State agency's counseling standards must address special situations where the patient or the patient's representative, is not readily available to receive the offer to counsel or the actual counseling, for example, prescriptions delivered offsite or through the mail. The State agency, at a minimum, must also address the following issues in their counseling standards:

(i) Whether the offer to counsel is required for new prescriptions only, or for both new and refill prescriptions;

(ii) Whether pharmacists must make the offer to counsel or auxiliary personnel are authorized to make the offer;

(iii) Whether only a patient's refusal of the offer to counsel must be documented, or whether documentation of all offers is required;

(iv) Whether documentation of counseling is required; and

(v) Whether counseling is required in situations where the patient's representative is not readily available to receive a counseling offer or the counseling itself.

(2) The standards must meet the following requirements:

(i) They must require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Mail order pharmacies are required to provide toll-free telephone service for long distance calls.

(ii) They need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses that consultation.

(iii) They must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

(3) The standards must specify that the counseling include those matters listed in paragraphs (c)(3)(i) through (c)(3)(viii) of this section that, in the exercise of his or her professional judgement (consistent with State law regarding the provision of such information), the pharmacist considers significant as well as other matters the pharmacist considers significant.

(i) The name and description of the medication;

(ii) The dosage form, dosage, route of administration, and duration of drug therapy;

(iii) Special directions and precautions for preparation, administration, and use by the patient;

(iv) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) Techniques for self-monitoring drug therapy;

(vi) Proper storage;

(vii) Prescription refill information; and

(viii) Action to be taken in the event of a missed dose.

(d) *Profiling.* The State agency must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing, at a minimum, the information listed in paragraphs (d)(1) through (d)(3) of this section.

(1) Name, address, telephone number, date of birth (or age), and gender of the patient;

(2) Individual history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist's comments relevant to the individual's drug therapy.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.709 Retrospective drug use review.

(a) *General.* The State plan must provide for a retrospective DUR program for ongoing periodic examination (no less frequently than quarterly) of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. This examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. This program must be provided through the State's mechanized drug claims processing and information retrieval systems approved by CMS (that is, the Medicaid Management Information System (MMIS)) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use existing systems provided that the results of the examination of drug claims as described in this section are integrated within their existing system.

(b) *Use of predetermined standards.* Retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

(1) Therapeutic appropriateness, that is, drug prescribing and dispensing that is in conformity with the predetermined standards.

(2) Overutilization and underutilization, as defined in § 456.702.

(3) Appropriate use of generic products, that is, use of such products in conformity with State product selection laws.

(4) Therapeutic duplication as described in §456.705(b)(1).

(5) Drug-disease contraindication as described in §456.705(b)(2).

(6) Drug-drug interaction as described in §456.705(b)(3).

(7) Incorrect drug dosage as described in §456.705(b)(4).

(8) Incorrect duration of drug treatment as described in §456.705(b)(5).

(9) Clinical abuse or misuse as described in §456.705(b)(7).

§456.711 Educational program.

The State plan must provide for ongoing educational outreach programs that, using DUR Board data on common drug therapy problems, educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The program may be established directly by the DUR Board or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies, or other organizations. The program must include the interventions listed in paragraphs (a) through (d) of this section. The DUR Board determines the content of education regarding common therapy problems and the circumstances in which each of the interventions is to be used.

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards required by §456.705(c) for use in assessing drug use.

(b) Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.

(c) Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.

(d) Intensified review or monitoring of selected prescribers or dispensers.

§456.712 Annual report.

(a) *DUR Board report.* The State must require the DUR Board to prepare and submit an annual DUR report to the Medicaid agency that contains information specified by the State.

(b) *Medicaid agency report.* The Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter. After the first annual report, only changes must be reported.

(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at §456.703(f) and with the access to the predetermined standards requirement at §456.703(g). After the first annual report, only changes must be reported.

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations. After the first annual report, only changes must be reported.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities. After the first annual report, only changes must be reported.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

§ 456.714 DUR/surveillance and utilization review relationship.

(a) The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455 of this chapter.

(b) A State agency may direct DUR staffs to limit review activities to those that focus on what constitutes appropriate and medically necessary care to avoid duplication of activities relating to fraud and abuse under the SUR program.

[59 FR 48825, Sept. 23, 1994]

§ 456.716 DUR Board.

(a) *State DUR Board requirement and member qualifications.* Each State must establish, either directly or through a contract with a private organization, a DUR Board. The DUR Board must include health care professionals who have recognized knowledge and expertise in at least one of the following:

(1) Clinically appropriate prescribing of covered outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of covered outpatient drugs.

(3) Drug use review, evaluation, and intervention.

(4) Medical quality assurance.

(b) *Board composition.* At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed.

(c) *Medicaid agency/DUR Board relationship.* The Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

(d) *DUR Board activities.* The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

(1) *Application of predetermined standards: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(iii) Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.

(2) *Application of predetermined standards: Medicaid agency role.* The Medicaid agency or its contractor should perform the following activities:

(i) Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.

(ii) If prospective DUR is conducted using an electronic claims management (ECM) system, apply software approved by the Board.

(iii) If prospective DUR is not conducted through an ECM system, as part of general compliance monitoring, ensure that Medicaid participating pharmacies conduct prospective drug review that screens for the potential drug therapy problems listed in section 1927(g)(2)(A) of the Act.

(3) *Retrospective DUR: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(4) *Retrospective DUR: Medicaid agency role.* The Medicaid agency or its contractor should apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

(5) *Education program (including interventions): Board's activities.* The DUR Board must perform the following activities:

(i) Identify and develop educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.

(ii) Make recommendations as to which mix of the interventions set forth in §§ 456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy. The DUR board recommendations must be based upon an in-depth review of the results of the application of predetermined standards against claims data reports, must be appropriate based upon program experience, and must match the educational program with the drug therapy problems identified.

(iii) Periodically re-evaluate and, if necessary, modify the interventions.

(6) *Education program (including interventions): Medicaid agency's role.* The Medicaid agency or its contractor should perform the following activities.

(i) Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and interventions and furnish those reports to the Board.

(ii) Carry out the educational programs and interventions specified by the Board.

(e) *Funding for the Board.* FFP is available for expenses associated with the operation of the DUR Board in carrying out its responsibilities, and payment is made under procedures established in part 433 of this chapter as follows:

(1) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are met, at the rate of 75 percent.

(2) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are not met, at the rate specified in § 456.719.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48825, Sept. 23, 1994]

§ 456.719 Funding for DUR program.

FFP is available for sums that the Secretary determines are attributable to the Statewide adoption of a DUR program as described in this subpart, and payment is made under procedures established in part 433 of this chapter as follows:

(a) For funds expended by the State during calendar years 1991 through 1993, at the rate of 75 percent.

(b) For funds expended by the State after December 31, 1993, at the rate of 50 percent.

§ 456.722 Electronic claims management system.

(a) *Point-of-sale system.* Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The State determines who

must participate in an ECM system and who may decline to do so. If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) *Functional requirements.* The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. The real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State to permit claims to be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and Medicaid agency.

(1) Eligibility verification, including identification of the following:

(i) Third-party payers.

(ii) Recipients in managed care programs.

(iii) Recipients and providers in restricted service programs (for example, lock-in and lock-out).

(iv) Properly enrolled providers.

(2) Claims data capture, including the following:

(i) Transfer of claims information from the pharmacy to the Medicaid agency or the Medicaid agency's contractor.

(ii) Identification of prescriber.

(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

(c) *Additional requirements.* In order to receive FFP for its ECM system, the State must meet the following requirements:

(1) The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G-O of OMB circular A–102. The request for proposal (RFP) may be substituted for the advance planning and implementation documents otherwise required by part 433 of this chapter, 45 CFR 95.205, and 45 CFR part 307. A cost-benefit analysis must accompany the RFP. If in its advance planning document, a State establishes that a separate procurement is not cost-effective, modification of an existing fiscal agent contract will be acceptable. In this case, procurement of network services and equipment (but not software modifications) must be competitively procured.

(2) States wishing to do prospective DUR as part of their ECM must do the following:

(i) Submit a cost benefit analysis showing the cost-effectiveness of such a system. A State's decisions as to who must participate in the ECM system and who may decline to do so must be included in the cost-benefit analysis.

(ii) Establish a central State-wide electronic repository for capturing, storing, and updating data for all prescriptions dispensed and for providing access to such data by all authorized participants.

(iii) Design the system to assess data for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. The type of review conducted must meet the requirements for prospective drug review set forth in § 456.705.

(3) ECM is considered a subsystem and must be fully integrated with the remainder of the State's MMIS. In addition, information about ECM claims must be part of the single comprehensive utilization and management reporting system used by the DUR program.

§ 456.725 Funding of ECM system.

(a) For funds expended during calendar quarters in fiscal years 1991 and 1992 and attributable to the design, development, and implementation of an on-line, real-time claims management

system (that is, the most cost-effective telecommunications network and automatic data processing services and equipment) that meets the requirements of §456.722, FFP is available at a matching rate of 90 percent. After fiscal year 1992, ECM subsystems are funded at the standard applicable MMIS enhanced rates, subject to the requirements of part 433, subpart A of this chapter.

(b) FFP is available at a matching rate of 75 percent for funds expended for the following:

(1) Telecommunications equipment and other equipment to directly access MMIS files.

(2) Telecommunications equipment (such as modems and point of sale terminals) furnished to providers.

(3) Operational costs including telecommunications network costs, provided that the ECM system includes eligibility verification systems, electronic claims capture, claims adjudication (except for payment), and a claims data process that is integrated into a single comprehensive utilization and information reporting system.

SUBCHAPTER D—STATE CHILDREN'S HEALTH INSURANCE PROGRAMS (SCHIPs)

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Subpart A—Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

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§ 457.1 Program description.

Title XXI of the Social Security Act, enacted in 1997 by the Balanced Budget Act, authorizes Federal grants to States for provision of child health assistance to uninsured, low-income children. The program is jointly financed by the Federal and State governments and administered by the States. Within broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures.

§ 457.2 Basis and scope of subchapter D.

(a) *Basis.* This subchapter implements title XXI of the Act, which authorizes Federal grants to States for the provision of child health assistance to uninsured, low-income children.

(b) *Scope.* The regulations in subchapter D set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP) to enable States to provide health benefits coverage to targeted low-income children, as defined at § 457.310.

§ 457.10 Definitions and use of terms.

For purposes of this part the following definitions apply:

American Indian/Alaska Native (AI/AN) means—

(1) A member of a Federally recognized Indian tribe, band, or group;

(2) An Eskimo or Aleut or other Alaska Native enrolled by the Secretary of the Interior pursuant to the Alaska Native Claims Settlement Act, 43 U.S.C. 1601 et. seq.; or

(3) A person who is considered by the Secretary of the Interior to be an Indian for any purpose.

Applicant means a child who has filed an application (or who has an application filed on their behalf) for health benefits coverage through the Children's Health Insurance Program. A child is an applicant until the child receives coverage through CHIP.

Child means an individual under the age of 19 including the period from conception to birth.

Child health assistance means payment for part or all of the cost of health benefits coverage provided to targeted low-income children for the services listed at § 457.402.

Children's Health Insurance Program (CHIP) means a program established and administered by a State, jointly funded with the Federal government, to provide child health assistance to uninsured, low-income children through a separate child health program, a Medicaid expansion program, or a combination program.

Combination program means a program under which a State implements both a Medicaid expansion program and a separate child health program.

Cost sharing means premium charges, enrollment fees, deductibles, coinsurance, copayments, or other similar fees that the enrollee has responsibility for paying.

Creditable health coverage has the meaning given the term ''creditable coverage'' at 45 CFR 146.113 and includes coverage that meets the requirements of § 457.410 and is provided to a targeted low-income child.

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(1) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of a woman or her unborn child;

(2) Serious impairment of bodily function; or

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

Emergency services means health care services that are—

(1) Furnished by any provider qualified to furnish such services; and (2) Needed to evaluate, treat, or stabilize an emergency medical condition.

Enrollee means a child who receives health benefits coverage through CHIP.

Enrollment cap means a limit, established by the State in its State plan, on the total number of children permitted to enroll in a State's separate child health program.

Family income means income as determined by the State for a family as defined by the State.

Federal fiscal year starts on the first day of October each year and ends on the last day of the following September.

Fee-for-service entity has the meaning assigned in §457.902.

Group health insurance coverage has the meaning assigned at 45 CFR 144.103.

Group health plan has the meaning assigned at 45 CFR 144.103.

Health benefits coverage means an arrangement under which enrolled individuals are protected from some or all liability for the cost of specified health care services.

Health care services means any of the services, devices, supplies, therapies, or other items listed in §457.402.

Health insurance coverage has the meaning assigned at 45 CFR 144.103.

Health insurance issuer has the meaning assigned at 45 CFR 144.103.

Health maintenance organization (HMO) plan has the meaning assigned at §457.420.

Health services initiatives means activities that protect the public health, protect the health of individuals, improve or promote a State's capacity to deliver public health services, or strengthen the human and material resources necessary to accomplish public health goals relating to improving the health of children (including targeted low-income children and other low-income children).

Joint application has the meaning assigned at §457.301.

Low-income child means a child whose family income is at or below 200 percent of the poverty line for the size of the family involved.

Managed care entity (MCE) means an entity that enters into a contract to provide services in a managed care delivery system, including but not limited to managed care organizations, prepaid health plans, and primary care case managers.

Medicaid applicable income level means, with respect to a child, the effective income level (expressed as a percentage of the poverty line) specified under the policies of the State plan under title XIX of the Act (including for these purposes, a section 1115 waiver authorized by the Secretary or under the authority of section 1902(r)(2) of the Act) as of March 31, 1997 for the child to be eligible for medical assistance under either section 1902(l)(2) or 1905(n)(2) of the Act.

Medicaid expansion program means a program under which a State receives Federal funding to expand Medicaid eligibility to optional targeted low-income children.

Optional targeted low-income child has the meaning assigned at §435.4 (for States) and §436.3 (for Territories) of this chapter.

Period of presumptive eligibility has the meaning assigned at §457.301.

Poverty line/Federal poverty level means the poverty guidelines updated annually in the FEDERAL REGISTER by the U.S. Department of Health and Human Services under authority of 42 U.S.C. 9902(2).

Preexisting condition exclusion has the meaning assigned at 45 CFR 144.103.

Premium assistance program means a component of a separate child health program, approved under the State plan, under which a State pays part or all of the premiums for a CHIP enrollee or enrollees' group health insurance coverage or coverage under a group health plan.

Presumptive income standard has the meaning assigned at §457.301.

Public agency has the meaning assigned in §457.301.

Qualified entity has the meaning assigned at §457.301.

Separate child health program means a program under which a State receives Federal funding from its title XXI allotment to provide child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act and §457.402.

State means all States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa and the Northern Mariana Islands. The Territories are excluded from this definition for purposes of §457.740.

State health benefits plan has the meaning assigned in §457.301.

State plan means the title XXI State child health plan.

Targeted low-income child has the meaning assigned in § 457.310.

Uncovered or uninsured child means a child who does not have creditable health coverage.

Well-baby and well-child care services means regular or preventive diagnostic and treatment services necessary to ensure the health of babies, children and adolescents as defined by the State. For purposes of cost sharing, the term has the meaning assigned at § 457.520.

[66 FR 2670, Jan. 11, 2001, as amended at 67 FR 61974, Oct. 2, 2002; 75 FR 48852, Aug. 11, 2010]

§ 457.30 Basis, scope, and applicability of subpart A.

(a) *Statutory basis.* This subpart implements the following sections of the Act:

(1) Section 2101(b), which requires that the State submit a State plan.

(2) Section 2102(a), which sets forth requirements regarding the contents of the State plan.

(3) Section 2102(b), which relates to eligibility standards and methodologies.

(4) Section 2102(c), which requires that the State plan include a description of the procedures to be used by the State to accomplish outreach and coordination with other health insurance programs.

(5) Section 2106, which specifies the process for submission, approval, and amendment of State plans.

(6) Section 2107(c), which requires that the State plan include a description of the process used to involve the public in the design and implementation of the plan.

(7) Section 2107(d), which requires that the State plan include a description of the budget for the plan.

(8) Section 2107(e), which provides that certain provisions of title XIX and title XI of the Act apply under title XXI in the same manner that they apply under title XIX.

(b) *Scope.* This subpart sets forth provisions governing the administration of CHIP, the general requirements for a State plan, and a description of the process for review of a State plan or plan amendment.

(c) *Applicability.* This subpart applies to all States that request Federal financial participation to provide child health assistance under title XXI.

§ 457.40 State program administration.

(a) *Program operation.* The State must implement its program in accordance with the approved State plan, any approved State plan amendments, the requirements of title XXI and title XIX (as appropriate), and the requirements in this chapter. CMS monitors the operation of the approved State plan and plan amendments to ensure compliance with the requirements of title XXI, title XIX (as appropriate) and this chapter.

(b) *State authority to submit State plan.* A State plan or plan amendment must be signed by the State Governor, or signed by an individual who has been delegated authority by the Governor to submit it.

(c) *State program officials.* The State must identify in the State plan or State plan amendment, by position or title, the State officials who are responsible for program administration and financial oversight.

(d) *State legislative authority.* The State plan must include an assurance that the State will not claim expenditures for child health assistance prior to the time that the State has legislative authority to operate the State plan or plan amendment as approved by CMS.

§ 457.50 State plan.

The State plan is a comprehensive written statement, submitted by the State to CMS for approval, that describes the purpose, nature, and scope of the State's CHIP and gives an assurance that the program is administered in conformity with the specific requirements of title XXI, title XIX (as appropriate), and the regulations in this chapter. The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

§ 457.60 Amendments.

A State may seek to amend its approved State plan in whole or in part at any time through the submission of an amendment to CMS. When the State plan amendment has a significant impact on the approved budget, the amendment must include an amended budget that describes the State's planned expenditures for a 1-year period. A State must amend its State plan whenever necessary to reflect—

(a) Changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in the approved State plan;

(b) Changes in State law, organization, policy, or operation of the program that affect the following program elements described in the State plan:

(1) Eligibility standards, enrollment caps, and disenrollment policies as described in § 457.305.

(2) Procedures to prevent substitution of private coverage as described in § 457.805, and in § 457.810 for premium assistance programs.

(3) The type of health benefits coverage offered, consistent with the options described in § 457.410.

(4) Addition or deletion of specific categories of benefits covered under the State plan.

(5) Basic delivery system approach as described in § 457.490.

(6) Cost-sharing as described in § 457.505.

(7) Screen and enroll procedures, and other Medicaid coordination procedures as described in § 457.350.

(8) Review procedures as described in § 457.1120.

(9) Other comparable required program elements.

(c) Changes in the source of the State share of funding, except for changes in the type of non-health care related revenues used to generate general revenue.

[66 FR 2670, Jan. 11, 2001, as amended at 66 FR 33822, June 25, 2001]

§ 457.65 Effective date and duration of State plans and plan amendments.

(a) *Effective date in general.* Except as otherwise limited by this section—

(1) A State plan or plan amendment takes effect on the day specified in the plan or plan amendment, but no earlier than October 1, 1997.

(2) The effective date may be no earlier than the date on which the State begins to incur costs to implement its State plan or plan amendment.

(3) A State plan amendment that takes effect prior to submission of the amendment to CMS may remain in effect only until the end of the State fiscal year in which the State makes it effective, or, if later, the end of the 90-day period following the date on which the State makes it effective, unless the State submits the amendment to CMS for approval before the end of that State fiscal year or that 90-day period.

(b) *Amendments relating to eligibility or benefits.* A State plan amendment that eliminates or restricts eligibility or benefits may not be in effect for longer than a 60-day period, unless the amendment is submitted to CMS before the end of that 60-day period. The amendment may not take effect unless—

(1) The State certifies that it has provided prior public notice of the proposed change in a form and manner provided under applicable State law; and

(2) The public notice was published before the requested effective date of the change.

(c) *Amendments relating to cost sharing.* A State plan amendment that implements cost-sharing charges, increases existing cost-sharing charges, or increases the cumulative cost-sharing maximum as set forth at § 457.560 is considered an amendment that restricts benefits and must meet the requirements in paragraph (b) of this section.

(d) *Amendments relating to enrollment procedures.* A State plan amendment that implements a required period of uninsurance, increases the length of existing required periods of uninsurance, or institutes or extends the use of waiting lists, enrollments caps or closed enrollment periods is considered an amendment that restricts eligibility and must meet the requirements in paragraph (b) of this section.

(e) *Amendments relating to the source of State funding.* A State plan amendment that changes the source of the State share of funding can take effect

no earlier than the date of submission of the amendment.

(f) *Continued approval.* An approved State plan continues in effect unless—

(1) The State adopts a new plan by obtaining approval under § 457.60 of an amendment to the State plan;

(2) Withdraws its plan in accordance with § 457.170(b); or

(3) The Secretary finds substantial noncompliance of the plan with the requirements of the statute or regulations.

§ 457.70 Program options.

(a) *Health benefits coverage options.* A State may elect to obtain health benefits coverage under its plan through—

(1) A separate child health program;

(2) A Medicaid expansion program; or

(3) A combination program.

(b) *State plan requirement.* A State must include in the State plan or plan amendment a description of the State's chosen program option.

(c) *Medicaid expansion program requirements.* A State plan under title XXI for a State that elects to obtain health benefits coverage through its Medicaid plan must—

(1) Meet the requirements of—

(i) Subpart A;

(ii) Subpart B (to the extent that the State claims administrative costs under title XXI);

(iii) Subpart F (with respect to determination of the allotment for purposes of the enhanced matching rate, determination of the enhanced matching rate, and payment of any claims for administrative costs under title XXI only);

(iv) Subpart G; and

(v) Subpart J (if the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims based on a community based health delivery system).

(2) Be consistent with the State's Medicaid State plan, or an approvable amendment to that plan, as required under title XIX.

(d) *Separate child health program requirements.* A State that elects to obtain health benefits coverage under its plan through a separate child health program must meet all the requirements of part 457.

(e) *Combination program requirements.* A State that elects to obtain health benefits coverage through both a separate child health program and a Medicaid expansion program must meet the requirements of paragraphs (c) and (d) of this section.

§ 457.80 Current State child health insurance coverage and coordination.

A State plan must include a description of—

(a) The extent to which, and manner in which, children in the State, including targeted low-income children and other classes of children, by income level and other relevant factors, currently have creditable health coverage (as defined in § 457.10) and, if sufficient information is available, whether the creditable health coverage they have is under public health insurance programs or health insurance programs that involve public-private partnerships;

(b) Current State efforts to provide or obtain creditable health coverage for uncovered children, including the steps the State is taking to identify and enroll all uncovered children who are eligible to participate in public health insurance programs and health insurance programs that involve public-private partnerships; and

(c) Procedures the State uses to accomplish coordination of CHIP with other public and private health insurance programs, sources of health benefits coverage for children, and relevant child health programs, such as title V, that provide health care services for low-income children. Such procedures include those designed to—

(1) Increase the number of children with creditable health coverage;

(2) Assist in the enrollment in CHIP of children determined ineligible for Medicaid; and

(3) Ensure that only eligible targeted low-income children are covered under CHIP, such as those procedures required under §§ 457.350 and 457.353, as applicable.

§ 457.90 Outreach.

(a) *Procedures required.* A State plan must include a description of procedures used to inform families of children likely to be eligible for child

health assistance under the plan or under other public or private health coverage programs of the availability of the programs, and to assist them in enrolling their children in one of the programs.

(b) *Examples.* Outreach strategies may include but are not limited to the following:

(1) Education and awareness campaigns, including targeted mailings and information distribution through various organizations.

(2) Enrollment simplification, such as simplified or joint application forms.

(3) Application assistance, including opportunities to apply for child health assistance under the plan through community-based organizations and in combination with other benefits and services available to children.

§457.110 Enrollment assistance and information requirements.

(a) *Information disclosure.* The State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants and enrollees, and provide assistance to these families in making informed decisions about their health plans, professionals, and facilities.

(b) *Required information.* The State must make available to potential applicants and provide applicants and enrollees the following information in a timely manner:

(1) Types of benefits, and amount, duration and scope of benefits available under the program.

(2) Cost-sharing requirements as described in §457.525.

(3) Names and locations of current participating providers.

(4) If an enrollment cap is in effect or the State is using a waiting list, a description of the procedures relating to the cap or waiting list, including the process for deciding which children will be given priority for enrollment, how children will be informed of their status on a waiting list and the circumstances under which enrollment will reopen.

(5) Information on physician incentive plans as required by §457.985.

(6) Review processes available to applicants and enrollees as described in the State plan pursuant to §457.1120.

§457.120 Public involvement in program development.

A State plan must include a description of the method the State uses to—

(a) Involve the public in both the design and initial implementation of the program;

(b) Ensure ongoing public involvement once the State plan has been implemented; and

(c) Ensure interaction with Indian Tribes and organizations in the State on the development and implementation of the procedures required at §457.125.

§457.125 Provision of child health assistance to American Indian and Alaska Native children.

(a) *Enrollment.* A State must include in its State plan a description of procedures used to ensure the provision of child health assistance to American Indian and Alaska Native children.

(b) *Exemption from cost sharing.* The procedures required by paragraph (a) of this section must include an exemption from cost sharing for American Indian and Alaska Native children in accordance with §457.535.

§457.130 Civil rights assurance.

The State plan must include an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR part 80, part 84, and part 91, and 28 CFR part 35.

§457.135 Assurance of compliance with other provisions.

The State plan must include an assurance that the State will comply, under title XXI, with the following provisions of titles XIX and XI of the Social Security Act:

(a) Section 1902(a)(4)(C) (relating to conflict of interest standards).

(b) Paragraphs (2), (16) and (17) of section 1903(i) (relating to limitations on payment).

(c) Section 1903(w) (relating to limitations on provider donations and taxes).

(d) Section 1132 (relating to periods within which claims must be filed).

§ 457.140 Budget.

The State plan, or plan amendment that has a significant impact on the approved budget, must include a budget that describes the State's planned expenditures for a 1-year period. The budget must describe—

(a) Planned use of funds, including—

(1) Projected amount to be spent on health services;

(2) Projected amount to be spent on administrative costs, such as outreach, child health initiatives, and evaluation; and

(3) Assumptions on which the budget is based, including cost per child and expected enrollment; and

(b) Projected sources of non-Federal plan expenditures, including any requirements for cost sharing by enrollees.

§ 457.150 CMS review of State plan material.

(a) *Basis for action.* CMS reviews each State plan and plan amendment to determine whether it meets or continues to meet the requirements for approval under relevant Federal statutes, regulations, and guidelines furnished by CMS to assist in the interpretation of these regulations.

(b) *Action on complete plan.* CMS approves or disapproves the State plan or plan amendment only in its entirety.

(c) *Authority.* The CMS Administrator exercises delegated authority to review and then to approve or disapprove the State plan or plan amendment, or to determine that previously approved material no longer meets the requirements for approval. The Administrator does not make a final determination of disapproval without first consulting the Secretary.

(d) *Initial submission.* The Administrator designates an official to receive the initial submission of State plans.

(e) *Review process.* (1) The Administrator designates an individual to coordinate CMS's review for each State that submits a State plan.

(2) CMS notifies the State of the identity of the designated individual in the first correspondence relating to that plan, and at any time there is a change in the designated individual.

(3) In the temporary absence of the designated individual during regular business hours, an alternate individual will act in place of the designated individual.

§ 457.160 Notice and timing of CMS action on State plan material.

(a) *Notice of final determination.* The Administrator provides written notification to the State of the approval or disapproval of a State plan or plan amendment.

(b) *Timing.* (1) A State plan or plan amendment will be considered approved unless CMS, within 90 calendar days after receipt of the State plan or plan amendment in the CMS central office, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of additional information it needs in order to make a final determination.

(2) A State plan or plan amendment is considered received when the designated official or individual, as determined in § 457.150(d) and (e), receives an electronic, fax or paper copy of the complete material.

(3) If CMS requests additional information, the 90-day review period for CMS action on the State plan or plan amendment—

(i) Stops on the day CMS sends a written request for additional information or the next business day if the request is sent on a Federal holiday or weekend; and

(ii) Resumes on the next calendar day after the CMS designated individual receives an electronic, fax, or hard copy from the State of all the requested additional information, unless the information is received after 5 p.m. eastern standard time on a day prior to a non-business day or any time on a non-business day, in which case the review period resumes on the following business day.

(4) The 90-day review period cannot stop or end on a non-business day. If the 90th calendar day falls on a non-business day, CMS will consider the 90th day to be the next business day.

(5) CMS may send written notice of its need for additional information as many times as necessary to obtain the complete information necessary to review the State plan or plan amendment.

§ 457.170 Withdrawal process.

(a) *Withdrawal of proposed State plans or plan amendments.* A State may withdraw a proposed State plan or plan amendment, or any portion of a proposed State plan or plan amendment, at any time during the review process by providing written notice to CMS of the withdrawal.

(b) *Withdrawal of approved State plans.* A State may request withdrawal of an approved State plan by submitting a State plan amendment to CMS in accordance with § 457.60.

Subpart B—General Administration—Reviews and Audits; Withholding for Failure to Comply; Deferral and Disallowance of Claims; Reduction of Federal Medical Payments

§ 457.200 Program reviews.

(a) *Review of State and local administration of the CHIP plan.* In order to determine whether the State is complying with the Federal requirements and the provisions of its plan, CMS reviews State and local administration of the CHIP plan through analysis of the State's policies and procedures, on-site reviews of selected aspects of agency operation, and examination of samples of individual case records.

(b) *Action on review findings.* If Federal or State reviews reveal serious problems with respect to compliance with any Federal or State plan requirement, the State must correct its practice accordingly.

§ 457.202 Audits.

(a) *Purpose.* The Department's Office of Inspector General (OIG) periodically audits State operations in order to determine whether—

(1) The program is being operated in a cost-efficient manner; and

(2) Funds are being properly expended for the purposes for which they were appropriated under Federal and State law and regulations.

(b) *Reports.* (1) The OIG releases audit reports simultaneously to State officials and the Department's program officials.

(2) The reports set forth OIG opinion and recommendations regarding the practices it reviewed, and the allowability of the costs it audited.

(3) Cognizant officials of the Department make final determinations on all audit findings.

(c) *Action on audit exceptions*—(1) *Concurrence or clearance.* The State agency has the opportunity of concurring in the exceptions or submitting additional facts that support clearance of the exceptions.

(2) *Appeal.* Any exceptions that are not disposed of under paragraph (c)(1) of this section are included in a disallowance letter that constitutes the Department's final decision unless the State requests reconsideration by the Appeals Board. (Specific rules are set forth in § 457.212.)

(3) *Adjustment.* If the decision by the Board requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

§ 457.203 Administrative and judicial review of action on State plan material.

(a) *Request for reconsideration.* Any State dissatisfied with the Administrator's action on State plan material under § 457.150 may, within 60 days after receipt of the notice of final determination provided under § 457.160(a), request that the Administrator reconsider whether the State plan or plan amendment conforms with the requirements for approval.

(b) *Notice of hearing.* Within 30 days after receipt of the request, the Administrator notifies the State of the time and place of a hearing to be held for the purpose of reconsideration.

(c) *Hearing procedures.* The hearing procedures set forth in part 430, subpart D of this chapter govern a hearing requested under this section.

(d) *Effect of hearing decision.* CMS does not delay the denial of Federal funds, if required by the Administrator's original determination, pending a

hearing decision. If the Administrator determines that his or her original decision was incorrect, CMS will pay the State a lump sum equal to any funds incorrectly denied.

[66 FR 2674, Jan. 11, 2001]

§ 457.204 Withholding of payment for failure to comply with Federal requirements.

(a) *Basis for withholding.* CMS withholds payments to the State, in whole or in part, only if, after giving the State notice, a reasonable opportunity for correction, and an opportunity for a hearing, the Administrator finds—

(1) That the plan is in substantial noncompliance with the requirements of title XXI of the Act; or

(2) That the State is conducting its program in substantial noncompliance with either the State plan or the requirements of title XXI of the Act. (Hearings are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These efforts may be continued even if a date and place have been set for the hearing.)

(b) *Noncompliance of the plan.* A question of noncompliance of a State plan may arise from an unapprovable change in the approved State plan or the failure of the State to change its approved plan to conform to a new Federal requirement for approval of State plans.

(c) *Noncompliance in practice.* A question of noncompliance in practice may arise from the State's failure to actually comply with a Federal requirement, regardless of whether the plan itself complies with that requirement.

(d) *Notice, reasonable opportunity for correction, and implementation of withholding.* If the Administrator makes a finding of noncompliance under paragraph (a) of this section, the following steps apply:

(1) *Preliminary notice.* The Administrator provides a preliminary notice to the State—

(i) Of the findings of noncompliance;

(ii) The proposed enforcement actions to withhold payments; and

(iii) If enforcement action is proposed, that the State has a reasonable opportunity for correction, described in paragraph (d)(2) of this section, before the Administrator takes final action.

(2) *Opportunity for corrective action.* If enforcement actions are proposed, the State must submit evidence of corrective action related to the findings of noncompliance to the Administrator within 30 days from the date of the preliminary notification. Corrective action is action to ensure that the plan is, and will be, administered consistent with applicable law and regulations, to ameliorate past deficiencies in plan administration, or to ensure that enrollees will be treated equitably.

(3) *Final notice.* Taking into account any evidence submitted by the State under paragraph (d)(2) of this section, the Administrator makes a final determination related to the findings of noncompliance, and provides a final notice to the State—

(i) Of the final determination on the findings of noncompliance;

(ii) If enforcement action is appropriate—

(A) No further payments will be made to the State (or that payments will be made only for those portions or aspects of the programs that are not affected by the noncompliance); and

(B) The total or partial withholding will continue until the Administrator is satisfied that the State's plan and practice are, and will continue to be, in compliance with Federal requirements.

(4) *Hearing.* An opportunity for a hearing will be provided to the State prior to withholding under paragraph (d)(5) of this section.

(5) Withholding. CMS withholds payments, in whole or in part, until the Administrator is satisfied regarding the State's compliance.

[65 FR 33622, May 24, 2000, as amended at 66 FR 2674, Jan. 11, 2001]

§ 457.206 Administrative appeals under CHIP.

Three distinct types of determinations are subject to Departmental reconsideration upon request by a State.

(a) *Compliance with Federal requirements.* A determination that a State's plan or proposed plan amendments, or its practice under the plan do not meet

(or continue to meet) Federal requirements are subject to the hearing provisions of 42 CFR part 430, subpart D of this chapter.

