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Title 42
Public Health

Parts 430 to 481

Revised as of October 1, 2022

Containing a codification of documents
of general applicability and future effect

As of October 1, 2022

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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 17 through Title 27.....as of April 1
Title 28 through Title 41.....as of July 1
Title 42 through Title 50.....as of October 1

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OLIVER A. POTTS,
Director,
Office of the Federal Register
October 1, 2022

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 430–481, 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 430–481) 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, 2022.

For this volume, Cheryl E. Sirofchuck was Chief Editor. The Code of Federal Regulations publication program is under the direction of John Hyrum Martinez, assisted by Stephen J. Frattini.

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; 69 FR 18803, Apr. 9, 2004; and 77 FR 29028, July 16, 2012.

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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 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

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; 81 FR 3011, Jan. 20, 2016]

§ 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 a standardized template, issued and updated by CMS, that includes both basic requirements and individualized content that reflects the characteristics of the State's program. The Secretary will periodically update the template and format specifications for State plans and plan amendments through a process consistent with the requirements of the Paperwork Reduction Act.

(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; 81 FR 86447, Nov. 30, 2016]

§ 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 beneficiaries. 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 beneficiaries 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 beneficiaries to choose among competing health care plans.

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

(iv) Limit beneficiaries' 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 beneficiaries who would otherwise need inpatient care that is furnished in a hospital, SNF, ICF, or ICF/IID, 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 beneficiaries 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 beneficiaries 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 beneficiaries 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) of the Act.* (A) The initial waiver is for a period of 3 years and may be renewed thereafter for periods of 5 years.

(B) For waivers that include individuals who are dually eligible for Medicare and Medicaid, 5-year initial approval periods may be granted at the discretion of the Secretary for waivers meeting all necessary programmatic, financial and quality requirements, and in a manner consistent with the interests of beneficiaries and the objectives of the Medicaid program.

(ii) *Waivers under section 1915(b) of the Act.* (A) The initial waiver is for a period of 2 years and may be renewed for additional periods of up to 2 years as determined by the Administrator.

(B) For waivers that include individuals who are dually eligible for Medicare and Medicaid, 5-year initial and renewal approval periods may be granted at the discretion of the Secretary for waivers meeting all necessary programmatic, financial and quality requirements, and in a manner consistent with the interests of beneficiaries and the objectives of the Medicaid program.

(iii) *Waivers under section 1916 of the Act.* The initial waiver is for a period of 2 years and may be renewed for additional periods of up to 2 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, as amended at 79 FR 3028, Jan. 16, 2014]

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–37 (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 75, which establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

(1) Cost sharing or matching, 45 CFR 75.306; and

(2) Financial reporting, 45 CFR 75.341.

[53 FR 36571, Sept. 21, 1988, as amended at 77 FR 31507, May 29, 2012; 81 FR 3011, Jan. 20, 2016]

§ 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 Administrator or the Departmental 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; 77 FR 31507, May 29, 2012]

§ 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 Administrator or current Designee questions its allowability and needs additional information 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 current Designee 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 current Designee 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 current Designee disallows the claim.

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

(6) If the current Designee 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 Administrator or current Designee 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.

[53 FR 36571, Sept. 21, 1988, as amended at 77 FR 31507, May 29, 2012]

§ 430.42 Disallowance of claims for FFP.

(a) *Notice of disallowance and of right to reconsideration.* When the Administrator or current Designee 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) or (f)(2) of this section.

(b) *Reconsideration of a disallowance.* (1) The Administrator will reconsider Medicaid disallowance determinations.

(2) To request reconsideration of a disallowance, a State must complete the following:

(i) Submit the following within 60 days after receipt of the disallowance letter:

(A) A written request to the Administrator that includes the following:

(*1*) A copy of the disallowance letter.

(*2*) A statement of the amount in dispute.

(*3*) A brief statement of why the disallowance should be reversed or revised, including any information to support the State's position with respect to each issue.

(*4*) Additional information regarding factual matters or policy considerations.

(B) A copy of the written request to the Regional Office.

(C) Send all requests for reconsideration via registered or certified mail to establish the date the reconsideration was received by CMS.

(ii) In all cases, the State has the burden of documenting the allowability of its claims for FFP.

(iii) Additional information regarding the legal authority for the disallowance will not be reviewed in the reconsideration but may be presented in any appeal to the Departmental Appeals Board under paragraph (f)(2) of this section.

(3) A State may request to retain the FFP during the reconsideration of the disallowance under section 1116(e) of the Act, in accordance with § 433.38 of this subchapter.

(4) The State is not required to request reconsideration before seeking review from the Departmental Appeals Board.

(5) The State may also seek reconsideration, and following the reconsideration decision, request a review from the Board.

(6) If the State elects reconsideration, the reconsideration process must be completed or withdrawn before requesting review by the Board.

(c) *Procedures for reconsideration of a disallowance.* (1) Within 60 days after receipt of the disallowance letter, the State shall, in accordance with (b)(2) of this section, submit in writing to the Administrator any relevant evidence, documentation, or explanation and shall simultaneously submit a copy thereof to the Regional Office.

(2) After consideration of the policies and factual matters pertinent to the issues in question, the Administrator shall, within 60 days from the date of receipt of the request for reconsideration, issue a written decision or a request for additional information as described in paragraph (c)(3) of this section.

(3) At the Administrator's option, CMS may request from the State any additional information or documents necessary to make a decision. The request for additional information must be sent via registered or certified mail to establish the date the request was sent by CMS and received by the State.

(4) Within 30 days after receipt of the request for additional information, the State must submit to the Administrator, with a copy to the Regional Office in readily reviewable form, all requested documents and materials.

(i) If the Administrator finds that the materials are not in readily reviewable form or that additional information is needed, he or she shall notify the State via registered or certified mail that it has 15 business days from the date of receipt of the notice to submit the readily reviewable or additional materials.

(ii) If the State does not provide the necessary materials within 15 business days from the date of receipt of such notice, the Administrator shall affirm the disallowance in a final reconsideration decision issued within 15 days from the due date of additional information from the State.

(5) If additional documentation is provided in readily reviewable form under the paragraph (c)(4) of this section, the Administrator shall issue a written decision, within 60 days from the due date of such information.

(6) The final written decision shall constitute final CMS administrative action on the reconsideration and shall be (within 15 business days of the decision) mailed to the State agency via registered or certified mail to establish the date the reconsideration decision was received by the State.

(7) If the Administrator does not issue a decision within 60 days from the date of receipt of the request for reconsideration or the date of receipt of the requested additional information, the disallowance shall be deemed to be affirmed upon reconsideration.

(8) No section of this regulation shall be interpreted as waiving the Department's right to assert any provision or exemption under the Freedom of Information Act.

(d) *Withdrawal of a request for reconsideration of a disallowance.* (1) A State may withdraw the request for reconsideration at any time before the notice of the reconsideration decision is received by the State without affecting its right to submit a notice of appeal to the Board. The request for withdrawal must be in writing and sent to the Administrator, with a copy to the Regional Office, via registered or certified mail.

(2) Within 60 days after CMS' receipt of a State's withdrawal request, a State may, in accordance with (f)(2) of this section, submit a notice of appeal to the Board.

(e) *Implementation of decisions for reconsideration of a disallowance.* (1) After

undertaking a reconsideration, the Administrator may affirm, reverse, or revise the disallowance and shall issue a final written reconsideration decision to the State in accordance with paragraph (c)(4) of this section.

(2) If the reconsideration decision requires an adjustment of FFP, either upward or downward, a subsequent grant award will be issued in the amount of such increase or decrease.

(3) Within 60 days after the receipt of a reconsideration decision from CMS a State may, in accordance with paragraph (f)(2) of this section, submit a notice of appeal to the Board.

(f) *Appeal of Disallowance.* (1) The Departmental Appeals Board reviews disallowances of FFP under title XIX.

(2) A State that wishes to appeal a disallowance to the Board must:

(i) Submit a notice of appeal to the Board at the address given on the Departmental Appeals Board's web site within 60 days after receipt of the disallowance letter.

(A) If a reconsideration of a disallowance was requested, within 60 days after receipt of the reconsideration decision; or

(B) If reconsideration of a disallowance was requested and no written decision was issued, within 60 days from the date the decision on reconsideration of the disallowance was due to be issued by CMS.

(ii) Include all of the following:

(A) A copy of the disallowance letter.

(B) A statement of the amount in dispute.

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

(3) The Board's decision of an appeal under paragraph (f)(2) of this section shall be the final decision of the Secretary and shall be subject to reconsideration by the Board only upon a motion by either party that alleges a clear error of fact or law and is filed during the 60-day period that begins on the date of the Board's decision or to judicial review in accordance with paragraph (f)(2)(i) of this section.

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

(1) In all cases, the State has the burden of documenting the allowability of its claims for FFP.

(2) The Board shall conduct a thorough review of the issues, taking into account all relevant evidence, including such documentation as the State may submit and the Board may require.

(h) *Implementation of decisions.* (1) The Board may affirm the disallowance, reverse the disallowance, modify the disallowance, or remand the disallowance to CMS for further consideration.

(2) The Board will issue a final written decision to the State consistent with 45 CFR part 16.

(3) If the appeal decision requires an adjustment of FFP, either upward or downward, a subsequent grant award will be issued in the amount of increase or decrease.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8846, Mar. 1, 1991; 77 FR 31507, May 29, 2012]

§ 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 all of the following conditions are met:

(1) The amount to be repaid exceeds 0.25 percent of the estimated or actual

annual State share for the Medicaid program.

(2) The State has given the Regional Office 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 0.25 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 for the current year, as shown on the State's latest Medicaid Program Budget Report (CMS–37). The current year is the year in which the State requests the repayment by installments.

(2) If the Medicaid program has been terminated by Federal law or by the State, CMS uses the actual State share that is shown on the State's CMS–64 Quarterly Expense Report for the last four quarters filed.

(c) *Standard 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 maximum number of quarters allowed for the standard repayment schedule is 12 quarters (3 years), except as provided in paragraphs (c)(4) and (e) of this section.

(3) *Quarterly repayment amounts.* (i) The quarterly repayment amounts for each of the quarters in the repayment schedule will be the larger of the repayment amount divided by 12 quarters or the minimum repayment amount;

(ii) The minimum quarterly repayment amounts for each of the quarters in the repayment schedule is 0.25 percent of the estimated State share of the current annual expenditures for Medicaid;

(iii) The repayment period may be less than 12 quarters when the minimum repayment amount is required.

(4) *Extended schedule.* (i) The repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100 percent of the estimated State share of the current annual expenditures;

(ii) The quarterly repayment amount will be 8⅓ percent of the estimated State share of the current annual expenditures until fully repaid.