(b) *FFP in State CHIP expenditures.* Disallowances of FFP in State CHIP expenditures (mandatory grants) are subject to Departmental reconsideration by the Departmental Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16.

(c) *Discretionary grants disputes.* Determinations listed in 45 CFR part 16, appendix A, pertaining to discretionary grants, such as grants for special demonstration projects under Section 1115 of the Act, that may be awarded to an CHIP agency, are subject to reconsideration by the Departmental Grant Appeals Board.

§457.208 Judicial review.

(a) *Right to judicial review.* Any State dissatisfied with the Administrator's final determination on approvability of plan material (§457.203) or compliance with Federal requirements (§457.204) has a right to judicial review.

(b) *Petition for review.* (1) The State must file a petition for review with the U.S. Court of Appeals for the circuit in which the State is located, within 60 days after it is notified of the determination.

(2) After the clerk of the court files a copy of the petition with the Administrator, the Administrator files in the court the record of the proceedings on which the determination was based.

(c) *Court action.* (1) The court is bound by the Administrator's findings of fact, if they are supported by substantial evidence.

(2) The court has jurisdiction to affirm the Administrator's decision, to set it aside in whole or in part, or, for good cause, to remand the case for additional evidence.

(d) *Response to remand.* (1) If the court remands the case, the Administrator may make new or modified findings of fact and may modify his or her previous determination.

(2) The Administrator certifies to the court the transcript and record of the further proceedings.

(e) *Review by the Supreme Court.* The judgment of the appeals court is subject to review by the U.S. Supreme Court upon certiorari or certification, as provided in 28 U.S.C. 1254.

[65 FR 33622, May 24, 2000, as amended at 66 FR 2674, Jan. 11, 2001]

§457.210 Deferral of claims for FFP.

(a) *Requirements for deferral.* Payment of a claim or any portion of a claim for FFP is deferred only if—

(1) The Regional Administrator or the Administrator questions its allowability and needs additional information in order to resolve the question; and

(2) CMS takes action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with CMS instructions) that includes that claim.

(b) *Notice of deferral and State's responsibility.* (1) Within 15 days of the action described in paragraph (a)(2) of this section, the Regional Administrator sends the State a written notice of deferral that—

(i) Identifies the type and amount of the deferred claim and specifies the reason for deferral; and

(ii) Requests the State to make available all the documents and materials the CMS regional office believes are necessary to determine the allowability of the claim.

(2) It is the responsibility of the State to establish the allowability of a deferred claim.

(c) *Handling of documents and materials.* (1) Within 60 days (or within 120 days if the State requests an extension) after receipt of the notice of deferral, the State must make available to the CMS regional office, in readily reviewable form, all requested documents and materials except any that it identifies as not being available.

(2) CMS regional office staff initiates review within 30 days after receipt of the documents and materials.

(3) If the Regional Administrator finds that the materials are not in readily reviewable form or that additional information is needed, he or she promptly notifies the State that it has 15 days to submit the readily reviewable or additional materials.

(4) If the State does not provide the necessary materials within 15 days, the

Regional Administrator disallows the claim.

(5) The Regional Administrator has 90 days, after all documentation is available in readily reviewable form, to determine the allowability of the claim.

(6) If the Regional Administrator cannot complete review of the material within 90 days, CMS pays the claim, subject to a later determination of allowability.

(d) *Effect of decision to pay a deferred claim.* Payment of a deferred claim under paragraph (c)(6) of this section does not preclude a subsequent disallowance based on the results of an audit or financial review. (If there is a subsequent disallowance, the State may request reconsideration as provided in paragraph (e)(2) of this section.)

(e) *Notice and effect of decision on allowability.* (1) The Regional Administrator or the Administrator gives the State written notice of his or her decision to pay or disallow a deferred claim.

(2) If the decision is to disallow, the notice informs the State of its right to reconsideration in accordance with 45 CFR part 16.

§ 457.212 Disallowance of claims for FFP.

(a) *Notice of disallowance and of right to reconsideration.* When the Regional Administrator or the Administrator determines that a claim or portion of claim is not allowable, he or she promptly sends the State a disallowance letter that includes the following, as appropriate:

(1) The date or dates on which the State's claim for FFP was made.

(2) The time period during which the expenditures in question were made or claimed to have been made.

(3) The date and amount of any payment or notice of deferral.

(4) A statement of the amount of FFP claimed, allowed, and disallowed and the manner in which these amounts were computed.

(5) Findings of fact on which the disallowance determination is based or a reference to other documents previously furnished to the State or included with the notice (such as a report of a financial review or audit) that contain the findings of fact on which the disallowance determination is based.

(6) Pertinent citations to the law, regulations, guides and instructions supporting the action taken.

(7) A request that the State make appropriate adjustment in a subsequent expenditure report.

(8) Notice of the State's right to request reconsideration of the disallowance and the time allowed to make the request.

(9) A statement indicating that the disallowance letter is the Department's final decision unless the State requests reconsideration under paragraph (b)(2) of this section.

(b) *Reconsideration of FFP disallowance.* (1) The Departmental Appeals Board reviews disallowances of FFP under title XXI.

(2) A State may request reconsideration with a request to the Chair, Departmental Appeals Board, within 30 days after receipt of the disallowance letter, which must include—

(i) A copy of the disallowance letter;

(ii) A statement of the amount in dispute; and

(iii) A brief statement of why the disallowance is wrong.

(c) *Reconsideration procedures.* The reconsideration procedures are those set forth in 45 CFR part 16.

(d) *Implementation of decisions.* If the reconsideration decision requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

§ 457.216 Treatment of uncashed or canceled (voided) CHIP checks.

(a) *Purpose.* This section provides rules to ensure that States refund the Federal portion of uncashed or canceled (voided) checks under title XXI.

(b) *Definitions.* As used in this section—

Canceled (voided) check means an CHIP check issued by a State or fiscal agent that prior to its being cashed is canceled (voided) by the State or fiscal agent, thus preventing disbursement of funds.

Fiscal agent means an entity that processes or pays vendor claims for the CHIP agency.

Uncashed check means an CHIP check issued by a State or fiscal agent that has not been cashed by the payee.

Warrant means an order by which the CHIP agency or local agency without the authority to issue checks recognizes a claim. Presentation of a warrant by the payee to a State officer with authority to issue checks will result in release of funds due.

(c) *Refund of Federal financial participation (FFP) for uncashed checks*—(1) *General provisions.* If a check remains uncashed beyond a period of 180 days from the date it was issued; that is, the date of the check, it is no longer regarded as an allowable program expenditure. If the State has claimed and received FFP for the amount of the uncashed check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State agency must identify those checks that remain uncashed beyond a period of 180 days after issuance. The CHIP agency must refund all FFP that it received for uncashed checks by adjusting the Quarterly Statement of Expenditures for that quarter. If an uncashed check is cashed after the refund is made, the State may file a claim. The claim will be considered to be an adjustment to the costs for the quarter in which the check was originally claimed. This claim will be paid if otherwise allowed by the Act and the regulations issued in accordance with the Act.

(3) If the State does not refund the appropriate amount as specified in paragraph (c)(2) of this section, the amount will be disallowed.

(d) *Refund of FFP for canceled (voided) checks*—(1) *General provisions.* If the State has claimed and received FFP for the amount of a canceled (voided) check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the CHIP agency must identify those checks that were canceled (voided). The State must refund all FFP that it received for canceled (voided) checks by adjusting the Quarterly Statement of Expenditures for that quarter.

(3) If the State does not refund the appropriate amount as specified in paragraph (d)(2) of this section, the amount will be disallowed.

§457.218 Repayment of Federal funds by installments.

(a) *Basic conditions.* When Federal payments have been made for claims that are later found to be unallowable, the State may repay the Federal Funds by installments if the following conditions are met:

(1) The amount to be repaid exceeds 2½ percent of the estimated or actual annual State share for the State CHIP program; and

(2) The State has given the Regional Administrator written notice, before total repayment was due, of its intent to repay by installments.

(b) *Annual State share determination.* CMS determines whether the amount to be repaid exceeds 2½ percent of the annual State share as follows:

(1) If the State CHIP program is ongoing, CMS uses the annual estimated State share of State CHIP expenditures. This is the sum of the estimated State shares for four consecutive quarters, beginning with the quarter in which the first installment is to be paid, as shown on the State's latest CMS–21B form.

(2) If the State CHIP program has been terminated by Federal law or by the State, CMS uses the actual State share. The actual State share is that shown on the State's Quarterly Statement of Expenditures reports for the last four quarters before the program was terminated.

(c) *Repayment amounts, schedules, and procedures*—(1) *Repayment amount.* The repayment amount may not include any amount previously approved for installment repayment.

(2) *Repayment schedule.* The number of quarters allowed for repayment is determined on the basis of the ratio of the repayment amount to the annual State share of State CHIP expenditures. The higher the ratio of the total repayment amount is to the annual State share, the greater the number of quarters allowed, as follows:

Total repayment amount as percentage of State share of annual expenditures for State CHIP	Number of quarters to make repayment
2.5 pct. or less	1

Total repayment amount as percentage of State share of annual expenditures for State CHIP	Number of quarters to make repayment
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5 ...	9
Greater than 47.5, but not greater than 65 ...	10
Greater than 65, but not greater than 82.5 ...	11
Greater than 82.5, but not greater than 100	12

(3) *Quarterly repayment amounts.* The quarterly repayment amounts for each of the quarters in the repayment schedule may not be less than the following percentages of the estimated State share of the annual expenditures for CHIP:

For each of the following quarters	Repayment installment may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 to 12	17.5

(4) *Extended schedule.* The repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100 percent of the estimated State share of annual expenditures. In these circumstances, the repayment schedule in paragraph (c)(2) of this section is followed for repayment of the amount equal to 100 percent of the annual State share. The remaining amount of the repayment is in quarterly amounts equal to not less than 17.5 percent of the estimated State share of annual expenditures.

(5) *Repayment process.* Repayment is accomplished through adjustment in the quarterly grants over the period covered by the repayment schedule. If the State chooses to repay amounts representing higher percentages during the early quarters, any corresponding reduction in required minimum percentages is applied first to the last scheduled payment, then to the next to the last payment, and so forth as necessary.

(6) *Offsetting of retroactive claims.* (i) The amount of a retroactive claim to be paid a State is offset against any amounts to be, or already being, repaid by the State in installments. Under this provision, the State may choose to:

(A) Suspend payments until the retroactive claim due the State has, in fact, been offset; or

(B) Continue payments until the reduced amount of its debt (remaining after the offset), has been paid in full. This second option would result in a shorter payment period.

(ii) A retroactive claim for the purpose of this regulation is a claim applicable to any period ending 12 months or more before the beginning of the quarter in which CMS would pay that claim.

[65 FR 33622, May 24, 2000; 65 FR 38027, June 19, 2000; 65 FR 52042, Aug. 28, 2000]

§ 457.220 Funds from units of government as the State share of financial participation.

(a) Funds from units of government may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (b) and (c) of this section.

(b) The funds from units of government are appropriated directly to the State or local Medicaid agency, or are transferred from other units of government (including Indian tribes) to the State or local agency and are under its administrative control, or are certified by the contributing unit of government as representing expenditures eligible for FFP under this section. Certified public expenditures must be expenditures within the meaning of 45 CFR 95.13 that are supported by auditable documentation in a form approved by the Secretary that, at a minimum—

(1) Identifies the relevant category of expenditures under the State plan;

(2) Explains whether the contributing unit of government is within the scope of the exception to limitations on provider-related taxes and donations;

(3) Demonstrates the actual expenditures incurred by the contributing unit of government in providing services to eligible individuals receiving medical assistance or in administration of the State plan; and

(4) Is subject to periodic State audit and review.

(c) The funds from units of government are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

[72 FR 29835, May 29, 2007]

§ 457.222 FFP for equipment.

Claims for Federal financial participation in the cost of equipment under CHIP are determined in accordance with subpart G of 45 CFR part 95. Requirements concerning the management and disposition of equipment under CHIP are also prescribed in subpart G of 45 CFR part 95.

§ 457.224 FFP: Conditions relating to cost sharing.

(a) No FFP is available for the following amounts, even when related to services or benefit coverage which is or could be provided under a State CHIP program—

(1) Any cost sharing amounts that beneficiaries should have paid as enrollment fees, premiums, deductibles, coinsurance, copayments, or similar charges.

(2) Any amounts paid by the agency for health benefits coverage or services furnished to individuals who would not be eligible for that coverage or those services under the approved State child health plan, whether or not the individual paid any required premium or enrollment fee.

(b) The amount of expenditures under the State child health plan must be reduced by the amount of any premiums and other cost-sharing received by the State.

§ 457.226 Fiscal policies and accountability.

A State plan must provide that the CHIP agency and, where applicable, local agencies administering the plan will—

(a) Maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements;

(b) Retain records for 3 years from date of submission of a final expenditure report;

(c) Retain records beyond the 3-year period if audit findings have not been resolved; and

(d) Retain records for nonexpendable property acquired under a Federal grant for 3 years from the date of final disposition of that property.

§ 457.228 Cost allocation.

A State plan must provide that the single or appropriate CHIP Agency will have an approved cost allocation plan on file with the Department in accordance with the requirements contained in subpart E of 45 CFR part 95. Subpart E also sets forth the effect on FFP if the requirements contained in that subpart are not met.

§ 457.230 FFP for State ADP expenditures.

FFP is available for State ADP expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems and for the operation of certain systems. Additional HHS regulations and CMS procedures regarding the availability of FFP for ADP expenditures are in 45 CFR part 74, 45 CFR part 95, subpart F, and part 11, State Medicaid Manual.

§ 457.232 Refunding of Federal Share of CHIP overpayments to providers and referral of allegations of waste, fraud or abuse to the Office of Inspector General.

(a) Quarterly Federal payments to the States under title XXI (CHIP) of the Act are to be reduced or increased to make adjustment for prior overpayments or underpayments that the Secretary determines have been made.

(b) The Secretary will consider the pro rata Federal share of the net amount recovered by a State during any quarter to be an overpayment.

(c) Allegations or indications of waste fraud and abuse with respect to the CHIP program shall be referred promptly to the Office of Inspector General.

§ 457.236 Audits.

The CHIP agency must assure appropriate audit of records on costs of provider services.

§ 457.238 Documentation of payment rates.

The CHIP agency must maintain documentation of payment rates and make it available to HHS upon request.

Subpart C—State Plan Requirements: Eligibility, Screening, Applications, and Enrollment

SOURCE: 66 FR 2675, Jan. 11, 2001, unless otherwise noted.

§ 457.300 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2102 of the Act, which relates to eligibility standards and methodologies, coordination with other health insurance programs, and outreach and enrollment efforts to identify and enroll children who are eligible to participate in other public health insurance programs;

(2) Section 2105(c)(6)(B) of the Act, which relates to the prohibition against expenditures for child health assistance provided to children eligible for coverage under other Federal health care programs other than programs operated or financed by the Indian Health Service; and

(3) Section 2110(b) of the Act, which provides a definition of targeted low-income child.

(b) *Scope.* This subpart sets forth the requirements relating to eligibility standards and to screening, application and enrollment procedures.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program. Regulations relating to eligibility, screening, applications and enrollment that are applicable to a Medicaid expansion program are found at § 431.636, § 435.4, § 435.229, § 435.1102, § 436.3, § 436.229, and § 436.1102 of this chapter.

§ 457.301 Definitions and use of terms.

As used in this subpart—

Joint application means a form used to apply for the separate child health program that, when transmitted to the Medicaid agency following a screening that shows the child is potentially eligible for Medicaid, may also be used to apply for Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a separate child health program application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf an application for the separate child health program has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish eligibility of a child of the age involved.

Public agency means a State, county, city or other type of municipal agency, including a public school district, transportation district, irrigation district, or any other type of public entity.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is authorized to determine eligibility of a child for medical assistance

under the Medicaid State plan, or eligibility of a child for child health assistance under the Children's Health Insurance Program;

(6) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(7) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(8) Is a State or Tribal child support enforcement agency;

(9) Is an organization that—

(i) Provides emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(ii) Is a State or Tribal office or entity involved in enrollment in the program under this title, Part A of title IV, or title XXI; or

(iii) Determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 et seq.); and

(10) Any other entity the State so deems, as approved by the Secretary.

State health benefits plan means a health insurance coverage plan that is offered or organized by the State government on behalf of State employees or other public agency employees within the State. The term does not include a plan in which the State provides no contribution toward the cost of coverage and in which no State employees participate, or a plan that provides coverage only for a specific type of care, such as dental or vision care.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001; 75 FR 48852, Aug. 11, 2010]

§ 457.305 State plan provisions.

The State plan must include a description of—

(a) The standards, consistent with §§ 457.310 and 457.320, used to determine the eligibility of children for coverage under the State plan.

(b) The State's policies governing enrollment and disenrollment; processes for screening applicant children for and, if eligible, facilitating their enrollment in Medicaid; and processes for implementing waiting lists and enrollment caps (if any).

§ 457.310 Targeted low-income child.

(a) *Definition.* A targeted low-income child is a child who meets the standards set forth below and the eligibility standards established by the State under § 457.320.

(b) *Standards.* A targeted low-income child must meet the following standards:

(1) *Financial need standard.* A targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved;

(ii) Resides in a State with no Medicaid applicable income level or;

(iii) Resides in a State that has a Medicaid applicable income level and has family income that either—

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points; or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage standard.* A targeted low-income child must not be—

(i) Found eligible or potentially eligible for Medicaid under policies of the State plan (determined through either the Medicaid application process or the screening process described at § 457.350); or

(ii) Covered under a group health plan or under health insurance coverage, as defined in section 2791 of the Public Health Service Act, unless the plan or health insurance coverage program has been in operation since before July 1, 1997 and is administered by a State that receives no Federal funds for the program's operation. A child is not considered covered under a group health plan or health insurance coverage if the child does not have reasonable geographic access to care under that plan.

(3) For purposes of this section, policies of the State plan under title XIX plan include policies under a Statewide demonstration project under section

1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

(c) *Exclusions.* Notwithstanding paragraph (a) of this section, the following groups are excluded from the definition of targeted low-income children:

(1) *Children eligible for certain State health benefits coverage.* (i) A targeted low-income child may not be eligible for health benefits coverage under a State health benefits plan in the State on the basis of a family member's employment with a public agency, even if the family declines to accept the coverage.

(ii) A child is considered eligible for health benefits coverage under a State health benefits plan if a more than nominal contribution to the cost of health benefits coverage under a State health benefits plan is available from the State or public agency with respect to the child or would have been available from those sources on November 8, 1999. A contribution is considered more than nominal if the State or public agency makes a contribution toward the cost of an employee's dependent(s) that is $10 per family, per month, more than the State or public agency's contribution toward the cost of covering the employee only.

(2) *Residents of an institution.* A child must not be—

(i) An inmate of a public institution as defined at § 435.1010 of this chapter; or

(ii) A patient in an institution for mental diseases, as defined at § 435.1010 of this chapter, at the time of initial application or any redetermination of eligibility.

[66 FR 2675, Jan. 11, 2001, as amended at 71 FR 39229, July 12, 2006]

§ 457.320 Other eligibility standards.

(a) *Eligibility standards.* To the extent consistent with title XXI of the Act and except as provided in paragraph (b) of this section, the State plan may adopt eligibility standards for one or more groups of children related to—

(1) Geographic area(s) served by the plan;

(2) Age (up to, but not including, age 19);

(3) Income;

(4) Resources;

(5) Spenddowns;

(6) Disposition of resources;

(7) Residency, in accordance with paragraph (d) of this section;

(8) Disability status, provided that such standards do not restrict eligibility;

(9) Access to, or coverage under, other health coverage; and

(10) Duration of eligibility, in accordance with paragraph (e) of this section.

(b) *Prohibited eligibility standards.* In establishing eligibility standards and methodologies, a State may *not*—

(1) Cover children with a higher family income without covering children with a lower family income within any defined group of covered targeted low-income children;

(2) Deny eligibility based on a preexisting medical condition;

(3) Discriminate on the basis of diagnosis;

(4) Require any family member who is not requesting services to provide a social security number (including those family members whose income or resources might be used in making the child's eligibility determination);

(5) Exclude American Indian or Alaska Native children based on eligibility for, or access to, medical care funded by the Indian Health Service;

(6) Exclude individuals based on citizenship or nationality, to the extent that the children are U.S. citizens, U.S. nationals or qualified aliens, (as defined at section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996, as amended by the BBA of 1997, except to the extent that section 403 of PRWORA precludes them from receiving Federal means-tested public benefits); or

(7) Violate any other Federal laws or regulations pertaining to eligibility for a separate child health program under title XXI.

(c) *Self-declaration of citizenship.* In establishing eligibility for coverage under a separate child health plan, a State may accept self-declaration of citizenship (including nationals of the U.S.), provided that the State has implemented effective, fair, and nondiscriminatory procedures for ensuring the integrity of its application process.

(d) *Residency.* The State may establish residency requirements, except that a State may not—

(1) Impose a durational residency requirement;

(2) Preclude the following individuals from declaring residence in a State—

(i) A non-institutionalized child who is not a ward of the State, if the child is physically located in that State, including as a result of the parent's or caretaker's employment in that State;

(ii) An institutionalized child who is not a ward of a State, if the State is the State of residence of the child's custodial parent's or caretaker at the time of placement;

(iii) A child who is a ward of a State, regardless of the child's physical location; or

(iv) A child whose custodial parent or caretaker is involved in work of a transient nature, if the State is the parent's or caretaker's home State.

(e) *Duration of eligibility.* (1) The State may not impose a lifetime cap or other time limit on the eligibility of an individual applicant or enrollee, based on the length of time such applicant or enrollee has received benefits under the State's separate child health program.

(2) Eligibility must be redetermined at least every 12 months.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001]

§457.340 Application for and enrollment in a separate child health program.

(a) *Application assistance.* A State must afford families an opportunity to apply for child health assistance without delay, provided that the State has not reached an approved enrollment cap, and offer assistance to families in understanding and completing applications and in obtaining any required documentation.

(b) *Use of social security number.* A State may require a social security number for each individual requesting services consistent with the requirements at §435.910(b), (e), (f), and (g) of this chapter.

(c) *Notice of rights and responsibilities.* A State must inform applicants at the time of application, in writing and orally if appropriate, about the application and eligibility requirements, the time frame for determining eligibility, and the right to review of eligibility determinations as described in §457.1130.

(d) *Timely determinations of eligibility.* (1) The agency must promptly determine eligibility and issue a notice of decision within the time standards established, except in circumstances that are beyond the agency's control.

(2) A State must establish time standards for determining eligibility. These standards may not exceed forty-five calendar days (excluding days during which the application has been suspended, pursuant to §457.350(f)(1)).

(3) In applying the time standards, the State must define ''date of application'' and must count each calendar day from the date of application to the day the agency mails or otherwise provides notice of its eligibility decision.

(e) *Notice of decision concerning eligibility.* A State must provide each applicant or enrollee a written notice of any decision on the application or other determination concerning eligibility.

(1) If eligibility is approved, the notice must include information on the enrollee's rights and responsibilities under the program, including the opportunity for review of matters described in §457.1130.

(2) If eligibility is denied, suspended or terminated, the State must provide notice in accordance with §457.1180. In the case of a suspension or termination of eligibility, the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to allow coverage to continue without interruption.

(f) *Effective date of eligibility.* A State must specify a method for determining the effective date of eligibility for its separate child health program, which can be determined based on the date of

application or through any other reasonable method.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001]

§ 457.350 Eligibility screening and facilitation of Medicaid enrollment.

(a) *State plan requirement.* The State plan must include a description of—

(1) The screening procedures that the State will use, at intake and any follow-up eligibility determination, including any periodic redetermination, to ensure that only targeted low-income children are furnished child health assistance under the plan; and

(2) The procedures that the State will use to ensure that the Medicaid application and enrollment process is initiated and that Medicaid enrollment is facilitated for children found, through the screening process, to be potentially eligible for Medicaid.

(b) *Screening objectives.* (1) A State must use screening procedures to identify, at a minimum, any applicant or enrollee who is potentially eligible for Medicaid under one of the poverty-level-related groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act, applying whichever standard and corresponding methodology generally results in a higher income eligibility level for the age group of the child being screened.

(2) Screening procedures must also identify any applicant or enrollee who would be potentially eligible for Medicaid services based on the eligibility of his or her mother under one of the poverty level groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act.

(c) *Income eligibility test.* To identify the children described in paragraph (b) of this section, a State must either initially apply the gross income test described in paragraph (c)(1) of this section and then use an adjusted income test described in paragraph (c)(2) of this section for applicants whose gross income is above the appropriate Medicaid income standard, or use only the adjusted income test.

(1) *Initial gross income test.* Under this test, a State initially screens for Medicaid eligibility by comparing gross family income to the appropriate Medicaid income standard.

(2) *Adjusted income test.* Under this test, a State screens for Medicaid eligibility by comparing adjusted family income to the appropriate Medicaid income standard. The State must apply Medicaid standards and methodologies relating to income for the particular Medicaid eligibility group, including all income exclusions and disregards, except those that apply only in very limited circumstances.

(d) *Resource eligibility test.* (1) If a State applies a resource test for children under the Medicaid eligibility group used for screening purposes as described in paragraph (b) of this section and a child has been determined potentially income eligible for Medicaid, the State must also screen for Medicaid eligibility by comparing family resources to the appropriate Medicaid resource standard.

(2) In conducting the screening, the State must apply Medicaid standards and methodologies related to resources for the particular Medicaid eligibility group, including all resource exclusions and disregards, except those that apply only in very limited circumstances.

(e) *Children found potentially ineligible for Medicaid.* If a State uses a screening procedure other than a full determination of Medicaid eligibility under all possible eligibility groups, and the screening process reveals that the child does not appear to be eligible for Medicaid, the State must provide the child's family with the following in writing:

(1) A statement that based on a limited review, the child does not appear eligible for Medicaid, but Medicaid eligibility can only be determined based on a full review of a Medicaid application under all Medicaid eligibility groups;

(2) Information about Medicaid eligibility and benefits; and

(3) Information about how and where to apply for Medicaid under all eligibility groups.

(4) The State will determine the written format and timing of the information regarding Medicaid eligibility,

benefits, and the application process required under this paragraph (e).

(f) *Children found potentially eligible for Medicaid.* If the screening process reveals that the child is potentially eligible for Medicaid, the State must establish procedures in coordination with the Medicaid agency that facilitate enrollment in Medicaid and avoid duplicative requests for information and documentation and must—

(1) Except as provided in §457.355, find the child ineligible, provisionally ineligible, or suspend the child's application for the separate child health program unless and until a completed Medicaid application for that child is denied, or the child's circumstances change, and promptly transmit the separate child health application to the Medicaid agency as provided in paragraph (f)(3)(ii) of this section; and

(2) If a State uses a joint application for its Medicaid and separate child health programs, promptly transmit the application, or the information obtained through the application, and all relevant documentation to the Medicaid agency; or

(3) If a State does not use a joint application for its Medicaid and separate child health programs:

(i) Promptly inform the child's parent or caretaker in writing and, if appropriate, orally that the child has been found likely to be eligible for Medicaid; provide the family with a Medicaid application and offer information about what, if any, further information, documentation, or other steps are needed to complete the Medicaid application process; and offer assistance in completing the application process;

(ii) Promptly transmit the separate child health program application; or the information obtained through the application, and all other relevant information and documentation, including the results of the screening process, to the Medicaid agency for a final determination of Medicaid eligibility in accordance with the requirements of §§431.636 and 457.1110 of this chapter; or

(4) Establish other effective and efficient procedures, in coordination with the Medicaid agency, as described and approved in the State plan that ensure that children who are screened as potentially eligible for Medicaid are able to apply for Medicaid without delay and, if eligible, are enrolled in Medicaid in a timely manner; and

(5) Determine or redetermine eligibility for the separate child health program, if—

(i) The State is notified pursuant to §431.636 of this chapter that the child has been found ineligible for Medicaid, consistent with the time standards established pursuant to §457.340(c); or

(ii) The State is notified prior to the final Medicaid eligibility determination that the child's circumstances have changed and another screening shows that the child is not likely to be eligible for Medicaid.

(g) *Informed application decisions.* To enable a family to make an informed decision about applying for Medicaid or completing the Medicaid application process, a State must provide the child's family with information, in writing, about—

(1) The State's Medicaid program, including the benefits covered, and restrictions on cost sharing; and

(2) Eligibility rules that prohibit children who have been screened eligible for Medicaid from being enrolled in a separate child health program, other than provisional temporary enrollment while a final Medicaid eligibility determination is being made.

(3) The State will determine the written format and timing of the information regarding Medicaid eligibility, benefits, and the application process required under this paragraph (g).

(h) *Waiting lists, enrollment caps and closed enrollment.* The State must establish procedures to ensure that—

(1) The procedures developed in accordance with this section have been followed for each child applying for a separate child health program before placing the child on a waiting list or otherwise deferring action on the child's application for the separate child health program; and

(2) Families are informed that a child may be eligible for Medicaid if circumstances change while the child is on a waiting list for separate child health program.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001; 67 FR 61974, Oct. 2, 2002]

§ 457.353 Monitoring and evaluation of screening process.

States must monitor and establish a mechanism to evaluate the screen and enroll process described at § 457.350 to ensure that children who are screened potentially eligible for Medicaid are enrolled in Medicaid, if eligible, and that children who are found ineligible for Medicaid are enrolled in the separate child health program, if eligible.

§ 457.355 Presumptive eligibility.

(a) *General rule.* Consistent with subpart D of this part, the State may pay costs of coverage under a separate child health program, during a period of presumptive eligibility for children applying for coverage under the separate child health program, pending the screening process and a final determination of eligibility (including applicants found through screening to be potentially eligible for Medicaid)

(b) *Expenditures for coverage during a period of presumptive eligibility.* Expenditures for coverage during a period of presumptive eligibility implemented in accordance with § 435.1102 of this chapter may be considered as expenditures for child health assistance under the plan.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001]

§ 457.380 Eligibility verification.

(a) The State must establish procedures to ensure the integrity of the eligibility determination process.

(b) A State may establish reasonable eligibility verification mechanisms to promote enrollment of eligible children and may permit applicants and enrollees to demonstrate that they meet eligibility requirements through self-declaration or affirmation except that a State may permit self-declaration of citizenship only if the State has effective, fair and non-discriminatory procedures to ensure the integrity of the application process in accordance with § 457.320(c).

Subpart D—State Plan Requirements: Coverage and Benefits

SOURCE: 66 FR 2678, Jan. 11, 2001, unless otherwise noted.

§ 457.401 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2102(a)(7) of the Act, which requires that States make assurances relating to, the quality and appropriateness of care, and access to covered services;

(2) Section 2103 of the Act, which outlines coverage requirements for children's health insurance;

(3) Section 2109 of the Act, which describes the relation of the CHIP program to other laws;

(4) Section 2110(a) of the Act, which describes child health assistance; and

(5) Section 2110(c) of the Act, which contains definitions applicable to this subpart.

(b) *Scope.* This subpart sets forth requirements for health benefits coverage and child health assistance under a separate child health plan.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program and do not apply to a Medicaid expansion program.

§ 457.402 Definition of child health assistance.

For the purpose of this subpart, the term ''child health assistance'' means payment for part or all of the cost of health benefits coverage provided to targeted low-income children for the following services:

(a) Inpatient hospital services.

(b) Outpatient hospital services.

(c) Physician services.

(d) Surgical services.

(e) Clinic services (including health center services) and other ambulatory health care services.

(f) Prescription drugs and biologicals and the administration of these drugs and biologicals, only if these drugs and biologicals are not furnished for the purpose of causing, or assisting in causing, the death, suicide, euthanasia, or mercy killing of a person.

(g) Over-the-counter medications.

(h) Laboratory and radiological services.

(i) Prenatal care and pre-pregnancy family planning services and supplies.

(j) Inpatient mental health services, other than services described in paragraph (r) of this section but including services furnished in a State-operated mental hospital and including residential or other 24-hour therapeutically planned structured services.

(k) Outpatient mental health services, other than services described in paragraph (s) of this section but including services furnished in a State-operated mental hospital and including community-based services.

(l) Durable medical equipment and other medically-related or remedial devices (such as prosthetic devices, implants, eyeglasses, hearing aids, dental devices and adaptive devices).

(m) Disposable medical supplies.

(n) Home and community-based health care services and related supportive services (such as home health nursing services, personal care, assistance with activities of daily living, chore services, day care services, respite care services, training for family members and minor modification to the home.)

(o) Nursing care services (such as nurse practitioner services, nurse midwife services, advanced practice nurse services, private duty nursing, pediatric nurse services and respiratory care services) in a home, school, or other setting.

(p) Abortion only if necessary to save the life of the mother or if the pregnancy is the result of rape or incest.

(q) Dental services.

(r) Inpatient substance abuse treatment services and residential substance abuse treatment services.

(s) Outpatient substance abuse treatment services.

(t) Case management services.

(u) Care coordination services.

(v) Physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders.

(w) Hospice care.

(x) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services (whether in a facility, home, school, or other setting) if recognized by State law and only if the service is—

(1) Prescribed by or furnished by a physician or other licensed or registered practitioner within the scope of practice as defined by State law;

(2) Performed under the general supervision or at the direction of a physician; or

(3) Furnished by a health care facility that is operated by a State or local government or is licensed under State law and operating within the scope of the license.

(y) Premiums for private health care insurance coverage.

(z) Medical transportation.

(aa) Enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals.

(bb) Any other health care services or items specified by the Secretary and not excluded under this subchapter.

§457.410 Health benefits coverage options.

(a) *Types of health benefits coverage.* States may choose to obtain any of the following four types of health benefits coverage:

(1) Benchmark coverage in accordance with §457.420.

(2) Benchmark-equivalent coverage in accordance with §457.430.

(3) Existing comprehensive State-based coverage in accordance with §457.440.

(4) Secretary-approved coverage in accordance with §457.450.

(b) *Required coverage.* Regardless of the type of health benefits coverage, described at paragraph (a) of this section, that the State chooses to obtain, the State must obtain coverage for—

(1) Well-baby and well-child care services as defined by the State;

(2) Age-appropriate immunizations in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP); and

(3) Emergency services as defined in §457.10.

§ 457.420 Benchmark health benefits coverage.

Benchmark coverage is health benefits coverage that is substantially equal to the health benefits coverage in one of the following benefit plans:

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

(b) *State employee plan.* A health benefits plan that is offered and generally available to State employees in the State.

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

§ 457.430 Benchmark-equivalent health benefits coverage.

(a) *Aggregate actuarial value.* Benchmark-equivalent coverage is health benefits coverage that has an aggregate actuarial value determined in accordance with § 457.431 that is at least actuarially equivalent to the coverage under one of the benchmark packages specified in § 457.420.

(b) *Required coverage.* In addition to the coverage required under § 457.410(b), benchmark-equivalent health benefits coverage must include coverage for the following categories of services:

(1) Inpatient and outpatient hospital services.

(2) Physicians' surgical and medical services.

(3) Laboratory and x-ray services.

(c) *Additional coverage.* (1) In addition to the categories of services in paragraph (b) of this section, benchmark-equivalent coverage may include coverage for any additional services specified in § 457.402.

(2) If the benchmark coverage package used by the State for purposes of comparison in establishing the aggregate actuarial value of the benchmark-equivalent coverage package includes coverage for prescription drugs, mental health services, vision services or hearing services, then the actuarial value of the coverage for each of these categories of service in the benchmark-equivalent coverage package must be at least 75 percent of the value of the coverage for such a category or service in the benchmark plan used for comparison by the State.

(3) If the benchmark coverage package does not cover one of the categories of services in paragraph (c)(2) of this section, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service.

§ 457.431 Actuarial report for benchmark-equivalent coverage.

(a) To obtain approval for benchmark-equivalent health benefits coverage described under § 457.430, the State must submit to CMS an actuarial report that contains an actuarial opinion that the health benefits coverage meets the actuarial requirements under § 457.430. The report must also specify the benchmark coverage used for comparison.

(b) The actuarial report must state that it was prepared—

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

(2) Using generally accepted actuarial principles and methodologies of the American Academy of Actuaries;

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

(4) Using a standardized population that is representative of privately insured children of the age of those expected to be covered under the State plan;

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

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

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

(c) The actuary who prepares the opinion must select and specify the standardized set and population to be

used under paragraphs (b)(3) and (b)(4) of this section.

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

§457.440 Existing comprehensive State-based coverage.

(a) *General requirements.* Existing comprehensive State-based health benefits is coverage that—

(1) Includes coverage of a range of benefits;

(2) Is administered or overseen by the State and receives funds from the State;

(3) Is offered in the State of New York, Florida or Pennsylvania; and

(4) Was offered as of August 5, 1997.

(b) *Modifications.* A State may modify an existing comprehensive State-based coverage program described in paragraph (a) of this section if—

(1) The program continues to include a range of benefits;

(2) The State submits an actuarial report demonstrating that the modification does not reduce the actuarial value of the coverage under the program below the lower of either—

(i) The actuarial value of the coverage under the program as of August 5, 1997; or

(ii) The actuarial value of a benchmark benefit package as described in §457.430 evaluated at the time the modification is requested.

§457.450 Secretary-approved coverage.

Secretary-approved coverage is health benefits coverage that, in the determination of the Secretary, provides appropriate coverage for the population of targeted low-income children covered under the program. Secretary-approved coverage, for which no actuarial analysis is required, may include, but is not limited to the following:

(a) Coverage that is the same as the coverage provided to children under the Medicaid State plan.

(b) Comprehensive coverage for children offered by the State under a Medicaid demonstration project approved by the Secretary under section 1115 of the Act.

(c) Coverage that either includes the full Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) benefit or that the State has extended to the entire Medicaid population in the State.

(d) Coverage that includes benchmark health benefits coverage, as specified in §457.420, plus any additional coverage.

(e) Coverage that is the same as the coverage provided under §457.440.

(f) Coverage, including coverage under a group health plan purchased by the State, that the State demonstrates to be substantially equivalent to or greater than coverage under a benchmark health benefits plan, as specified in §457.420, through use of a benefit-by-benefit comparison which demonstrates that coverage for each benefit meets or exceeds the corresponding coverage under the benchmark health benefits plan.

[66 FR 33823, June 25, 2001]

§457.470 Prohibited coverage.

A State is not required to provide health benefits coverage under the plan for an item or service for which payment is prohibited under title XXI even if any benchmark health benefits plan includes coverage for that item or service.

§457.475 Limitations on coverage: Abortions.

(a) *General rule.* FFP under title XXI is not available in expenditures for an abortion, or in expenditures for the purchase of health benefits coverage that includes coverage of abortion services unless the abortion services meet the conditions specified in paragraph (b) of this section.

(b) *Exceptions*—(1) *Life of mother.* FFP is available in expenditures for abortion services when a physician has found that the abortion is necessary to save the life of the mother.

(2) *Rape or incest.* FFP is available in expenditures for abortion services performed to terminate a pregnancy resulting from an act of rape or incest.

(c) *Partial Federal funding prohibited.* (1) FFP is not available to a State for any amount expended under the title XXI plan to assist in the purchase, in

whole or in part, of health benefits coverage that includes coverage of abortions other than those specified in paragraph (b) of this section.

(2) If a State wishes to have managed care entities provide abortions in addition to those specified in paragraph (b) of this section, those abortions must be provided under a separate contract using non-Federal funds. A State may not set aside a portion of the capitated rate paid to a managed care entity to be paid with State-only funds, or append riders, attachments or addenda to existing contracts with managed care entities to separate the additional abortion services from the other services covered by the contract.

(3) Nothing in this section affects the expenditure by a State, locality, or private person or entity of State, local, or private funds (other than those expended under the State plan) for any abortion services or for health benefits coverage that includes coverage of abortion services.

§ 457.480 Preexisting condition exclusions and relation to other laws.

(a) *Preexisting condition exclusions.* (1) Except as permitted under paragraph (a)(2) of this section, the State may not permit the imposition of any pre-existing condition exclusion for covered services under the State plan.

(2) If the State obtains health benefits coverage through payment or a contract for health benefits coverage under a group health plan or group health insurance coverage, the State may permit the imposition of a pre-existing condition exclusion but only to the extent that the exclusion is permitted under the applicable provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (ERISA) and title XXVII of the Public Health Service Act.

(b) *Relation of title XXI to other laws.* (1) ERISA. Nothing in this title affects or modifies section 514 of ERISA with respect to a group health plan as defined by section 2791(a)(1) of the Public Health Service Act.

(2) *Health Insurance Portability and Accountability Act (HIPAA).* Health benefits coverage provided under a State plan and coverage provided as a cost-effective alternative, as described in subpart J of this part, is creditable coverage for purposes of part 7 of subtitle B of title II of ERISA, title XXVII of the Public Health Service Act, and subtitle K of the Internal Revenue Code of 1986.

(3) *Mental Health Parity Act (MHPA).* Health benefits coverage under a group health plan provided under a State plan must comply with the requirements of the MHPA of 1996 regarding parity in the application of annual and lifetime dollar limits to mental health benefits in accordance with 45 CFR 146.136.

(4) *Newborns and Mothers Health Protection Act (NMHPA).* Health benefits coverage under a group health plan provided under a State plan must comply with the requirements of the NMHPA of 1996 regarding requirements for minimum hospital stays for mothers and newborns in accordance with 45 CFR 146.130 and 148.170.

§ 457.490 Delivery and utilization control systems.

A State that elects to obtain health benefits coverage through a separate child health program must include in its State plan a description of the child health assistance provided under the plan for targeted low-income children, including a description of the proposed methods of delivery and utilization control systems. A State must—

(a) Describe the methods of delivery of child health assistance including the choice of financing and the methods for assuring delivery of the insurance products and delivery of health care services covered by such products to the enrollees, including any variations; and

(b) Describe utilization control systems designed to ensure that enrollees receiving health care services under the State plan receive only appropriate and medically necessary health care consistent with the benefit package described in the approved State plan.

§ 457.495 State assurance of access to care and procedures to assure quality and appropriateness of care.

A State plan must include a description of the methods that a State uses for assuring the quality and appropriateness of care provided under the

plan, including how the State will assure:

(a) Access to well-baby care, well-child care, well-adolescent care and childhood and adolescent immunizations.

(b) Access to covered services, including emergency services as defined at §457.10.

(c) Appropriate and timely procedures to monitor and treat enrollees with chronic, complex, or serious medical conditions, including access to an adequate number of visits to specialists experienced in treating the specific medical condition and access to out-of-network providers when the network is not adequate for the enrollee's medical condition.

(d) That decisions related to the prior authorization of health services are completed as follows:

(1) In accordance with the medical needs of the patient, within 14 days after receipt of a request for services. A possible extension of up to 14 days may be permitted if the enrollee requests the extension or if the physician or health plan determines that additional information is needed; or

(2) In accordance with existing State law regarding prior authorization of health services.

[66 FR 2678, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

Subpart E—State Plan Requirements: Enrollee Financial Responsibilities

SOURCE: 66 FR 2681, Jan. 11, 2001, unless otherwise noted.

§457.500 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Section 2101(a) of the Act, which provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; and

(2) Section 2103(e) of the Act, which sets forth provisions regarding State plan requirements and options for cost sharing.

(b) *Scope.* This subpart consists of provisions relating to the imposition under a separate child health program of cost-sharing charges including enrollment fees, premiums, deductibles, coinsurance, copayments, and similar cost-sharing charges.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs.

§457.505 General State plan requirements.

The State plan must include a description of—

(a) The amount of premiums, deductibles, coinsurance, copayments, and other cost sharing imposed;

(b) The methods, including the public schedule, the State uses to inform enrollees, applicants, providers and the general public of the cost-sharing charges, the cumulative cost-sharing maximum, and any changes to these amounts;

(c) The disenrollment protections as required under §457.570;

(d) In the case of coverage obtained through premium assistance for group health plans—

(1) The procedures the State uses to ensure that eligible children are not charged copayments, coinsurance, deductibles or similar fees on well-baby and well-child care services described at §457.520, and that any cost sharing complies with the requirements of this subpart;

(2) The procedures to ensure that American Indian and Alaska Native children are not charged premiums, copayments, coinsurance, deductibles, or similar fees in accordance with §457.535;

(3) The procedures to ensure that eligible children are not charged cost sharing in excess of the cumulative cost-sharing maximum specified in §457.560.

(e) Procedures that do not primarily rely on a refund given by the State for overpayment on behalf of an eligible child to ensure compliance with this subpart.

[66 FR 2681, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.510 Premiums, enrollment fees, or similar fees: State plan requirements.

When a State imposes premiums, enrollment fees, or similar fees on enrollees, the State plan must describe—

(a) The amount of the premium, enrollment fee or similar fee imposed on enrollees;

(b) The time period for which the charge is imposed;

(c) The group or groups that are subject to the premiums, enrollment fees, or similar charges;

(d) The consequences for an enrollee or applicant who does not pay a charge, and the disenrollment protections adopted by the State in accordance with § 457.570; and

(e) The methodology used to ensure that total cost-sharing liability for a family does not exceed the cumulative cost-sharing maximum specified in § 457.560.

§ 457.515 Co-payments, coinsurance, deductibles, or similar cost-sharing charges: State plan requirements.

To impose copayments, coinsurance, deductibles or similar charges on enrollees, the State plan must describe—

(a) The service for which the charge is imposed;

(b) The amount of the charge;

(c) The group or groups of enrollees that may be subject to the cost-sharing charge;

(d) The consequences for an enrollee who does not pay a charge, and the disenrollment protections adopted by the State in accordance with § 457.570;

(e) The methodology used to ensure that total cost-sharing liability for a family does not exceed the cumulative cost-sharing maximum specified in § 457.560; and

(f) An assurance that enrollees will not be held liable for cost-sharing amounts for emergency services that are provided at a facility that does not participate in the enrollee's managed care network beyond the copayment amounts specified in the State plan for emergency services as defined in § 457.10.

§ 457.520 Cost sharing for well-baby and well-child care services.

(a) A State may not impose copayments, deductibles, coinsurance or other cost sharing with respect to the well-baby and well-child care services covered under the State plan in either the managed care delivery setting or the fee-for-service delivery setting.

(b) For the purposes of this subpart, at a minimum, any of the following services covered under the State plan will be considered well-baby and well-child care services:

(1) All healthy newborn physician visits, including routine screening, whether provided on an inpatient or outpatient basis.

(2) Routine physical examinations as recommended and updated by the American Academy of Pediatrics (AAP) ''Guidelines for Health Supervision III'' and described in ''Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents.''

(3) Laboratory tests associated with the well-baby and well-child routine physical examinations as described in paragraph (b)(2) of this section.

(4) Immunizations and related office visits as recommended and updated by the Advisory Committee on Immunization Practices (ACIP).

(5) Routine preventive and diagnostic dental services (such as oral examinations, prophylaxis and topical fluoride applications, sealants, and x-rays) as described in the most recent guidelines issued by the American Academy of Pediatric Dentistry (AAPD).

§ 457.525 Public schedule.

(a) The State must make available to the groups in paragraph (b) of this section a public schedule that contains the following information:

(1) Current cost-sharing charges.

(2) Enrollee groups subject to the charges.

(3) Cumulative cost-sharing maximums.

(4) Mechanisms for making payments for required charges.

(5) The consequences for an applicant or an enrollee who does not pay a charge, including the disenrollment protections required by § 457.570.

(b) The State must make the public schedule available to the following groups:

(1) Enrollees, at the time of enrollment and reenrollment after a redetermination of eligibility, and when cost-sharing charges and cumulative cost-sharing maximums are revised.

(2) Applicants, at the time of application.

(3) All participating providers.

(4) The general public.

§457.530 General cost-sharing protection for lower income children.

The State may vary premiums, deductibles, coinsurance, copayments or any other cost sharing based on family income only in a manner that does not favor children from families with higher income over children from families with lower income.

§457.535 Cost-sharing protection to ensure enrollment of American Indians and Alaska Natives.

States may not impose premiums, deductibles, coinsurance, copayments or any other cost-sharing charges on children who are American Indians or Alaska Natives, as defined in §457.10.

§457.540 Cost-sharing charges for children in families with incomes at or below 150 percent of the FPL.

The State may impose premiums, enrollment fees, deductibles, copayments, coinsurance, cost sharing and other similar charges for children whose family income is at or below 150 percent of the FPL as long as—

(a) Aggregate monthly enrollment fees, premiums, or similar charges imposed on a family are less than or equal to the maximum amounts permitted under §447.52 of this chapter for a Medicaid eligible family of the same size and income;

(b) Any copayments, coinsurance, deductibles or similar charges for children whose family income is at or below 100 percent of the FPL are equal to or less than the amounts permitted under §447.54 of this chapter;

(c) For children whose family income is from 101 percent to 150 percent of the FPL, any copayments, coinsurance, deductibles or similar charges are equal to or less than the maximum amounts permitted under §457.555;

(d) The State does not impose more than one type of cost-sharing charge (deductible, copayment, or coinsurance) on a service;

(e) The State only imposes one copayment based on the total cost of services furnished during one office visit; and

(f) Aggregate annual cost sharing of all types, with respect to all targeted low-income children in a family, does not exceed the maximum permitted under §457.560(a).

[66 FR 2681, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§457.555 Maximum allowable cost-sharing charges on targeted low-income children in families with income from 101 to 150 percent of the FPL.

(a) *Non-institutional services.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State plan must provide that for non-institutional services, including emergency services, the following requirements must be met:

(1)(i) For Federal FY 2009, any copayment or similar charge the State imposes under a fee-for-service delivery system may not exceed the amounts shown in the following table:

State payment for the service	Maximum Copayment
$15 or less	$1.15
$15.01 to $40	$2.30
$40.01 to $80	$3.40
$80.01 or more	$5.70

(ii) Thereafter, any copayments may not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(2) For Federal FY 2009, any co-payment that the State imposes for services provided by a managed care organization may not exceed $5.70 per visit. In succeeding years, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component

of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(3) Any coinsurance rate the State imposes may not exceed 5 percent of the payment the State directly or through contract makes for the service; and

(4) For Federal FY 2009, any deductible the State imposes may not exceed $3.40 per month, per family for each period of eligibility. Thereafter, any deductible may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(b) *Institutional services.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the maximum deductible, coinsurance or copayment charge for each institutional admission may not exceed 50 percent of the payment the State would make under the Medicaid fee-for-service system for the first day of care in the institution.

(c) *Institutional emergency services.* For Federal FY 2009, any copayment that the State imposes on emergency services provided by an institution may not exceed $5.70. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(d) *Non-emergency use of the emergency room.* For Federal FY 2009, for targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of $11.35 for services furnished in a hospital emergency room if those services are not emergency services as defined in § 457.10. Thereafter, any charge may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(e) *Standard copayment amount.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, a standard copayment amount for any service may be determined by applying the maximum copayment amounts specified in paragraphs (a), (b), and (c) of this section to the State's average or typical payment for that service.

[66 FR 2681, Jan. 11, 2001, as amended at 73 FR 71854, Nov. 25, 2008; 75 FR 30265, May 28, 2010]

§ 457.560 Cumulative cost-sharing maximum.

(a) A State may not impose premiums, enrollment fees, copayments, coinsurance, deductibles, or similar cost-sharing charges that, in the aggregate, exceed 5 percent of a family's total income for the length of a child's eligibility period in the State.

(b) The State must inform the enrollee's family in writing and orally if appropriate of their individual cumulative cost-sharing maximum amount at the time of enrollment and reenrollment.

[66 FR 2681, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.570 Disenrollment protections.

(a) The State must give enrollees reasonable notice of and an opportunity to pay past due premiums, copayments, coinsurance, deductibles or similar fees prior to disenrollment.

(b) The disenrollment process must afford the enrollee an opportunity to show that the enrollee's family income has declined prior to disenrollment for non payment of cost-sharing charges, and in the event that such a showing indicates that the enrollee may have become eligible for Medicaid or for a lower level of cost sharing, the State must facilitate enrolling the child in Medicaid or adjust the child's cost-sharing category as appropriate.

(c) The State must provide the enrollee with an opportunity for an impartial review to address disenrollment from the program in accordance with § 457.1130(a)(3).

Subpart F—Payments to States

§457.600 Purpose and basis of this subpart.

This subpart interprets and implements—

(a) Section 2104 of the Act which specifies the total allotment amount available for allotment to each State for child health assistance for fiscal years 1998 through 2007, the formula for determining each State allotment for a fiscal year, including the Commonwealth and Territories, and the amounts of payments for expenditures that are applied to reduce the State allotments.

(b) Section 2105 of the Act which specifies the provisions for making payment to States, the limitations and conditions on such payments, and the calculation of the enhanced Federal medical assistance percentage.

§457.602 Applicability.

The provisions of this subpart apply to the 50 States and the District of Columbia, and the Commonwealths and Territories.

§457.606 Conditions for State allotments and Federal payments for a fiscal year.

(a) *Basic conditions.* In order to receive a State allotment for a fiscal year, a State must have a State child health plan submitted in accordance with section 2106 of the Act, and

(1) For fiscal years 1998 and 1999, the State child health plan must be approved before October 1, 1999;

(2) For fiscal years after 1999, the State child health plan must be approved by the end of the fiscal year;

(3) An allotment for a fiscal year is not available to a State prior to the beginning of the fiscal year; and

(4) Federal payments out of an allotment are based on State expenditures which are allowable under the approved State child health plan.

(b) Federal payments for Children's Health Insurance Program (CHIP) expenditures under an approved State child health plan are—

(1) Limited to the amount of available funds remaining in State allotments calculated in accordance with the allotment process and formula specified in §§457.608 and 457.610, and payment process in §§457.614 and 457.616.

(2) Available based on a percentage of State CHIP expenditures, at a rate equal to the enhanced Federal medical assistance percentage (FMAP) for each fiscal year, calculated in accordance with §457.622.

(3) Available through the grants process specified in §457.630.

[65 FR 33622, May 24, 2000, as amended at 75 FR 48852, Aug. 11, 2010]

§457.608 Process and calculation of State allotments for a fiscal year.

(a) *General*—(1) State allotments for a fiscal year are determined by CMS for each State and the District of Columbia with an approved State child health plan, as described in paragraph (e) of this section, and for each Commonwealth and Territory, as described in paragraph (f) of this section.

(2) In order to determine each State allotment, CMS determines the national total allotment amount for each fiscal year available to the 50 States and the District of Columbia, as described in paragraph (c) of this section, and the total allotment amount available for each fiscal year for allotment to the Commonwealths and Territories, as described in paragraph (d) of this section.

(3) The amount of allotments redistributed under section 2104(f) of the Act will not be applied or taken into account in determining the amounts of a fiscal year allotment for a State and the District of Columbia under this section.

(b) *Definition of Proportion.* As used in this section, *proportion* means the amount of the allotment for a State or the District of Columbia for a fiscal year, divided by the national total allotment amount available for allotment to all States and the District of Columbia, as specified in paragraph (c) of this section, for that fiscal year.

(c) *National total allotment amount for the 50 States and the District of Columbia.* (1) The national total allotment amount available for allotment to the 50 States and the District of Columbia is determined by subtracting the following amounts in the following order from the total appropriation specified

in section 2104(a) of the Act for the fiscal year—

(i) The total allotment amount available for allotment for each fiscal year to the Commonwealths and Territories, as determined in paragraph (d)(1) of this section;

(ii) The total amount of the grant for the fiscal year for children with Type I Diabetes under Section 4921 of Public Law 105–33. This is $30,000,000 for each of the fiscal years 1998 through 2002; and

(iii) The total amount of the grant for the fiscal year for diabetes programs for Indians under Section 4922 of Public Law 105–33. This is $30,000,000 for each of the fiscal years 1998 through 2002.

(2) The following formula illustrates the calculation of the national total allotment amount available for allotment to the 50 States and the District of Columbia for a fiscal year:

$$A_{TA} = S_{2104(a)} - T_{2104(c)} - D_{4921} - D_{4922}$$

A_{TA} = National total allotment amount available for allotment to the 50 States and the District of Columbia for the fiscal year.

$S_{2104(a)}$ = Total appropriation for the fiscal year indicated in Section 2104(a) of the Act.

$T_{2104(c)}$ = Total allotment amount for a fiscal year available for allotment to the Commonwealths and Territories; as determined under paragraph (d)(1) of this section.

D_{4921} = Amount of total grant for children with Type I Diabetes under Section 4921 of Public Law 105–33. This is $30,000,000 for each of the fiscal years 1998 through 2002.

(d) *Total allotment amount available to the Commonwealths and Territories*—(1) *General.* The total allotment amount available to all the Commonwealths and Territories for a fiscal year is equal to .25 percent of the total appropriation for the fiscal year indicated in section 2104(a) of the Act, plus the additional amount for the fiscal year specified in paragraph (d)(2) of this section.

(2) *Additional amounts for allotment to the Commonwealths and Territories.* The following amounts are available for allotment to the Commonwealths and Territories for the indicated fiscal years in addition to the amount specified in paragraph (d)(1) of this section: For FY 1999, $32 million; for each of FY 2000 and FY 2001, $34.2 million; for each fiscal year FY 2002 through 2004, $25.2 million; for each fiscal year FY 2005 and FY 2006, $32.4 million; and for FY 2007, $40 million. The additional amount for allotment for FY 1999 for the Commonwealths and Territories was provided under Public Law 105–277. The additional amounts for allotment for FY 2000 through FY 2007 were provided for the Commonwealths and Territories under section 702 of Public Law 106–113.

(e) *Determination of State allotments for a fiscal year*—(1) *General.* The allotment for a State and the District of Columbia for a fiscal year is the product of:

(i) The proportion for the State or the District of Columbia for the fiscal year, as defined in paragraph (b) of this section, and determined after application of the provisions of paragraphs (e)(2) and (3), related to the preadjusted proportion, and the floors, ceilings, and reconciliation process, respectively; and

(ii)(A) The national total allotment amount available for allotment for the fiscal year, as specified in paragraph (c) of this section. The State and the District of Columbia's allotment for a fiscal year is determined in accordance with the following general formula:

$$SA_i = P_i \times A_{TA}$$

SA_i = Allotment for a State or District of Columbia for a fiscal year.

P_i = Proportion for a State or District of Columbia for a fiscal year.

A_{TA} = Total amount available for allotment to the 50 States and the District of Columbia for the fiscal year.

(B) There are two steps for determining the proportion for a State and the District of Columbia. The first step determines the preadjusted proportions, and is described under paragraph (e)(2) of this section. The first step applies in determining the proportion for all fiscal years. The second step applies floors and ceilings and, if necessary, applies a reconciliation to the preadjusted proportion. The second step is described in paragraph (e)(3) of this section. The second step applies in determining the proportion only for FY 2000 and subsequent fiscal years. For FY 1998 and FY 1999, the preadjusted proportion is the State or District of

Columbia's proportion for the fiscal year.

(2) *Determination of the Preadjusted Proportions for a Fiscal Year.* (i)The methodology for determining the State preadjusted proportion, referring to the determination of the proportion before the application of floors and ceilings and reconciliation for a fiscal year is in accordance with the following formula:

$$PP_i = (C_i \times SCF_i) / \Sigma(C_i \times x\ SCF_i)$$

PP_i = Preadjusted proportion for a State or District of Columbia for a fiscal year.

C_i = *Number of children* in a State (section 2104(b)(1)(A)(I) of the Act) for a fiscal year. This number is based on the number of low-income children for a State for a fiscal year and the number of low-income children for a State for a fiscal year with no health insurance coverage for the fiscal year determined on the basis of the arithmetic average of the number of such children as reported and defined in the 3 most recent March supplements to the Current Population Survey (CPS) of the Bureau of the Census, and for FY 2000 and subsequent fiscal years, officially available before the beginning of the calendar year in which the fiscal year begins. For FY 1998 and FY 1999, the availability of the CPS data obtained from the Bureau of the Census is as specified in paragraphs (e)(4) and (5) of this section, respectively. (section 2104(b)(2)(B) of the Act).

(ii) For each of the fiscal years 1998 and 1999, the number of children is equal to the number of low-income children in the State for the fiscal year with no health insurance coverage. For fiscal year 2000, the number of children is equal to the sum of 75 percent of the number of low-income children in the State for the fiscal year with no health insurance coverage and 25 percent of the number of low-income children in the State for the fiscal year. For fiscal years 2001 and thereafter, the number of children is equal to the sum of 50 percent of the number of low-income children in the State for the fiscal year with no health insurance coverage and 50 percent of the number of low-income children in the State for the fiscal year. (section 2104(b)(2)(A) of the Act).

SCF_i = *State cost factor for a State* (section 2104(b)(1)(A)(ii) of the Act). For a fiscal year, this is equal to: $.15 + .85 \times (W_i/W_N)$ (section 2104(b)(3)(A) of the Act).

W_i = The annual average wages per employee for a State for such year (section 2104(b)(3)(A)(ii)(I) of the Act).

W_N = The annual average wages per employee for the 50 States and the District of Columbia (section 2104(b)(3)(A)(ii)(II) of the Act). The annual average wages per employee for a State or for all States and the District of Columbia for a fiscal year is equal to the average of such wages for employees in the health services industry (SIC 80), as reported by the Bureau of Labor Statistics of the Department of Labor for each of the most recent 3 years, and for FY 2000 and subsequent fiscal years, finally available before the beginning of the calendar year in which the fiscal year begins. For FY 1998 and FY 1999, the availability of the wage data obtained from the Bureau of Labor Statistics is as specified in paragraphs (e)(4) and (5), respectively. (section 2104(b)(3)(B) of the Act).

$\Sigma(C_i \times SCF_i)$ = The sum of the products of $(C_i \times SCF_i)$ for each State (section 2104(b)(1)(B) of the Act).

A_{TA} = Total amount available for allotment to the 50 States and the District of Columbia for the fiscal year as determined under paragraph (c) of this section.

(3) *Application of floors and ceilings and reconciliation in determining proportion.* (i) *Floors and ceilings in proportions.* The preadjusted State proportions for a fiscal year are subject to the application of floors and ceilings in paragraphs (e)(3)(i)(A) and (B) of this section.

(A) The proportion floors, or minimum proportions, that apply in determining a State's proportion for the fiscal year are:

(*1*) $2,000,000 divided by the total of the amount available nationally;

(*2*) 90 percent of the State's proportion for the previous fiscal year; and

(*3*) 70 percent of the State's proportion for FY 1999.

(B) The proportion ceiling, or maximum proportion, for a fiscal year that applies in determining the State's fiscal year proportion is 145 percent of the State's proportion for FY 1999.

(ii) *Reconciliation of State proportions.* If, after the application of the floors and ceilings in paragraph (e)(3)(i), the sum of the States' proportions is not equal to one, the Secretary will reconcile the States' proportions by applying either paragraph (e)(3)(i)(A) or (B) of this paragraph, as appropriate, such that the sum of the proportions

after reconciliation equals one. If, after the application of the floors and ceilings in paragraph (e)(3)(i), the sum of the States' proportions is equal to one, no reconciliation is necessary, and the States' proportions will be the same as the preadjusted proportions determined under paragraph (e)(2) of this section.

(A) If, after the application of the floors and ceilings under paragraphs (e)(3)(i)(A) and (B) of this section, the sum of the States' proportions is greater than one, the Secretary will establish a maximum percentage increase in States' proportions, such that when applied to the States' proportions, the sum of the proportions is exactly equal to one.

(B) If, after the application of the floors and ceilings under paragraphs (e)(3)(i)(A) and (B), the sum of the proportions is less than one, the Secretary will increase States' proportions (as computed before the application of the floors under paragraph (e)(3)(i)(A)) in a pro rata manner (but not to exceed the 145 percent ceiling computed under paragraph (e)(3)(i)(B)), such that when applied to the States' proportions, the sum of the proportions is exactly equal to one.

(4) *Data used for calculating the FY 1998 CHIP allotments.* The FY 1998 CHIP allotments were calculated in accordance with the methodology described in paragraphs (e)(1) and (2) of this section, using the most recent official and final data that were available from the Bureau of the Census and the Bureau of Labor Statistics, respectively, prior to the September 1 before the beginning of FY 1998 (that is, through August 31, 1997). In particular, through August 31, 1997, the only official data available on the numbers of children were data from the 3 March CPSs conducted in March 1994, 1995, and 1996 that reflected data for the 3 calendar years 1993, 1994, and 1995.

(5) *Data used for calculating the FY 1999 CHIP allotments.* In accordance with section 101(f) of Public Law 105–277, the FY 1999 allotments were calculated in accordance with the methodology described in paragraph (e)(2) of this section, using the same data as were used in calculating the FY 1998 CHIP allotments.

(f) *Methodology for determining the Commonwealth and Territory allotments for a fiscal year.* The total amount available for the Commonwealths and Territories for each fiscal year, as determined under paragraph (d) of this section, is allotted to each Territory and Commonwealth below which has an approved State child health plan. These allotments are in the proportion that the following percentages for each Commonwealth Territory bear to the sum of such percentages, as specified in section 2104(c)(2) of the Act:

Puerto Rico—91.6%
Guam—3.5%
Virgin Islands—2.6%
American Samoa—1.2%
Northern Mariana Islands—1.1%

(g) *Reserved State allotments for a fiscal year.* (1) For FY 2000 and subsequent fiscal years, CMS determines and publishes the State reserved allotments for a fiscal year for each State, the District of Columbia, and Commonwealths and Territories in the FEDERAL REGISTER based on the most recent official and final data available before the beginning of the calendar year in which the fiscal year begins for the number of children and the State cost factor.

(2) For FY 1998 and FY 1999, CMS determined and published the State reserved allotments using the available data described in paragraphs (e)(4) and (e)(5) of this section, respectively, on the basis of the statutory allotment formula as it existed prior to the enactment of Public Law 106–113.

(3) If all States, the District of Columbia, and the Commonwealths and Territories have approved State child health plans in place prior to the beginning of the fiscal year, as appropriate, CMS may publish the allotments as final in the FEDERAL REGISTER, without the need for publication as reserved allotments.

(h) *Final allotments.* (1) Final State allotments for FY 1998 and FY 1999 for each State, the District of Columbia, and the Commonwealths and Territories are determined by CMS based only on those States, the District of Columbia, and the Commonwealths and Territories that have approved State child health plans by the end of fiscal year 1999, in accordance with the formula and methodology specified in

paragraphs (a) through (g) of this section.

(2) Final State allotments for a fiscal year after FY 1999 for each State, the District of Columbia, and the Commonwealths and Territories are determined by CMS based only on those States, the District of Columbia, and the Commonwealths and Territories that have approved State child health plans by the end of the fiscal year, in accordance with the formula and methodology specified in paragraphs (a) through (g) of this section.

(3) CMS determines and publishes the States' final fiscal year allotments in the FEDERAL REGISTER based on the same data, with respect to the number of children and State cost factor, as were used in determining the reserved allotments for the fiscal year.

§457.610 Period of availability for State allotments for a fiscal year.

The amount of a final allotment for a fiscal year, as determined under §457.608(h) and reduced to reflect certain Medicaid expenditures in accordance with §457.616, remains available until expended for Federal payments based on expenditures claimed during a 3-year period of availability, beginning with the fiscal year of the final allotment and ending with the end of the second fiscal year following the fiscal year.

§457.614 General payment process.

(a) A State may make claims for Federal payment based on expenditures incurred by the State prior to or during the period of availability related to that fiscal year.

(b) In order to receive Federal financial participation (FFP) for a State's claims for payment for the State's expenditures, a State must—

(1) Submit budget estimates of quarterly funding requirements for Medicaid and the Children's Health Insurance Programs; and

(2) Submit an expenditure report.

(c) Based on the State's quarterly budget estimates, CMS—

(1) Issues an advance grant to a State as described in §457.630;

(2) Tracks and applies Federal payments claimed quarterly by each State, the District of Columbia, and each Commonwealth and Territory to ensure that payments do not exceed the applicable allotments for the fiscal year; and

(3) Track and apply relevant State, District of Columbia, Commonwealth and Territory expenditures reported each quarter against the 10 percent limit on expenditures other than child health assistance for standard benefit package, on a fiscal year basis as specified in §457.618.

[65 FR 33622, May 24, 2000, as amended at 75 FR 48852, Aug. 11, 2010]

§457.616 Application and tracking of payments against the fiscal year allotments.

(a) *Categories of payments applied to reduce the State allotments.* In accordance with the principles described in paragraph (c) of this section, the following categories of payments are applied to reduce the State allotments for a fiscal year:

(1) Payments made to the State for expenditures claimed during the fiscal year under its title XIX Medicaid program, to the extent the payments were made on the basis of the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for expenditures attributable to children described in section 1905(u)(2) of the Act.

(2) Payments made to the State for expenditures claimed during the fiscal year under its title XIX Medicaid program, to the extent the payments were made on the basis of the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for expenditures attributable to children described in section 1905(u)(3) of the Act.