(5) *Repayment process.* (i) Repayment is accomplished through deposits into the State's Payment Management System (PMS) account;

(ii) A State may choose to make payment by Automated Clearing House (ACH) direct deposit, by check, or by Fedwire transfer.

(6) *Reductions.* 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.

(d) *Alternate repayment amounts, schedules, and procedures for States experiencing economic distress immediately prior to the repayment period*—(1) *Repayment amount.* The repayment amount may not include amounts previously approved for installment repayment if a State initially qualifies for the alternate repayment schedule at the onset of an installment repayment period.

(2) *Qualifying period of economic distress.* (i) A State will qualify to avail itself of the alternate repayment schedule if it demonstrates the State is experiencing a period of economic distress;

(ii) A period of economic distress is one in which the State demonstrates distress for at least each of the previous 6 months, ending the month prior to the date of the State's written request for an alternate repayment schedule, as determined by a negative percent change in the monthly Philadelphia Federal Reserve Bank State coincident index.

(3) *Repayment schedule.* The maximum number of quarters allowed for the alternate repayment schedule is 12 quarters (3 years), except as provided in paragraph (d)(5) of this section.

(4) *Quarterly repayment amounts.* (i) The quarterly repayment amounts for each of the first 8 quarters in the repayment schedule will be the smaller of the repayment amount divided by 12 quarters or the maximum quarterly repayment amount;

(ii) The maximum quarterly repayment amounts for each of the first 8 quarters in the repayment schedule is

0.25 percent of the annual State share determination as defined in paragraph (b) of this section;

(iii) For the remaining 4 quarters, the quarterly repayment amount equals the remaining balance of the overpayment amount divided by the remaining 4 quarters.

(5) *Extended schedule.* (i) For a State that initiated its repayment under an alternate payment schedule for economic distress, the repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100 percent of the estimated State share of current annual expenditures;

(A) In these circumstances, paragraph (d)(3) of this section is followed for repayment of the amount equal to 100 percent of the estimated State share of current annual expenditures.

(B) The remaining amount of the repayment is in quarterly amounts equal to 8⅓ percent of the estimated State share of current annual expenditures until fully repaid.

(ii) Upon request by the State, the repayment schedule may be extended beyond 12 quarterly installments if the State has qualifying periods of economic distress in accordance with paragraph (d)(2) of this section during the first 8 quarters of the alternate repayment schedule.

(A) To qualify for additional quarters, the States must demonstrate a period of economic distress in accordance with paragraph (d)(2) of this section for at least 1 month of a quarter during the first 8 quarters of the alternate repayment schedule.

(B) For each quarter (of the first 8 quarters of the alternate payment schedule) identified as qualified period of economic distress, one quarter will be added to the remaining 4 quarters of the original 12 quarter repayment period.

(C) The total number of quarters in the alternate repayment schedule shall not exceed 20 quarters.

(6) *Repayment process.* (i) Repayment is accomplished through deposits into the State's Payment Management System (PMS) account;

(ii) A State may choose to make payment by Automated Clearing House (ACH) direct deposit, by check, or by Fedwire transfer.

(7) 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.

(e) *Alternate repayment amounts, schedules, and procedures for States entering into distress during a standard repayment schedule*—(1) *Repayment amount.* The repayment amount may include amounts previously approved for installment repayment if a State enters into a qualifying period of economic distress during an installment repayment period.

(2) *Qualifying period of economic distress.* (i) A State will qualify to avail itself of the alternate repayment schedule if it demonstrates the State is experiencing economic distress;

(ii) A period of economic distress is one in which the State demonstrates distress for each of the previous 6 months, that begins on the date of the State's request for an alternate repayment schedule, as determined by a negative percent change in the monthly Philadelphia Federal Reserve Bank State coincident index.

(3) *Repayment schedule.* The maximum number of quarters allowed for the alternate repayment schedule is 12 quarters (3 years), except as provided in paragraph (e)(5) of this section.

(4) *Quarterly repayment amounts.* (i) The quarterly repayment amounts for each of the first 8 quarters in the repayment schedule will be the smaller of the repayment amount divided by 12 quarters or the maximum repayment amount;

(ii) The maximum quarterly repayment amounts for each of the first 8 quarters in the repayment schedule is 0.25 percent of the annual State share determination as defined in paragraph (b) of this section;

(iii) For the remaining 4 quarters, the quarterly repayment amount equals the remaining balance of the overpayment amount divided by the remaining 4 quarters.

(5) *Extended schedule.* (i) For a State that initiated its repayment under the

standard payment schedule and later experienced periods of economic distress and elected an alternate repayment schedule, the repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount of the remaining balance of the standard schedule, exceeds 100 percent of the estimated State share of the current annual expenditures;

(ii) In these circumstances, paragraph (d)(3) of this section is followed for repayment of the amount equal to 100 percent of the estimated State share of current annual expenditures;

(iii) The remaining amount of the repayment is in quarterly amounts equal to 8⅓ percent of the estimated State share of the current annual expenditures until fully repaid.

(6) *Repayment process.* (i) Repayment is accomplished through deposits into the State's Payment Management System (PMS) account;

(ii) A State may choose to make payment by Automated Clearing House (ACH) direct deposit, by check, or by Fedwire transfer.

(7) 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.

[77 FR 31509, May 29, 2012]

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

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AUTHORITY: 42 U.S.C. 1302.

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

EDITORIAL NOTE: Nomenclature changes to part 431 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, purpose, and definitions.* (1) This section implements section 1902(a)(4) and (5) of the Act.

(2) For purposes of this part—

Appeals decision means a decision made by a hearing officer adjudicating a fair hearing under subpart E of this part.

Exchange has the meaning given to the term in 45 CFR 155.20.

Exchange appeals entity has the meaning given to the term ''appeals entity,'' as defined in 45 CFR 155.500.

Medicaid agency is the 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.

(3) The single State agency is responsible for determining eligibility for all individuals applying for or receiving benefits in accordance with regulations in part 435 of this chapter and for fair hearings filed in accordance with subpart E of this part.

(c) *Delegations.* (1) Subject to the requirement in paragraph (c)(2) of this section, the Medicaid agency—

(i)(A) May, in the approved state plan, delegate authority to determine eligibility for all or a defined subset of individuals to—

(*1*) 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 Federal agency administering the supplemental security income program under title XVI of the Act; or

(*3*) The Exchange.

(B) Must in the approved state plan specify to which agency, and the individuals for which, authority to determine eligibility is delegated.

(ii) Delegate authority to conduct fair hearings under subpart E of this part for denials of eligibility for individuals whose income eligibility is determined based on the applicable modified adjusted gross income standard described in § 435.911(c) of this chapter, to an Exchange or Exchange appeals entity, provided that individuals who have requested a fair hearing of such a denial are given a choice to have their fair hearing instead conducted by the Medicaid agency.

(2) The Medicaid agency may delegate authority to make eligibility determinations or to conduct fair hearings under this section only to a government agency which maintains personnel standards on a merit basis.

(3) The Medicaid agency—

(i) Must ensure that any agency to which eligibility determinations or appeals decisions are delegated—

(A) Complies with all relevant Federal and State law, regulations and policies, including, but not limited to, those related to the eligibility criteria applied by the agency under part 435 of this chapter; prohibitions against conflicts of interest and improper incentives; and safeguarding confidentiality, including regulations set forth at subpart F of this part.

(B) Informs applicants and beneficiaries how they can directly contact and obtain information from the agency; and

(ii) Must exercise appropriate oversight over the eligibility determinations and appeals decisions made by such agencies to ensure compliance with paragraphs (c)(2) and (c)(3)(i) of this section and institute corrective action as needed, including, but not limited to, rescission of the authority delegated under this section.

(iii) If authority to conduct fair hearings is delegated to the Exchange or Exchange appeals entity under paragraph (c)(1)(ii) of this section, the agency may establish a review process whereby the agency may review fair hearing decisions made under that delegation, but that review will be limited to the proper application of federal and state Medicaid law and regulations, including sub-regulatory guidance and written interpretive policies, and must be conducted by an impartial official not directly involved in the initial determination.

(d) *Agreement with Federal, State or local entities making eligibility determinations or appeals decisions.* The plan must provide for written agreements between the Medicaid agency and the Exchange or any other State or local agency that has been delegated authority under paragraph (c)(1)(i) of this section to determine Medicaid eligibility and for written agreements between the agency and the Exchange or Exchange appeals entity that has been delegated authority to conduct Medicaid fair hearings under paragraph (c)(1)(ii) of this section. Such agreements must be available to the Secretary upon request and must include provisions for:

(1) The relationships and respective responsibilities of the parties, including but not limited to the respective

responsibilities to effectuate the fair hearing rules in subpart E of this part;

(2) Quality control and oversight by the Medicaid agency, including any reporting requirements needed to facilitate such control and oversight;

(3) Assurances that the entity to which authority to determine eligibility or conduct fair hearings will comply with the provisions set forth in paragraph (c)(3) of this section.

(4) For appeals, procedures to ensure that individuals have notice and a full opportunity to have their fair hearing conducted by either the Exchange or Exchange appeals entity or the Medicaid agency.

(e) *Authority of the single State agency*. The Medicaid agency may not delegate, to other than its own officials, the authority to supervise the plan or to develop or issue policies, rules, and regulations on program matters.

[44 FR 17930, Mar. 23, 1979, as amended at 77 FR 17202, Mar. 23, 2012; 78 FR 42300, July 15, 2013]

§ 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) *Description of organization*. (1) The plan must include a description of the organization and functions of the Medicaid agency.

(2) When submitting a state plan amendment related to the designation, authority, organization or functions of the Medicaid agency, the Medicaid agency must provide an organizational chart reflecting the key components of the Medicaid agency and the functions each performs.

(c) *Eligibility determined or fair hearings decided by other entities*. If eligibility is determined or fair hearings decided by Federal or State entities 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 entities and the functions they perform in carrying out their responsibilities.

[44 FR 17931, Mar. 23, 1979, as amended at 77 FR 17203, Mar. 23, 2012; 78 FR 42301, July 15, 2013]

§ 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 beneficiaries, 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary, 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 beneficiaries who live in that area and chose to receive services from that HMO or rural health clinic. beneficiaries 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 beneficiaries 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 beneficiary 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 beneficiary 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 beneficiary.

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

(2) A beneficiary 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 beneficiaries' 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 beneficiary 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 beneficiary'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 beneficiaries 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 beneficiaries 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.

(3) Section 1915(i) of the Act provides that a State may provide, as medical assistance, home and community-based services under an approved State plan amendment that meets certain requirements, without regard to the requirements of sections 1902(a)(10)(B) and

1902(a)(10)(C)(i)(III) of the Act, with respect to such services.