(3) Payments made to a State under section 1903(a) of the Act for expenditures claimed by the State during a fiscal year that are attributable to the provision of medical assistance to a child during a presumptive eligibility period under section 1920A of the Act.

(4) Payments made to a State under its title XXI State Children's Health Insurance Program with respect to section 2105(a) of the Act for expenditures claimed by the State during a fiscal year.

(b) *Application of principles.* CMS applies the principles in paragraph (c) of this section to—

(1) Coordinate the application of the payments made to a State for the State's expenditures claimed under the Medicaid and State Children's Health Insurance programs against the State allotment for a fiscal year;

(2) Determine the order of these payments in that application; and

(3) Determine the application of payments against multiple State Child Health Insurance Program fiscal year allotments.

(c) *Principles for applying Federal payments against the allotment.* CMS—

(1) Applies the payments attributable to Medicaid expenditures specified in paragraphs (a)(1) through (a)(3) of this section, against the State child health plan allotment for a fiscal year before State child health plan expenditures specified in paragraph (a)(4) of this section are applied.

(2) Applies the payments attributable to Medicaid and State child health plan expenditures specified in paragraph (a) of this section against the applicable allotments for a fiscal year based on the quarter in which the expenditures are claimed by the State.

(3) Applies payments against the State allotments for a fiscal year in a manner that is consistent for all States.

(4) Applies payments attributable to Medicaid expenditures specified in paragraphs (a)(1) through (a)(3) of this section, in an order that maximizes Federal reimbursement for States. Expenditures for which the enhanced FMAP is available are applied before expenditures for which the regular FMAP is available.

(5) Applies payments for expenditures against State Child Health Insurance Program fiscal year allotments in the least administratively burdensome, and most effective and efficient manner; payments are applied on a quarterly basis as they are claimed by the State, and are applied to reduce the earliest fiscal year State allotments before the payments are applied to reduce later fiscal year allotments.

(6) Subject to paragraphs (c)(6)(i) and (ii) of this section, applies payments for expenditures for a fiscal year's allotment against a subsequent fiscal year's allotment; however, the subsequent fiscal year's allotment must be available at the time of application. For example, if the allotment for fiscal year 1998 has been fully expended, payments for expenditures claimed in fiscal year 1998 are carried over for application against the fiscal year 1999 allotment when it becomes available.

(i) In accordance with § 457.618, the amount of non-primary expenditures that are within the 10 percent limit for the fiscal year for which they are claimed may be applied against a fiscal year allotment or allotments available in a subsequent fiscal year.

(ii) In accordance with § 457.618, the amounts of non-primary expenditures that exceed the 10 percent limit for the fiscal year for which they are claimed may not be applied against a fiscal year allotment or allotments available in a subsequent fiscal year.

(7) Carries over unexpended amounts of a State's allotment for a fiscal year for use in subsequent fiscal years through the end of the 3-year period of availability. For example, if the amounts of the fiscal year 1998 allotment are not fully expended by the end of fiscal year 1998, these amounts are carried over to fiscal year 1999 and are available to provide FFP for expenditures claimed by the State for that fiscal year.

(d) *Amount of Federal payment for expenditures claimed.* The amount of the Federal payment for expenditures claimed by a State, District of Columbia, or the Commonwealths and Territories is determined by the enhanced FMAP applicable to the fiscal year in which the State paid the expenditure. For example, Federal payment for an expenditure paid by a State in fiscal year 1998 that was carried over to fiscal year 1999 (in accordance with paragraph (c)(6) of this section), because the State exceeded its fiscal year 1998 allotment, is available at the fiscal year 1998 enhanced FMAP rate.

§ 457.618 Ten percent limit on certain Children's Health Insurance Program expenditures.

(a) *Expenditures.* (1) *Primary expenditures* are expenditures under a State plan for child health assistance to targeted low-income children in the form of a standard benefit package, and Medicaid expenditures claimed during

the fiscal year to the extent Federal payments made for these expenditures on the basis of the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act that are used to calculate the 10 percent limit.

(2) *Non-primary expenditures* are other expenditures under a State plan. Subject to the 10 percent limit described in paragraph (c) of this section, a State may receive Federal funds at the enhanced FMAP for 4 categories of non-primary expenditures:

(i) Administrative expenditures;

(ii) Outreach;

(iii) Health initiatives; and

(iv) Certain other child health assistance.

(b) *Federal payment.* Federal payment will not be available based on a State's non-primary expenditures for a fiscal year which exceed the 10 percent limit of the total of expenditures under the plan, as specified in paragraph (c) of this section.

(c) *10 Percent Limit.* The 10 percent limit is—

(1) Applied on an annual fiscal year basis;

(2) Calculated based on the total computable expenditures claimed by the State on quarterly expenditure reports submitted for a fiscal year. Expenditures claimed on a quarterly report for a different fiscal year may not be used in the calculation; and

(3) Calculated using the following formula:

$$L10\% = (A1 + U2 + U3)/9;$$

L10% = 10 Percent Limit for a fiscal year

A1 = Total computable amount of expenditures for the fiscal year under section 2105(a)(1) of the Act for which Federal payments are available at the enhanced FMAP described in Section 2105(b) of the Act;

U2 = Total computable expenditures for medical assistance for which Federal payments are made during the fiscal year based on the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for individuals described in section 1905(u)(2) of the Act; and

U3 = Total computable expenditures for medical assistance for which Federal payments are made during the fiscal year based on the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for individuals described in section 1905(u)(3) of the Act.

(d) The expenditures under section 2105(a)(2) of the Act that are subject to the 10 percent limit are applied—

(1) On an annual fiscal year basis; and

(2) Against the 10 percent limit in the fiscal year for which the State submitted a quarterly expenditure report including the expenditures. Expenditures claimed on a quarterly report for one fiscal year may not be applied against the 10 percent limit for any other fiscal year.

(e)(1) The 10 percent limit for a fiscal year, as calculated under paragraph (c)(3) of this section, may be no greater than 10 percent of the total computable amount (determined under paragraph (e)(2) of this section) of the State allotment or allotments available in that fiscal year. Therefore, the 10 percent limit is the lower of the amount calculated under paragraph (c)(3) of this section, and 10 percent of the total computable amount of the State allotment available in that fiscal year.

(2) As used in paragraph (e)(1) of this section, the total computable amount of a State's allotment for a fiscal year is determined by dividing the State's allotment for the fiscal year by the State's enhanced FMAP for the year. For example, if a State allotment for a fiscal year is $65 million and the enhanced FMAP rate for the fiscal year is 65 percent, the total computable amount of the allotment for the fiscal year is $100 million ($65 million/.65). In this example, the 10 percent limit may be no greater than a total computable amount of $10 million (10 percent of $100 million).

[65 FR 33622, May 24, 2000, as amended at 75 FR 48852, Aug. 11, 2010]

§ 457.622 Rate of FFP for State expenditures.

(a) *Basis.* Sections 1905(b), 2105(a) and 2105(b) of the Act provides for payments to States from the States' allotments for a fiscal year, as determined under § 457.608, for part of the cost of expenditures for services and administration made under an approved State child health assistance plan. The rate of payment is generally the enhanced Federal medical assistance percentage described below.

(b) *Enhanced Federal medical assistance percentage (Enhanced FMAP)—Computations.* The enhanced FMAP is the lower of the following:

(1) 70 percent of the regular FMAP determined under section 1905(b) of the Act, plus 30 percentage points; or

(2) 85 percent.

(c) *Conditions for availability of enhanced FMAP based on a State's expenditures*—The enhanced FMAP is available for payments based on a State's expenditures claimed under the State's title XXI program from the State's fiscal year allotment only under the following conditions:

(1) The State has an approved title XXI State child health plan;

(2) The expenditures are allowable under the State's approved title XXI State child health plan;

(3) State allotment amounts are available in the fiscal year, that is, the State's allotment or allotments (as reduced in accordance with § 457.616) remain available for a fiscal year and have not been fully expended.

(4) Expenditures claimed against the 10 percent limit are within the State's 10 percent limit for the fiscal year.

(5) For States that elect to extend eligibility to unborn children under the approved Child Health Plan, the State does not adopt eligibility standards and methodologies for purposes of determining a child's eligibility under the Medicaid State plan that were more restrictive than those applied under policies of the State plan in effect on June 1, 1997. This limitation applies also to more restrictive standards and methodologies for determining eligibility for services for a child based on the eligibility of a pregnant woman.

(d) *Categories of expenditures for which enhanced FMAP are available.* Except as otherwise provided below, the enhanced FMAP is available with respect to the following States' expenditures:

(1) Child health assistance under the plan for targeted low-income children in the form of providing health benefits coverage that meets the requirements of section 2103 of the Act; and

(2) Subject to the 10 percent limit provisions under § 457.618(a)(2), the following expenditures:

(i) Payment for other child health assistance for targeted low-income children;

(ii) Expenditures for health services initiatives under the State child health assistance plan for improving the health of children (including targeted low-income children);

(iii) Expenditures for outreach activities; and

(iv) Other reasonable costs incurred by the State to administer the State child health assistance plan.

(e) *CHIP administrative expenditures and CHIP related title XIX administrative expenditures*—(1) *General rule.* Allowable title XXI administrative expenditures should support the operation of the State child health assistance plan. In general, FFP for administration under title XXI is not available for costs of activities related to the operation of other programs.

(2) *Exception.* FFP is available under title XXI, at the enhanced FFP rate, for Medicaid administrative expenditures attributable to the provision of medical assistance to children described in sections 1905(u)(2) and 1905(u)(3), and during the presumptive eligibility period described in section 1920A of the Act, to the extent that the State does not claim those costs under the Medicaid program.

(3) FFP is not available in expenditures for administrative activities for items or services included within the scope of another claimed expenditure.

(4) FFP is available in expenditures for activities defined in sections 2102(c)(1) and 2105(a)(2)(C) of the Act as outreach to families of children likely to be eligible for child health assistance under the plan or under other public or private health coverage programs to inform these families of the availability of, and to assist them in enrolling their children in such a program.

(5) FFP is available in administrative expenditures for activities specified in sections 2102(c)(2) of the Act as coordination of the administration of the Children's Health Insurance Program with other public and private health insurance programs. FFP would not be available for the costs of administering

the other public and private health insurance programs. Coordination activities must be distinguished from other administrative activities common among different programs.

[65 FR 33622, May 24, 2000, as amended at 67 FR 61974, Oct. 2, 2002; 75 FR 48852, Aug. 11, 2010]

§457.626 Prevention of duplicate payments.

(a) *General rule.* No payment shall be made to a State for expenditures for child health assistance under its State child health plan to the extent that:

(1) A non-governmental health insurer would have been obligated to pay for those services but for a provision of its insurance contract that has the effect of limiting or excluding those obligations based on the actual or potential eligibility of the individual for child health assistance under the State child health insurance plan.

(2) Payment has been made or can reasonably be expected to be made promptly under any other Federally operated or financed health insurance or benefits program, other than a program operated or financed by the Indian Health Service.

(3) Services are for an unborn child and are payable under Medicaid as a service to an eligible pregnant woman under that program.

(b) *Definitions.* As used in paragraph (a) of this section—

Non-governmental health insurer includes any health insurance issuer, group health plan, or health maintenance organization, as those terms are defined in 45 CFR 144.103, which is not part of, or wholly owned by, a governmental entity.

Prompt payment can reasonably be expected when payment is required by applicable statute, or under an approved State plan.

Programs operated or financed by the Indian Health Service means health programs operated by the Indian Health Service, or Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement or compact with the Indian Health Service under the authority of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450, *et seq.*), or by an urban Indian organization in accordance with a grant or contract with the Indian Health Service under the authority of title V of the Indian Health Care Improvement Act (25 U.S.C. 1601, *et seq.*).

[65 FR 33622, May 24, 2000, as amended at 67 FR 61974, Oct. 2, 2002]

§457.628 Other applicable Federal regulations.

Other regulations applicable to CHIP programs include the following:

(a) HHS regulations in §433.50 through §433.74 of this chapter (sources of non-Federal share and Health Care-Related Taxes and Provider-Related Donations) and §447.207 of this chapter (Retention of payments) apply to States' CHIP programs in the same manner as they apply to States' Medicaid programs.

(b) HHS Regulations in 45 CFR subtitle A:

Part 16—Procedures of the Departmental Appeals Board.

Part 74—Administration of Grants (except as specifically excepted).

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of title VI of the Civil Rights Act of 1964.

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80.

Part 84—Nondiscrimination on the Basis of Handicap in Programs and activities Receiving or Benefiting From Federal Financial Assistance.

Part 95—General Administration—grant programs (public assistance and medical assistance).

[66 FR 2670, Jan. 11, 2001, as amended at 72 FR 29836, May 29, 2007]

§457.630 Grants procedures.

(a) *General provisions.* Once CMS has approved a State child health plan, CMS makes quarterly grant awards to the State to cover the Federal share of expenditures for child health assistance, other child health assistance, special health initiatives, outreach and administration.

(1) For fiscal year 1998, a State must submit a budget request in an appropriate format for the 4 quarters of the fiscal year. CMS bases the grant awards for the 4 quarters of fiscal year 1998 based on the State's budget requests for those quarters.

(2) For fiscal years after 1998, a State must submit a budget request in an appropriate format for the first 3 quarters of the fiscal year. CMS bases the grant awards for the first 3 quarters of the fiscal year on the State's budget requests for those quarters.

(3) For fiscal years after 1998, a State must also submit a budget request for the fourth quarter of the fiscal year. The amount of this quarter's grant award is based on the difference between a State's final allotment for the fiscal year, and the total of the grants for the first 3 quarters that were already issued in order to ensure that the total of all grant awards for the fiscal year are equal to the State's final allotment for that fiscal year.

(4) The amount of the quarterly grant is determined on the basis of information submitted by the State (in quarterly estimate and quarterly expenditure reports) and other pertinent information. This information must be submitted by the State through the Medicaid Budget and Expenditure System (MBES) for the Medicaid program, and through the Child Health Budget and Expenditure System (CBES) for the title XXI program.

(b) *Quarterly estimates.* The Children's Health Insurance Program agency must submit Form CMS–21B (State Children's Health Insurance Program Budget Report for State Children's Health Insurance Program State expenditures) to the CMS central office (with a copy to the CMS regional office) 45 days before the beginning of each quarter.

(c) *Expenditure reports.* (1) The State must submit Form CMS–64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) and Form CMS–21 (Quarterlye Children's Health Insurance Program Statement of Expenditures for title XXI), to central office (with a copy to the regional office) not later than 30 days after the end of the quarter.

(2) This report is the State's accounting of actual recorded expenditures. This disposition of Federal funds may not be reported on the basis of estimates.

(d) *Additional required information.* A State must provide CMS with the following information regarding the administration of the title XXI program:

(1) Name and address of the State Agency/organization administering the program;

(2) The employer identification number (EIN); and

(3) A State official contact name and telephone number.

(e) *Grant award*—(1) *Computation by CMS.* Regional office staff analyzes the State's estimates and sends a recommendation to the central office. Central office staff considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (e)(2) of this section, and computes the grant.

(2) *Content of award.* The grant award computation form shows the estimate of expenditures for the ensuing quarter, and the amounts by which that estimate is increased or decreased because of an increase or overestimate for prior quarters, or for any of the following reasons:

(i) Penalty reductions imposed by law.

(ii) Deferrals or disallowances.

(iii) Interest assessments.

(iv) Mandated adjustments such as those required by Section 1914 of the Act.

(3) *Effect of award.* The grant award authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements.

(4) *Draw procedure.* The draw is through a commercial bank and the Federal Reserve system against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee. (The letter of credit payment system was established in accordance with Treasury Department regulations—Circular No.1075.)

(f) *General administrative requirements.* With the following exceptions, the provisions of 45 CFR part 74, that establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

(1) Subpart G—Matching and Cost Sharing; and

(2) Subpart I—Financial Report Requirement.

[65 FR 33622, May 24, 2000, as amended at 75 FR 48852, Aug. 11, 2010]

Subpart G—Strategic Planning, Reporting, and Evaluation

SOURCE: 66 FR 2683, Jan. 11, 2001, unless otherwise noted.

§ 457.700 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Sections 2107(a), (b) and (d) of the Act, which set forth requirements for strategic planning, reports, and program budgets; and

(2) Section 2108 of the Act, which sets forth provisions regarding annual reports and evaluation.

(b) *Scope.* This subpart sets forth requirements for strategic planning, monitoring, reporting and evaluation under title XXI.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs and Medicaid expansion programs.

§ 457.710 State plan requirements: Strategic objectives and performance goals.

(a) *Plan description.* A State plan must include a description of—

(1) The strategic objectives as described in paragraph (b) of this section;

(2) The performance goals as described in paragraph (c) of this section; and

(3) The performance measurements, as described in paragraph (d) of this section, that the State has established for providing child health assistance to targeted low-income children under the plan and otherwise for maximizing health benefits coverage for other low-income children and children generally in the State.

(b) *Strategic objectives.* The State plan must identify specific strategic objectives relating to increasing the extent of creditable health coverage among targeted low-income children and other low-income children.

(c) *Performance goals.* The State plan must specify one or more performance goals for each strategic objective identified.

(d) *Performance measurements.* The State plan must describe how performance under the plan is—

(1) Measured through objective, independently verifiable means; and

(2) Compared against performance goals.

(e) *Core elements.* The State's strategic objectives, performance goals and performance measures must include a common core of national performance goals and measures consistent with the data collection, standard methodology, and verification requirements, as developed by the Secretary.

§ 457.720 State plan requirement: State assurance regarding data collection, records, and reports.

A State plan must include an assurance that the State collects data, maintains records, and furnishes reports to the Secretary, at the times and in the standardized format the Secretary may require to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under Title XXI of the Act. This includes collection of data and reporting as required under § 431.970 of this chapter.

[71 FR 51084, Aug. 28, 2006]

§ 457.740 State expenditures and statistical reports.

(a) *Required quarterly reports.* A State must submit reports to CMS that contain quarterly program expenditures and statistical data no later than 30 days after the end of each quarter of the Federal fiscal year. A State must collect required data beginning on the date of implementation of the approved State plan. Territories are exempt from the definition of ''State'' for purposes of the required quarterly reporting under this section. The quarterly reports must include data on—

(1) Program expenditures;

(2) The number of children enrolled in the title XIX Medicaid program, the separate child health program, and the Medicaid expansion program, as applicable, as of the last day of each quarter of the Federal fiscal year; and

(3) The number of children under 19 years of age who are enrolled in the title XIX Medicaid program, the separate child health program, and in the Medicaid expansion program, as appropriate, by the following categories:

(i) Age (under 1 year of age, 1 through 5 years of age, 6 through 12 years of age, and 13 through 18 years of age).

(ii) Gender, race, and ethnicity.

(iii) Service delivery system (managed care, fee-for-service, and primary care case management).

(iv) Family income as a percentage of the Federal poverty level as described in paragraph (b) of this section.

(b) *Reportable family income categories.* (1) A State that does not impose cost sharing or a State that imposes cost sharing based on a fixed percentage of income must report by two family income categories:

(i) At or below 150 percent of FPL.

(ii) Over 150 percent of FPL.

(2) A State that imposes a different level or percentage of cost sharing at different poverty levels must report by poverty level categories that match the poverty level categories used for purposes of cost sharing.

(c) *Required unduplicated counts.* Thirty days after the end of the Federal fiscal year, the State must submit an unduplicated count for the Federal fiscal year of children who were enrolled in the Medicaid program, the separate child health program, and the Medicaid expansion program, as appropriate, by age, gender, race, ethnicity, service delivery system, and poverty level categories described in paragraphs (a) and (b) of this section.

§ 457.750 Annual report.

(a) *Report required for each Federal fiscal year.* A State must report to CMS by January 1 following the end of each Federal fiscal year, on the results of the State's assessment of the operation of the State plan.

(b) *Contents of annual report.* In the annual report required under paragraph (a) of this section, a State must—

(1) Describe the State's progress in reducing the number of uncovered, low-income children and; in meeting other strategic objectives and performance goals identified in the State plan; and provide information related to a core set of national performance goals and measures as developed by the Secretary;

(2) Report on the effectiveness of the State's policies for discouraging the substitution of public coverage for private coverage;

(3) Identify successes and barriers in State plan design and implementation, and the approaches the State is considering to overcome these barriers;

(4) Describe the State's progress in addressing any specific issues (such as outreach) that the State plan proposed to periodically monitor and assess;

(5) Provide an updated budget for a 3-year period that describes those elements required in § 457.140, including any changes in the sources of the non-Federal share of State plan expenditures;

(6) Identify the total State expenditures for family coverage and total number of children and adults, respectively, covered by family coverage during the preceding Federal fiscal year;

(7) Describe the State's current income standards and methodologies for its Medicaid expansion program, separate child health program, and title XIX Medicaid program, as appropriate.

(c) *Methodology for estimate of number of uninsured, low-income children.* (1) To report on the progress made in reducing the number of uninsured, low-income children as required in paragraph (b) of this section, a State must choose a methodology to establish an initial baseline estimate of the number of low-income children who are uninsured in the State.

(i) A State may base the estimate on data from—

(A) The March supplement to the Current Population Survey (CPS);

(B) A State-specific survey;

(C) A statistically adjusted CPS; or

(D) Another appropriate source.

(ii) If the State does not base the estimate on data from the March supplement to the CPS, the State must submit a description of the methodology used to develop the initial baseline estimate and the rationale for its use.

(2) The State must provide an annual estimate of changes in the number of uninsured in the State using—

(i) The same methodology used in establishing the initial baseline; or

(ii) Another methodology based on new information that enables the State to establish a new baseline.

(3) If a new methodology is used, the State must also provide annual estimates based on either the March supplement to the CPS or the methodology used to develop the initial baseline.

[66 FR 2683, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

Subpart H—Substitution of Coverage

SOURCE: 66 FR 2684, Jan. 11, 2001, unless otherwise noted.

§457.800 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements section 2102(b)(3)(C) of the Act, which provides that the State plan must include a description of procedures the State uses to ensure that health benefits coverage provided under the State plan does not substitute for coverage under group health plans.

(b) *Scope.* This subpart sets forth State plan requirements relating to substitution of coverage in general and specific requirements relating to substitution of coverage under premium assistance programs.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs.

§457.805 State plan requirement: Procedures to address substitution under group health plans.

The State plan must include a description of reasonable procedures to ensure that health benefits coverage provided under the State plan does not substitute for coverage provided under group health plans as defined at §457.10.

§457.810 Premium assistance programs: Required protections against substitution.

A State that operates a premium assistance program, as defined at §457.10, must provide the protections against substitution of CHIP coverage for coverage under group health plans specified in this section. The State must describe these protections in the State plan; and report on results of monitoring of substitution in its annual reports.

(a) *Minimum period without coverage under a group health plan.* For health benefits coverage provided through premium assistance for group health plans, the following rules apply:

(1) An enrollee must not have had coverage under a group health plan for a period of at least 6 months prior to enrollment in a premium assistance program. A State may not require a minimum period without coverage under a group health plan that exceeds 12 months.

(2) States may permit reasonable exceptions to the requirement for a minimum period without coverage under a group health plan for—

(i) Involuntary loss of coverage under a group health plan, due to employer termination of coverage for all employees and dependents;

(ii) Economic hardship;

(iii) Change to employment that does not offer dependent coverage; or

(iv) Other reasons proposed by the State and approved as part of the State plan.

(3) The requirement for a minimum period without coverage under a group health plan does not apply to a child who, within the previous 6 months, has received coverage under a group health plan through Medicaid under section 1906 of the Act.

(4) The Secretary may waive the 6-month waiting period requirement described in this section at her discretion.

(b) *Employer contribution.* For health benefits coverage obtained through premium assistance for group health plans, the employee who is eligible for the coverage must apply for the full premium contribution available from the employer.

(c) *Cost effectiveness.* In establishing cost effectiveness—

(1) The State's cost for coverage for children under premium assistance programs must not be greater than the cost of other CHIP coverage for these children; and

(2) The State may base its demonstration of cost effectiveness on an assessment of the cost of coverage for children under premium assistance programs to the cost of other CHIP coverage for these children, done on a case-by-case basis, or on the cost of premium assisted coverage in the aggregate.

(d) *State evaluation.* The State must evaluate and report in the annual report (in accordance with § 457.750(b)(2)) the amount of substitution that occurs as a result of premium assistance programs and the effect of those programs on access to coverage.

Subpart I—Program Integrity

SOURCE: 66 FR 2685, Jan. 11, 2001, unless otherwise noted.

§ 457.900 Basis, scope and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Section 2101(a) of the Act, which provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; and

(2) Section 2107(e) of the Act, which provides that certain title XIX and title XI provisions, including the following, apply to States under title XXI in the same manner as they apply to a State under title XIX:

(i) Section 1902(a)(4)(C) of the Act, relating to conflict of interest standards.

(ii) Paragraphs (2), (16), and (17), of section 1903(i) of the Act, relating to limitations on payment.

(iii) Section 1903(w) of the Act, relating to limitations on provider taxes and donations.

(iv) Section 1124 of the Act, relating to disclosure of ownership and related information.

(v) Section 1126 of the Act, relating to disclosure of information about certain convicted individuals.

(vi) Section 1128 of the Act, relating to exclusions.

(vii) Section 1128A of the Act, relating to civil monetary penalties.

(viii) Section 1128B(d) of the Act, relating to criminal penalties for certain additional charges.

(ix) Section 1132 of the Act, relating to periods within which claims must be filed.

(b) *Scope.* This subpart sets forth requirements, options, and standards for program integrity assurances that must be included in the approved State plan.

(c) *Applicability.* This subpart applies to separate child health programs. Medicaid expansion programs are subject to the program integrity rules and requirements specified under title XIX.

§ 457.902 Definitions

As used in this subpart—

Actuarially sound principles means generally accepted actuarial principles and practices that are applied to determine aggregate utilization patterns, are appropriate for the population and services to be covered, and have been certified by actuaries who meet the qualification standards established by the Actuarial Standards Board.

Fee-for-service entity means any individual or entity that furnishes services under the program on a fee-for-service basis, including health insurance services.

§ 457.910 State program administration.

The State's child health program must include—

(a) Methods of administration that the Secretary finds necessary for the proper and efficient operation of the separate child health program; and

(b) Safeguards necessary to ensure that—

(1) Eligibility will be determined appropriately in accordance with subpart C of this part; and

(2) Services will be provided in a manner consistent with administrative simplification and with the provisions of subpart D of this part.

§ 457.915 Fraud detection and investigation.

(a) *State program requirements.* The State must establish procedures for ensuring program integrity and detecting fraudulent or abusive activity. These procedures must include the following:

(1) Methods and criteria for identifying suspected fraud and abuse cases.

(2) Methods for investigating fraud and abuse cases that—

(i) Do not infringe on legal rights of persons involved; and

(ii) Afford due process of law.

(b) *State program integrity unit.* The State may establish an administrative agency responsible for monitoring and maintaining the integrity of the separate child health program.

(c) *Program coordination.* The State must develop and implement procedures for referring suspected fraud and abuse cases to the State program integrity unit (if such a unit is established) and to appropriate law enforcement officials. Law enforcement officials include the—

(1) U.S. Department of Health and Human Services Office of Inspector General (OIG);

(2) U.S. Attorney's Office, Department of Justice (DOJ);

(3) Federal Bureau of Investigation (FBI); and

(4) State Attorney General's office.

§ 457.925 Preliminary investigation.

If the State agency receives a complaint of fraud or abuse from any source or identifies questionable practices, the State agency must conduct a preliminary investigation or take otherwise appropriate action within a reasonable period of time to determine whether there is sufficient basis to warrant a full investigation.

§ 457.930 Full investigation, resolution, and reporting requirements.

The State must establish and implement effective procedures for investigating and resolving suspected and apparent instances of fraud and abuse. Once the State determines that a full investigation is warranted, the State must implement procedures including, but not limited to the following:

(a) Cooperate with and refer potential fraud and abuse cases to the State program integrity unit, if such a unit exists.

(b) Conduct a full investigation.

(c) Refer the fraud and abuse case to appropriate law enforcement officials.

§ 457.935 Sanctions and related penalties.

(a) A State may not make payments for any item or service furnished, ordered, or prescribed under a separate child health program to any provider who has been excluded from participating in the Medicare and Medicaid programs.

(b) The following provisions and their corresponding regulations apply to a State under title XXI, in the same manner as these provisions and regulations apply to a State under title XIX:

(1) Part 455, subpart B of this chapter.

(2) Section 1124 of the Act pertaining to disclosure of ownership and related information.

(3) Section 1126 of the Act pertaining to disclosure by institutions, organizations, and agencies of owners and certain other individuals who have been convicted of certain offenses.

(4) Section 1128 of the Act pertaining to exclusions.

(5) Section 1128A of the Act pertaining to civil monetary penalties.

(6) Section 1128B of the Act pertaining to criminal penalties for acts involving Federal health care programs.

(7) Section 1128E of the Act pertaining to the reporting of final adverse actions on liability findings made against health care providers, suppliers, and practitioners under the health care fraud and abuse data collection program.

§ 457.940 Procurement standards.

(a) A State must submit to CMS a written assurance that title XXI services will be provided in an effective and efficient manner. The State must submit the assurance—

(1) With the initial State plan; or

(2) For States with approved plans, with the first request to amend the approved plan.

(b) A State must—

(1) Provide for free and open competition, to the maximum extent practical, in the bidding of all procurement contracts for coverage or other services in accordance with the procurement requirements of 45 CFR 74.43 or 45 CFR 92.36, as applicable; or

(2) Use payment rates based on public or private payment rates for comparable services for comparable populations, consistent with principles of actuarial soundness as defined at § 457.902.

(c) A State may establish higher rates than permitted under paragraph (b) of this section if such rates are necessary to ensure sufficient provider participation, provider access, or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

(d) All contracts under this part must include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74 or 45 CFR part 92, as applicable.

(e) The State must provide to CMS, if requested, a description of the manner in which rates were developed in accordance with the requirements of paragraphs (b) or (c) of this section.

[66 FR 2685, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.945 Certification for contracts and proposals.

Entities that contract with the State under a separate child health program must certify the accuracy, completeness, and truthfulness of information in contracts and proposals, including information on subcontractors, and other related documents, as specified by the State.

§ 457.950 Contract and payment requirements including certification of payment-related information.

(a) *Managed care entity (MCE).* A State that makes payments to an MCE under a separate child health program, based on data submitted by the MCE, must ensure that its contract requires the MCE to provide—

(1) Enrollment information and other information required by the State;

(2) An attestation to the accuracy, completeness, and truthfulness of claims and payment data, under penalty of perjury;

(3) Access for the State, CMS, and the HHS Office of the Inspector General to enrollee health claims data and payment data, in conformance with the appropriate privacy protections in the State; and

(4) A guarantee that the MCE will not avoid costs for services covered in its contract by referring enrollees to publicly supported health care resources.

(b) *Fee-for-service entities.* A State that makes payments to fee-for-service entities under a separate child health program must—

(1) Establish procedures to ensure that the entity certifies and attests that information on claim forms is truthful, accurate, and complete;

(2) Ensure that fee-for-service entities understand that payment and satisfaction of the claims will be from Federal and State funds, and that any false claims may be prosecuted under applicable Federal or State laws; and

(3) Require, as a condition of participation, that fee-for-service entities provide the State, CMS and/or the HHS Office of the Inspector General with access to enrollee health claims data, claims payment data and related records.

§ 457.955 Conditions necessary to contract as a managed care entity (MCE).

(a) The State must assure that any entity seeking to contract as an MCE under a separate child health program has administrative and management arrangements or procedures designed to safeguard against fraud and abuse.

(b) The State must ensure that the arrangements or procedures required in paragraph (a) of this section—

(1) Enforce MCE compliance with all applicable Federal and State standards;

(2) Prohibit MCEs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of a managed care entity for the purpose of influencing the individual to enroll with the entity; and

(3) Include a mechanism for the MCE to report to the State, to CMS, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors or enrollees of an MCE and other individuals.

(c) With respect to enrollees, the reporting requirement in paragraph (b)(3) of this section applies only to information on violations of law that pertain

to enrollment in the plan, or the provision of, or payment for, health services.

(d) The State may inspect, evaluate, and audit MCEs at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity.

§457.960 Reporting changes in eligibility and redetermining eligibility.

If the State requires reporting of changes in circumstances that may affect the enrollee's eligibility for child health assistance, the State must:

(a) Establish procedures to ensure that enrollees make timely and accurate reports of any such change; and

(b) Promptly redetermine eligibility when the State has information about these changes.

§457.965 Documentation.

The State must include in each applicant's record facts to support the State's determination of the applicant's eligibility for CHIP.

§457.980 Verification of enrollment and provider services received.

The State must establish and maintain systems to identify, report, and verify the accuracy of claims for those enrolled children who meet requirements of section 2105(a) of the Act, where enhanced Federal medical assistance percentage computations apply.

[66 FR 2685, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§457.985 Integrity of professional advice to enrollees.

The State must ensure through its contracts for coverage and services that its contractors comply with—

(a) Section 422.206(a) of this chapter, which prohibits interference with health care professionals' advice to enrollees and requires that professionals provide information about treatment in an appropriate manner; and

(b) Sections 422.208 and 422.210 of this chapter, which place limitations on physician incentive plans, and information disclosure requirements related to those physician incentive plans, respectively.

Subpart J—Allowable Waivers: General Provisions

SOURCE: 66 FR 2686, Jan. 11, 2001, unless otherwise noted.

§457.1000 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2105(c)(2)(B) of the Act, which sets forth the requirements to permit a State to exceed the 10 percent cost limit on expenditures other than benefit expenditures; and

(2) Section 2105(c)(3) of the Act, which permits the purchase of family coverage.

(b) *Scope.* This subpart sets forth requirements for obtaining a waiver under title XXI.

(c) *Applicability.* This subpart applies to separate child health programs; and applies to Medicaid expansion programs when the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for use of a community-based health delivery system. This subpart does not apply to demonstrations requested under section 1115 of the Act.

[66 FR 2686, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§457.1003 CMS review of waiver requests.

CMS will review the waiver requests under this subpart using the same time frames used for State plan amendments, as specified in §457.160.

§457.1005 Cost-effective coverage through a community-based health delivery system.

(a) *Availability of waiver.* The Secretary may waive the requirements of §457.618 (the 10 percent limit on expenditures not used for health benefits coverage for targeted low-income children, that meets the requirements of §457.410) in order to provide child health assistance to targeted low-income children under the State plan through a cost-effective, community-based health care delivery system, such as through contracts with health centers receiving funds under section 330 of the Public Health Service Act or

with hospitals such as those that receive disproportionate share payment adjustments under section 1886(c)(5)(F) or section 1923 of the Act.

(b) *Requirements for obtaining a waiver.* To obtain a waiver for cost-effective coverage through a community-based health delivery system, a State must demonstrate that—

(1) The coverage meets all of the requirements of this part, including subpart D and subpart E.

(2) The cost of such coverage, on an average per child basis, does not exceed the cost of coverage under the State plan.

(c) *Three-year approval period.* An approved waiver remains in effect for no more than 3 years.

(d) *Application of cost savings.* If the cost of coverage of a child under a community-based health delivery system is equal to or less than the cost of coverage of a child under the State plan, the State may use the difference in the cost of coverage for each child enrolled in a community-based health delivery system for—

(1) Other child health assistance, health services initiatives, or outreach; or

(2) Any reasonable costs necessary to administer the State's program.

§ 457.1010 Purchase of family coverage.

A State may purchase family coverage that includes coverage for targeted low-income children if the State establishes that—

(a) Purchase of family coverage is cost-effective under the standards described in § 457.1015;

(b) The State does not purchase the coverage if it would otherwise substitute for health insurance coverage that would be provided to targeted, low-income children but for the purchase of family coverage; and

(c) The coverage for the family otherwise meets the requirements of this part.

§ 457.1015 Cost-effectiveness.

(a) *Definition.* For purposes of this subpart, ''cost-effective'' means that the State's cost of purchasing family coverage that includes coverage for targeted low-income children is equal to or less than the State's cost of obtaining coverage under the State plan only for the eligible targeted low-income children involved.

(b) *Cost comparisons.* A State may demonstrate cost-effectiveness by comparing the cost of coverage for the family to the cost of coverage only for the targeted low-income children under the health benefits package offered by the State under the State plan for which the child is eligible.

(c) *Individual or aggregate basis.* (1) The State may base its demonstration of the cost-effectiveness of family coverage on an assessment of the cost of family coverage for individual families, done on a case-by-case basis, or on the cost of family coverage in the aggregate.

(2) The State must assess cost-effectiveness in its initial request for a waiver and then annually.

(3) For any State that chooses the aggregate cost method, if an annual assessment of the cost-effectiveness of family coverage in the aggregate reveals that it is not cost-effective, the State must assess cost-effectiveness on a case-by-case basis.

(d) *Reports on family coverage.* A State with a waiver under this section must include in its annual report pursuant to § 457.750, the cost of family coverage purchased under the waiver, and the number of children and adults, respectively, covered under family coverage pursuant to the waiver.

Subpart K—State Plan Requirements: Applicant and Enrollee Protections

SOURCE: 66 FR 2687, Jan. 11, 2001, unless otherwise noted.

§ 457.1100 Basis, scope and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2101(a) of the Act, which states that the purpose of title XXI of the Act is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner;

(2) Section 2102(a)(7)(B) of the Act, which requires that the State plan include a description of the methods used to assure access to covered services, including emergency services;

(3) Section 2102(b)(2) of the Act, which requires that the State plan include a description of methods of establishing and continuing eligibility and enrollment; and

(4) Section 2103 of the Act, which outlines coverage requirements for a State that provides child health assistance through a separate child health program.

(b) *Scope.* This subpart sets forth minimum standards for privacy protection and for procedures for review of matters relating to eligibility, enrollment, and health services.

(c) *Applicability.* This subpart only applies to a separate child health program.

§457.1110 Privacy protections.

The State must ensure that, for individual medical records and any other health and enrollment information maintained with respect to enrollees, that identifies particular enrollees (in any form), the State establishes and implements procedures to—

(a) Abide by all applicable Federal and State laws regarding confidentiality and disclosure, including those laws addressing the confidentiality of information about minors and the privacy of minors, and privacy of individually identifiable health information;

(b) Comply with subpart F of part 431 of this chapter;

(c) Maintain the records and information in a timely and accurate manner;

(d) Specify and make available to any enrollee requesting it—

(1) The purposes for which information is maintained or used; and

(2) To whom and for what purposes the information will be disclosed outside the State;

(e) Except as provided by Federal and State law, ensure that each enrollee may request and receive a copy of records and information pertaining to the enrollee in a timely manner and that an enrollee may request that such records or information be supplemented or corrected.

§457.1120 State plan requirement: Description of review process.

(a) The State must have one of the following review processes:

(1) *Program specific review.* A process that meets the requirements of §§457.1130, 457.1140, 457.1150, 457.1160, 457.1170, and 457.1180; or

(2) *Statewide Standard Review.* A process that complies with State review requirements currently in effect for all health insurance issuers (as defined in section 2791 of the Public Health Service Act) in the State.

(b) The State plan must include a description of the State's review process.

[66 FR 33824, June 25, 2001]

§457.1130 Program specific review process: Matters subject to review.

(a) *Eligibility or enrollment matter.* A State must ensure that an applicant or enrollee has an opportunity for review, consistent with §§457.1140 and 457.1150, of a—

(1) Denial of eligibility;

(2) Failure to make a timely determination of eligibility; and

(3) Suspension or termination of enrollment, including disenrollment for failure to pay cost sharing.

(b) *Health services matter.* A State must ensure that an enrollee has an opportunity for external review of a—

(1) Delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of services; and

(2) Failure to approve, furnish, or provide payment for health services in a timely manner.

(c) *Exception.* A State is not required to provide an opportunity for review of a matter described in paragraph (a) or (b) of this section if the sole basis for the decision is a provision in the State plan or in Federal or State law requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances.

§ 457.1140 Program specific review process: Core elements of review.

In adopting the procedures for review of matters described in § 457.1130, a State must ensure that—

(a) Reviews are conducted by an impartial person or entity in accordance with § 457.1150;

(b) Review decisions are timely in accordance with § 457.1160;

(c) Review decisions are written; and

(d) Applicants and enrollees have an opportunity to—

(1) Represent themselves or have representatives of their choosing in the review process;

(2) Timely review their files and other applicable information relevant to the review of the decision;

(3) Fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and

(4) Receive continued enrollment in accordance with § 457.1170.

§ 457.1150 Program specific review process: Impartial review.

(a) *Eligibility or enrollment matter.* The review of a matter described in § 457.1130(a) must be conducted by a person or entity who has not been directly involved in the matter under review.

(b) *Health services matter.* The State must ensure that an enrollee has an opportunity for an independent external review of a matter described in § 457.1130(b). External review must be conducted by the State or a contractor other than the contractor responsible for the matter subject to external review.

§ 457.1160 Program specific review process: Time frames.

(a) *Eligibility or enrollment matter.* A State must complete the review of a matter described in § 457.1130(a) within a reasonable amount of time. In setting time frames, the State must consider the need for expedited review when there is an immediate need for health services.

(b) *Health services matter.* The State must ensure that reviews are completed in accordance with the medical needs of the patient. If the medical needs of the patient do not dictate a shorter time frame, the review must be completed within the following time frames:

(1) *Standard timeframe.* A State must ensure that external review, as described in § 457.1150(b), is completed within 90 calendar days of the date an enrollee requests internal (if available) or external review. If both internal and external review are available to the enrollee, both types of review must be completed within the 90 calendar day period.

(2) *Expedited timeframe.* A State must ensure that external review, as described in § 457.1150(b), is completed within 72 hours of the time an enrollee requests external review, if the enrollee's physician or health plan determines that operating under the standard time frame could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. If the enrollee has access to internal and external review, then each level of review may take no more than 72 hours. The State may extend the 72-hour time frame by up to 14 calendar days, if the enrollee requests an extension.

§ 457.1170 Program specific review process: Continuation of enrollment.

A State must ensure the opportunity for continuation of enrollment pending the completion of review of a suspension or termination of enrollment, including a decision to disenroll for failure to pay cost sharing.

§ 457.1180 Program specific review process: Notice.

A State must provide enrollees and applicants timely written notice of any determinations required to be subject to review under § 457.1130 that includes the reasons for the determination, an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, the manner in which a review can be requested, and the circumstances under which enrollment may continue pending review.

§457.1190 Application of review procedures when States offer premium assistance for group health plans.

A State that has a premium assistance program through which it provides coverage under a group health plan that does not meet the requirements of a program specific review or a Statewide standard review, as described in §457.1120, must give applicants and enrollees the option to obtain health benefits coverage other than through that group health plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

[66 FR 2686, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

SUBCHAPTER E—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

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AUTHORITY: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

SOURCE: 64 FR 66279, Nov. 24, 1999, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 460 appear at 67 FR 61504, Oct. 1, 2002.

Subpart A—Basis, Scope, and Definitions

§460.2 Basis.

This part implements sections 1894, 1905(a), and 1934 of the Act, which authorize the following:

(a) Medicare payments to, and coverage of benefits under, PACE.

(b) The establishment of PACE as a State option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE.

§460.4 Scope and purpose.

(a) *General.* This part sets forth the following:

(1) The requirements that an entity must meet to be approved as a PACE organization that operates a PACE program under Medicare and Medicaid.

(2) How individuals may qualify to enroll in a PACE program.

(3) How Medicare and Medicaid payments will be made for PACE services.

(4) Provisions for Federal and State monitoring of PACE programs.

(5) Procedures for sanctions and terminations.

(b) *Program purpose.* PACE provides pre-paid, capitated, comprehensive health care services designed to meet the following objectives:

(1) Enhance the quality of life and autonomy for frail, older adults.

(2) Maximize dignity of, and respect for, older adults.

(3) Enable frail, older adults to live in the community as long as medically and socially feasible.

(4) Preserve and support the older adult's family unit.

§460.6 Definitions.

As used in this part, unless the context indicates otherwise, the following definitions apply:

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS.

Medicare beneficiary means an individual who is entitled to Medicare Part A benefits or enrolled under Medicare Part B, or both.

Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a PACE program.

Medicare participant means a Medicare beneficiary who is enrolled in a PACE program.

PACE stands for programs of all-inclusive care for the elderly.

PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

PACE organization means an entity that has in effect a PACE program agreement to operate a PACE program under this part.

PACE program means a program of all-inclusive care for the elderly that is

operated by an approved PACE organization and that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE program agreement.

PACE program agreement means an agreement between a PACE organization, CMS, and the State administering agency for the operation of a PACE program.

Participant means an individual who is enrolled in a PACE program.

Services includes both items and services.

State administering agency means the State agency responsible for administering the PACE program agreement.

Trial period means the first 3 contract years in which a PACE organization operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

Subpart B—PACE Organization Application and Waiver Process

§ 460.10 Purpose.

This subpart sets forth the application requirements for an entity that seeks approval from CMS as a PACE organization and the process by which a PACE organization may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

[67 FR 61504, Oct. 1, 2002]

§ 460.12 Application requirements.

(a) *General.* (1) An individual authorized to act for the entity must submit to CMS a complete application that describes how the entity meets all requirements in this part.

(2) CMS accepts applications from entities that seek approval as PACE organizations beginning on February 22, 2000 except for the following:

(i) Beginning on November 24, 1999, CMS accepts applications from entities that meet the requirements for priority consideration in processing of applications.

(ii) Beginning on January 10, 2000, CMS accepts applications from entities that meet the requirements for special consideration in processing applications.

(b) *State assurance.* An entity's application must be accompanied by an assurance from the State administering agency of the State in which the program is located indicating that the State—

(1) Considers the entity to be qualified to be a PACE organization; and

(2) Is willing to enter into a PACE program agreement with the entity.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71334, Dec. 8, 2006]

§ 460.14 [Reserved]

§ 460.16 [Reserved]

§ 460.18 CMS evaluation of applications.

CMS evaluates an application for approval as a PACE organization on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained through onsite visits conducted by CMS or the State administering agency.

(c) Information obtained by the State administering agency.

§ 460.20 Notice of CMS determination.

(a) *Time limit for notification of determination.* Within 90 days after an entity submits a complete application to CMS, CMS takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

(3) Requests additional information needed to make a final determination.

(b) *Additional information requested.* If CMS requests from an entity additional information needed to make a final determination, within 90 days after CMS receives all requested information from the entity, CMS takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis

for the denial and the process for requesting reconsideration of the denial.

(c) *Deemed approval.* An application is deemed approved if CMS fails to act on the application within 90 days after one of the following dates:

(1) The date the application is submitted by the organization.

(2) The date CMS receives all requested additional information.

(d) *Date of submission.* For purposes of the 90-day time limit described in this section, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS.

§ 460.22 Service area designation.

(a) An entity must state in its application the service area it proposes for its program.

(b) CMS, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

§ 460.24 Limit on number of PACE program agreements.

(a) *Numerical limit.* Except as specified in paragraph (b) of this section, CMS does not permit the number of PACE organizations with which agreements are in effect under this part or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, to exceed the following:

(1) As of August 5, 1997—40.

(2) As of each succeeding August 5, the numerical limit for the preceding year plus 20, without regard to the actual number of agreements in effect on a previous anniversary date. (For example, the limit is 60 on August 5, 1998 and 80 on August 5, 1999.)

(b) *Exception.* The numerical limit does not apply to a private, for-profit PACE organization that meets the following conditions:

(1) Is operating under a demonstration project waiver under section 1894(h) and 1934(h) of the Act.

(2) Was operating under a waiver and subsequently qualifies for PACE organization status in accordance with sections 1894(a)(3)(B)(ii) and 1934(a)(3)(B)(ii) of the Act.

§ 460.26 Submission and evaluation of waiver requests.

(a)(1) A PACE organization must submit its waiver request through the State administering agency for initial review. The State administering agency forwards waiver requests to CMS along with any concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may submit a waiver request. The entity must submit its waiver request through the State administering agency for initial review. The State administering agency forwards the waiver requests to CMS along with any concerns or conditions regarding the waiver. The waiver request is submitted as a document separate from the application but may be submitted in conjunction with and at the same time as the application.

(b) CMS evaluates a waiver request from a PACE organization on the basis of the following information:

(1) The adequacy of the description and rationale for the waiver provided by the PACE organization or PACE applicant, including any additional information requested by CMS.

(2) Information obtained by CMS and the State administering agency in on-site reviews and monitoring of the PACE organization.

(c) Requirements related to the following principles may not be waived:

(1) A focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

(2) The delivery of comprehensive, integrated acute and long-term care services.

(3) An interdisciplinary team approach to care management and service delivery.

(4) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.

(5) The assumption by the provider of full financial risk.

[67 FR 61505, Oct. 1, 2002; 67 FR 63966, Oct. 16, 2002; 71 FR 71334, Dec. 8, 2006]

§ 460.28 Notice of CMS determination on waiver requests.

(a) *Time limit for notification of determination.* Within 90 days after receipt of a waiver request, CMS takes one of the following actions:

(1) Approves the request.

(2) Denies the request and notifies the PACE organization or PACE applicant in writing of the basis of the denial.

(b) *Date of receipt.* For purposes of the 90-day time limit described in this section, the date that a waiver request is received by CMS from the State administering agency is the date on which the request is delivered to the address designated by CMS.

(c) *Waiver approval.* (1) A waiver request is deemed approved if CMS fails to act on the request within 90 days after the date the waiver request is received by CMS.

(2) CMS may withdraw approval of a waiver for good cause.

[67 FR 61505, Oct. 1, 2002, as amended at 71 FR 71334, Dec. 8, 2006]

Subpart C—PACE Program Agreement

§ 460.30 Program agreement requirement.

(a) A PACE organization must have an agreement with CMS and the State administering agency for the operation of a PACE program by the PACE organization under Medicare and Medicaid.

(b) The agreement must be signed by an authorized official of CMS, the PACE organization and the State administering agency.

(c) CMS may only sign program agreements with PACE organizations that are located in States with approved State plan amendments electing PACE as an optional benefit under their Medicaid State plan.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002]

§ 460.32 Content and terms of PACE program agreement.

(a) *Required content.* A PACE program agreement must include the following information:

(1) A designation of the service area of the organization's program. The area may be identified by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, as applicable. CMS and the State administering agency must approve any change in the designated service area.

(2) The organization's commitment to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans With Disabilities Act.

(3) The effective date and term of the agreement.

(4) A description of the organizational structure of the PACE organization and information on administrative contacts, including the following:

(i) Name and phone number of the program director.

(ii) Name of all governing body members.

(iii) Name and phone number of a contact person for the governing body.

(5) A participant bill of rights approved by CMS and an assurance that the rights and protections will be provided.

(6) A description of the process for handling participant grievances and appeals.

(7) A statement of the organization's policies on eligibility, enrollment, voluntary disenrollment, and involuntary disenrollment.

(8) A description of services available to participants.

(9) A description of the organization's quality assessment and performance improvement program.

(10) A statement of the levels of performance required by CMS on standard quality measures.

(11) A statement of the data and information required by CMS and the State administering agency to be collected on participant care.

(12) The Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate.

(13) A description of procedures that the organization will follow if the PACE program agreement is terminated.

(b) *Optional content.* (1) An agreement may provide additional requirements

for individuals to qualify as PACE program eligible individuals, in accordance with § 460.150(b)(4).

(2) An agreement may contain any additional terms and conditions agreed to by the parties if the terms and conditions are consistent with sections 1894 and 1934 of the Act and regulations in this part.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§ 460.34 Duration of PACE program agreement.

An agreement is effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate.

Subpart D—Sanctions, Enforcement Actions, and Termination

§ 460.40 Violations for which CMS may impose sanctions.

In addition to other remedies authorized by law, CMS may impose any of the sanctions specified in §§ 460.42 and 460.46 if CMS determines that a PACE organization commits any of the following violations:

(a) Fails substantially to provide to a participant medically necessary items and services that are covered PACE services, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the participant.

(b) Involuntarily disenrolls a participant in violation of § 460.164.

(c) Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid recipients, or both, who are eligible to enroll in a PACE program, on the basis of an individual's health status or need for health care services.

(d) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by § 460.150, by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.

(e) Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.

(f) Misrepresents or falsifies information that is furnished—

(1) To CMS or the State under this part; or

(2) To an individual or any other entity under this part.

(g) Prohibits or otherwise restricts a covered health care professional from advising a participant who is a patient of the professional about the participant's health status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides benefits for that care or treatment, if the professional is acting within his or her lawful scope of practice.

(h) Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.

(i) Employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under section 1128 or section 1128A of the Act (or with any entity that employs or contracts with that individual) for the provision of health care, utilization review, medical social work, or administrative services.

§ 460.42 Suspension of enrollment or payment by CMS.

(a) *Enrollment.* If a PACE organization commits one or more violations specified in § 460.40, CMS may suspend enrollment of Medicare beneficiaries after the date CMS notifies the organization of the violation.

(b) *Payment.* If a PACE organization commits one or more violations specified in § 460.40, for individuals enrolled after the date CMS notifies the PACE organization of the violation, CMS may take the following actions:

(1) Suspend Medicare payment to the PACE organization.

(2) Deny payment to the State for medical assistance for services furnished under the PACE program agreement.

(c) *Term of suspension.* A suspension or denial of payment remains in effect until CMS is satisfied that the following conditions are met:

(1) The PACE organization has corrected the cause of the violation.

(2) The violation is not likely to recur.

§ 460.46 Civil money penalties.

(a) CMS may impose civil money penalties up to the following maximum amounts:

(1) For each violation regarding enrollment or disenrollment specified in § 460.40 (c) or (d), $100,000 plus $15,000 for each individual not enrolled as a result of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment.

(2) For each violation regarding excessive premiums specified in § 460.40(e), $25,000 plus double the excess amount above the permitted premium charged a participant by the PACE organization. (The excess amount charged is deducted from the penalty and returned to the participant).

(3) For each misrepresentation or falsification of information, specified in § 460.40(f)(1), $100,000.

(4) For any other violation specified in § 460.40, $25,000.

(b) The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to a civil money penalty under this section in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

§ 460.48 Additional actions by CMS or the State.

After consultation with the State administering agency, if CMS determines that the PACE organization is not in substantial compliance with requirements in this part, CMS or the State administering agency may take one or more of the following actions:

(a) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.

(b) Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency.

(c) Terminate the PACE program agreement.

§ 460.50 Termination of PACE program agreement.

(a) *Termination of agreement by CMS or State.* CMS or a State administering agency may terminate at any time a PACE program agreement for cause, including, but not limited to the circumstances in paragraphs (b) or (c) of this section.

(b) *Termination due to uncorrected deficiencies.* CMS or the State administering agency may terminate a PACE program agreement if CMS or the State administering agency determines that both of the following circumstances exist:

(1) Either—

(i) There are significant deficiencies in the quality of care furnished to participants; or

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement.

(2) Within 30 days of the date of the receipt of written notice of a determination made under paragraph (b)(1) of this section, the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies, or failed to continue implementation of the plan of correction.

(c) *Termination due to health and safety risk.* CMS or a State administering agency may terminate a PACE program agreement if CMS or the State administering agency determines that the PACE organization cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies that CMS or the State administering agency determines cannot be corrected.

(d) *Termination of agreement by PACE organization.* A PACE organization may terminate an agreement after timely notice to CMS, the State administering agency, and participants, as follows:

(1) To CMS and the State administering agency, 90 days before termination.

(2) To participants, 60 days before termination.

§ 460.52 Transitional care during termination.

(a) The PACE organization must develop a detailed written plan for phase-down in the event of termination, which describes how the organization plans to take the following actions:

(1) Inform participants, the community, CMS and the State administering

agency in writing about termination and transition procedures.

(2) Assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits.

(3) Transition participants' care to other providers.

(4) Terminate marketing and enrollment activities.

(b) An entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

§ 460.54 Termination procedures.

(a) Except as provided in paragraph (b) of this section, if CMS terminates an agreement with a PACE organization, it furnishes the PACE organization with the following:

(1) A reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of CMS's determination that cause exists for termination.

(2) Reasonable notice and opportunity for hearing (including the right to appeal an initial determination) before terminating the agreement.

(b) CMS may terminate an agreement without invoking the procedures described in paragraph (a) of this section if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

Subpart E—PACE Administrative Requirements

§ 460.60 PACE organizational structure.

(a) A PACE organization must be, or be a distinct part of, one of the following:

(1) An entity of city, county, State, or Tribal government.

(2) A private not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation.

(b) *Program director.* The organization must employ, or contract with in accordance with § 460.70, a program director who is responsible for oversight and administration of the entity.

(c) *Medical director.* The organization must employ, or contract with in accordance with § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.

(d) *Organizational chart.* (1) The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities.

(2) The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.

(3) A PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71334, Dec. 8, 2006]

§ 460.62 Governing body.

(a) *Governing body.* A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

(1) Governance and operation of the organization.

(2) Development of policies consistent with the mission.

(3) Management and provision of all services, including the management of contractors.

(4) Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities.

(5) Fiscal operations.

(6) Development of policies on participant health and safety, including a

comprehensive, systemic operational plan to ensure the health and safety of participants.

(7) Quality assessment and performance improvement program.

(b) *Participant advisory committee.* (1) A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

(2) The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

(c) *Participant representation on the governing body.* (1) A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body.

(2) The participant representative is a liaison of the participant advisory committee to the PACE organization governing body.

(3) *Duty of the participant representative.* The participant representative must present issues from the participant advisory committee to the governing body.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) *General qualification requirements.* Each member of the PACE organization's staff that has direct participant contact, (employee or contractor) must meet the following conditions:

(1) Be legally authorized (for example, currently licensed, registered or certified if applicable) to practice in the State in which he or she performs the function or action;

(2) Only act within the scope of his or her authority to practice;

(3) Have 1 year of experience with a frail or elderly population;

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization and approved by CMS before working independently.

(5) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

(b) *Federally-defined qualifications for physician.* In addition to the qualification specified in paragraph (a) of this section, a physician must meet the qualifications and conditions in § 410.20 of this chapter.

[71 FR 71334, Dec. 8, 2006]

§ 460.66 Training.

(a) The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.

(b) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.

(c) Personal care attendants must exhibit competency before performing personal care services independently.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.68 Program integrity.

(a) *Persons with criminal convictions.* A PACE organization must not employ individuals or contract with organizations or individuals—

(1) Who have been excluded from participation in the Medicare or Medicaid programs;

(2) Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act; or

(3) In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

(b) *Direct or indirect interest in contracts.* The PACE organization shall identify members of its governing body or any immediate family member having a direct or indirect interest in any

contract that supplies any administrative or care-related service or materials to the PACE organization.

(1) PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family.

(2) In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must—

(i) Fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and

(ii) Recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

(c) *Disclosure and recusal requirements.* A PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006]

§ 460.70 Contracted services.

(a) *General rule.* The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in § 460.100.

(b) *Contract requirements.* A contract between a PACE organization and a contractor must meet the following requirements:

(1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:

(i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.

(2) A contractor must be accessible to participants, located either within or near the PACE organization's service area.

(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.

(c) *List of contractors.* A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

(d) *Content of contract.* Each contract must be in writing and include the following information:

(1) Name of contractor.

(2) Services furnished (including work schedule if appropriate).

(3) Payment rate and method.

(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.

(5) Contractor agreement to do the following:

(i) Furnish only those services authorized by the PACE interdisciplinary team.

(ii) Accept payment from the PACE organization as payment in full, and not bill participants, CMS, the State administering agency, or private insurers.

(iii) Hold harmless CMS, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.

(iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.

(v) Submit reports required by the PACE organization.

(vi) Agree to perform all the duties related to its position as specified in this part.

(vii) Participate in interdisciplinary team meeting as required.

(viii) Agree to be accountable to the PACE organization.

(ix) Cooperate with the competency evaluation program and direct participant care requirements specified in § 460.71.

(e) *Contracting with another entity to furnish PACE Center services.* (1) A PACE organization may only contract for PACE Center services if it is fiscally sound as defined in § 460.80(a) of this part and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the State administering agency.

(2) The PACE organization retains responsibility for all participants and may only contract for the PACE Center services identified in § 460.98(d).

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006]

§ 460.71 Oversight of direct participant care.

(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.

(1) The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.

(2) The PACE organization must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors).

(3) The competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals.

(4) The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.

(2) Comply with the requirements of § 460.68(a) regarding persons with criminal convictions.

(3) Have verified current certifications or licenses for their respective positions.

(4) Are free of communicable diseases and are up to date with immunizations before performing direct patient care.

(5) Have been oriented to the PACE program.

(6) Agree to abide by the philosophy, practices, and protocols of the PACE organization.

[67 FR 61505, Oct. 1, 2002, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.72 Physical environment.

(a) *Space and equipment*—(1) *Safe design.* A PACE center must meet the following requirements:

(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.

(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.

(2) *Primary care clinic.* The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.

(3) *Equipment maintenance.* (i) A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

(ii) A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the organization's written plan.

(b) *Fire safety*—(1) *General rule.* Except as otherwise provided in this section—

(i) A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association

that apply to the type of setting in which the center is located. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to PACE centers.

(2) *Exceptions.* (i) The Life Safety Code provisions do not apply in a State in which CMS determines that a fire and safety code imposed by State law adequately protects participants and staff.

(ii) CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the Pace center, but only if the waiver does not adversely affect the health and safety of the participants and staff.

(3) Beginning March 13, 2006, a PACE center must be in compliance with Chapter 9.2.9, Emergency Lighting.

(4) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to PACE centers.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(c) *Emergency and disaster preparedness*—(1) *Procedures.* The PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public.

(2) *Emergencies defined.* Emergencies include, but are not limited, to the following:

(i) Fire.

(ii) Equipment, water, or power failure.

(iii) Care-related emergencies.

(iv) Natural disasters likely to occur in the organization's geographic area. (An organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location.)

(3) *Emergency training.* A PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and participants to ensure that staff demonstrate a knowledge of emergency

procedures, including informing participants what to do, where to go, and whom to contact in case of an emergency.

(4) *Availability of emergency equipment.* Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

(5) *Annual test of emergency and disaster plan.* At least annually, a PACE organization must actually test, evaluate, and document the effectiveness of its emergency and disaster plans.

[64 FR 66279, Nov. 24, 1999, as amended at 68 FR 1386, Jan. 10, 2003; 69 FR 49266, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006; 71 FR 71335, Dec. 8, 2006]

§ 460.74 Infection control.

(a) *Standard procedures.* The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

(b) *Infection control plan.* The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:

(1) Ensures a safe and sanitary environment.

(2) Prevents and controls the transmission of disease and infection.

(c) *Contents of infection control plan.* The infection control plan must include, but is not limited to, the following:

(1) Procedures to identify, investigate, control, and prevent infections in every Pace center and in each participant's place of residence.

(2) Procedures to record any incidents of infection.

(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§ 460.76 Transportation services.

(a) *Safety, accessibility, and equipment.* A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

(b) *Maintenance of vehicles.* (1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

(c) *Communication with PACE center.* The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

(d) *Training.* The PACE organization must train all transportation personnel (employees and contractors) in the following:

(1) Managing the special needs of participants.

(2) Handling emergency situations.

(e) *Changes in care plan.* As part of the interdisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§ 460.78 Dietary services.

(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs. Each meal must meet the following requirements:

(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.

(ii) Be prepared in a form designed to meet individual needs.

(iii) Be prepared and served at the proper temperature.

(2) The PACE organization must provide substitute foods or nutritional

supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:

(i) Refuses the food served.

(ii) Cannot tolerate the food served.

(iii) Does not eat adequately.

(3) The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

(b) *Sanitary conditions.* The PACE organization must do the following:

(1) Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization.

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.

(3) Dispose of garbage and refuse properly.

[64 FR 66279, Nove. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.80 Fiscal soundness.

(a) *Fiscally sound operation.* A PACE organization must have a fiscally sound operation, as demonstrated by the following:

(1) Total assets greater than total unsubordinated liabilities.

(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency.

(b) *Insolvency plan.* The organization must have a documented plan in the event of insolvency, approved by CMS and the State administering agency, which provides for the following:

(1) Continuation of benefits for the duration of the period for which capitation payment has been made.

(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.

(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

(c) *Arrangements to cover expenses.* (1) A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

(i) One month's total capitation revenue to cover expenses the month before insolvency.

(ii) One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operations.

(2) Arrangements to cover expenses may include, but are not limited to, the following:

(i) Insolvency insurance or reinsurance.

(ii) Hold harmless arrangement.

(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

§ 460.82 Marketing.

(a) *Information that a PACE organization must include in its marketing materials.* (1) A PACE organization must inform the public about its program and give prospective participants the following written information:

(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.

(ii) PACE enrollment procedures.

(iii) Description of benefits and services.

(iv) Premiums.

(v) Other information necessary for prospective participants to make an informed decision about enrollment.

(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.

(b) *Approval of marketing information.* (1) CMS must approve all marketing information before distribution by the PACE organization, including any revised or updated material.

(2) CMS reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following:

(i) *Time period for approval.* CMS approves or disapproves marketing information within 45 days after CMS receives the information from the organization.

(ii) *Deemed approval.* Marketing information is deemed approved, and the organization can distribute it, if CMS and the State administering agency do not disapprove the marketing material within the 45-day review period.

(c) *Special language requirements.* A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:

(1) In English and in any other principal languages of the community.

(2) In Braille, if necessary.

(d) *Information on restriction of services.* (1) Marketing materials must inform a potential participant that he or she must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or from an entity authorized by the PACE organization.

(2) All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

(e) *Prohibited marketing practices.* A PACE organization must ensure that its employees or its agents do not use prohibited marketing practices which includes the following:

(1) Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age.

(2) Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, CMS, or the State administering agency.

(3) Gifts or payments to induce enrollment.

(4) Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment.

(5) Unsolicited door-to-door marketing.

(f) *Marketing Plan.* A PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

Subpart F—PACE Services

§ 460.90 PACE benefits under Medicare and Medicaid.

If a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, the following conditions apply:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

§ 460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(a) All Medicare-covered items and services.

(b) All Medicaid-covered items and services, as specified in the State's approved Medicaid plan.

(c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

[71 FR 71335, Dec. 8, 2006]

§ 460.94 Required services for Medicare participants.

(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:

(1) The scope of hospital insurance benefits described in part 409 of this chapter.

(2) The scope of supplemental medical insurance benefits described in part 410 of this chapter.

(b) *Waivers of Medicare coverage requirements.* The following Medicare requirements are waived for purposes of the PACE program and do not apply:

(1) The provisions of subpart F of part 409 of this chapter that limit coverage of institutional services.

(2) The provisions of subparts G and H of part 409 of this chapter, and parts 412 through 414 of this chapter that relate to payment for benefits.

(3) The provisions of subparts D and E of part 409 of this chapter that limit coverage of extended care services or home health services.

(4) The provisions of subpart D of part 409 of this chapter that impose a 3-day prior hospitalization requirement for coverage of extended care services.

(5) Section 411.15(g) and § 411.15(k) of this chapter that may prevent payment for PACE program services that are provided to PACE participants.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.96 Excluded services.

The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the interdisciplinary team, even if it is a required service, unless it is an emergency service.

(b) In an inpatient facility, private room and private duty nursing services (unless medically necessary), and non-medical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the interdisciplinary team as part of the participant's plan of care).

(c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.

(d) Experimental medical, surgical, or other health procedures.

(e) Services furnished outside of the United States, except as follows:

(1) In accordance with § 424.122 and § 424.124 of this chapter.

(2) As permitted under the State's approved Medicaid plan.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.98 Service delivery.

(a) *Plan.* A PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care.

(2) These services must be furnished in at least the PACE center, the home, and inpatient facilities.

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.

(c) *Minimum services furnished at each PACE center.* At a minimum, the following services must be furnished at each PACE center:

(1) Primary care, including physician and nursing services.

(2) Social services.

(3) Restorative therapies, including physical therapy and occupational therapy.

(4) Personal care and supportive services.

(5) Nutritional counseling.

(6) Recreational therapy.

(7) Meals.

(d) *Pace Center operation.* (1) A PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

(2) A PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.

(3) If a PACE organization operates more than one center, each Pace center must offer the full range of services and have sufficient staff to meet the needs of participants.

(e) *Center attendance.* The frequency of a participant's attendance at a center is determined by the interdisciplinary team, based on the needs and preferences of each participant.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, 71335, Dec. 8, 2006]

§ 460.100 Emergency care.

(a) *Written plan.* A PACE organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services.

(b) *Emergency care.* Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:

(1) Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area.

(2) Are needed to evaluate or stabilize an emergency medical condition.

(c) An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(1) Serious jeopardy to the health of the participant.

(2) Serious impairment to bodily functions.

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

(d) *Explanation to participant.* The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services and that no prior authorization is needed.