(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 beneficiaries 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 beneficiaries 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 beneficiaries.

(e) *Lock-in of beneficiaries who overutilize Medicaid services.* If a Medicaid agency finds that a beneficiary 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 beneficiary 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 beneficiary notice and opportunity for a hearing (in accordance with procedures established by the agency) before imposing the restrictions.

(2) The agency ensures that the beneficiary 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 beneficiary.

(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 beneficiaries 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.

(h) *State plan home and community-based services.* The requirements of § 440.240 of this chapter related to comparability of services do not apply with respect to State plan home and community-based services defined in § 440.182 of this chapter.

[56 FR 8847, Mar. 1, 1991, as amended at 72 FR 68091, Dec. 4, 2007; 79 FR 3028, Jan. 16, 2014]

§ 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 beneficiary. 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 beneficiaries 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 beneficiaries 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 beneficiaries the cost savings resulting from the beneficiaries' 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 beneficiary; and

(ii) Services expressly offered by the State as an inducement for beneficiaries 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 beneficiaries 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 beneficiaries residing at a long-term care facility when a restriction is imposed unless the State arranges for reasonable and adequate beneficiary 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.

§ 431.60 Beneficiary access to and exchange of data.

(a) *Application Programming Interface to support Medicaid beneficiaries.* A State must implement and maintain a standards-based Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of a current beneficiary or the beneficiary's personal representative, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the beneficiary.

(b) *Accessible content.* A State must make the following information accessible to its current beneficiaries or the beneficiary's personal representative through the API described in paragraph (a) of this section:

(1) Data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and beneficiary cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(2) Encounter data no later than one (1) business day after receiving the data from providers, other than MCOs, PIHPs, and PAHPs, compensated on the basis of capitation payments;

(3) Clinical data, including laboratory results, if the State maintains any such data, no later than one (1) business day after the data is received by the State; and

(4) Information about covered outpatient drugs and updates to such information, including, where applicable, preferred drug list information, no later than one (1) business day after the effective date of any such information or updates to such information.

(c) *Technical requirements.* A State implementing an API under paragraph (a) of this section:

(1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215;

(2) Must conduct routine testing and monitoring, and update as appropriate, to ensure the API functions properly, including assessments to verify that the API is fully and successfully implementing privacy and security features such as, but not limited to, those required to comply with HIPAA privacy and security requirements in 45 CFR parts 160 and 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;

(3) Must comply with the content and vocabulary standards requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are applicable to the data type or element, as appropriate; and

(ii) Content and vocabulary standards at 45 CFR part 162 and § 423.160 of this chapter where required by law, or where such standards are applicable to the data type or element, as appropriate.

(4) May use an updated version of any standard or all standards required under paragraph (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Use of the updated version of a standard does not disrupt an end user's ability to access the data described in paragraph (b) of this section through the API described in paragraph (a) of this section.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, a State must make publicly accessible, by posting directly on its website or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum the information listed in this paragraph. For the purposes of this section, ''publicly accessible'' means that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps, such as a fee for access to the documentation; a requirement to receive a copy of the material via email; a requirement to register or create an account to receive the documentation; or a requirement to read promotional material or agree to receive future communications from the organization making the documentation available;

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* A State may deny or discontinue any third-party application's connection to the API required under paragraph (a) of this section if the State:

(1) Reasonably determines, consistent with its security risk analysis under 45 CFR part 164 subpart C, that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of protected health information on the State's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which beneficiaries seek to access their electronic health information as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) *Beneficiary resources regarding privacy and security.* The State must provide in an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former beneficiaries seeking to access their health information held by the State Medicaid agency, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application including secondary uses of

data, and the importance of understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC), and how to submit a complaint to:

(i) The HHS Office for Civil Rights (OCR); and

(ii) The Federal Trade Commission (FTC).

(g) *Data availability*. (1) The State must comply with the requirements in paragraph (a) through (f) of this section beginning January 1, 2021 with regard to data:

(i) With a date of service on or after January 1, 2016; and

(ii) That are maintained by the State.

(2) [Reserved]

[85 FR 25634, May 1, 2020]

§ 431.70 Access to published provider directory information.

(a) The State must implement and maintain a publicly accessible, standards-based Application Programming Interface (API) that is conformant with the technical requirements at § 431.60(c), excluding the security protocols related to user authentication and authorization and any other protocols that restrict the availability of this information to particular persons or organizations, the documentation requirements at § 431.60(d), and is accessible via a public-facing digital endpoint on the State's website.

(b) The API must provide a complete and accurate directory of—

(1) The State's provider directory information specified in section 1902(a)(83) of the Act, updated no later than 30 calendar days after the State receives provider directory information or updates to provider directory information.

(2) [Reserved]

(c) This section is applicable beginning January 1, 2021.

[85 FR 25635, May 1, 2020]

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 beneficiaries.

(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 beneficiaries;

(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 beneficiary, 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 beneficiaries 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/IID 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/IID

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 Individuals with Intellectual Disabilities (ICF/IID) 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/IID 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/IID*. If an ICF/IID 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/IID 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/IID.

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 Beneficiaries

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 non-emergency transportation PAHP (as defined in § 438.9(a) of this chapter) takes action, as stated in this subpart, to suspend, terminate, or reduce services, or of an adverse benefit determination by an MCO, PIHP or PAHP 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.

(d) Implements section 1943(b)(3) of the Act and section 1413 of the Affordable Care Act to permit coordinated hearings and appeals among insurance affordability programs.

[67 FR 41094, June 14, 2002, as amended at 81 FR 27852, May 6, 2016; 81 FR 86448, Nov. 30, 2016]

§ 431.201 Definitions.

For purposes of this subpart:

Action means a termination, suspension of, or reduction in covered benefits or services, or a termination, suspension of, or reduction in Medicaid eligibility or an increase in beneficiary liability, including a determination that a beneficiary must incur a greater amount of medical expenses in order to establish income eligibility in accordance with § 435.121(e)(4) or § 435.831 of this chapter or is subject to an increase in premiums or cost-sharing charges under subpart A of part 447 of this chapter. It also means a determination by a skilled nursing facility or nursing facility to transfer or discharge a resident and an adverse determination by a State with regard to the preadmission screening and 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.

Joint fair hearing request means a request for a Medicaid fair hearing which is included in an appeal request submitted to an Exchange or Exchange appeals entity under 45 CFR 155.520 or other insurance affordability program or appeals entity, in accordance with the signed agreement between the agency and an Exchange or Exchange appeals entity or other program or appeals entity described in § 435.1200(b)(3) of this chapter .

Local evidentiary hearing means a hearing held on the local or county level serving a specified portion of the State.

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

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

Send means deliver by mail or in electronic format consistent with § 435.918 of this chapter.

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; 78 FR 42301, July 15, 2013; 81 FR 86448, Nov. 30, 2016]

§ 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—

(i) The Medicaid agency; or

(ii) For the denial of eligibility for individuals whose income eligibility is determined based on the applicable modified adjusted gross income standard described in§ 435.911(c) of this chapter, the Exchange or Exchange appeals entity to which authority to conduct fair hearings has been delegated under § 431.10(c)(1)(ii), provided that individuals who have requested a fair hearing are given the choice to have their fair hearing conducted instead by the Medicaid agency; at state option the Exchange or Exchange appeals entity decision may be subject to review by the Medicaid agency in accordance with § 431.10(c)(3)(iii); or

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

(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.

(e) The hearing system must be accessible to persons who are limited English proficient and persons who have disabilities, consistent with § 435.905(b) of this chapter.

(f) The hearing system must comply with 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, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, and section 1557 of the Affordable Care Act and implementing regulations.

[44 FR 17932, Mar. 29, 1979, as amended at 78 FR 42301, July 15, 2013; 81 FR 86448, Nov. 30, 2016]

§ 431.206 Informing applicants and beneficiaries.

(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 beneficiary in writing—

(1) Of his or her right to a fair hearing and right to request an expedited fair hearing;

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

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

(4) Of the time frames in which the agency must take final administrative action, in accordance with § 431.244(f).

(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 the agency denies an individual's claim for eligibility, benefits or services; or denies a request for exemption from mandatory enrollment in an Alternative Benefit Plan; or takes other action, as defined at § 431.201; or whenever a hearing is otherwise required in accordance with § 431.220(a);

(3) At the time a skilled nursing facility or a nursing facility notifies a resident in accordance with § 483.15 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.

(d) If, in accordance with § 431.10(c)(1)(ii), the agency has delegated authority to the Exchange or Exchange appeals entity to conduct the fair hearing, the agency must inform the individual in writing that—

(1) He or she has the right to have his or her hearing before the agency, instead of the Exchange or the Exchange appeals entity; and

(2) The method by which the individual may make such election;

(e) The information required under this subpart must be accessible to individuals who are limited English proficient and to individuals with disabilities, consistent with § 435.905(b) of this chapter, and may be provided in electronic format in accordance with § 435.918 of this chapter.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993; 78 FR 42301, July 15, 2013; 81 FR 68847, Oct. 4, 2016; 81 FR 86448, Nov. 30, 2016]

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 agency, skilled nursing facility, or nursing facility intends to take and the effective date of such action;

(b) A clear statement of the specific reasons supporting 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 a local 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; 81 FR 86448, Nov. 30, 2016]

§ 431.211 Advance notice.

The State or local agency must send a notice at least 10 days before the date of action, except as permitted under §§ 431.213 and 431.214.

[78 FR 42301, July 15, 2013]

§ 431.213 Exceptions from advance notice.

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

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

(b) The agency receives a clear written statement signed by a beneficiary 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 beneficiary has been admitted to an institution where he is ineligible under the plan for further services;

(d) The beneficiary'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 beneficiary's whereabouts become known);

(e) The agency establishes the fact that the beneficiary 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 beneficiary'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 § 483.15(b)(4)(ii) and (b)(8), which provides exceptions to the 30 days notice requirements of § 483.15(b)(4)(i) of this chapter.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993; 78 FR 42301, July 15, 2013; 81 FR 68847, Oct. 4, 2016]

§ 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 beneficiary; 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 individual who requests it because he or she believes the agency has taken an action erroneously, denied his or her claim for eligibility or for covered benefits or services, or issued a determination of an individual's liability, or has not acted upon the claim with reasonable promptness including, if applicable—

(i) An initial or subsequent decision regarding eligibility;

(ii) A determination of the amount of medical expenses that an individual must incur in order to establish eligibility in accordance with § 435.121(e)(4) or § 435.831 of this chapter; or

(iii) A determination of the amount of premiums and cost sharing charges under subpart A of part 447 of this chapter;

(iv) A change in the amount or type of benefits or services; or

(v) A request for exemption from mandatory enrollment in an Alternative Benefit Plan.

(2) 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.

(3) 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.

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

(5) Any enrollee in a non-emergency medical transportation PAHP (as that term is defined in § 438.9 of this chapter) who has an action as stated in this subpart.

(6) 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 beneficiaries.

[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; 81 FR 27853, May 6, 2016; 81 FR 86448, Nov. 30, 2016]

§ 431.221 Request for hearing.

(a)(1) The agency must establish procedures that permit an individual, or an authorized representative as defined at § 435.923 of this chapter, to—

(i) Submit a hearing request via any of the modalities described in § 435.907(a) of this chapter, except that

the requirement to establish procedures for submission of a fair hearing request described in § 435.907(a)(1), (2) and (5) of this chapter (relating to submissions via Internet Web site, telephone and other electronic means) is effective no later than the date described in § 435.1200(i) of this chapter; and

(ii) Include in a hearing request submitted under paragraph (a)(1)(i) of this section, a request for an expedited fair hearing.

(2) [Reserved]

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

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

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

[44 FR 17932, Mar. 29, 1979, as amended at 81 FR 86448, Nov. 30, 2016]

§ 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 beneficiary withdraws the request. The agency must accept withdrawal of a fair hearing request via any of the modalities available per § 431.221(a)(1)(i). For telephonic hearing withdrawals, the agency must record the individual's statement and telephonic signature. For telephonic, online and other electronic withdrawals, the agency must send the affected individual written confirmation, via regular mail or electronic notification in accordance with the individual's election under § 435.918(a) of this chapter.

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

[44 FR 17932, Mar. 29, 1979, as amended at 81 FR 86449, Nov. 30, 2016]

§ 431.224 Expedited appeals.

(a) *General rule.* (1) The agency must establish and maintain an expedited fair hearing process for individuals to request an expedited fair hearing, if the agency determines that the time otherwise permitted for a hearing under § 431.244(f)(1) could jeopardize the individual's life, health or ability to attain, maintain, or regain maximum function.

(2) The agency must take final administrative action within the period of time permitted under § 431.244(f)(3) if the agency determines that the individual meets the criteria for an expedited fair hearing in paragraph (a)(1) of this section.

(b) *Notice.* The agency must notify the individual whether the request is granted or denied as expeditiously as possible. Such notice must be provided orally or through electronic means in accordance with § 435.918 of this chapter, if consistent with the individual's election under such section; if oral notice is provided, the agency must follow up with written notice, which may be through electronic means if consistent with the individual's election under § 435.918.

[81 FR 86449, Nov. 30, 2016]

PROCEDURES

§ 431.230 Maintaining services.

(a) If the agency sends the 10-day or 5-day notice as required under § 431.211 or § 431.214 of this subpart, and the beneficiary 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 beneficiary 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 beneficiary to recoup the cost of any services furnished the beneficiary, 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; 78 FR 42302, July 15, 2013]

§ 431.231 Reinstating services.

(a) The agency may reinstate services if a beneficiary 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 beneficiary requests a hearing within 10 days from the date that the individual receives the notice of action. The date on which the notice is received is considered to be 5 days after the date on the notice, unless the beneficiary shows that he or she did not receive the notice within the 5-day period; and

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

(d) If a beneficiary'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.

[44 FR 17932, Mar. 29, 1979, as amended at 78 FR 42302, July 15, 2013]

§ 431.232 Adverse decision of local evidentiary hearing.

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

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

(b) Inform the applicant or beneficiary in writing that he or she has a right to appeal the decision to the State agency within 10 days after the individual receives the notice of the adverse decision. The date on which the notice is received is considered to be 5 days after the date on the notice, unless the individual shows that he or she did not receive the notice within the 5-day period; and

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

(d) Discontinue services after the adverse decision.

[44 FR 17932, Mar. 29, 1979, as amended at 81 FR 86449, Nov. 30, 2016]

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

(a) Unless the applicant or beneficiary 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.

(c) A hearing officer must have access to agency information necessary to issue a proper hearing decision, including information concerning State policies and regulations.

[44 FR 17932, Mar. 29, 1979, as amended at 78 FR 42302, July 15, 2013]

§ 431.241 Matters to be considered at the hearing.

The hearing must cover—

(a) Any matter described in § 431.220(a)(1) for which an individual requests a fair hearing.

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

(c) 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, as amended at 81 FR 86449, Nov. 30, 2016]]

§ 431.242 Procedural rights of the applicant or beneficiary.

The applicant or beneficiary, 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 beneficiary's case file and electronic account, as defined in § 435.4 of this chapter; 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.

(f) Request an expedited fair hearing.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56506, Nov. 30, 1992; 81 FR 86449, Nov. 30, 2016]

§ 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 beneficiary 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:

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

(ii) For all other fair hearings, the date the agency receives a request for a fair hearing in accordance with § 431.221(a)(1).

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

that, as indicated by the MCO, PIHP, or PAHP—

(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) In the case of individuals granted an expedited fair hearing in accordance with § 431.224(a)—

(i) For a claim related to eligibility described in § 431.220(a)(1), or any claim described in § 431.220(a)(2) (relating to a nursing facility) or § 431.220(a)(3) (related to preadmission and annual resident review), as expeditiously as possible and, effective no later than the date described in § 435.1200(i) of this chapter, no later than 7 working days after the agency receives a request for expedited fair hearing; or

(ii) For a claim related to services or benefits described in § 431.220(a)(1) as expeditiously as possible and, effective no later than the date described in § 435.1200(i) of this chapter, within the time frame in paragraph (f)(2) of this section.

(iii) For a claim related to services or benefits described in § 431.220(a)(4), (5) or (6), in accordance with the time frame in paragraph (f)(2) of this section.

(4)(i) The agency must take final administrative action on a fair hearing request within the time limits set forth in this paragraph except in unusual circumstances when—

(A) The agency cannot reach a decision because the appellant requests a delay or fails to take a required action; or

(B) There is an administrative or other emergency beyond the agency's control.

(ii) The agency must document the reasons for any delay in the appellant's record.

(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; 81 FR 27853, May 6, 2016; 81 FR 86449, Nov. 30, 2016]

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

The agency must notify the applicant or beneficiary 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 beneficiary; or

(b) The agency decides in the applicant's or beneficiary'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 beneficiary, his representative, and witnesses to and from the hearing;

(2) Meeting other expenses of the applicant or beneficiary 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 Beneficiaries

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 beneficiaries 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) For purposes of this subpart, information concerning an applicant or beneficiary includes information on a non-applicant, as defined in §435.4 of this subchapter.

(c) Section 1137 of the Act, which requires agencies to exchange information to verify the income and eligibility of applicants and beneficiaries (see §435.940 through §435.965 of this subchapter), 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)(7) of the Internal Revenue Code 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.

(d) Section 1943 of the Act and section 1413 of the Affordable Care Act.

[51 FR 7210, Feb. 28, 1986, as amended at 77 FR 17203, Mar. 23, 2012]

§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 beneficiaries 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 beneficiaries; 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 beneficiaries.

§431.304 Publicizing safeguarding requirements.

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

(b) The agency must provide copies of these provisions to applicants and beneficiaries 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 beneficiaries 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 § 435.940 through § 435.965 of this subchapter). Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data, including section 6103 of the Internal Revenue Code, as applicable.

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

(8) Social Security Numbers.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987; 77 FR 17203, Mar. 23, 2012]

§ 431.306 Release of information.

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

(b) Access to information concerning applicants or beneficiaries 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 beneficiaries.

(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 beneficiary, 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 subchapter, the agency must execute data exchange agreements with those agencies, as specified in § 435.945(i) of this subchapter.

(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; 77 FR 17203, Mar. 23, 2012]

§ 431.307 Distribution of information materials.

(a) All materials distributed to applicants, beneficiaries, 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 beneficiaries, 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]

Subpart G—Section 1115 Demonstrations

SOURCE: 77 FR 11696, Feb. 27, 2012, unless otherwise noted.

§ 431.400 Basis and purpose.

(a) *Basis*. This subpart implements provisions in section 1115(d) of the Act, which requires all of the following:

(1) The establishment of application requirements for Medicaid and CHIP demonstration projects that provide for:

(i) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedure Act, or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance.

(ii) Requirements relating to all of the following:

(A) The goals of the program to be implemented or renewed under the demonstration project.

(B) Expected State and Federal costs and coverage projections of the State demonstration project.

(C) Specific plans of the State to ensure the demonstration project will be in compliance with titles XIX or XXI of the Act.

(2) A process for public notice and comment after a demonstration application is received by the Secretary that is sufficient to ensure a meaningful level of public input.

(3) A process for the submission of reports to the Secretary by a State relating to the implementation of a demonstration project.

(4) Periodic evaluation of demonstration projects by the Secretary.

(b) *Purpose*. This subpart sets forth a process for application and review of Medicaid and CHIP demonstration projects that provides for transparency and public participation.

§ 431.404 Definitions.

For the purposes of this subpart:

Demonstration means any experimental, pilot, or demonstration project which the Secretary approves under the authority of section 1115 of the Act because, in the judgment of the Secretary, it is likely to assist in promoting the statutory objectives of the Medicaid or CHIP program.

Indian Health Program means a program as defined at section 4(12) of the Indian Health Care Improvement Act, (Pub. L. 94–437).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action, consistent with the provisions of § 431.408 of this subpart.

§ 431.408 State public notice process.

(a) *General*. A State must provide at least a 30-day public notice and comment period regarding applications for a demonstration project, or an extension of an existing demonstration project that the State intends to submit to CMS for review and consideration.

(1) *Public notice and comment period*. Prior to submitting an application to CMS for a new demonstration project or an extension of a previously approved demonstration project, the State must provide at least a 30-day public notice and comment period, and the public notice shall include all of the following information:

(i) A comprehensive description of the demonstration application or extension to be submitted to CMS that contains a sufficient level of detail to

ensure meaningful input from the public, including:

(A) The program description, goals, and objectives to be implemented or extended under the demonstration project, including a description of the current or new beneficiaries who will be impacted by the demonstration.

(B) To the extent applicable, the proposed health care delivery system and the eligibility requirements, benefit coverage and cost sharing (premiums, co-payments, and deductibles) required of individuals that will be impacted by the demonstration, and how such provisions vary from the State's current program features.

(C) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable. This includes a financial analysis of any changes to the demonstration requested by the State in its extension request.

(D) The hypothesis and evaluation parameters of the demonstration.

(E) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

(ii) The locations and Internet address where copies of the demonstration application are available for public review and comment.