(e) *On-call providers.* The plan must provide for the following:

(1) An on-call provider, available 24-hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.

(2) Coverage of urgently needed out-of-network and post-stabilization care services when either of the following conditions are met:

(i) The services are preapproved by the PACE organization.

(ii) The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.

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

(i) Post stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which POs are obligated to cover. Rather, they are non-emergency services that the PO should approve before they are provided outside the service area.

(ii) Urgent care means the care provided to a PACE participant who is out of the PACE service area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or function is not in severe jeopardy.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§ 460.102 Interdisciplinary team.

(a) *Basic requirement.* A PACE organization must meet the following requirements:

(1) Establish an interdisciplinary team at each Pace center to comprehensively assess and meet the individual needs of each participant.

(2) Assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.

(b) *Composition of interdisciplinary team.* The interdisciplinary team must be composed of at least the following members:

(1) Primary care physician.

(2) Registered nurse.

(3) Master's-level social worker.

(4) Physical therapist.

(5) Occupational therapist.

(6) Recreational therapist or activity coordinator.

(7) Dietitian.

(8) PACE center manager.

(9) Home care coordinator.

(10) Personal care attendant or his or her representative.

(11) Driver or his or her representative.

(c) *Primary care physician.* (1) Primary medical care must be furnished to a participant by a PACE primary care physician.

(2) Each primary care physician is responsible for the following:

(i) Managing a participant's medical situations.

(ii) Overseeing a participant's use of medical specialists and inpatient care.

(d) *Responsibilities of interdisciplinary team.* (1) The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery.

(2) Each team member is responsible for the following:

(i) Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant.

(ii) Remaining alert to pertinent input from other team members, participants, and caregivers.

(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation polices established by the medical director.

(3) The members of the interdisciplinary team must serve primarily PACE participants.

(e) *Exchange of information between team members.* The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e).

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61506, Oct. 1, 2002; 71 FR 71334, 71336, Dec. 8, 2006]

§ 460.104 Participant assessment.

(a) *Initial comprehensive assessment*—(1) *Basic requirement.* The interdisciplinary team must conduct an initial comprehensive assessment on each participant. The assessment must be completed promptly following enrollment.

(2) As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person, at appropriate intervals, and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Master's-level social worker.

(iv) Physical therapist.

(v) Occupational therapist.

(vi) Recreational therapist or activity coordinator.

(vii) Dietitian.

(viii) Home care coordinator.

(3) At the recommendation of individual team members, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the comprehensive assessment process.

(4) *Comprehensive assessment criteria.* The comprehensive assessment must include, but is not limited to, the following:

(i) Physical and cognitive function and ability.

(ii) Medication use.

(iii) Participant and caregiver preferences for care.

(iv) Socialization and availability of family support.

(v) Current health status and treatment needs.

(vi) Nutritional status.

(vii) Home environment, including home access and egress.

(viii) Participant behavior.

(ix) Psychosocial status.

(x) Medical and dental status.

(xi) Participant language.

(b) *Development of plan of care.* The interdisciplinary team must promptly consolidate discipline-specific assessments into a single plan of care for each participant through discussion in team meetings and consensus of the entire interdisciplinary team. In developing the plan of care, female participants must be informed that they are

entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

(c) *Periodic reassessment*—(1) *Semiannual reassessment.* On at least a semiannual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Master's-level social worker.

(iv) Recreational therapist or activity coordinator.

(v) Other team members actively involved in the development or implementation of the participant's plan of care, for example, home care coordinator, physical therapist, occupational therapist, or dietitian.

(2) *Annual reassessment.* On at least an annual basis, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Physical therapist.

(ii) Occupational therapist.

(iii) Dietitian.

(iv) Home care coordinator.

(d) *Unscheduled reassessments.* In addition to annual and semiannual reassessments, unscheduled reassessments may be required based on the following:

(1) *A change in participant status.* If the health or psychosocial status of a participant changes, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment.

(2) *At the request of the participant or designated representative.* If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment.

(i) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.

(ii) Except as provided in paragraph (d)(2)(iii) of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the interdisciplinary team receives the request for reassessment.

(iii) The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:

(A) The participant or designated representative requests the extension.

(B) The team documents its need for additional information and how the delay is in the interest of the participant.

(iv) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for the following:

(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in § 460.122.

(B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in § 460.122(e).

(v) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

(e) *Changes to plan of care.* Team members who conduct a reassessment must meet the following requirements:

(1) Reevaluate the participant's plan of care.

(2) Discuss any changes in the plan with the interdisciplinary team.

(3) Obtain approval of the revised plan from the interdisciplinary team and the participant (or designated representative).

(4) Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires.

(f) *Documentation.* Interdisciplinary team members must document all assessment and reassessment information in the participant's medical record.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006]

§460.106 Plan of care.

(a) *Basic requirement.* The interdisciplinary team must promptly develop a comprehensive plan of care for each participant.

(b) *Content of plan of care.* The plan of care must meet the following requirements:

(1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.

(2) Identify measurable outcomes to be achieved.

(c) *Implementation of the plan of care.* (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.

(2) The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other providers.

(d) *Evaluation of plan of care.* On at least a semi-annual basis, the interdisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

(e) *Participant and caregiver involvement in plan of care.* The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must document the plan of care, and any changes made to it, in the participant's medical record.

Subpart G—Participant Rights

§460.110 Bill of rights.

(a) *Written bill of rights.* A PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the ones specified in §460.112.

(b) *Explanation of rights.* The organization must inform a participant upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation.

(c) *Protection of rights.* The organization must protect and provide for the exercise of the participant's rights.

§460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

(b) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions. Specifically, each participant has the following rights:

(1) To be fully informed in writing of the services available from the PACE organization, including identification of all services that are delivered through contracts, rather than furnished directly by the PACE organization at the following times:

(i) Before enrollment.

(ii) At enrollment.

(iii) At the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

(2) To have the enrollment agreement, described in § 460.154, fully explained in a manner understood by the participant.

(3) To examine, or upon reasonable request, to be assisted to examine the results of the most recent review of the PACE organization conducted by CMS or the State administering agency and any plan of correction in effect.

(c) *Choice of providers.* Each participant has the right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right to the following:

(1) To choose his or her primary care physician and specialists from within the PACE network.

(2) To request that a qualified specialist for women's health services furnish routine or preventive women's health services.

(3) To disenroll from the program at any time.

(d) *Access to emergency services.* Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(e) *Participation in treatment decisions.* Each participant has the right to participate fully in all decisions related to his or her treatment. A participant who is unable to participate fully in treatment decisions has the right to designate a representative. Specifically, each participant has the following rights:

(1) To have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.

(2) To have the PACE organization explain advance directives and to establish them, if the participant so desires, in accordance with §§ 489.100 and 489.102 of this chapter.

(3) To be fully informed of his or her health and functional status by the interdisciplinary team.

(4) To participate in the development and implementation of the plan of care.

(5) To request a reassessment by the interdisciplinary team.

(6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (that is, due to medical reasons or for the participant's welfare, or that of other participants). The PACE organization must document the justification in the participant's medical record.

(f) *Confidentiality of health information.* Each participant has the right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care information protected. Each participant also has the right to review and copy his or her own medical records and request amendments to those records. Specifically, each participant has the following rights:

(1) To be assured of confidential treatment of all information contained in the health record, including information contained in an automated data bank.

(2) To be assured that his or her written consent will be obtained for the release of information to persons not otherwise authorized under law to receive it.

(3) To provide written consent that limits the degree of information and the persons to whom information may be given.

(g) *Complaints and appeals.* Each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, each participant has the following rights:

(1) To be encouraged and assisted to voice complaints to PACE staff and outside representatives of his or her choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

(2) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006]

§ 460.114 Restraints.

(a) The PACE organization must limit use of restraints to the least restrictive and most effective method available. The term restraint includes either a physical restraint or a chemical restraint.

(1) A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

(2) A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.

(b) If the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:

(1) Be imposed for a defined, limited period of time, based upon the assessed needs of the participant.

(2) Be imposed in accordance with safe and appropriate restraining techniques.

(3) Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or others from harm.

(4) Be removed or ended at the earliest possible time.

(c) The condition of the restrained participant must be continually assessed, monitored, and reevaluated.

§ 460.116 Explanation of rights.

(a) *Written policies.* A PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, if any, and staff understand these rights.

(b) *Explanation of rights.* The PACE organization must fully explain the rights to the participant and his or her representative, if any, at the time of enrollment in a manner understood by the participant.

(c) *Display.* The PACE organization must meet the following requirements:

(1) Write the participant rights in English and in any other principal languages of the community.

(2) Display the participant rights in a prominent place in the PACE center.

§ 460.118 Violation of rights.

The PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights.

§ 460.120 Grievance process.

For purposes of this part, a grievance is a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.

(a) *Process to resolve grievances.* A PACE organization must have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, their family members, or representatives.

(b) *Notification to participants.* Upon enrollment, and at least annually

thereafter, the PACE organization must give a participant written information on the grievance process.

(c) *Minimum requirements.* At a minimum, the PACE organization's grievance process must include written procedures for the following:

(1) How a participant files a grievance.

(2) Documentation of a participant's grievance.

(3) Response to, and resolution of, grievances in a timely manner.

(4) Maintenance of confidentiality of a participant's grievance.

(d) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(e) *Explaining the grievance process.* The PACE organization must discuss with and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance.

(f) *Analyzing grievance information.* The PACE organization must maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the PACE organization's internal quality assessment and performance improvement program.

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services.

(a) *PACE organization's written appeals process.* The PACE organization must have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service.

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a request for services or payment, the PACE organization must give a participant written information on the appeals process.

(c) *Minimum requirements.* At a minimum, the PACE organization's appeals process must include written procedures for the following:

(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.104(c)(3).

(2) How a participant files an appeal.

(3) Documentation of a participant's appeal.

(4) Appointment of an appropriately credentialed and impartial third party who was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal.

(5) Responses to, and resolution of, appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives an appeal.

(6) Maintenance of confidentiality of appeals.

(d) *Notification.* A PACE organization must give all parties involved in the appeal the following:

(1) Appropriate written notification.

(2) A reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

(e) *Services furnished during appeals process.* During the appeals process, the PACE organization must meet the following requirements:

(1) For a Medicaid participant, continue to furnish the disputed services until issuance of the final determination if the following conditions are met:

(i) The PACE organization is proposing to terminate or reduce services currently being furnished to the participant.

(ii) The participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.

(2) Continue to furnish to the participant all other required services, as specified in subpart F of this part.

(f) *Expedited appeals process.* (1) A PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.

(2) Except as provided in paragraph (f)(3) of this section, the PACE organization must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal.

(3) The PACE organization may extend the 72-hour timeframe by up to 14 calendar days for either of the following reasons:

(i) The participant requests the extension.

(ii) The organization justifies to the State administering agency the need for additional information and how the delay is in the interest of the participant.

(g) Determination in favor of participant. A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.

(h) Determination adverse to participant. For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:

(1) CMS.

(2) The State administering agency.

(3) The participant.

(i) *Analyzing appeals information.* A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality assessment and performance improvement program.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006]

§460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

Subpart H—Quality Assessment and Performance Improvement

§460.130 General rule.

(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program.

(b) The program must reflect the full range of services furnished by the PACE organization.

(c) A PACE organization must take actions that result in improvements in its performance in all types of care.

§460.132 Quality assessment and performance improvement plan.

(a) *Basic rule.* A PACE organization must have a written quality assessment and performance improvement plan.

(b) *Annual review.* The PACE governing body must review the plan annually and revise it, if necessary.

(c) *Minimum plan requirements.* At a minimum, the plan must specify how the PACE organization proposes to meet the following requirements:

(1) Identify areas to improve or maintain the delivery of services and patient care.

(2) Develop and implement plans of action to improve or maintain quality of care.

(3) Document and disseminate to PACE staff and contractors the results from the quality assessment and performance improvement activities.

§460.134 Minimum requirements for quality assessment and performance improvement program.

(a) *Minimum program requirements.* A PACE organization's quality assessment and performance improvement program must include, but is not limited to, the use of objective measures to demonstrate improved performance with regard to the following:

(1) Utilization of PACE services, such as decreased inpatient hospitalizations and emergency room visits.

(2) Caregiver and participant satisfaction.

(3) Outcome measures that are derived from data collected during assessments, including data on the following:

(i) Physiological well being.

(ii) Functional status.

(iii) Cognitive ability.

(iv) Social/behavioral functioning.

(v) Quality of life of participants.

(4) Effectiveness and safety of staff-provided and contracted services, including the following:

(i) Competency of clinical staff.

(ii) Promptness of service delivery.

(iii) Achievement of treatment goals and measurable outcomes.

(5) Nonclinical areas, such as grievances and appeals, transportation services, meals, life safety, and environmental issues.

(b) *Basis for outcome measures.* Outcome measures must be based on current clinical practice guidelines and professional practice standards applicable to the care of PACE participants.

(c) *Minimum levels of performance.* The PACE organization must meet or exceed minimum levels of performance, established by CMS and the State administering agency, on standardized quality measures, such as influenza immunization rates, which are specified in the PACE program agreement.

(d) *Accuracy of data.* The PACE organization must ensure that all data used for outcome monitoring are accurate and complete.

§ 460.136 Internal quality assessment and performance improvement activities.

(a) *Quality assessment and performance improvement requirements.* A PACE organization must do the following:

(1) Use a set of outcome measures to identify areas of good or problematic performance.

(2) Take actions targeted at maintaining or improving care based on outcome measures.

(3) Incorporate actions resulting in performance improvement into standards of practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.

(4) Set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes.

(5) Immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant.

(b) *Quality assessment and performance improvement coordinator.* A PACE organization must designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities.

(c) *Involvement in quality assessment and performance improvement activities.* (1) A PACE organization must ensure that all interdisciplinary team members, PACE staff, and contract providers are involved in the development and implementation of quality assessment and performance improvement activities and are aware of the results of these activities.

(2) The quality improvement coordinator must encourage a PACE participant and his or her caregivers to be involved in quality assessment and performance improvement activities, including providing information about their satisfaction with services.

§ 460.138 Committees with community input.

A PACE organization must establish one or more committees, with community input, to do the following:

(a) Evaluate data collected pertaining to quality outcome measures.

(b) Address the implementation of, and results from, the quality assessment and performance improvement plan.

(c) Provide input related to ethical decisionmaking, including end-of-life issues and implementation of the Patient Self-Determination Act.

§ 460.140 Additional quality assessment activities.

A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with § 460.202.

Subpart I—Participant Enrollment and Disenrollment

§ 460.150 Eligibility to enroll in a PACE program.

(a) *General rule.* To enroll in a PACE program, an individual must meet eligibility requirements specified in this section. To continue to be eligible for

PACE, an individual must meet the annual recertification requirements specified in §460.160.

(b) *Basic eligibility requirements.* To be eligible to enroll in PACE, an individual must meet the following requirements:

(1) Be 55 years of age or older.

(2) Be determined by the State administering agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(3) Reside in the service area of the PACE organization.

(4) Meet any additional program specific eligibility conditions imposed under the PACE program agreement. These additional conditions may not modify the requirements of paragraph (b)(1) through (b)(3) of this section.

(c) *Other eligibility requirements.* (1) At the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety.

(2) The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.

(d) *Eligibility under Medicare and Medicaid.* Eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient. A potential PACE enrollee may be, but is not required to be, any or all of the following:

(1) Entitled to Medicare Part A.

(2) Enrolled under Medicare Part B.

(3) Eligible for Medicaid.

§460.152 Enrollment process.

(a) *Intake process.* Intake is an intensive process during which PACE staff members make one or more visits to a potential participant's place of residence and the potential participant makes one or more visits to the PACE center. At a minimum, the intake process must include the following activities:

(1) The PACE staff must explain to the potential participant and his or her representative or caregiver the following information:

(i) The PACE program, using a copy of the enrollment agreement described in §460.154, specifically references the elements of the agreement including but not limited to §460.154(e), (i) through (m), and (r).

(ii) The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization guarantees access to services, but not to a specific provider.

(iii) A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers under §460.70(c).

(iv) Monthly premiums, if any.

(v) Any Medicaid spenddown obligations.

(vi) Post-eligibility treatment of income.

(2) The potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid.

(3) The State administering agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(4) PACE staff must assess the potential participant to ensure that he or she can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility specified in this part.

(b) *Denial of Enrollment.* If a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must meet the following requirements:

(1) Notify the individual in writing of the reason for the denial.

(2) Refer the individual to alternative services, as appropriate.

(3) Maintain supporting documentation of the reason for the denial.

(4) Notify CMS and the State administering agency and make the documentation available for review.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

§ 460.154 Enrollment agreement.

If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the following information:

(a) Applicant's name, sex, and date of birth.

(b) Medicare beneficiary status (Part A, Part B, or both) and number, if applicable.

(c) Medicaid recipient status and number, if applicable.

(d) Other health insurance information, if applicable.

(e) Conditions for enrollment and disenrollment in PACE.

(f) Description of participant premiums, if any, and procedures for payment of premiums.

(g) Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under § 460.184.

(h) Notification that a Medicare participant may not enroll or disenroll at a Social Security office.

(i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE.

(j) Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE.

(k) Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization.

(l) Description of the procedures for obtaining emergency and urgently needed out-of-network services.

(m) The participant bill of rights.

(n) Information on the process for grievances and appeals and Medicare/Medicaid phone numbers for use in appeals.

(o) Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area.

(p) An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider.

(q) A statement that the PACE organization has an agreement with CMS and the State administering agency that is subject to renewal on a periodic basis and, if the agreement is not renewed, the program will be terminated.

(r) The applicant's authorization for disclosure and exchange of personal information between CMS, its agents, the State administering agency, and the PACE organization.

(s) The effective date of enrollment.

(t) The signature of the applicant or his or her designated representative and the date.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

§ 460.156 Other enrollment procedures.

(a) *Items a PACE organization must give a participant upon enrollment.* After the participant signs the enrollment agreement, the PACE organization must give the participant the following:

(1) A copy of the enrollment agreement.

(2) A PACE membership card.

(3) Emergency information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services.

(4) Stickers for the participant's Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization.

(b) *Submittal of participant information to CMS and the State.* The PACE organization must submit participant information to CMS and the State administering agency, in accordance with established procedures.

(c) *Changes in enrollment agreement information.* If there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must meet the following requirements:

(1) Give an updated copy of the information to the participant.

(2) Explain the changes to the participant and his or her representative or caregiver in a manner they understand.

§460.158 Effective date of enrollment.

A participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

§460.160 Continuation of enrollment.

(a) *Duration of enrollment.* Enrollment continues until the participant's death, regardless of changes in health status, unless either of the following actions occur:

(1) The participant voluntarily disenrolls.

(2) The participant is involuntarily disenrolled, as described in §460.164.

(b) *Annual recertification requirement.* At least annually, the State administering agency must reevaluate whether a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services.

(1) *Waiver of annual requirement.* (i) The State administering agency may permanently waive the annual recertification requirement for a participant if it determines that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity.

(ii) The PACE organization must retain in the participant's medical record the documentation of the reason for waiving the annual recertification requirement.

(2) *Deemed continued eligibility.* If the State administering agency determines that a PACE participant no longer meets the State Medicaid nursing facility level of care requirements, the participant may be deemed to continue to be eligible for the PACE program until the next annual reevaluation, if, in the absence of continued coverage under this program, the participant reasonably would be expected to meet the nursing facility level of care requirement within the next 6 months.

(3) *Continued eligibility criteria.* (i) The State administering agency, must establish criteria to use in making the determination of ''deemed continued eligibility.'' The State administering agency, in consultation with the PACE organization, makes a determination of deemed continued eligibility based on a review of the participant's medical record and plan of care. These criteria must be applied in reviewing the participant's medical record and plan of care.

(ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

§460.162 Voluntary disenrollment.

A PACE participant may voluntarily disenroll from the program without cause at any time.

§460.164 Involuntary disenrollment.

(a) *Reasons for involuntary disenrollment.* A participant may be involuntarily disenrolled for any of the following reasons:

(1) The participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization after a 30-day grace period.

(2) The participant engages in disruptive or threatening behavior, as described in paragraph (b) of this section.

(3) The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days, unless the PACE organization agrees to a longer absence due to extenuating circumstances.

(4) The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.

(5) The PACE program agreement with CMS and the State administering agency is not renewed or is terminated.

(6) The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers.

(b) *Disruptive or threatening behavior.* For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:

(1) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or

(2) A participant with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement.

(c) *Documentation of disruptive or threatening behavior.* If a PACE organization proposes to disenroll a participant who is disruptive or threatening, the organization must document the following information in the participant's medical record:

(1) The reasons for proposing to disenroll the participant.

(2) All efforts to remedy the situation.

(d) *Noncompliant behavior.* (1) A PACE organization may not disenroll a PACE participant on the grounds that the participant has engaged in noncompliant behavior if the behavior is related to a mental or physical condition of the participant, unless the participant's behavior jeopardizes his or her health or safety, or the safety of others.

(2) For purposes of this section, noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments.

(e) *State administering agency review and final determination.* Before an involuntary disenrollment is effective, the State administering agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

§ 460.166 Effective date of disenrollment.

(a) In disenrolling a participant, the PACE organization must take the following actions:

(1) Use the most expedient process allowed under Medicare and Medicaid procedures, as set forth in the PACE program agreement.

(2) Coordinate the disenrollment date between Medicare and Medicaid (for a participant who is eligible for both Medicare and Medicaid).

(3) Give reasonable advance notice to the participant.

(b) Until the date enrollment is terminated, the following requirements must be met:

(1) PACE participants must continue to use PACE organization services and remain liable for any premiums.

(2) The PACE organization must continue to furnish all needed services.

§ 460.168 Reinstatement in other Medicare and Medicaid programs.

To facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must do the following:

(a) Make appropriate referrals and ensure medical records are made available to new providers in a timely manner.

(b) Work with CMS and the State administering agency to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.

§ 460.170 Reinstatement in PACE.

(a) A previously disenrolled participant may be reinstated in a PACE program.

(b) If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage.

§ 460.172 Documentation of disenrollment.

A PACE organization must meet the following requirements:

(a) Have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.

(b) Make documentation available for review by CMS and the State administering agency.

(c) Use the information on voluntary disenrollments in the PACE organization's internal quality assessment and performance improvement program.

Subpart J—Payment

§460.180 Medicare payment to PACE organizations.

(a) *Principle of payment.* Under a PACE program agreement, CMS makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant in a payment area based on the rate it pays to a Medicare Advantage organization.

(b) *Determination of rate.* (1) The PACE program agreement specifies the methodology used to calculate the monthly capitation amount applicable to a PACE organization.

(2) Except as specified in paragraph (b)(4) of this section, the monthly capitation amount is based on the Part A and Part B payment rates established for purposes of payment to Medicare Advantage organizations. As used in this section, ''Medicare Advantage rates'' means the Part A and Part B rates calculated by CMS for making payment to Medicare Advantage organizations under section 1853(c) of the Act.

(3) CMS will adjust the monthly capitation payment amount derived under paragraph (b)(2) of this section based on a risk adjustment that reflects the individual's health status. CMS will ensure that payments take into account the comparative frailty of PACE enrollees relative to the general Medicare population.

(4) For Medicare participants who require ESRD services, the monthly capitation amount is based on the Medicare Advantage ESRD risk adjustment model.

(5) CMS may adjust the monthly capitation amount to take into account other factors CMS determines to be appropriate.

(6) The monthly capitation payment is a fixed amount, regardless of changes in the participant's health status.

(7) The monthly capitation payment amount is an all-inclusive payment for Medicare benefits provided to participants. A PACE organization must not seek any additional payment from Medicare. The only additional payment that a PACE organization may collect from, or on behalf of, a Medicare participant for PACE services is the following:

(i) Any applicable premium amount specified in §460.186.

(ii) Any charge permitted under paragraph (d) of this section when Medicare is not the primary payer.

(iii) Any payment from the State, as specified in §460.182, for a participant who is eligible for both Medicare and Medicaid.

(iv) Payment with respect to any applicable spenddown liability under §§435.121 and 435.831 of this chapter and any amount due under the post-eligibility treatment of income process under §460.184 for a participant who is eligible for both Medicare and Medicaid.

(8) CMS computes the Medicare monthly capitation payment amount under a PACE program agreement so that the total payment level for all participants is less than the projected payment under Medicare for a comparable population not enrolled under a PACE program.

(c) *Adjustments to payments.* If the actual number of Medicare participants differs from the estimated number of participants on which the amount of the prospective monthly payment was based, CMS adjusts subsequent monthly payments to account for the difference.

(d) *Application of Medicare secondary payer provisions*—(1) *Basic rule.* CMS does not pay for services to the extent that Medicare is not the primary payer under part 411 of this chapter.

(2) *Responsibilities of the PACE organization.* The PACE organization must do the following:

(i) Identify payers that are primary to Medicare under part 411 of this chapter.

(ii) Determine the amounts payable by those payers.

(iii) Coordinate benefits to Medicare participants with the benefits of the primary payers.

(3) *Charges to other entities.* The PACE organization may charge other individuals or entities for PACE services covered under Medicare for which Medicare is not the primary payer, as specified in paragraphs (d)(4) and (5) of this section.

(4) *Charge to other insurers or the participant.* If a Medicare participant receives from a PACE organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PACE organization may charge any of the following:

(i) The insurance carrier, the employer, or any other entity that is liable for payment for the services under part 411 of this chapter.

(ii) The Medicare participant, to the extent that he or she has been paid by the carrier, employer, or other entity.

(5) *Charge to group health plan (GHP) or large group health plan (LGHP).* If Medicare is not the primary payer for services that a PACE organization furnished to a Medicare participant who is covered under a GHP or LGHP, the organization may charge the following:

(i) GHP or LGHP for those services.

(ii) Medicare participant to the extent that he or she has been paid by the GHP or LGHP for those services.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

§ 460.182 Medicaid payment.

(a) Under a PACE program agreement, the State administering agency makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicaid participant.

(b) The monthly capitation payment amount is negotiated between the PACE organization and the State administering agency, and specified in the PACE program agreement. The amount represents the following:

(1) Is less than the amount that would otherwise have been paid under the State plan if the participants were not enrolled under the PACE program.

(2) Takes into account the comparative frailty of PACE participants.

(3) Is a fixed amount regardless of changes in the participant's health status.

(4) Can be renegotiated on an annual basis.

(c) The PACE organization must accept the capitation payment amount as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other form of payment from the State administering agency or from, or on behalf of, the participant, except as follows:

(1) Payment with respect to any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under § 460.184.

(2) Medicare payment received from CMS or from other payers, in accordance with § 460.180(d).

(d) State procedures for the enrollment and disenrollment of participants in the State's system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month, are included in the PACE program agreement.

§ 460.184 Post-eligibility treatment of income.

(a) A State may provide for post-eligibility treatment of income for Medicaid participants in the same manner as a State treats post-eligibility income for individuals receiving services under a waiver under section 1915(c) of the Act.

(b) Post-eligibility treatment of income is applied as it is under a waiver of section 1915(c) of the Act, as specified in §§ 435.726 and 435.735 of this chapter, and section 1924 of the Act.

§ 460.186 PACE premiums.

The amount that a PACE organization can charge a participant as a monthly premium depends on the participant's eligibility under Medicare and Medicaid, as follows:

(a) *Medicare Parts A and B.* For a participant who is entitled to Medicare Part A, enrolled under Medicare Part B, but not eligible for Medicaid, the

premium equals the Medicaid capitation amount.

(b) *Medicare Part A only.* For a participant who is entitled to Medicare Part A, not enrolled under Medicare Part B, and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part B capitation rate.

(c) *Medicare Part B only.* For a participant who is enrolled only under Medicare Part B and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

(d) *Medicaid, with or without Medicare.* A PACE organization may not charge a premium to a participant who is eligible for both Medicare and Medicaid, or who is only eligible for Medicaid.

Subpart K—Federal/State Monitoring

§ 460.190 Monitoring during trial period.

(a) *Trial period review.* During the trial period, CMS, in cooperation with the State administering agency, conducts comprehensive annual reviews of the operations of a PACE organization to ensure compliance with the requirements of this part.

(b) *Scope of review.* The review includes the following:

(1) An onsite visit to the PACE organization, which may include, but is not limited to, the following:

(i) Review of participants' charts.

(ii) Interviews with staff.

(iii) Interviews with participants and caregivers.

(iv) Interviews with contractors.

(v) Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals.

(2) A comprehensive assessment of an organization's fiscal soundness.

(3) A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants.

(4) Any other elements that CMS or the State administering agency find necessary.

§ 460.192 Ongoing monitoring after trial period.

(a) At the conclusion of the trial period, CMS, in cooperation with the State administering agency, continues to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with all of the requirements of this part.

(b) Reviews include an on-site visit at least every 2 years.

§ 460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified during reviews.

(b) CMS or the State administering agency monitors the effectiveness of corrective actions.

(c) Failure to correct deficiencies may result in sanctions or termination, as specified in subpart D of this part.

§ 460.196 Disclosure of review results.

(a) CMS and the State administering agency promptly report the results of reviews under §§460.190 and 460.192 to the PACE organization, along with any recommendations for changes to the organization's program.

(b) CMS and the State administering agency make the results of reviews available to the public upon request.

(c) The PACE organization must post a notice of the availability of the results of the most recent review and any plans of correction or responses related to the most recent review.

(d) The PACE organization must make the review results available for examination in a place readily accessible to participants.

Subpart L—Data Collection, Record Maintenance, and Reporting

§ 460.200 Maintenance of records and reporting of data.

(a) *General rule.* A PACE organization must collect data, maintain records, and submit reports as required by CMS and the State administering agency.

(b) *Access to data and records.* A PACE organization must allow CMS and the State administering agency access to

data and records including, but not limited to, the following:

(1) Participant health outcomes data.

(2) Financial books and records.

(3) Medical records.

(4) Personnel records.

(c) *Reporting.* A PACE organization must submit to CMS and the State administering agency all reports that CMS and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

(d) *Safeguarding data and records.* A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(e) *Confidentiality of health information.* A PACE organization must establish written policies and implement procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain complete records and relevant information in an accurate and timely manner.

(3) Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, and other participant health information.

(f) *Retention of records.* (1) A PACE organization must retain records for the longest of the following periods:

(i) The period of time specified in State law.

(ii) Six years from the last entry date.

(iii) For medical records of disenrolled participants, 6 years after the date of disenrollment.

(2) If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

§ 460.202 Participant health outcomes data.

(a) A PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants.

(b) A PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by CMS and the State administering agency. The items collected are specified in the PACE program agreement.

§ 460.204 Financial recordkeeping and reporting requirements.

(a) *Accurate reports.* A PACE organization must provide CMS and the State administering agency with accurate financial reports that are—

(1) Prepared using an accrual basis of accounting; and

(2) Verifiable by qualified auditors.

(b) *Accrual accounting.* A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

(1) Accurately documents all financial transactions.

(2) Provides an audit trail to source documents.

(3) Generates financial statements.

(c) *Accepted reporting practices.* Except as specified under Medicare principles of reimbursement, as defined in part 413 of this chapter, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

(d) *Audit or inspection.* A PACE organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:

(1) Any aspect of services furnished.

(2) Reconciliation of participants' benefit liabilities.

(3) Determination of Medicare and Medicaid amounts payable.

§460.208 Financial statements.

(a) *General rule.* (1) Not later than 180 days after the organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.

(2) The financial statement must be certified by an independent certified public accountant.

(b) *Contents.* At a minimum, the certified financial statement must consist of the following:

(1) A certification statement.

(2) A balance sheet.

(3) A statement of revenues and expenses.

(4) A source and use of funds statement.

(c) *Quarterly financial statement*—(1) *During trial period.* A PACE organization must submit a quarterly financial statement throughout the trial period within 45 days after the last day of each quarter of the PACE organization's fiscal year.

(2) *After trial period.* If CMS or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

§460.210 Medical records.

(a) *Maintenance of medical records.* (1) A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

(2) The medical record for each participant must meet the following requirements:

(i) Be complete.

(ii) Accurately documented.

(iii) Readily accessible.

(iv) Systematically organized.

(v) Available to all staff.

(vi) Maintained and housed at the PACE center where the participant receives services.

(b) *Content of medical records.* At a minimum, the medical record must contain the following:

(1) Appropriate identifying information.

(2) Documentation of all services furnished, including the following:

(i) A summary of emergency care and other inpatient or long-term care services.

(ii) Services furnished by employees of the PACE center.

(iii) Services furnished by contractors and their reports.

(3) Interdisciplinary assessments, reassessments, plans of care, treatment, and progress notes that include the participant's response to treatment.

(4) Laboratory, radiological and other test reports.

(5) Medication records.

(6) Hospital discharge summaries, if applicable.

(7) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin).

(8) Enrollment Agreement.

(9) Physician orders.

(10) Discharge summary and disenrollment justification, if applicable.

(11) Advance directives, if applicable.

(12) A signed release permitting disclosure of personal information.

(c) *Transfer of medical records.* The organization must promptly transfer copies of medical record information between treatment facilities.

(d) *Authentication of medical records.* (1) All entries must be legible, clear, complete, and appropriately authenticated and dated.

(2) Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

SUBCHAPTER F—QUALITY IMPROVEMENT ORGANIZATIONS

PART 475—QUALITY IMPROVEMENT ORGANIZATIONS

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Subpart B [Reserved]

Subpart C—Utilization and Quality Control Quality Improvement Organizations

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475.101 Eligibility requirements for QIO contracts.
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475.103 Eligibility of physician-access organizations.
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475.105 Prohibition against contracting with health care facilities.
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475.107 QIO contract award.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 475.1 Definitions.

For purposes of this part:

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to 5 percent or more; or

(d) Is the owner of an interest of 5 percent or more in any obligation secured by an entity, if the interest equals at least 5 percent of the value of the property or assets of the entity.

Health care facility means an institution that directly provides or supplies health care services for which payment may be made in whole or in part under Title XVIII of the Act. A health care facility may be a hospital, skilled nursing facility, home health agency, free-standing ambulatory surgical center, or outpatient facility or any other entity which provides or supplies direct care to Medicare beneficiaries.

Managing employee means a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over the entity or organization, or who, directly or indirectly, conducts the day-to-day operations of the entity or organization.

Payor organization means any organization, other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a QIO contract. ''Payor organization'' also means any organization which is affiliated with any entity which makes payments as described above, by virtue of the organization having two or more governing body members who are also either governing body members, officers, partners, 5 percent or more owners or managing employees in a health maintenance organization or competitive medical plan.

Physician means:

(1) A doctor of medicine or osteopathy licensed under State law to practice medicine, surgery, or osteopathy in the State in which the QIO is located;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice medicine, surgery, or osteopathy in the QIO area; and

(3) An individual licensed to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

[43 FR 32085, July 24, 1978, as amended at 49 FR 7206, Feb. 27, 1984. Redesignated at 50 FR 15327, Apr. 17, 1985, and amended at 50 FR 15328, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986. Redesignated at 64 FR 66279, Nov. 24, 1999]

Subpart B [Reserved]

Subpart C—Utilization and Quality Control Quality Improvement Organizations

SOURCE: 49 FR 7207, Feb. 27, 1984, unless otherwise noted. Redesignated at 50 FR 15327, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999.

§475.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) of the Social Security Act as amended by the Peer Review Improvement Act of 1982 (Pub. L. 97–248). It defines the types of organizations eligible to become QIOs and establishes certain limitations and priorities regarding QIO contracting.

§475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO contract an organization must—

(a) Be either a physician-sponsored organization as described in §462.102; or a physician-access organization as described in §462.103; and

(b) Demonstrate its ability to perform review as set forth in §462.104.

§475.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored QIO, an organization must meet the following conditions:

(1) Be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area and who are representative of the physicians practicing in the area.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in §462.105.

(b) In order to meet the requirements of paragraph (a)(1) of this section, an organization must state and have documentation in its files showing that it is composed of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area.

(c) In order to meet the requirements or paragraph (a)(2) of this section, an organization must—

(1) State and have documentation in its files demonstrating that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area; or

(2) If the organization is not composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, then the organization must demonstrate in its contract proposal, through letters of support from physicians or physician organizations, or through other means, that it is representative of the area physicians.

(d) Organizations that meet the requirements in paragraph (a) of this section will receive, during the contract evaluation process, a set number of bonus points.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999]

§475.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access QIO, an organization must meet the following conditions:

(1) Have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in §462.105.

(b) An organization meets the requirements of paragraph (a)(1) of this section if it demonstrates—

(1) That it has available to it at least one physician in every generally recognized specialty; and

(2) The existence of an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

[50 FR 15328, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 475.104 Requirements for demonstrating ability to perform review.

(a) A physician-sponsored or physician-access organization will be found capable of conducting review if CMS determines that the organization is able to set quantifiable performance objectives and perform the utilization and quality review functions established under section 1154 of the Social Security Act in an efficient and effective manner.

(b) CMS will determine that the organization is capable of conducting utilization and quality review if—

(1) The organization's proposed review system is adequate; and

(2) The organization has available sufficient resources (including access to medical review skills) to implement that system; and

(3) The organization's quantifiable objectives are acceptable.

(c) CMS may consider prior similar review experience in making determinations under paragraph (b) of this section.

(d) A State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to the satisfaction of CMS that it will act with complete independence and objectivity.

§ 475.105 Prohibition against contracting with health care facilities.

(a) *Basic rule.* Except as permitted under paragraph (b) of this section, the following are not eligible for QIO contracts:

(1) A health care facility in the QIO area.

(2) An association of health care facilities in the QIO area.

(3) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the QIO area.

(b) *Exceptions.* Effective November 15, 1984, the prohibition stated in paragraph (a) of this section will not apply to a payor organization if CMS determines under § 462.106 that there is no other eligible organization available.

(c) *Subcontracting.* A QIO must not subcontract with a facility to conduct any review activities except for the review of the quality of care.

[50 FR 15328, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 475.106 Prohibition against contracting with payor organizations.

Payor organizations are not eligible to become QIOs for the area in which they make payments until November 15, 1984. If no QIO contract for an area is awarded before November 15, 1984, a payor organization will be determined eligible by CMS, if an eligible organization that is not a payor organization is unavailable at that time. CMS may determine the unavailability of nonpayor organizations based on the lack of response to an appropriate Request for Proposal.

[50 FR 15328, Apr. 17, 1985]

§ 475.107 QIO contract award.

CMS, in awarding QIO contracts, will take the following actions—

(a) Identify from among all proposals submitted in response to an RFP for a given QIO area all proposals submitted by organizations that meet the requirements of § 462.102 or § 462.103;

(b) Identify from among all proposals identified in paragraph (a) of this section all proposals that set forth minimally acceptable plans in accordance with the requirements of § 462.104 and the RFPs;

(c) Assign bonus points not to exceed 10% of the total points available to all physician-sponsored organizations identified in paragraph (b) of this section, consistent with statute; and

(d) Subject to the limitations established by §§ 462.105 and 462.106, award the contract for the given QIO area to the selected organization for a period of two years.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999]

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

Subpart A—General Provisions

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Subpart B [Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

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476.100 Use of norms and criteria.
476.102 Involvement of health care practitioners other than physicians.
476.104 Coordination of activities.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 32081, June 4, 1979, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

Subpart A—General Provisions

§476.1 Definitions.

As used in this part, unless the context indicates otherwise:

Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) to order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a QIO of the medical necessity and appropriateness of a patient's admission to a specific facility.

Continued stay review means QIO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

Criteria means predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a QIO validates that DRG assignments are based on the correct diagnostic and procedural information.

Elective, when applied to admission or to a health care service, means an admission or a service that can be delayed without substantial risk to the health of the individual.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or

(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or *facility* means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Health care practitioners other than physicians means those health professionals who do not hold a doctor of medicine or doctor of osteopathy degree, who meet all applicable State or Federal requirements for practice of their professions, and who are in active practice.

Hospital means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)–(g) of the Act, other than a religious nonmedical institution as defined in § 440.170(b) of this chapter.

Initial denial determination means an initial negative decision by a QIO, regarding the medical necessity, quality, or appropriateness of health care services furnished, or proposed to be furnished, to a patient.

Major clinical area means medicine, surgery, pediatrics, obstetrics and gynecology, or psychiatry.

Major procedure means a diagnostic or therapeutic procedure which involves a surgical or anesthetic risk or requires highly trained personnel or special facilities or equipment.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the QIO area.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Norms means numerical or statistical measures of average observed performance in the delivery of health care services.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Peer review means review by health care practitioners of services ordered or furnished by other practitioners in the same professional field.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

Preadmission review means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

QIO review means review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors.

Profile means aggregated data in formats that display patterns of health care services over a defined period of time.

Profile analysis means review and analysis of profiles to identify and consider patterns of health care services.

Quality review study means an assessment conducted by or for a QIO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Regional norms, criteria, and standards means norms, criteria, and standards that apply to a geographic division which is larger than a QIO area.

Retrospective review means review that is conducted after services are provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

Review responsibility means (1) the responsibility of the QIO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98–21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between CMS and the QIO; and (3) the authority of a QIO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a religious nonmedical institution as defined in §440.170(b) of this chapter

Standards means professionally developed expressions of the range of acceptable variation from a norm or criterion.

Subcontractor means a facility or a non-facility organization under contract with a QIO to perform QIO review functions.

Working day means any one of at least five days of each week (excluding, at the option of each QIO, legal holidays) on which the necessary personnel are available to perform review.

[44 FR 32081, June 4, 1979, as amended at 45 FR 67545, Oct. 10, 1980; 46 FR 48569, Oct. 1, 1981. Redesignated and amended at 50 FR 15328, 15329, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 64 FR 67052, Nov. 30, 1999]

Subpart B [Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

SOURCE: 50 FR 15330, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

GENERAL PROVISIONS

§476.70 Statutory bases and applicability.

(a) *Statutory basis.* Sections 1154, 1866(a)(1)(F) and 1886(f)(2) of the Act require that a QIO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary. Section 1154(a)(4) of the Act requires QIOs, or, in certain circumstances, non-QIO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a QIO and its subcontractors. Section 466.72 of this part also applies, for purposes of quality of care reviews under section 1154(a)(4) of the Act, to non-QIO entities that enter into contracts to perform reviews of services furnished under risk-basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter.

[52 FR 37457, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999]

§476.71 QIO review requirements.

(a) *Scope of QIO review.* In its review, the QIO must determine (in accordance with the terms of its contract)—

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of a malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care;

(3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type;

(4) Through DRG validation, the validity of diagnostic and procedural information supplied by the hospital;

(5) The completeness, adequacy and quality of hospital care provided;

(6) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges;

(7) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter; and

(8) Whether a hospital has misrepresented admission or discharge information or has taken an action that results in—

(i) The unnecessary admission of an individual entitled to benefits under part A;

(ii) Unnecessary multiple admissions of an individual; or

(iii) Other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(b) *Payment determinations.* On the basis of the review specified under paragraphs (a) (1), (3), (6), (7), and (8) of this section, the QIO must determine whether payment may be made for these services. A QIO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the service(s) would not be made under the Medicare program as specified in § 405.330(b).

(c) *Other duties and functions.* (1) The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by CMS, the QIO must review changes in DRG and LTC-DRG assignments made by the intermediary under the provisions of §§ 412.60(d) and 412.513(c) of this chapter that result in the assignment of a higher-weighted DRG or a different LTC-DRG. The QIO's review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(d) *Coordination of sanction activities.* The QIO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

[52 FR 37457, Oct. 7, 1987; 52 FR 47003, Dec. 11, 1987, as amended at 59 FR 45402, Sept. 1, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999; 67 FR 56056, Aug. 30, 2002]

§ 476.72 Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans.

(a) (1) For purposes of a review under section 1154(a)(4) of the Act, a QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by an HMO or CMP meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

(2) Paragraph (a)(1) of this section will not apply with respect to a contract year if another entity has been awarded a contract to perform those reviews under section 1154(a)(4)(C) of the Act.

(b) For purposes of reviews under this section, non-QIO entities selected to perform these reviews under section 1154(a)(4)(C) of the Act are subject to the requirements of paragraph (a)(1) of this section and—

(1) Part 476 of this chapter regarding acquisition, protection, and disclosure of peer review information; and

(2) Part 1004 of Chapter V regarding a QIO's responsibilities, and sanctions on health care practitioners and providers.

[52 FR 37457, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.73 Notification of QIO designation and implementation of review.

(a) *Notice of CMS's decision.* CMS sends written notification of a QIO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the QIO contract and specifies the area and types of health care facilities to be reviewed by the QIO. The QIO must make a similar notification when review responsibilities are subcontracted.

(b) *Notification to health care facilities and the public.* As specified in its contract with CMS, the QIO must—

(1) Provide, to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the QIO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in § 466.78(b)(3) of this part.

(2) Publish, in at least one local newspaper of general circulation in the QIO area, a notice that states the date the QIO will assume review responsibilities and lists each area health care facility to be under review. The QIO must indicate that its plan for the review of health care services as approved in its contract with CMS is available for public inspection in the QIO's business office and give the address, telephone number and usual hours of business.

[50 FR 15330, Apr. 17, 1985. Redesignated at 52 FR 37457, Oct. 7, 1987, and further redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.74 General requirements for the assumption of review.

(a) A QIO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with CMS.

(b) A QIO must notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A QIO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare fiscal intermediaries and carriers;

(2) A copy of its currently approved review plan that includes the QIO's method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A QIO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The QIO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by CMS, a QIO is responsible for compiling statistics based on the criteria contained in § 405.332 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by CMS, QIOs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in part 405, subpart G of this chapter for Medicare Part A related determinations and part 405, subpart H of this chapter for Medicare Part B related determinations.

(f) A QIO must make its responsibilities under its contract with CMS, primary to all other interests and activities that the QIO undertakes.

§ 476.76 Cooperation with health care facilities.

Before implementation of review, a QIO must make a good faith effort to discuss the QIO's administrative and review procedures with each involved health care facility.

§ 476.78 Responsibilities of health care facilities.

(a) Every hospital seeking payment for services furnished to Medicare beneficiaries must maintain a written agreement with a QIO operating in the area in which the hospital is located. These agreements must provide for the QIO review specified in § 466.71.

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review. Providers must—

(1) Allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. The provider must photocopy and deliver to the QIO all required information within 30 days of a request. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the QIO. When the QIO does postadmission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to QIO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requries inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the QIO, that each case subject to preadmission review has been reviewed and approved by the QIO before admission to the hospital or a timely request has been made for QIO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the QIO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a QIO, makes a timely request for preadmission review and the QIO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the QIO.

(c) *Photocopying reimbursement methodology for prospective payment system providers.* Providers subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the providers' responsibility to the QIOs to provide photocopies of requested provider records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by CMS as follows:

(1) *Step one.* CMS adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB Circular A–76.

(2) *Step two.* CMS divides the amount determined in paragraph (c)(1) of this section by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.

(3) CMS adds to the per-page labor cost determined in paragraph (c)(2) of this section the per-page costs of supplies.

(4) CMS will periodically review the photocopy reimbursement rate to ensure that it still accurately reflects provider costs. CMS will publish any changes to the rate in a FEDERAL REGISTER notice.

(d) *Appeals.* Reimbursement for the costs of photocopying and mailing records for QIO review is an additional payment to providers under the prospective payment system, as specified in § 412.115, § 413.355, and § 484.265 of this chapter. Thus, appeals concerning these costs are subject to the review

process specified in part 405, subpart R of this chapter.

[50 FR 15330, Apr. 17, 1985, as amended at 57 FR 47787, Oct. 20, 1992; 59 FR 45402, Sept. 1, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999; 68 FR 67960, Dec. 5, 2003]

§ 476.80 Coordination with Medicare fiscal intermediaries and carriers.

(a) *Procedures for agreements.* The Medicare fiscal intermediary or carrier must have a written agreement with the QIO. The QIO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The QIO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, CMS will assist them in resolving matters in dispute.

(2) The QIO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from CMS, before it makes conclusive determinations for the Medicare program, unless CMS finds that the fiscal intermediary or carrier has—

(i) Refused to negotiate in good faith or in a timely manner, or

(ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) *Content of agreement.* The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

(i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and

(ii) Initial denial determinations and revisions of these determinations as a result of reconsideration, or reopening all approvals and denials with respect to cases subject to preadmission review, and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by CMS; and

(4) Any other matters that are necessary for the coordination of functions.

(c) *Action by CMS.* (1) Within the time specified in its contract, the QIO must submit to CMS for approval its agreement with the Medicare fiscal intermediaries and carriers, or if an agreement has not been established, the QIO's proposed administrative procedures, including any comments by the Medicare fiscal intermediaries and carriers.

(2) If CMS approves the agreement or the administrative procedures (after a finding by CMS as specified in paragraph (a)(2) of this section), the QIO may begin to make determinations under its contract with CMS.

(3) If CMS disapproves the agreement or procedures, it will—

(i) Notify the QIO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the QIO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) *Modification of agreements.* Agreements or procedures may be modified, with CMS's approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the QIO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) *Role of the fiscal intermediary.* (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the QIO, until it receives notice that the QIO has approved the admission after preadmission or retrospective review.

(2) A QIO's determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.82 Continuation of functions not assumed by QIOs.

Any of the duties and functions under Part B of Title XI of the Act for which a QIO has not assumed responsibility under its contract with CMS must be

performed in the manner and to the extent otherwise provided for under the Act or in regulations.

QIO REVIEW FUNCTIONS

§ 476.83 Initial denial determinations.

A determination by a QIO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under part 473 of this chapter.

§ 476.84 Changes as a result of DRG validation.

A provider or practitioner may obtain a review by a QIO under part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of QIO validation activities.

§ 476.85 Conclusive effect of QIO initial denial determinations and changes as a result of DRG validations.

A QIO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in part 473—

(a) The initial denial determination is reconsidered and revised; or

(b) The change as a result of DRG validation is reviewed and revised.

§ 476.86 Correlation of Title XI functions with Title XVIII functions.

(a) *Payment determinations.* (1) QIO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:

(i) Whether inpatient care furnished in a psychiatric hospital meets the requirements of § 424.14 of this chapter.

(ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is precluded under § 489.50 of this chapter because of failure to perform review of long-stay cases.

(iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under § 405.310(g) or § 405.310(k) of this chapter.

(iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.

(2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fiscal intermediaries or carriers except as outlined in paragraph (c) of this section.

(3) QIOs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the QIO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

(4) QIO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

(b) *Utilization review activities.* QIO review activities to determine whether inpatient hospital or SNF care services are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) *Coverage.* Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding CMS or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:

(1) In the case of items or services not reviewed by a QIO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier

must use a QIO to make a determination on those issues if a QIO is conducting review in the area and must abide by the QIO's determination.

(2) Whether any claim meets coverage requirements of Title XVIII relating to issues other than medical necessity, reasonableness or appropriateness of placement at an acute level of patient care.

(d) *Payment.* Medicare fiscal intermediaries and carriers are not precluded from making payment determinations with regard to coverage determinations made under paragraph (c) of this section.

(e) *Survey, compliance and assistance activities.* QIO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§ 421.100(d) and 421.200(f) of this chapter.

(f) *Appeals.* The requirements and procedures for QIO review of changes as a result of DRG validation and the reconsideration, hearing and judicial review of QIO initial denial determinations are set forth in part 473 of this chapter.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985, as amended at 53 FR 6648, Mar. 2, 1988. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.88 Examination of the operations and records of health care facilities and practitioners.

(a) *Authorization to examine records.* A facility claiming Medicare payment must permit a QIO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and are necessary for the QIO or its subcontractor to—

(1) Perform review functions including, but not limited to—

(i) DRG validation;

(ii) Outlier review in facilities under a prospective payment system; and

(iii) Implementation of corrective action and fraud and abuse prevention activities;

(2) Evaluate cases that have been identified as deviating from the QIO norms and criteria, or standards; and

(3) Evaluate the capability of the facility to perform quality review functions under a subcontract with the QIO.

(b) *Limitations on access to records.* A QIO has access to the records of non-Medicare patients if—

(1) The records relate to review performed under a non-Medicare QIO contract and if authorized by those patients in accordance with State law; or

(2) The QIO needs the records to perform its quality review responsibilities under the Act and receives authorization from the facility or practitioner.

(c) *Conditions of examination.* When examining a facility's operation or records the QIO must—

(1) Examine only those operations and records (including information on charges) required to fulfill the purposes of paragraph (a) of this section;

(2) Cooperate with agencies responsible for other examination functions under Federal or Federally assisted programs in order to minimize duplication of effort;

(3) Conduct the examinations during reasonable hours; and

(4) Maintain in its principal office written records of the results of the examination of the facility.

§ 476.90 Lack of cooperation by a health care facility or practitioner.

(a) If a health care facility or practitioner refuses to allow a QIO to enter and perform the duties and functions required under its contract with CMS, the QIO may—

(1) Determine that the health care facility or practitioner has failed to comply with the requirements of § 474.30(c) of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a QIO provides a facility with sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if

the facility does not respond in a timely manner, the QIO will deny the claim.

§ 476.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a QIO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient's attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the QIO physician advisor and to explain the nature of the patient's need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 476.94 Notice of QIO initial denial determination and changes as a result of a DRG validation.

(a) *Notice of initial denial determination*—(1) *Parties to be notified.* A QIO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient's next of kin, guardian or other representative or sponsor;

(ii) The attending physician, or other attending health care practitioner;

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

(2) *Timing of the notice.* The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination;

(ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged;

(iii) For preprocedure review, before the procedure is performed;

(iv) For preadmission review, before admission;

(v) If identification as a Medicare program patient has been delayed, within three working days of identification;

(vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working days of the initial denial determination; and

(vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) *Preadmission review.* In the case of preadmission review, the QIO must document that the patient and the facility received notice of the initial denial determination.

(b) *Notice of changes as a result of a DRG validation.* The QIO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the QIO's decision.

(c) *Content of the notice.* The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation;

(2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients' health care needs;

(3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of part 473, subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or

(ii) Reconsideration of the initial denial determination;

(4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;

(5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and

(6) A statement concerning the duties and functions of the QIO under the Act.

(d) *Notice to payers.* The QIO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the

Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) *Record of initial denial determination and changes as a result of a DRG validation.* (1) The QIO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—

(i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and

(ii) A copy of the determination or change in DRG notices sent to all parties and identification of each party and the date on which the notice was mailed or delivered.

§ 476.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

(a) *General timeframe.* A QIO or its subcontractor—

(1) Within one year of the date of the claim containing the service in question, may review and deny payment; and

(2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) *Extended timeframes.* (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if CMS approves.

(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the QIO's decision if—

(i) Additional information is received on the patient's condition;

(ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;

(iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or

(iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

(c) *Fraud and abuse.* (1) A QIO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

(2) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

§ 476.98 Reviewer qualifications and participation.

(a) *Peer review by physician.* (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the QIO area.

(2) If a QIO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.

(3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands as ''medical officers'' may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(b) *Peer review by health care practitioners other than physicians.* Health care practitioners other than physicians may review services furnished by other practitioners in the same professional field.

(c) *DRG validation review.* Decisions about procedural and diagnostic information must be made by physicians. Technical coding issues must be reviewed by individuals with training and experience in ICD–9–CM coding.

(d) *Persons excluded from review.* (1) A person may not review health care

services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—

(i) Participated in developing or executing the beneficiary's treatment plan;

(ii) Is a member of the beneficiary's family; or

(iii) Is a governing body member, officer, partner, 5 percent or more owner, or managing employee in the health care facility where the services were or are to be furnished.

(2) A member of a reviewer's family is a spouse (other than a spouse who is legally separated under a decree of divorce or separate maintenance), child (including a legally adopted child), grandchild, parent, or grandparent.

§ 476.100 Use of norms and criteria.

(a) *Use of norms.* As specified in its contract, a QIO must use national, or where appropriate, regional norms in conducting review to achieve QIO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a QIO must use national admission norms.

(b) *Use of criteria.* In assessing the need for and appropriateness of an inpatient health care facility stay, a QIO must apply criteria to determine—

(1) The necessity for facility admission and continued stay (in cases of day outliers in hospitals under prospective payment);

(2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or

(3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The QIO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective.

(c) *Establishment of criteria and standards.* For the conduct of review a QIO must—

(1) Establish written criteria based upon typical patterns of practice in the QIO area, or use national criteria where appropriate; and

(2) Establish written criteria and standards to be used in conducting quality review studies.

(d) *Variant criteria and standards.* A QIO may establish specific criteria and standards to be applied to certain locations and facilities in the QIO area if the QIO determines that—

(1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the QIO area; and

(2) There is a reasonable basis for the difference which makes the variation appropriate.

§ 476.102 Involvement of health care practitioners other than physicians.

(a) *Basic requirement.* Except as provided in paragraph (b) of this section, a QIO must meet the following requirements:

(1) Consult with the peers of the practitioners who furnish the services under review if the QIO reviews care and services delivered by health care practitioners other than physicians.

(2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—

(i) Developing QIO criteria and standards;

(ii) Selecting norms to be used; and

(iii) Developing review mechanisms for care furnished by their peers.

(3) Ensure that an initial denial determination or a change as a result of DRG validation of services provided by a health care practitioner other than a physician is made by a physician only after consultation with a peer of that practitioner. Initial denial determinations and changes as a result of DRG validations must be made only by a physician or dentist.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply if—

(1) The QIO has been unable to obtain a roster of peer practitioners available to perform review; or

(2) The practitioners are precluded from performing review because they participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest

in the health care facility as described in §466.98(d).

(c) *Peer involvement in quality review studies.* Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a QIO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the QIO's responsibility for review.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§476.104 Coordination of activities.

In order to achieve efficient and economical review, a QIO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;

(b) Other QIOs; and

(c) Other public or private review organizations as may be appropriate.

PART 478—RECONSIDERATIONS AND APPEALS

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organization (QIO) Reconsiderations and Appeals

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organization (QIO) Reconsiderations and Appeals

SOURCE: 50 FR 15372, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

§478.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Quality Improvement Organization (QIO) or its subcontractor of initial denial determinations concerning services furnished or proposed to be furnished under Medicare;

(b) Hearings and judicial review of reconsidered determinations; and

(c) QIO review of a change in diagnostic and procedural coding information.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§478.12 Statutory basis.

(a) Under section 1154 of the Act, a QIO may make an initial determination that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting.

(b) Under section 1155 of the Act, the following rules apply:

(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with an initial denial determination under paragraph (a) of this section is entitled to a reconsideration by the QIO that made that determination.

(2) The beneficiary is also entitled to the following:

(i) A hearing by an administrative law judge if $200 or more is still in controversy after a reconsidered determination.

(ii) Judicial review if $2000 or more is still in controversy after a final determination by the Department.

(c) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the Medicare program must maintain an agreement with a QIO under which the QIO reviews the validity of diagnostic information furnished by the hospital.

[50 FR 15372, Apr. 17, 1985, as amended at 60 FR 50442, Sept. 29, 1995. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.14 Applicability.

(a) *Basic provision.* This subpart applies to reconsiderations and hearings of a QIO initial denial determination involving the following issues:

(1) Reasonableness of services.

(2) Medical necessity of services.

(3) Appropriateness of the inpatient setting in which services were furnished or are proposed to be furnished.

(b) *Concurrent appeal.* A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) *Nonapplicability of rules to related determinations.* (1) A QIO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or CMS should be read to mean initial and reconsidered determinations made by a QIO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.15 QIO review of changes resulting from DRG validation.

(a) *General rules.* (1) A provider or practitioner dissatisfied with a change to the diagnostic or procedural coding information made by a QIO as a result of DRG validation under section 1866(a)(1)(F) of the Act is entitled to a review of that change if—

(i) The change caused an assignment of a different DRG; and

(ii) Resulted in a lower payment.

(2) A beneficiary may obtain a review of a QIO DRG coding change only if that change results in noncoverage of a furnished service.

(3) The individual who reviews changes in DRG procedural or diagnostic information must be a physician, and the individual who reviews changes in DRG coding must be qualified through training and experience with ICD–9–CM coding.

(b) *Procedures.* Procedures described in §§ 473.18 through 473.36, and 473.48 (a) and (c) for a QIO reconsideration or reopening also apply to QIO review of a DRG coding change.

(c) *Finality of review.* No additional review or appeal for matters governed by paragraph (a) of this section is available.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.16 Right to reconsideration.

A beneficiary, provider or practitioner who is dissatisfied with a QIO initial denial determination on one of the issues specified in § 473.14(a) has a right to a reconsideration of that determination by the QIO that made the initial denial determination.

§ 478.18 Location for submitting requests for reconsideration.

(a) *Beneficiaries.* Except as provided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to

obtain a reconsideration must submit a written request to one of the following:

(1) The QIO or the QIO subcontractor that made the initial determination.

(2) An SSA District Office.

(3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.

(b) *Others.* A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the QIO or QIO subcontractor that made the initial determination.

(c) *Expedited reconsideration.* A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the QIO.

§478.20 Time limits for requesting reconsideration.

(a) *Basic rules.* (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under §473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of an initial determination.

(2) The date of receipt of the notice of the initial determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

(b) *Late filing of request.* A QIO will accept a request filed after 60 days after receipt of the notice of the initial determination if the QIO finds under the criteria set forth in §473.22 that there was good cause for the party's failure to file a timely request.

(c) *Request for expedited reconsideration.* A request for an expedited reconsideration under §473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§478.22 Good cause for late filing of a request for a reconsideration or hearing.

(a) *General Rule.* In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the QIO or ALJ, respectively, must consider the following:

(1) What circumstances kept the party from making the request on time.

(2) Whether an action by the QIO misled the party.

(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.

(b) *Examples.* Examples of circumstances in which good cause may exist include, but are not limited to, the following:

(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.

(2) There was a death or serious illness in a party's immediate family.

(3) Important records were accidentally destroyed or damaged by fire or other cause.

(4) A party made a diligent effort but could not find or obtain necessary relevent information within the appropriate time period.

(5) A party requested additional information to further explain the determination within the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for a Departmental Appeals Board hearing).

(6) The QIO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.

(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.

(8) Other unusual or unavoidable circumstances exist that—

(i) Show that a party could not have known of the need to file timely; or

(ii) Prevented a party from filing timely.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996. Redesignated at 64 FR 66279, Nov. 24, 1999]

§478.24 Opportunity for a party to obtain and submit information.

(a) Subject to the rules concerning disclosure of QIO information in section 1160 of the Act, at the request of a provider, practitioner or beneficiary,

the QIO must provide an opportunity for examination of the material upon which the initial denial determination was based. The QIO may not furnish a provider, practitioner or beneficiary with—

(1) A record of the QIO deliberation; or

(2) The identity of the QIO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.

(b) The QIO may require the requester to pay a reasonable fee for the reproduction of the material requested.

(c) The QIO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§ 478.26 Delegation of the reconsideration function.

A QIO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a QIO subcontractor.

§ 478.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

(a) Qualified under § 466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of QIO review.

§ 478.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on—

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§ 478.32 Time limits for issuance of the reconsidered determination.

(a) *Beneficiaries.* If a beneficiary files a timely request for reconsideration of an initial denial determination, the QIO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—

(1) Within three working days after the QIO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the QIO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the QIO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the QIO receives the request for reconsideration.

(3) Within 30 working days after the QIO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) *Providers or practitioners.* If the provider or practitioner files a request for reconsideration of an initial determination, the QIO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§ 478.34 Notice of a reconsidered determination.

(a) *Notice to parties.* A written notice of a QIO reconsidered determination must contain the following;

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

(3) A statement explaining the Medicare payment consequences of the reconsidered determination.

(4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.

(b) *Notice to payers.* (1) A QIO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 478.36 Record of reconsideration.

(a) *QIO requirements.* A QIO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the notice of the QIO's reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) *Contents of the record.* The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) *Confidentiality.* The record of a QIO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 478.38 Effect of a reconsidered determination.

A QIO reconsidered determination is binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with § 473.40 and a final decision rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with § 473.48.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985, as amended at 62 FR 25855, May 12, 1997; 62 FR 49938, Sept. 24, 1997. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a QIO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) *Subject matter.* A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services.

(3) Appropriateness of the setting in which the services were furnished.

(c) *Governing provisions.* The provisions of subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in subpart G to initial and reconsidered determinations made by an intermediary, carrier, or CMS should be read to mean initial and reconsidered determinations made by a QIO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 473.40 must submit a written request to one of the following:

(1) The office of the QIO or QIO subcontractor that made the initial determination.

(2) A SSA District Office.

(3) An office of the Office of Hearings and Appeals of SSA.

(4) An office of the Railroad Retirement Board, in the case of a beneficiary who is a railroad retiree.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 days of receipt of the notice of the QIO reconsidered determination, unless the time is extended for good cause as provided in § 473.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

§ 478.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ determines the amount in controversy in accordance with § 405.740(a) of this chapter for Part A services or § 405.817(a) of this chapter for Part B services. When two or more appellants submit a request for hearing, the ALJ determines the amount in controversy in accordance with § 405.740(b) of this chapter for Part A services and § 405.817(b) of this chapter for Part B services.

(b) If the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, notifies the parties to the hearing that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties to the hearing and the QIO that the QIO reconsidered determination is conclusive for Medicare payment purposes.

[50 FR 15372, Apr. 17, 1985, as amended at 59 FR 12184, Mar. 16, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.46 Departmental Appeals Board and judicial review.

(a) The circumstances under which the DAB will review an ALJ hearing decision or dismissal are the same as those set forth at 20 CFR 404.970, (''Cases the Appeals Council will review'').

(b) If $2,000 or more is in controversy, a party may obtain judicial review of an Departmental Appeals Board decision, or an ALJ hearing decision if a request for review by the Departmental Appeals Board was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Departmental Appeals Board decision or denial.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996; 62 FR 25855, May 12, 1997. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) *QIO reopenings*—(1) *General rule.* A QIO or QIO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in § 473.15, that is otherwise binding, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) *Extension of time limit.* A QIO or QIO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in § 473.15, that is otherwise binding, after one year but within four years of the date of the determination or review if—

(i) The QIO receives new material evidence;

(ii) The QIO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

(b) *ALJ and Departmental Appeals Board Reopening—Applicable procedures.*

The ALJ or the Departmental Appeals Board, whichever made the decision, may reopen and revise the decision in accordance with the procedures set forth in §405.750(b) of this chapter, which concerns reopenings and revisions under subpart G of part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Departmental Appeals Board may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996; 62 FR 25855, May 12, 1997. Redesignated at 64 FR 66279, Nov. 24, 1999]

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

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480.141 Disclosure of QIO interpretations on the quality of health care.
480.142 Disclosure of sanction reports.
480.143 QIO involvement in shared health data systems.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

SOURCE: 50 FR 15359, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

GENERAL PROVISIONS

§480.101 Scope and definitions.

(a) *Scope.* This subpart sets forth the policies and procedures governing—

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Quality Improvement Organization (QIO) (or the review component of a QIO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a QIO to comply with its responsibilities under the Act.

(b) *Definitions.* As used in this part:

Abuse means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

Aggregate statistical data means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

Confidential information means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) QIO deliberations.

Health care facility or *facility* means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Implicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.

Non-facility organization means a corporate entity that: (1) Is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the QIO area.

Patient representative means—(1) an individual designated by the patient, in writing, as authorized to request and receive QIO information that would otherwise be disclosable to that patient; or (2) an individual identified by the QIO in accordance with § 480.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

QIO deliberations means discussions or communications (within a QIO or between a QIO and a QIO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding QIO review responsibilities and appeals from QIO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

QIO information means any data or information collected, acquired or generated by a QIO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

QIO interpretations and generalizations on the quality of health care means an assessment of the quality of care furnished by an individual provider or group of providers based on the QIO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the QIO's review activities.

QIO review system means the QIO and those organizations and individuals who either assist the QIO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The QIO and its officers, members and employees;

(2) QIO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) QIO reviewers and supporting staff; and

(5) Data support organizations.

Public information means information which has been disclosed to the public.

Quality review study means an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Quality review study information means all documentation related to the quality review study process.

Reviewer means review coordinator, physician, or other person authorized to perform QIO review functions.

Sanction report means a report filed pursuant to section 1156 of the Act and part 474 of this chapter documenting the QIO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

Shared health data system means an agency or other entity authorized by Federal or State law that is used by the QIO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

Subcontractor means a facility or a non-facility organization under contract with a QIO to perform QIO review functions.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999; 69 FR 49267, Aug. 11, 2004]

§480.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires QIOs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires QIOs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by QIOs.

§480.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires QIOs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other QIOs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that QIO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart, to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§480.104 Procedures for disclosure by a QIO.

(a) *Notice to accompany disclosure.* (1) Any disclosure of information under the authority of this subpart is subject to the requirements in §480.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in §480.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under §480.107 that limits redisclosure.