(iii) Postal and Internet email addresses where written comments may be sent and reviewed by the public, and the minimum 30-day time period in which comments will be accepted.

(iv) The location, date, and time of at least two public hearings convened by the State to seek public input on the demonstration application.

(2) *Statement of public notice and public input procedures.* (i) The State shall publish its public notice process, public input process, planned hearings, the demonstration application(s), and a link to the relevant Medicaid demonstration page(s) on the CMS Web site in a prominent location on either the main page of the public Web site of the State agency responsible for making applications for demonstrations or on a demonstration-specific Web page that is linked in a readily identifiable way to the main page of the State agency's Web site. The State must maintain and keep current the public Web site throughout the entire public comment and review process.

(ii) The State shall also publish an abbreviated public notice which must include a summary description of the demonstration, the location and times of the two or more public hearings, and an active link to the full public notice document on the State's Web site in the State's administrative record in accordance with the State's Administrative Procedure Act, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS or in the newspapers of widest circulation in each city with a population of 100,000, or more, provided that such notice is provided at least 30 days prior to the submission of the demonstration application to CMS, or both.

(iii) The State must also utilize additional mechanisms, such as an electronic mailing list, to notify interested parties of the demonstration application(s).

(3) *Public hearings.* At least 20 days prior to submitting an application for a new demonstration project or extension of an existing demonstration project to CMS for review, the State must have conducted at least two public hearings, on separate dates and at separate locations, regarding the State's demonstration application at which members of the public throughout the State have an opportunity to provide comments. The State must use telephonic and/or Web conference capabilities for at least one of the two required public hearings to ensure statewide accessibility to the public hearing unless it can document it has afforded the public throughout the State the opportunity to provide comment, such as holding the two public hearings in geographically distinct areas of the State. The State must use at least two of the following public forums:

(i) The Medical Care Advisory Committee that operates in accordance with § 431.12 of this subpart; or

(ii) A commission or other similar process, where meetings are open to members of the public; or

(iii) A State legislative process, which would afford an interested party

the opportunity to learn about the contents of the demonstration application, and to comment on its contents; or

(iv) Any other similar process for public input that would afford an interested party the opportunity to learn about the contents of the demonstration application, and to comment on its contents.

(b) *Tribal consultation and seeking advice from Indian health providers and urban Indian organizations.* A State with Federally-recognized Indian tribes, Indian health programs, and/or urban Indian health organizations shall include a process to consult with the Indian tribes, and seek advice from Indian Health programs and urban Indian health organizations in the State, prior to submission of an application to CMS for a new demonstration project, or an extension of a previously approved demonstration project, that has or would have a direct effect on Indians, tribes, on Indian health programs, or on urban Indian health organizations.

(1) For initial applications and applications extending existing demonstration projects that have a direct effect on Indians, tribes, Indian health programs, and urban Indian health organizations in the State, the State must demonstrate that it has conducted consultation activities with tribes and sought advice from Indian health programs and urban Indian health organizations prior to submission of such application.

(2) Consultation with Federally-recognized Indian tribes and solicitation of advice from affected Indian health providers and urban Indian organizations must be conducted in accordance with the consultation process outlined in the July 17, 2001 letter or the State's formal tribal consultation agreement or process and the process for seeking advice from Indian Health providers must be conducted as outlined in the State's approved Medicaid State Plan.

(3) Documentation of the State's consultation activities must be included in the demonstration application, which must describe the notification process, the entities involved in the consultation(s), the date(s) and location(s) of the consultation(s), issues raised, and the potential resolution for such issues.

§431.412 Application procedures.

(a) *Initial demonstration application content.* (1) Applications for initial approval of a demonstration will not be considered complete unless they comply with the public notice process set forth in §431.408(a) of this subpart, and include the following:

(i) A comprehensive program description of the demonstration, including the goals and objectives to be implemented under the demonstration project.

(ii) A description of the proposed health care delivery system, eligibility requirements, benefit coverage and cost sharing (premiums, copayments, and deductibles) required of individuals who will be impacted by the demonstration to the extent such provisions would vary from the State's current program features and the requirements of the Act.

(iii) An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budgetary data, if applicable.

(iv) Current enrollment data, if applicable, and enrollment projections expected over the term of the demonstration for each category of beneficiary whose health care coverage is impacted by the demonstration.

(v) Other program features that the demonstration would modify in the State's Medicaid and CHIP programs.

(vi) The specific waiver and expenditure authorities that the State believes to be necessary to authorize the demonstration.

(vii) The research hypotheses that are related to the demonstration's proposed changes, goals, and objectives, a plan for testing the hypotheses in the context of an evaluation, and, if a quantitative evaluation design is feasible, the identification of appropriate evaluation indicators.

(viii) Written documentation of the State's compliance with the public notice requirements set forth in §431.408 of this subpart, with a report of the issues raised by the public during the comment period, which shall be no less than 30 days, and how the State considered those comments when developing the demonstration application.

(2) CMS may request, or the State may propose application modifications, as well as additional information to aid in the review of the application. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30-day public comment period.

(3) This section does not preclude a State from submitting to CMS a pre-application concept paper or from conferring with CMS about its intent to seek a demonstration prior to submitting a completed application.

(b) *Demonstration application procedures.* A State application for approval of a new demonstration project or an extension of an existing demonstration project must be submitted to CMS as both printed and electronic documents. Electronic documents must be submitted in a format that will be accessible to individuals with disabilities.

(1) Consistent with § 431.416(a) of this subpart, within 15 days of receipt of a complete application, CMS will send the State a written notice informing the State of receipt of the submitted application, the date in which the Secretary received the State's demonstration application and the start date of the 30-day Federal public notice process set forth in § 431.416 of this subpart. The written notice—

(i) Is provided for purposes of initiating the Federal-level public comment period and does not preclude a determination that, based on further review, further information is required to supplement or support the application, or that the application cannot be approved because a required element is missing or insufficient.

(ii) Does not prevent a State from modifying its application or submitting any supplementary information it determines necessary to support CMS' review of its application.

(2) Within 15 days of receipt of a demonstration application that CMS determines is incomplete, CMS will send the State a written notice of the elements missing from the application.

(3) CMS will publish on its Web site at regular intervals the status of all State submissions, including information received from the State while the State works with CMS to meet the demonstration application process set forth in this section.

(c) *Demonstration extension request.* A request to extend an existing demonstration under sections 1115(a), (e), and (f) of the Act will be considered only if it is submitted at least 12 months prior to the expiration date of the demonstration when requesting an extension under section 1115(e) of the Act or 6 months prior to the expiration date of the demonstration when requesting an extension under section 1115(a) or (f) of the Act, unless a longer time frame is specified in the Special Terms and Conditions for the original demonstration. An extension application, including an extension for the purpose of phasing out a demonstration, must be sent from the Governor of the State to the Secretary.

(1) *Changes to existing demonstration.* If an extension application includes substantial changes to the existing demonstration, CMS may, at its discretion, treat the application as an application for a new demonstration.

(2) *Demonstration extension application.* An application to extend an existing demonstration will be considered complete, for purposes of initiating the Federal-level public notice period, when the State provides the following:

(i) A historical narrative summary of the demonstration project, which includes the objectives set forth at the time the demonstration was approved, evidence of how these objectives have or have not been met, and the future goals of the program.

(ii) If changes are requested, a narrative of the changes being requested along with the objective of the change and the desired outcomes.

(iii) A list and programmatic description of the waivers and expenditure authorities that are being requested for the extension period, or a statement that the State is requesting the same waiver and expenditure authorities as those approved in the current demonstration.

(iv) Summaries of External Quality Review Organization (EQRO) reports, managed care organization (MCO) and State quality assurance monitoring, and any other documentation of the quality of and access to care provided

under the demonstration, such as the CMS Form 416 EPSDT/CHIP report.

(v) Financial data demonstrating the State's historical and projected expenditures for the requested period of the extension, as well as cumulatively over the lifetime of the demonstration. This includes a financial analysis of changes to the demonstration requested by the State.

(vi) An evaluation report of the demonstration, inclusive of evaluation activities and findings to date, plans for evaluation activities during the extension period, and if changes are requested, identification of research hypotheses related to the changes and an evaluation design for addressing the proposed revisions.

(vii) Documentation of the State's compliance with the public notice process set forth in §431.408 of this subpart, including the post-award public input process described in §431.420(c) of this subpart, with a report of the issues raised by the public during the comment period and how the State considered the comments when developing the demonstration extension application.

(3) CMS may request, or the State may propose application modifications, as well as additional information to aid in the review of an application to extend a demonstration. If an application modification substantially changes the original demonstration design, CMS may, at its discretion, direct an additional 30-day public comment period.

(4) Upon application from the State, the Secretary may extend existing demonstration projects on a temporary basis for the period during which a successor demonstration is under review, without regard to the date when the application was submitted.

(d) *Approvals*. Approval of a new demonstration or a demonstration extension will generally be prospective only and Federal Financial Participation (FFP) will not be available for changes to the demonstration that have not been approved by CMS.

§431.416 Federal public notice and approval process.

(a) *General*. Within 15 days of receipt of a complete application from the State for a new demonstration project or an extension of a previously approved demonstration project, CMS will:

(1) Send the State a written notice informing the State of receipt of the demonstration application, the date in which the Secretary received the State's demonstration application, the start dates of the 30-day Federal public notice process, and the end date of the 45-day minimum Federal decision-making period.

(2) Publish the written notice acknowledging receipt of the State's completed application on its Web site within the same 15-day timeframe.

(b) *Public comment period*. Upon notifying a State of a completed application, CMS will solicit public comment regarding such demonstration application for 30 days by doing the following:

(1) Publishing the following on the CMS Web site:

(i) The written notice of CMS receipt of the State's complete demonstration application.

(ii) Demonstration applications, including supporting information submitted by the State as part of the complete application, and associated concept papers, as applicable.

(iii) The proposed effective date of the demonstration.

(iv) Addresses to which inquiries and comments from the public may be directed to CMS by mail or email.

(2) Notifying interested parties through a mechanism, such an electronic mailing list, that CMS will create for this purpose.

(c) *Public disclosure*. CMS will publish on its Web site, at regular intervals, appropriate information, which may include, but is not limited to the following:

(1) Relevant status update(s);

(2) A listing of the issues raised through the public notice process.

(d) *Publishing of comments*. (1) CMS will publish written comments electronically through its Web site or an alternative Web site.

(2) CMS will review and consider all comments received by the deadline, but will not provide written responses to public comments. While comments may be submitted after the deadline, CMS cannot assure that these comments will be considered.

(e) *Approval of a demonstration application.* (1) CMS will not render a final decision on a demonstration application until at least 45 days after notice of receipt of a completed application, to receive and consider public comments.