(b) *QIO interpretations.* A QIO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) *Fees.* A QIO may charge a fee to cover the cost of providing information authorized under this subpart. These

fees may not exceed the amount necessary to recover the cost to the QIO for providing the information.

(d) *Format for disclosure of public information.* A QIO is required to disclose public information (§ 480.120(a)(6)) only in the form in which it is acquired by the QIO or in the form in which it is maintained for QIO use.

(e) *Medicare provider number.* A QIO must include the provider identification number assigned by the Medicare program on information that CMS requests.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.105 Notice of disclosures made by a QIO.

(a) *Notification of the disclosure of nonconfidential information.* Except as permitted under § 480.106, at least 30 calender days before disclosure of nonconfidential information, the QIO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to CMS or Medicare fiscal intermediaries, or to or from QIO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the QIO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A QIO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under § 480.132.

(2) A QIO must notify a practitioner or institution of the QIO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§ 480.137 and 480.138) except for cases specified in § 480.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the QIO discloses the identifying information. The QIO must forward with the information any comments submitted by the practitioner or institution in response to the QIO notice if received before disclosure, or forwarded separately if received after disclosure.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.106 Exceptions to QIO notice requirements.

(a) *Imminent danger to individuals or public health.* When the QIO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in § 480.105 may be sent simultaneously with the disclosure.

(b) *Fraud or Abuse.* The notification requirement in § 480.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

(c) *Other.* The notification requirements in § 480.105(a) and (b)(2) do not apply if:

(1) The institution or practitioner has requested, in writing, that the QIO make the disclosure;

(2) The institution or practitioner has provided, in writing, consent for the disclosure; or

(3) The information is public information as defined in § 480.101(b) and specified under § 480.120.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, 49267, Aug. 11, 2004]

§ 480.107 Limitations on redisclosure.

Persons or organizations that obtain confidential QIO information must not further disclose the information to any other person or organization except—

(a) As directed by the QIO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by CMS to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for CMS to carry out its responsibilities for appeals under section 1155 of the Act or for CMS to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the QIO from another source and the receiver of the information is authorized under its own authorities to acquire the information directly from the source, the receiver may disclose the information in accordance with the source's redisclosure rules;

(f) As necessary for the General Accounting Office to carry out its statutory responsibilities;

(g) Information pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner;

(h) An institution may disclose information pertaining to itself provided it does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by CMS may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§480.108 Penalties for unauthorized disclosure.

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than $1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

§480.109 Applicability of other statutes and regulations.

The provisions of 42 U.S.C. 290dd–3 and 290ee–3 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR part 2, are applicable to QIO information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

QIO Access to Information

§480.111 QIO access to records and information of institutions and practitioners.

(a) A QIO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the QIO area. The QIO may require the institution or practitioner to provide copies of such records or information to the QIO.

(b) A QIO may obtain non-Medicare patient records relating to review performed under a non-Medicare QIO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a QIO may have access to and obtain information from, the records of non-Medicare patients if authorized by the institution or practitioner.

(d) A QIO may reimburse for requested information at the rate of $.10 per page for photocopying plus first class postage. The photocopying amount includes the cost of labor, supplies, equipment, and overhead.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 65 FR 83154, Dec. 29, 2000]

§480.112 QIO access to records and information of intermediaries and carriers.

A QIO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the QIO determines that

the records or information are necessary to carry out QIO review responsibilities.

§ 480.113 QIO access to information collected for QIO purposes.

(a) Institutions and other entities must disclose to the QIO information collected by them for QIO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the QIO.

§ 480.114 Limitation on data collection.

A QIO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

QIO RESPONSIBILITIES

§ 480.115 Requirements for maintaining confidentiality.

(a) *Responsibilities of QIO officers and employees.* The QIO must provide reasonable physical security measures to prevent unauthorized access to QIO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each QIO must instruct its officers and employees and health care institution employees participating in QIO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of QIO information.

(b) *Responsible individuals within the QIO.* The QIO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the QIO review system. That individual must notify CMS of any violations of these regulations.

(c) *Training requirements.* The QIO must train participants of the QIO review system in the proper handling of confidential information.

(d) *Authorized access.* An individual participating in the QIO review system on a routine or ongoing basis must not have authorized access to confidential QIO information unless that individual—

(1) Has completed a training program in the handling of QIO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

(e) *Purging of personal identifiers.* (1) The QIO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by CMS that those identifiers are no longer necessary.

(2) The QIO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the QIO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

(f) *Data system procedures.* The QIO must assure that organizations and consultants providing data services to the QIO have established procedures for maintaining the confidentiality of QIO information in accordance with requirements defined by the QIO and consistent with procedures established under this part.

§ 480.116 Notice to individuals and institutions under review.

The QIO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(a) The title and address of the person responsible for maintenance of QIO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of QIO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

§480.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure specified in §§480.104 and 480.105, the QIO must disclose—

(a) Nonconfidential information to any person upon request, including—

(1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;

(2) Winning technical proposals for contracts from the Department, and winning technical proposals for subcontracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the QIO and institutions or between a QIO and the Medicare intermediary or Medicare carrier;

(4) Routine reports submitted by the QIO to CMS to the extent that they do not contain confidential information.

(5) Summaries of the proceedings of QIO regular and other meetings of the governing body and general membership except for those portions of the summaries involving QIO deliberations, which are confidential information and subject to the provisions of §480.139;

(6) Public information in its possession;

(7) Aggregate statiscal information that does not implicitly or explicitly identify individual patients, practitioners or reviewers;

(8) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§480.121 Optional disclosure of nonconfidential information.

A QIO may, on its own initiative, subject to the notification requirements in §480.105, furnish the information available under §480.120 to any person, agency, or organization.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

DISCLOSURE OF CONFIDENTIAL INFORMATION

§480.130 Disclosure to the Department.

Except as limited by §§480.139(a) and 480.140 of this subpart, QIOs must disclose all information requested by the Department to it in the manner and form required.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§480.131 Access to medical records for the monitoring of QIOs.

CMS or any person, organization or agency authorized by the Department or Federal statute to monitor a QIO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

§480.132 Disclosure of information about patients.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, a QIO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient's representative if—

(i) The patient or the patient's representative requests the information in writing;

(ii) The request by a patient's representative includes the designation, by the patient, of the representative; and

(iii) All other patient and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the QIO provides the requested information. If the attending practitioner states that the released information could harm the patient, the QIO must act in accordance with paragraph (c)(2) of this section. The QIO must make disclosure to the patient or patient's representative within 30 calendar days of receipt of the request.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the QIO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A QIO must disclose information regarding QIO deliberations only as specified in § 480.139(a).

(3) A QIO must disclose quality review study information only as specified in § 480.140.

(c) *Manner of disclosure.* (1) The QIO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the QIO must disclose the information to the patient's designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

The QIO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the QIO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the QIO must make a determination based on other reliable information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.133 Disclosure of information about practitioners, reviewers and institutions.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the QIO.

(1) *Disclosure to the identified individual or institution.* A QIO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) *Disclosure to others.* (i) A QIO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) In accordance with section 1160 of the Act, a QIO must disclose information that displays practice or performance patterns of a practitioner or institution in accordance with the procedures for disclosures specified in §§ 480.137 and 480.138 to—

(A) Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs, and

(B) Federal and State agencies that are responsible for licensing and certification of practitioners and providers.

(iii) A QIO may disclose to any person, agency, or organization information on a particular practitioner or reviewer at the written request of or with the written consent of that practitioner or reviewer. The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or reviewer as provided under this Subpart B.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the QIO must provide only the

information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under §473.24.

(2) A QIO must disclose information regarding QIO deliberations only as specified in §480.139(a).

(3) A QIO must disclose quality review study information only as specified in §480.140.

[50 FR 15359, Apr. 17, 1885, as amended at 52 FR 37458, Oct. 7, 1987; 52 FR 47004, Dec. 11, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, 29267, Aug. 11, 2004]

§480.134 Verification and amendment of QIO information.

(a) A QIO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the QIO.

(b) If the QIO agrees with the request for amendment, the QIO must correct the information in its possession. If the information being amended has already been disclosed, the QIO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the QIO disagrees with the request for amendment, a notation of the request, reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

[50 FR 15358, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§480.135 Disclosure necessary to perform review responsibilities.

(a) *Disclosure to conduct review.* The QIO must disclose or arrange for disclosure of information to individuals and institutions within the QIO review system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) *Disclosure to consultants and subcontractors.* The QIO must disclose to consultants or subcontractors the information they need to provide specified services to the QIO.

(c) *Disclosure to other QIO and medical review boards.* The QIO must disclose—

(1) To another QIO, information on patients and practitioners who are subject to review by the other QIO; and

(2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving or furnishing end stage renal disease services.

§480.136 Disclosure to intermediaries and carriers.

(a) *Required disclosure.* Except as specified in §§480.139(a) and 480.140 relating to disclosure of QIO deliberations and quality review study information, a QIO must disclose to intermediaries and carriers QIO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services, furnished in the manner and form agreed to by the QIO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) QIO information about a particular patient or practitioner if the QIO and the intermediary or carrier (or CMS if the QIO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) *Optional disclosure.* The QIO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§480.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs.

(a) *Required disclosure.* Except as specified in §§480.139(a) and 480.140 relating to disclosure of QIO deliberations and quality review study information, the QIO must disclose confidential information relevant to an investigation of fraud or abuse of the

Medicare or medicaid programs, including QIO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs that—

(1) Identifies the name and title of the individual initiating the request,

(2) Identifies the physician or institution about which information is requested, and

(3) States affirmatively that the institution or practitioner is currently under investigation for fraud or abuse of the Medicare or Medicaid programs and that the information is needed in furtherance of that investigation.

(b) *Optional disclosure.* The QIO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs, without a request.

[50 FR 15358, Apr. 17, 1985, as amended at 52 FR 37458, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.138 Disclosure for other specified purposes.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the QIO.

(1) *Disclosure to licensing and certification bodies.* (i) A QIO must disclose confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including QIO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the QIO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A QIO may provide the information specified in paragraph (a)(1)(i) of this section to the State or Federal licensing body without request.

(2) *Disclosure to State and local public health officials.* A QIO must disclose QIO information to State and local public health officials whenever the QIO determines that the disclosure of the information is necessary to protect against a substantial risk to the public health.

(3) *Disclosure to the courts.* Patient identified records in the possession of a QIO are not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding.

(b) *Exceptions.* (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A QIO must disclose information regarding QIO deliberations and quality review study information only as specified in §§ 480.139(a) and 480.140.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.139 Disclosure of QIO deliberations and decisions.

(a) *QIO deliberations.* (1) A QIO must not disclose its deliberations except to—

(i) CMS, at the QIO office or at a subcontracted organization;

(ii) CMS, to the extent that the deliberations are incorporated in sanction and appeals reports; or

(iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) QIO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim.

(b) *Reasons for QIO decisions.* (1) A QIO may disclose to those who have access to QIO information under other provisions of this subpart, the reasons

for QIO decisions pertaining to that information provided that the opinions or judgements of a particular individual or practitioner cannot be identified.

(2) A QIO must disclose, if requested in connection with the administrative hearing or review of a beneficiary's claim, the reasons for QIO decisions. The QIO must include the detailed facts, findings and conclusions supporting the QIO's determination. The QIO must insure that the opinions or judgements of a particular individual or practitioner cannot be identified through the materials that are disclosed.

§480.140 Disclosure of quality review study information.

(a) A QIO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; CMS; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

(b) A QIO must disclose quality review study information with identifiers of patients, practitioners or institutions to the Office of the Inspector General and the General Accounting Office as necessary to carry out statutory responsibilities.

(c) A QIO may disclose information offsite from a particular quality review study to any institution or practitioner involved in that study, provided the disclosed information is limited to that institution or practitioner.

(d) A QIO may disclose quality review study information with identifiers of particular practitioners or institutions, or both, at the written request of, or with the written consent of, the identified practitioner(s) or institution(s).

(1) The consent or request must specify the information that is to be disclosed and the intended recipient of the information.

(2) The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or institution as provided under this Subpart B.

(e) An institution or group of practitioners may redisclose quality review study information, if the information is limited to health care services they provided.

(f) Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding. This restriction does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(g) The QIO must disclose to CMS quality review study information collected as part of the Reporting Hospital Quality Data for Annual Payment Update program, under section 1886(b)(3)(B)(viii) of the Act following hospital review of the data. The quality review study information must include identifiers of MA plan beneficiaries, hospitals, practitioners, and services when CMS requests this information for the sole purpose of conducting activities related to MA organizations as described in §422.153 of this chapter.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, Aug. 11, 2004; 75 FR 19826, Apr. 15, 2010]

§480.141 Disclosure of QIO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified

in §§ 480.104 and 480.105, a QIO may disclose to the public QIO interpretations and generalizations on the quality of health care that identify a particular institution.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.142 Disclosure of sanction reports.

(a) The QIO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to CMS.

(b) The QIO must upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with § 480.137.

(c) CMS will disclose sanction determinations in accordance with part 474 of this chapter.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.143 QIO involvement in shared health data systems.

(a) *Information collected by a QIO.* Except as prohibited in paragraph (b) of this section, information collected by a QIO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) *QIO participation.* A QIO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the QIO from complying with the rules of this part.

(c) *Disclosure of QIO information obtained by a shared health data system.* QIO information must not be disclosed by the shared health data system unless—

(1) The source from which the QIO acquired the information consents to or requests disclosure; or

(2) The QIO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.

PART 481 [RESERVED]

FINDING AIDS

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Table of OMB Control Numbers

The OMB control numbers for chapter IV of title 42 appear in § 400.310. Sections 400.300 and 400.310 are reprinted below for the convenience of the user.

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless therwise noted.

§ 400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in CMS regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. CMS intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35 which requires that agencies shall not engage in a ''collection of information'' without obtaining a control number from OMB.

§ 400.310 Display of currently valid OMB control numbers.

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411.54	0938—0558
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489.20	0938—0564 and 0938—0667
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[60 FR 50445, Sept. 29, 1995, as amended at 60 FR 63188, Dec. 8, 1995]

List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations that were made by documents published in the FEDERAL REGISTER since January 1, 2001, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

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431.51 (a) introductory text, (b)(1) introductory text and (2) amended; (a)(4) and (5) revised; (a)(6) added 6403
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431.200 Revised 6403
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431.201 Amended 6403
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431.220 (a) introductory text revised; (a)(1), (2) and (3) amended; (a)(5) added 6403
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431.636 Added 2666
Regulation at 66 FR 2666 eff. date delayed 11547, 31178
431.865 (b) amended 2666
Regulation at 66 FR 2666 eff. date delayed 11547, 31178
433 Authority citation revised 2666
433.10 (c)(4) added 2666
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433.11 Added 2666
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434.1 (a) revised 6403
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434.6 (a)(1) amended 6403
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434.50—434.67 (Subpart E) Removed 6403
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434.71 Removed 6404
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434.75 Removed 6404
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441 Clarification 28116
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447.46 Added 6426
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447.53 (b) introductory text amended; (b)(6) removed; (e) added 6426
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447.60 Added 6426
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447.304 (c) and note revised 3176
447.321 Revised 3176
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447.361 Removed 6426
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457.1—457.170 (Subpart A) Added 2670
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457.505 Regulation at 66 FR 2681 delayed; (d)(1), (3) and (e) revised; interim 33824
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457.560 Regulation at 66 FR 2682 delayed; (a) and (b) removed; amended 33824
457.624 Removed 2683
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457.700—457.750 (Subpart G) Added 2683

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457.750 Regulation at 66 FR 2684 delayed; (b)(7) removed; new (b)(8) redesignated as new (b)(7); interim 33824
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457.940 Regulation at 66 FR 2685 delayed; (b)(1) and (d) amended; interim 33824
457.980 Regulation at 66 FR 2686 delayed; (a) and (b) designation removed; interim 33824
457.1000—457.1015 (Subpart J) Added 2683
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457.1005 Regulation at 66 FR 2687 delayed; heading amended; interim 33824
457.1010 Regulation at 66 FR 2687 delayed; heading amended; interim 33824
457.1100—457.1190 (Subpart K) Added 2683
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457.1120 Regulation at 66 FR 2687 delayed; revised; interim 33824
457.1130 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1140 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1150 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1160 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1170 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1180 Regulation at 66 FR 2688 delayed; amended; interim 33824
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434.42 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
434.44 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
434.50—434.67 (Subpart E) Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
434.70 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
Revised 41095
434.71 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
434.72 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 41095
Removed 41095
434.73 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
434.74 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
434.75 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
434.80 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
435 Technical correction 42609
435.212 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Amended 41095
435.326 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Revised 41095
435.1002 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
(a) amended 41095
438 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988

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Added 41095
Technical correction 42609
438.8 Corrected 65505
438.10 Corrected 65505
438.52 Corrected 65505
438.100 Corrected 65505
438.102 Corrected 65505
438.114 Corrected 65505
438.116 Corrected 65505
438.214 Corrected 54532
438.703 Corrected 65505
438.810 Corrected 65505
440 Technical correction 42609
440.168 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Added 41115
447 Technical correction 42609
447.46 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Added 41115
447.53 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
(b) introductory text amended; (b)(6) removed; (e) added 41116
447.58 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Amended 41116
447.60 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Added 41116
447.272 (b), (d), (e)(1)(ii) and (f) revised; (c)(1) removed; (c)(2), (3), (e)(2)(ii)(C)(*8*) and (iii) redesignated as (c)(1), (2), (e)(2)(iii) and (iv); (e)(2)(v) added 2610
Regulation at 67 FR 2610 eff. date delayed to 4–15–02 12479
447.321 (b) through (d), (e)(1)(ii) and (f) revised; (e)(2)(ii)(C)(*8*) and (iii) redesignated as (e)(2)(iii) and (iv); (e)(2)(v) added 2611
Regulation at 67 FR 2611 eff. date delayed to 4–15–02 12479
447.361 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Removed 41116
457.10 Amended 61974
457.350 (b) text redesignated as (b)(1); (b)(2) added 61974

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457.622 (c)(5) revised 61974
457.626 (a)(3) added 61974
460 Nomenclature change; eff. 10–31–02 61504
460.10—460.24 (Subpart B) Heading revised; eff. 10–31–02 61504
460.10 Revised; eff. 10–31–02 61504
460.12 (a)(2) removed; eff. 10–31–02 61505
460.26 Added; eff. 10–31–02 61505
Corrected 63966
460.28 Added; eff. 10–31–02 61505
460.30 (b) revised; (c) added; eff. 10–31–02 61505
460.60 (b) and (c) revised; eff. 10–31–02 61505
460.68 (b) revised; (c) removed; eff. 10–31–02 61505
460.70 (b)(1)(i) and (e)(2) revised; (e)(5)(vi) through (ix) and (f) added; eff. 10–31–02 61505
460.71 Added; eff. 10–31–02 61505
460.102 (d)(2)(iii) revised; (d)(3) amended; (f) and (g) removed; eff. 10–31–02 61506
476.71 (c)(2) revised 56056

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433.15 (b)(10) added 3635
438.310—438.370 (Subpart E) Added 3635
440 Technical correction 55882, 58756
440.40 (a)(1)(ii)(A) revised 46071
440.155 (c) introductory text revised 46071
447.500—447.550 (Subpart I) Added 51917
Regulation at 68 FR 51912 eff. date corrected 55527
460.72 (b)(1) revised; (b)(3) added 1386
476.78 (b) introductory text, (2), (c) introductory text and (d) revised; (c)(4) added 67960

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Title 42 Nomenclature change 18803
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440.110 (c)(2) revised; (c)(3) added 30587

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447.534 (h)(1) revised; interim 513
(h)(1)(i) revised; (h)(2) and (ii) at end of the section removed 68818
460 Application deadline 69536
460.72 (b)(1) and (3) revised; (b)(4) added 49266
480 Heading revised 49266
Application deadline 69536
480.101 (b) amended 49267
480.104 (a)(1), (2) and (d) amended 49267
480.105 (a), (b)(1) and (2) amended 49267
480.106 (c) added 49266
(a) and (b) amended 49267
480.120 Introductory text and (a)(5) amended 49267
480.121 Amended 49267
480.130 Amended 49267
480.132 (b)(2) and (3) amended 49267
480.133 (a)(2)(iii) revised 49266
(a)(2)(ii), (b)(2) and (3) amended 49267
480.136 (a) introductory text amended 49267
480.137 (a) introductory text amended 49267
480.138 (b)(2) amended 49267
480.140 (d) and (e) redesignated as (e) and (f); new (d) added 49266
480.141 Amended 49267
480.142 (b) amended 49267

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431.950—431.1002 (Subpart Q) Added; interim 58276
433.10 (c)(5) added; interim 50220
457.720 Revised; interim 58276
460.72 (b)(5) added; interim 15238

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Chapter IV
431.950—431.1002 (Subpart Q) Revised; interim 51081
433.10 (c)(5) revised; interim 25092
Regulation at 71 FR 25092 confirmed 60670
435.403 (b) amended; interim 39222

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435.406 (a)(1) and (2) revised; (a)(3), (4), (b) and (d) removed; (c) redesignated as new (b); interim 39222
435.407 Added; interim 39222
435.408 Removed; interim 39225
435.1002 (a) revised; interim 39225
435.1008 Redesignated as 435.1009; (a)(1) amended; new 435.1008 added; interim 39225
435.1009 Redesignated as 435.1010; redesignated from 435.1008; interim 39225
435.1010 Redesignated as 435.1011; redesignated from 435.1009; interim 39225
435.1011 Redesignated as 435.1012; redesignated from 435.1010; interim 39225
435.1012 Redesignated from 435.1011; interim 39225
436.403 (b) amended; interim 39225
436.406 (a)(1) and (2) revised; (a)(3), (4), (b) and (d) removed; (c) redesignated as new (b); interim 39225
436.407 Added; interim 39226
436.408 Removed; interim 39229
436.1004 Redesignated as 436.1005; (a)(1) amended; new 436.1004 added; interim 39229
436.1005 Redesignated as 436.1006 and amended; redesignated from 436.1004; interim 39229
436.1006 Redesignated from 436.1005; interim 39229
440.2 (a) amended; interim 39229
440.140 (b) amended; interim 39229
440.180 (d)(2)(i) amended; interim 39229
440.185 (b) amended; interim 39229
441.13 (c) amended 31046
(a)(1) amended; interim 39229
457.310 (c)(2)(i) and (ii) amended; interim 39229
457.720 Revised; interim 51084
460 (Subchapter E) Regulation at 64 FR 66279 confirmed 71334
460 Regulation at 67 FR 61504 confirmed 71334
460 Authority citation revised 71334
460.6 Amended 71334
460.10—460.24 (Subpart B) Regulation at 67 FR 61504 confirmed 71334

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460.10 Regulation at 67 FR 61504 confirmed 71334
460.12 Regulation at 67 FR 61505 confirmed; (a)(3) redesignated as (a)(2); new (a)(2)(i) and (ii) amended 71334
460.14 Removed 71334
460.16 Removed 71334
460.26 Regulation at 67 FR 61505 confirmed; (a) redesignated as (a)(1); (a)(2) added; (b) introductory text and (1) revised 71334
460.28 Regulation at 67 FR 61505 confirmed; (a)(2) revised 71334
460.30 Regulation at 67 FR 61505 confirmed 71334
460.32 (a)(12) revised 71334
460.60 Regulation at 67 FR 61505 confirmed; (d)(3) revised; (d)(4) and (5) removed 71334
460.62 (b) and (c) revised 71334
460.64 Revised 71334
460.66 (c) added 71335
460.68 Regulation at 67 FR 61505 confirmed; (d) redesignated as (c); (b) and new (c) heading revised 71335
460.70 Regulation at 67 FR 61505 confirmed 71334
(d) removed; (e) and (f) redesignated as (d) and (e) 71335
460.71 Regulation at 67 FR 61505 confirmed 71334
(b)(4) revised 71335
460.72 (b)(5)(iii) revised; (b)(5)(iv) amended; (b)(5)(v) added; eff. 10–23–06 55340
(b)(1), (2)(ii) and (4) amended 71334
(a)(3) revised 71335
460.74 (c)(1) amended 71334
460.78 (a)(1) introductory text revised 71335
460.92 Revised 71335
460.94 (b)(5) revised 71335
460.96 (e)(1) revised 71335
460.98 (d) heading, (3) and (e) heading amended 71334
(b)(3) revised 71335
460.100 (d) revised; (e)(3) added 71335
460.102 Regulation at 67 FR 61506 confirmed; (a)(1) amended 71334
(b)(3) revised 71336
460.104 (c)(3), (d) and (e) redesignated as (d), (e) and (f); (a)(2), (c)(1)(iii), (2) and new (d) revised 71336

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460.112 (a) introductory text and (b)(1)(iii) revised 71336
460.122 Introductory text and (f)(1) revised 71336
460.152 (a)(1)(vi) added 71337
460.154 (h) and (t) revised 71337
460.160 (b)(3) revised 71337
460.180 (a) and (b)(1) through (4) revised 71337
460.210 (b)(13) removed 71337
462—480 (Subchapter F) Regulation at 64 FR 66279 confirmed 71334
462 Regulation at 64 FR 66279 confirmed 71334
466 Regulation at 64 FR 66279 confirmed 71334
473 Regulation at 64 FR 66279 confirmed 71334
475 Regulation at 64 FR 66279 confirmed 71334
476 Regulation at 64 FR 66279 confirmed 71334
478 Regulation at 64 FR 66279 confirmed 71334
480 Regulation at 64 FR 66279 confirmed 71334

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431.51 (c)(2) and (3) amended; (c)(4) added; interim 68091
431.53 Revised 73650
431.54 (a) revised; (g) added; interim 68091
431.812 (b) revised 50513
431.970 (a)(1) revised 50513
431.978 (d)(2) revised 50513
433.20 Added 73650
433.50 (a)(1) revised 29832
433.51 Revised 29833
435.117 Revised 38690
435.403 Regulation at 71 FR 39222 confirmed 38690
435.406 Regulation at 71 FR 39222 confirmed 38690
(a)(1)(iii), (2) and (b) revised; (a)(1)(v) added 38691
435.407 Regulation at 71 FR 39222 confirmed 38690

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(a)(5) and (e)(2) through (9) removed; (e)(10) and (g) through (j) redesignated as new (e)(2) and (h) through (k); introductory text, (b)(11), (12), new (e)(3) and (g) added; (a)(4) amended; (b)(1), (5), (c), (d) introductory text, (2), (3), (4), (5)(vi), (e)(1), (f) and new (i) revised 38691
435.408 Regulation at 71 FR 39225 confirmed 38690
435.1002 Regulation at 71 FR 39225 confirmed 38690
435.1008 Regulation at 71 FR 39225 confirmed 38690
Revised 38694
435.1009 Regulation at 71 FR 39225 confirmed 38690
435.1010 Regulation at 71 FR 39225 confirmed 38690
435.1011 Regulation at 71 FR 39225 confirmed 38690
435.1012 Regulation at 71 FR 39225 confirmed 38690
436.124 Revised 38694
436.403 Regulation at 71 FR 39225 confirmed 38690
436.406 Regulation at 71 FR 39225 confirmed 38690
(a)(1)(iii), (2) and (b) revised; (a)(1)(v) added 38694
436.407 Regulation at 71 FR 39226 confirmed 38690
(e)(2) through (9) removed; (e)(10) and (g) through (j) redesignated as new (e)(2) and (h) through (k); introductory text, (b)(11), (12), new (e)(3) and (g) added; (a)(4), (b)(1), (5), (c), (d) introductory text, (2), (3), (4), (5)(vi), (e)(1), (f) and new (i) revised 38695
436.408 Regulation at 71 FR 39229 confirmed 38690
436.1004 Regulation at 71 FR 39229 confirmed 38690
Revised 38697
436.1005 Regulation at 71 FR 39229 confirmed 38690
436.1006 Regulation at 71 FR 39229 confirmed 38690
440.2 Regulation at 71 FR 39229 confirmed 38690
440.140 Regulation at 71 FR 39229 confirmed 38690
440.169 Added; interim 68091
440.170 (a)(1) revised 73651

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440.180 Regulation at 71 FR 39229 confirmed 38690
440.185 Regulation at 71 FR 39229 confirmed 38690
440.250 (r) added; interim 68092
441.10 (m) added; interim 68092
441.13 Regulation at 71 FR 39229 confirmed 38690
441.18 Added; interim 68092
447.206 Added 29833
447.207 Added 29834
447.271 Revised 29834
447.272 (a) through (d) revised 29834
447.300 Revised 39239
447.301 Removed 39239
447.321 (a) through (d) revised 29835
447.331 Removed 39239
447.332 Removed 39239
447.333 Removed 39239
447.334 Removed 39239
447.500—447.520 (Subpart I) Revised 39239
455.1 (c) added 67655
455.200—455.202 (Subpart C) Added 67655
457.220 Revised 29835
457.310 Regulation at 71 FR 39229 confirmed 38690
457.628 (a) revised 29836

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433.10 (c)(5)(ii), (iii) introductory text, (D) and (v) revised; (c)(5)(iii)(E) added; interim 70893
433.54 (c) revised 9698
433.56 (a)(4) and (8) revised 9698
433.57 (a) removed; (b) and (c) redesignated as new (a) and (b) 9698
433.58 Removed 9698
433.60 Removed 9698
433.66 Heading and (a) revised 9698
433.67 (a)(2) revised 9698
433.68 Heading, (a), (f)(1), (2), (3) introductory text and (i) revised; (f)(3)(ii) revised 9698
433.70 Heading revised; (a)(1) removed; (a)(2) designation removed 9699
440.1 Amended 77530
440.20 Heading and (a) revised 66198
440.170 (a)(2) revised; (a)(4) added 77530
440.300—440.390 (Subpart C) Added 73724

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441.450—441.484 (Subpart J) Added 57881
447.54 Heading, (a) introductory text, (1) and (3) revised; introductory text and (a)(4) added (eff. date pending) 71851
447.55 (b) revised (eff. date pending) 71851
447.60 Undesignated center heading and section added (eff. date pending) 71851
447.62 Added (eff. date pending) 71851
447.64 Added (eff. date pending) 71851
447.66 Added (eff. date pending) 71851
447.68 Added (eff. date pending) 71851
447.71 Added (eff. date pending) 71851
447.72 Added (eff. date pending) 71851
447.74 Added (eff. date pending) 71851
447.76 Added (eff. date pending) 71851
447.78 Added (eff. date pending) 71851
447.80 Added (eff. date pending) 71851
447.82 Added (eff. date pending) 71851
447.299 (c) and (d) redesignated as (d) and (e); new (c) added 77950
447.502 Amended; interim 13788
Regulation at 73 FR 13788 confirmed; amended 58497
455.200 Revised; eff. 10–27–08 55771
455.230 Added; eff. 10–27–08 55771
455.232 Added; eff. 10–27–08 55771
455.234 Added; eff. 10–27–08 55771
455.236 Added; eff. 10–27–08 55771
455.238 Added; eff. 10–27–08 55771
455.240 Added; eff. 10–27–08 55771
455.300—455.304 (Subpart D) Added 77951
457.555 (a) introductory text, (1), (2), (4), (c) and (d) revised 71854

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431.53 Revised 31195
433.20 Removed 31195

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433.54 Regulation at 73 FR 9698 enforcement delayed to 6–30–10 31196
433.68 Regulation at 73 FR 9698 enforcement delayed in part to 6–30–10 31196
440.20 Heading and (a) revised 31195
440.169 (c) removed 31196
440.170 (a)(1) revised 31196
440.300—440.390 (Subpart C) Regulation at 73 FR 73724 eff. date delayed 5808, 62501
Regulation at 73 FR 73724 eff. date delayed to 12–31–2009 15221
441.18 (a)(5), (8)(vi) and (viii) removed; (c) revised 31196
447.54 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.55 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.60 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
447.62 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.64 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.66 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.68 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501

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447.71 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.72 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.74 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.76 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.78 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.80 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.82 Regulation at 73 FR 71851 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71851 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501
447.299 (c)(16) correctly revised 18657
457.555 Regulation at 73 FR 71854 eff. date delayed to 3–27–09 4888
Regulation at 73 FR 71854 eff. date delayed to 12–31–09 13346
Regulation at 73 FR 71851 eff. date delayed 62501

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431 Nomenclature change 48852

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431.107 (b)(5) added; interim 24449
431.636 Heading amended 48847
431.806 (b) redesignated as (c); new (b) added 48847
431.812 (a)(2)(i) and (ii) amended; (a)(2)(iv) and (f) added 48847
431.814 (c)(4) revised 48847
431.950 Amended 48847
431.954 (a) revised 48847
431.958 Amended 48847
431.960 Added 48848
431.970 (a)(1) and (b) revised 48848
431.972 Added 48849
431.978 (a), (b), (c), (d)(1)(i), (ii), (3) and (4) revised 48849
431.980 (d) revised; (f) added 48850
431.988 (a), (b)(1) and (2) revised; (b)(3) and (4) redesignated as (b)(4) and (5); new (b)(3) added 48851
431.992 Revised 48851
431.998 Heading, (a) and (b) revised; (c) redesignated as (d); new (c) added 48851
440 Technical correction 60640
440.160 (b)(1) revised 50418
440.300—440.390 (Subpart C) Revised 23101
441 Technical correction 60640
441.151 (a)(2)(i) revised 50419
447.50 (b) added 30261
(b)(2) correctly added 38749
447.51 (a) and (c) introductory text revised 30261

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447.53 (b)(4) revised; (b)(6) added 30261
447.54 (a)(1), (3)(ii), (4) and (b) revised 30262
447.55 (b) revised 30262
447.57 (c) added 30262
447.62 Revised 30262
447.64 (a), (c) and (d) revised 30262
447.66 (a)(7) and (c) added 30262
447.68 (b), (c), (d) and (f) revised 30263
447.70 Revised 30263
447.71 (b)(1), (3) and (c) revised; (d) added 30264
447.72 (b) and (c) revised 30264
447.74 Revised 30264
(b) correctly revised 38749
447.76 (b)(1) revised; (c) added 30264
447.78 Revised 30264
447.80 (a)(3), (b) introductory text and (2) revised; (c) added 30265
447.82 Revised 30265
447.504 (g)(15) and (h)(23) amended 48852
457 Nomenclature change 48852
457.10 Amended 48852
457.301 Amended 48852
457.555 (a)(1)(i) and (2) revised 30265
457.606 (b) amended 48852
457.614 (b)(1) amended 48852
457.618 Heading amended 48852
457.622 (e)(5) amended 48852
457.630 (b) and (c)(1) amended 48852
480.140 (g) added 19826