(2) CMS may expedite this process under the exception to the normal public notice process provisions in § 431.416(g) of this subpart.

(f) *Administrative record.* (1) CMS will maintain, and publish on its public Web site, an administrative record that may include, but is not limited to the following:

(i) The demonstration application from the State.

(ii) The State's disaster exemption request and CMS' response, if applicable.

(iii) Written public comments sent to the CMS and any CMS responses.

(iv) If an application is approved, the final special terms and conditions, waivers, expenditure authorities, and award letter sent to the State.

(v) If an application is denied, the disapproval letter sent to the State.

(vi) The State acceptance letter, as applicable.

(vii) Specific requirements related to the approved and agreed upon terms and conditions, such as implementation reviews, evaluation design, quarterly progress reports, annual reports, and interim and/or final evaluation reports.

(viii) Notice of the demonstration's suspension or termination, if applicable.

(2) To ensure that the public has access to all documentation related to the demonstration project, including the aforementioned items, we will also provide a link to the State's public Web site.

(g) *Exemption from the normal public notice process.* (1) CMS may waive, in whole or in part, the Federal and State public notice procedures to expedite a decision on a proposed demonstration or demonstration extension request that addresses a natural disaster, public health emergency, or other sudden emergency threats to human lives.

(2) The Secretary may exempt a State from the normal public notice process or the required time constraints imposed in this section or § 431.408(a) of this subpart when the State demonstrates to CMS the existence of unforeseen circumstances resulting from a natural disaster, public health emergency, or other sudden emergency that directly threatens human lives that warrant an exception to the normal public notice process.

(i) The State is expected to discharge its basic responsibilities in submitting demonstration applications to the Secretary as required in § 431.412 of this subpart.

(ii) Such applications will be posted on the CMS Web site.

(3) A State must establish (or meet) all of the following criteria to obtain such an exemption from the normal public notice process requirements:

(i) The State acted in good faith, and in a diligent, timely, and prudent manner.

(ii) The circumstances constitute an emergency and could not have been reasonably foreseen.

(iii) Delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of beneficiaries.

(4) CMS will publish on its Web site any disaster exemption determinations within 15 days of approval, as well as the revised timeline for public comment or post-award processes, if applicable.

§ 431.420 Monitoring and compliance.

(a) *General.* (1) Any provision of the Social Security Act that is not expressly waived by CMS in its approval of the demonstration project are not waived, and States may not stop compliance with any of these provisions not expressly waived. Waivers may be limited in scope to the extent necessary to achieve a particular purpose or to the extent of a particular regulatory requirement implementing the statutory provision.

(2) States must comply with the terms and conditions of the agreement between the Secretary and the State to implement a State demonstration project.

(b) *Implementation reviews.* (1) The terms and conditions will provide that the State will perform periodic reviews

of the implementation of the demonstration.

(2) CMS will review documented complaints that a State is failing to comply with requirements specified in the special terms and conditions and implementing waivers of any approved demonstration.

(3) CMS will promptly share with the State complaints that CMS has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within 6 months after the implementation date of the demonstration and annually thereafter, the State must hold a public forum—

(1) To solicit comments on the progress of a demonstration project.

(2) At which members of the public have an opportunity to provide comments and in such time as to include a summary of the forum in the quarterly report associated with the quarter in which the forum was held, as well as in its annual report to CMS.

(3) The public forum to solicit feedback on the progress of a demonstration project must occur using one of the following:

(i) A Medical Care Advisory Committee that operates in accordance with §431.412 of this subpart.

(ii) A commission or other similar process, where meetings are open to members of the public, and would afford an interested party the opportunity to learn about the demonstration's progress.

(iii) The State must publish the date, time, and location of the public forum in a prominent location on the State's public Web site, at least 30 days prior to the date of the planned public forum.

(4) [Reserved]

(d) *Terminations and suspensions.* (1) The Secretary may suspend or terminate a demonstration in whole or in part, any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the demonstration project.

(2) The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes.

(3) The terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.

(e) *Closeout costs.* When a demonstration is terminated, suspended, or if waivers or expenditure authority are withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination of the demonstration or expenditure authority, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) The State must fully cooperate with CMS or an independent evaluator selected by CMS to undertake an independent evaluation of any component of the demonstration.

(2) The State must submit all requested data and information to CMS or the independent evaluator.

§431.424 Evaluation requirements.

(a) *General.* States are permitted and encouraged to use a range of appropriate evaluation strategies (including experimental and other quantitative and qualitative designs) in the application of evaluation techniques with the approval of CMS.

(b) *Demonstration evaluations.* Demonstration evaluations will include the following:

(1) *Quantitative research methods.* (i) These methods involve the empirical investigation of the impact of key programmatic features of the demonstration.

(ii) CMS will consider alternative evaluation designs when quantitative designs are technically infeasible or not well suited to the change made by the demonstration.

(2) *Approaches that minimize beneficiary impact.* The evaluation process must minimize burden on beneficiaries and protect their privacy in terms of implementing and operating the policy approach to be demonstrated while ensuring the impact of the demonstration is measured.

(c) *Evaluation design plan.* (1) The State will submit and receive CMS approval of a design for an evaluation of the demonstration project and publish

this document to the State's public Web site within 30 days of CMS approval.

(2) The draft demonstration evaluation design must include all of the following:

(i) A discussion of the demonstration hypotheses that are being tested including monitoring and reporting on the progress towards the expected outcomes.

(ii) The data that will be utilized and the baseline value for each measure.

(iii) The methods of data collection.

(iv) A description of how the effects of the demonstration will be isolated from those other changes occurring in the State at the same time through the use of comparison or control groups to identify the impact of significant aspects of the demonstration.

(v) A proposed date by which a final report on findings from evaluation activities conducted under the evaluation plan must be submitted to CMS.

(vi) Any other information pertinent to the State's research on the policy operations of the demonstration operations.

(d) *Evaluations for demonstration extensions.* (1) In the event that the State requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the State must submit an interim evaluation report as part of the State's request for a subsequent renewal of the demonstration.

(2) State evaluations must be published on the State's public Web site within 30 days of submission to CMS.

(e) *Approved evaluation designs.* The State must publish the CMS-approved demonstration evaluation design on the State's public Web site within 30 days of CMS approval.

(f) *Federal evaluations.* The State must comply with all requirements set forth in this subpart.

(g) *Federal public notice.* CMS will post, or provide a link to the State's public Web site, all evaluation materials, including research and data collection, on its Web site for purposes of sharing findings with the public within 30 days of receipt of materials.

§ 431.428 Reporting requirements.

(a) *Annual reports.* The State must submit an annual report to CMS documenting all of the following:

(1) Any policy or administrative difficulties in the operation of the demonstration.

(2) The status of the health care delivery system under the demonstration with respect to issues and/or complaints identified by beneficiaries.

(3) The impact of the demonstration in providing insurance coverage to beneficiaries and uninsured populations.

(4) Outcomes of care, quality of care, cost of care and access to care for demonstration populations.

(5) The results of beneficiary satisfaction surveys, if conducted during the reporting year, grievances and appeals.

(6) The existence or results of any audits, investigations or lawsuits that impact the demonstration.

(7) The financial performance of the demonstration.

(8) The status of the evaluation and information regarding progress in achieving demonstration evaluation criteria.

(9) Any State legislative developments that may impact the demonstration.

(10) The results/impact of any demonstration programmatic area defined by CMS that is unique to the demonstration design or evaluation hypothesis.

(11) A summary of the annual post-award public forum, including all public comments received regarding the progress of the demonstration project.

(b) *Submitting and publishing annual reports.* States must submit a draft annual report to CMS no later than 90 days after the end of each demonstration year, or as specified in the demonstration's STCs. The State must publish its draft annual report on its public Web site within 30 days of submission to CMS.

(1) Within 60 days of receipt of comments from CMS, the State must submit to CMS the final annual report for the demonstration year.

(2) The final annual report is to be published on the State's public Web site within 30 days of approval by CMS.

Subparts H–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 beneficiaries, 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 beneficiaries.

(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, HHAs, and ICF–IIDs, 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; 78 FR 72320, Dec. 2, 2013]

§ 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 beneficiaries 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 beneficiaries;

(iv) Payment or reimbursement;

(v) Exchange of reports of services furnished to beneficiaries;

(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 beneficiaries 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 beneficiaries 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 beneficiaries 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 beneficiary who is in alternative care;

(4) Access by the agency to the institution, the beneficiary, and the beneficiary's records when necessary to carry out the agency's responsibilities;

(5) Recording, reporting, and exchanging medical and social information about beneficiaries; 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 Intellectual Disability 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 Intellectual Disability 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 Intellectual Disability authorities, including arrangements for—(1) Joint planning between the parties to the agreement;

(2) Access by the agency to the State mental health and Intellectual Disability 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 Intellectual Disability 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 Intellectual Disability authorities are not countermanded by the State Medicaid agency, except through the appeals process, but that the State mental health and Intellectual Disability 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 beneficiaries 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 beneficiaries enrolled under Medicare Part B without obligating itself to provide the range of Part B benefits to other beneficiaries; and

(3) Section 1903 (a)(1) and (b) of the Act authorizes FFP for State payment of Medicare Part B premiums for certain beneficiaries.

(4) This section—

(i) Specifies the exception, relating to Part B coverage, from the requirement to provide comparable services to all beneficiaries; 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 beneficiaries enrolled under Medicare Part B, the portion that is to be paid by a Medicaid beneficiary must be reasonably related to the beneficiary'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 beneficiaries 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 beneficiary does not obligate it to pay on the beneficiary'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 beneficiary'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 beneficiary'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 beneficiaries unless the beneficiaries 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) Beneficiaries 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) Beneficiaries 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) Beneficiaries 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 beneficiaries 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 beneficiaries 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 beneficiaries.

[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 beneficiaries (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]

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

MEDICAID ELIGIBILITY QUALITY CONTROL (MEQC) PROGRAM

SOURCE: Sections 431.800 through 431.808 appear at 55 FR 22166, May 31, 1990, unless otherwise noted.

§ 431.800 Basis and scope.

This subpart establishes State requirements for the Medicaid Eligibility Quality Control (MEQC) Program designed to reduce erroneous expenditures by monitoring eligibility determinations and a claims processing assessment that monitors claims processing operations. MEQC will work in conjunction with the Payment Error Rate Measurement (PERM) Program established in subpart Q of this part. In years in which the State is required to participate in PERM, as stated in subpart Q of this part, it will only participate in the PERM program and will not be required to conduct a MEQC pilot. In the 2 years between PERM cycles, the State is required to conduct a MEQC pilot, as set forth in this subpart.

[82 FR 31182, July 5, 2017]

§ 431.804 Definitions.

As used in this subpart—

Active case means an individual determined to be currently authorized as eligible for Medicaid or CHIP by the State.

Corrective action means action(s) to be taken by the State to reduce major error causes, trends in errors or other vulnerabilities for the purpose of reducing improper payments in Medicaid and CHIP.

Deficiency means a finding in processing identified through active case review or negative case review that does not meet the definition of an eligibility error.

Eligibility means meeting the State's categorical and financial criteria for receipt of benefits under the Medicaid or CHIP programs.

Eligibility error is an error resulting from the States' improper application of Federal rules and the State's documented policies and procedures that causes a beneficiary to be determined eligible when he or she is ineligible for Medicaid or CHIP, causes a beneficiary to be determined eligible for the incorrect type of assistance, causes applications for Medicaid or CHIP to be improperly denied by the State, or causes existing cases to be improperly terminated from Medicaid or CHIP by the State. An eligibility error may also be caused when a redetermination did not occur timely or a required element of the eligibility determination process (for example income) cannot be verified as being performed/completed by the state.

Medicaid Eligibility Quality Control (MEQC) means a program designed to reduce erroneous expenditures by monitoring eligibility determinations and work in conjunction with the PERM program established in subpart Q of this part.

MEQC pilot refers to the process used to implement the MEQC Program.

MEQC review period is the 12-month timespan from which the State will sample and review cases.

Negative case means an individual denied or terminated eligibility for Medicaid or CHIP by the State.

Off-years are the scheduled 2-year period of time between a States' designated PERM years.

Payment Error Rate Measurement (PERM) Program means the program set forth at subpart Q of this part utilized to calculate a national improper payment rate for Medicaid and CHIP.

PERM year is the scheduled and designated year for a State to participate in, and be measured by, the PERM Program set forth at subpart Q of this part.

[82 FR 31182, July 5, 2017]

§ 431.806 State requirements.

(a) *General requirements.* (1) In a State's PERM year, the PERM measurement will meet the requirements of section 1903(u) of the Act.

(2) In the 2 years between each State's PERM year, the State is required to conduct one MEQC pilot, which will span parts of both off years.

(i) The MEQC pilot review period will span 12 months of a calendar year, beginning the January 1 following the end of the State's PERM year through December 31.

(ii) The MEQC pilot planning document described in § 431.814 is due no later than the first November 1 following the end of the State's PERM year.

(iii) A State must submit its MEQC pilot findings and its plan for corrective action(s) by the August 1 following the end of its MEQC pilot review period.

(b) *PERM measurement.* Requirements for the State PERM review process are set forth in subpart Q of this part.

(c) *MEQC pilots.* MEQC pilot requirements are specified in §§ 431.812 through 431.820.

(d) *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.

[82 FR 31182, July 5, 2017]

§ 431.808 Protection of beneficiary 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 beneficiaries.

§ 431.810 Basic elements of the Medicaid Eligibility Quality Control (MEQC) Program.

(a) *General requirements.* The State must operate the MEQC pilot in accordance with this section and §§ 431.812 through 431.820, as well as other instructions established by CMS.

(b) *Review requirements.* The State must conduct reviews for the MEQC pilot in accordance with the requirements specified in § 431.812 and other instructions established by CMS.

(c) *Pilot planning requirements.* The State must develop a MEQC pilot planning proposal in accordance with requirements specified in § 431.814 and other instructions established by CMS.

(d) *Reporting requirements.* The State must report the finding of the MEQC pilots in accordance with the requirements specified in § 431.816 and other instructions established by CMS.

(e) *Corrective action requirements.* The State must conduct corrective actions based on the findings of the MEQC pilots in accordance with the requirements specified in § 431.820 and other instructions established by CMS.

[82 FR 31183, July 5, 2017]

§ 431.812 Review procedures.

(a) *General requirements.* Each State is required to conduct a MEQC pilot during the 2 years between required PERM cycles in accordance with the approved pilot planning document specified in § 431.814, as well as other instructions established by CMS. The agency and personnel responsible for the development, direction, implementation, and evaluation of the MEQC reviews and associated activities, 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.

(b) *Active case reviews.* (1) The State must review all active cases selected from the universe of cases, as established in the State's approved MEQC pilot planning document, under § 431.814 to determine if the cases were eligible for services, as well as to identify deficiencies in processing subject to corrective actions.

(2) The State must select and review, at a minimum, 400 active cases in total from the Medicaid and CHIP universe.

(i) The State must review at least 200 Medicaid cases.

(ii) The State will identify in the pilot planning document at § 431.814 the sample size per program.

(iii) The State may sample more than 400 cases.

(3) The State may propose to focus the active case reviews on recent changes to eligibility policies and processes, areas where the state suspects vulnerabilities, or proven error prone areas.

(i) Unless otherwise directed by CMS, the State must propose its active case review approach in the pilot planning document described at § 431.814 or perform a comprehensive review.

(ii) When the State has a PERM eligibility improper payment rate that exceeds the 3 percent national standard for two consecutive PERM cycles, the State must follow CMS direction for its active case reviews. CMS guidance will be provided to any state meeting this criteria.

(c) *Negative case reviews.* (1) As established in the State's approved MEQC pilot planning document under § 431.814, the State must review negative cases selected from the State's universe of cases that are denied or terminated in the review month to determine if the denial, or termination, was correct, as well as to identify deficiencies in processing subject to corrective actions.

(2) The State must review, at a minimum, 200 negative cases from Medicaid and 200 negative cases from CHIP.

(i) The State may sample more than 200 cases from Medicaid and/or more than 200 cases from CHIP.

(ii) [Reserved]

(d) *Error definition.* (1) An active case error is an error resulting from the State's improper application of Federal rules and the State's documented policies and procedures that causes a beneficiary to be determined eligible when he or she is ineligible for Medicaid or CHIP, causes a beneficiary to be determined eligible for the incorrect type of assistance, or when a determination did not occur timely or cannot be verified.

(2) 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.

(e) *Active case payment reviews.* In accordance with instructions established by CMS, the State must also conduct payment reviews to identify payments for active case errors, as well as identify the individual's understated or overstated liability, and report payment findings as specified in § 431.816.

[82 FR 31183, July 5, 2017]

§ 431.814 Pilot planning document.

(a) *Plan approval.* For each MEQC pilot, the State must submit a MEQC pilot planning document that meets the requirements of this section to CMS for approval by the first November 1 following the end of the State's PERM year. The State must receive approval for a plan before the plan can be implemented.

(b) *Plan requirements.* The State must have an approved pilot planning document in effect for each MEQC pilot

that must be in accordance with instructions established by CMS and that includes, at a minimum, the following for—

(1) *Active case reviews.* (i) Focus of the active case reviews in accordance with § 431.812(b)(3) and justification for focus.

(ii) Universe development process.

(iii) Sample size per program.

(iv) Sample selection procedure.

(v) Case review process.

(2) *Negative case reviews.* (i) Universe development process.

(ii) Sample size per program.

(iii) Sample selection procedure.

(iv) Case review process.

[82 FR 31183, July 5, 2017]

§ 431.816 Case review completion deadlines and submittal of reports.

(a) The State 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 the MEQC pilot planning document, the State must complete case reviews and submit reports of findings to CMS in accordance with paragraphs (b)(1) and (2) of this section.

(1) For all active and negative cases reviewed, the State must submit a detailed case-level report in a format provided by CMS.

(2) All case-level findings will be due by August 1 following the end of the MEQC review period.

[82 FR 31183, July 5, 2017]

§ 431.818 Access to records.

The State, upon written request, must submit to the HHS staff, or other designated entity, 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.

[82 FR 31184, July 5, 2017]

§ 431.820 Corrective action under the MEQC program.

The State must—

(a) Take action to correct any active or negative case errors, including deficiencies, found in the MEQC pilot sampled cases in accordance with instructions established by CMS;

(b) By the August 1 following the MEQC review period, submit to CMS a report that—

(1) Identifies the root cause and any trends found in the case review findings.

(2) Offers corrective actions for each unique error and deficiency finding based on the analysis provided in paragraph (b)(1) of this section.

(c) In the corrective action report, the State must provide updates on corrective actions reported for the previous MEQC pilot.

[82 FR 31184, July 5, 2017]

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.

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 and provide support to Federal contractors as necessary to enable the Secretary to produce national improper payment estimates for Medicaid and the Children's Health Insurance Program (CHIP).

[82 FR 31184, July 5, 2017]

§ 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.

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.

Annual sample size means the number of fee-for-service claims, managed care payments, or eligibility cases that will be sampled for review in a given PERM cycle.

Appeals means a process that allows the State to dispute the PERM Review Contractor and Eligibility Review Contractor findings with CMS after the difference resolution process has been exhausted.

Beneficiary means an applicant for, or beneficiary of, Medicaid or CHIP program benefits.

Children's Health Insurance Program (CHIP) means the program authorized and funded under Title XXI of the Act.

Corrective action means actions to be taken by the State to reduce errors or other vulnerabilities for the purpose of reducing improper payments in Medicaid and CHIP.

Deficiency means a finding in which a claim or payment had a medical, data processing, and/or eligibility error that did not result in federal and/or state improper payment.

Difference resolution means a process that allows the State to dispute the PERM Review Contractor and Eligibility Review Contractor findings directly with the contractor.

Disallowance means the percentage of Federal medical assistance funds the State is required to return to CMS in accordance with section 1903(u) of the Act.

Eligibility means meeting the State's categorical and financial criteria for receipt of benefits under the Medicaid or CHIP programs.

Eligibility Review Contractor (ERC) means the CMS contractor responsible for conducting state eligibility reviews for the PERM Program.

Federal contractor means the ERC, RC, or SC which support CMS in executing the requirements of the PERM program.

Federally Facilitated Exchange (FFE) means the health insurance exchange established by the Federal government with responsibilities that include making Medicaid and CHIP determinations for states that delegate authority to the FFE.

Federally Facilitated Exchange—Determination (FFE–D) means cases determined by the FFE in states that have delegated the authority to make Medicaid/CHIP eligibility determinations to the FFE.

Federal financial participation means the Federal Government's share of the State's expenditures under the Medicaid program and CHIP.

Finding means errors and/or deficiencies identified through the medical, data processing, and eligibility reviews.

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 beneficiary, 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.

Improper payment 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.

Lower limit means the lower bound of the 95-percent confidence interval for the State's eligibility improper payment rate.

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.

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 means any claim or payment where federal and/or state dollars were paid improperly based on medical, data processing, and/or eligibility reviews.

PERM means the Payment Error Rate Measurement process to measure improper payment in Medicaid and CHIP.

PERM review period means the timeframe in which claims and eligibility are reviewed for national annual improper payment rate calculation purposes, July through June.

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.

Recoveries mean those monies for which the State is responsible to pay back to CMS based on the identification of Federal improper payments.

Review Contractor (RC) means the CMS contractor responsible for conducting state data processing and medical record reviews for the PERM Program.

Review year means the year being analyzed for improper payments under the PERM Program.

State eligibility system means any system, within the State or with a state-delegated contractor, that is used by the state to determine Medicaid and/or CHIP eligibility and/or that maintains documentation related to Medicaid and/or CHIP eligibility determinations.

State error includes, but is not limited to, dataprocessing errors and eligibility errors as described in § 431.960(b) and (d), as determined in accordance with documented State and Federal policies. State errors do not include the errors described in paragraph § 431.960(e)(2).

State payment system means any system within the State or with a state-delegated contractor that is used to adjudicate and pay Medicaid and/or CHIP FFS claims and/or managed care payments.

State-specific sample size means the sample size determined by CMS that is required from each individual State to support national improper payment rate precision requirements.

Statistical Contractor (SC) means the contractor responsible for collecting and sampling fee-for-service claims and managed care capitation payment data, as well as calculating Medicaid and CHIP state and national improper payment rates.

States means the 50 States and the District of Columbia.

[71 FR 51081, Aug. 28, 2006, as amended at 75 FR 48847, Aug. 11, 2010; 82 FR 31184, July 5, 2017]

§ 431.960 Types of payment errors.

(a) *General rule.* Errors identified for the Medicaid and CHIP improper payments measurement under the Improper Payments Information Act of 2002 must affect payment under applicable Federal 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 resulting in Federal and/or State improper payments.

(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 federal and state 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 resulting in Federal and/or State improper payments.

(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 applicable conditions of payment per 42 CFR parts 440 through 484, this part (431), and in accordance with 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 is an error resulting in an overpayment or underpayment that is determined from a review of a beneficiary's eligibility determination, in comparison to the documentation used to establish a beneficiary's eligibility and applicable federal and state regulations and policies, resulting in Federal and/or State improper payments.

(2) Eligibility errors include, but are not limited to, the following:

(i) Ineligible individual, but authorized as eligible when he or she received services.

(ii) Eligible individual 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) Was ineligible for managed care but enrolled in managed care.

(3) The dollars paid in error due to an eligibility error is the measure of the payment error.

(4) 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 or guidance, or, if applicable, has the Secretary's approval.

(e) *Errors for purposes of determining the national improper payment rates.* (1) The Medicaid and CHIP national improper payment rates include, but are not limited to, the errors described in paragraphs (b) through (d) of this section.

(2) Eligibility errors resulting solely from determinations of Medicaid or CHIP eligibility delegated to, and made by, the Federally Facilitated Exchange will be included in the national improper payment rate.

(f) *Errors for purposes of determining the State improper payment rates.* The Medicaid and CHIP State improper payment rates include, but are not limited to, the errors described in paragraphs (b) through (d) of this section, and do not include the errors described in paragraph (e)(2) of this section.

(g) *Error codes.* CMS will define different types of errors within the above categories for analysis and reporting purposes. Only Federal and/or State

dollars in error will factor into the State's PERM improper payment rate.

[82 FR 31185, July 5, 2017]

§ 431.970 Information submission and systems access requirements.

(a) The State 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 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, eligibility, 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;

(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) Case documentation to support the eligibility review, as requested by CMS;

(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 improper payment 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.

(c) The State must provide the Federal contractor(s) with access to all payment system(s) necessary to conduct the medical and data processing review, including the Medicaid Management Information System (MMIS), any systems that include beneficiary demographic and/or provider enrollment information, and any document imaging systems that store paper claims.

(d) The State must provide the Federal contractor(s) with access to all eligibility system(s) necessary to conduct the eligibility review, including any eligibility systems of record, any electronic document management system(s) that house case file information, and systems that house the results of third party data matches.

[82 FR 31185, July 5, 2017]

§ 431.972 Claims sampling procedures.

(a) *General requirements.* The State will submit quarterly FFS claims and managed care payments, as identified in § 431.970(a), to allow federal contractors to conduct data processing, medical record, and eligibility reviews to meet the requirements of the PERM measurement.

(b) *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 PERM review period, 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.

(c) *Sample size.* CMS estimates each State's annual sample size for the PERM review at the beginning of the PERM cycle.

(1) *Precision and confidence levels*. The national annual sample size will be estimated to achieve at least a minimum National-level improper payment rate with a 90 percent confidence interval of plus or minus 2.5 percent of the total amount of all payments for Medicaid and CHIP.

(2) *State-specific sample sizes*. CMS will develop State-specific sample sizes for each State. CMS may take into consideration the following factors in determining each State's annual state-specific sample size for the current PERM cycle:

(i) State-level precision goals for the current PERM cycle;

(ii) The improper payment rate and precision of that improper payment rate from the State's previous PERM cycle;

(iii) The State's overall Medicaid and CHIP expenditures; and

(iv) Other relevant factors as determined by CMS.

[82 FR 31186, July 5, 2017]

§431.992 Corrective action plan.

(a) The State must develop a separate corrective action plan for Medicaid and CHIP for each improper payment rate measurement, designed to reduce improper payments in each program based on its analysis of the improper payment causes in the FFS, managed care, and eligibility components.

(1) The corrective action plan must address all errors that are included in the State improper payment rate defined at §431.960(f)(1) and all deficiencies.

(2) For eligibility, the corrective action plan must include an evaluation of whether actions the State takes to reduce eligibility errors will also avoid increases in improper denials.

(b) In developing a corrective action plan, the State must take the following actions:

(1) *Error analysis*. The State must conduct analysis such as reviewing causes, characteristics, and frequency of errors that are associated with improper payments. The State must review the findings of the analysis to determine specific programmatic causes to which errors are attributed (for example, provider lack of understanding of the requirement to provide documentation), if any, and to identify root improper payment causes.

(2) *Corrective action planning*. The State must determine the corrective actions to be implemented that address the root improper payment causes and prevent that same improper payment from occurring again.

(3) *Implementation and monitoring*. (i) The State must develop an implementation schedule for each corrective action and implement those actions in accordance with the schedule.

(ii) The implementation schedule must identify all of the following for each action:

(A) The specific corrective action.

(B) Status.

(C) Scheduled or actual implementation date.

(D) Key personnel responsible for each activity.

(E) A monitoring plan for monitoring the effectiveness of the action.

(4) *Evaluation*. The State must submit an evaluation of the corrective action plan from the previous measurement. The State must evaluate the effectiveness of the corrective action(s) by assessing all of the following:

(i) Improvements in operations.

(ii) Efficiencies.

(iii) Number of errors.

(iv) Improper payments.

(v) Ability to meet the PERM improper payment rate targets assigned by CMS.

(c) The State 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 improper payment rates are posted on the CMS contractor's Web site.

(d) The State must provide updates on corrective action plan implementation progress annually and upon request by CMS.

(e) In addition to paragraphs (a) through (d) of this section, each State that has an eligibility improper payment rates over the allowable threshold of 3 percent for consecutive PERM years, must submit updates on the status of corrective action implementation to CMS every other month. Status updates must include, but are not limited to the following:

(1) Details on any setbacks along with an alternate corrective action or workaround.

(2) Actual examples of how the corrective actions have led to improvements in operations, and explanations for how the improvements will lead to a reduction in the number of errors, as well as the State's next PERM eligibility improper payment rate.

(3) An overall summary on the status of corrective actions, planning, and implementation, which demonstrates how the corrective actions will provide the State with the ability to meet the 3 percent threshold.

[82 FR 31186, July 5, 2017]

§ 431.998 Difference resolution and appeal process. Difference resolution and appeal process.

(a) The State may file, in writing, a request with the relevant Federal contractor to resolve differences in the Federal contractor's findings based on medical, data processing, or eligibility reviews in Medicaid or CHIP.

(b) The State must file requests to resolve differences based on the medical, data processing, or eligibility reviews within 25 business days after the report of review findings is shared with the State.

(c) To file a difference resolution request, the State must be able to demonstrate all of the following:

(1) Have a factual basis for filing the request.

(2) Provide the appropriate Federal contractor with valid evidence directly related to the finding(s) to support the State's position.

(d) For a finding in which the State and the Federal contractor cannot resolve the difference in findings, the State may appeal to CMS for final resolution by filing an appeal within 15 business days from the date the relevant Federal contractor's finding as a result of the difference resolution is shared with the State. There is no minimum dollar threshold required to appeal a difference in findings.

(e) To file an appeal request, the State must be able to demonstrate all of the following:

(1) Have a factual basis for filing the request.

(2) Provide CMS with valid evidence directly related to the finding(s) to support the State's position.

(f) All differences, including those pending in CMS for final decision that are not overturned in time for improper payment rate calculation, will be considered as errors in the improper payment rate calculation in order to meet the reporting requirements of the IPIA.

[82 FR 31187, July 5, 2017]

§ 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.

§ 431.1010 Disallowance of Federal financial participation for erroneous State payments (for PERM review years ending after July 1, 2020).

(a) *Purpose*. (1) This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical assistance payments due to eligibility improper payment errors, as detected through the PERM program required under this subpart, in effect on and after July 1, 2020.

(2) After the State's eligibility improper rate has been established for each PERM review period, CMS will compute the amount of the disallowance, removing any underpayments due to eligibility errors, and adjust the FFP payable to each State. The disallowance or withholding is only applicable to the State's PERM year.

(3) CMS will compute the amount to be withheld or disallowed as follows:

(i) Subtract the 3 percent allowable threshold from the lower limit of the State's eligibility improper payment

rate percentage excluding underpayments.

(ii) If the difference is greater than zero, the Federal medical assistance funds for the period, are multiplied by that percentage. This product is the amount of the disallowance or withholding.

(b) *Notice to States and showing of good faith.* (1) If CMS is satisfied that the State did not meet the 3 percent allowable threshold despite a good faith effort, CMS will reduce the funds being disallowed in whole.

(2) CMS may find that a State did not meet the 3 percent allowable threshold despite a good faith effort if the State has taken the action it believed was needed to meet the threshold, but the threshold was not met. CMS will grant a good faith waiver only if the State both:

(i) Participates in the MEQC pilot program in accordance with §§ 431.800 through 431.820, and

(ii) Implements PERM CAPs in accordance with § 431.992.

(3) Each State that has an eligibility improper payment rate above the allowable threshold will be notified by CMS of the amount of the disallowance.

(c) *Disallowance subject to appeal.* If the 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.

[82 FR 31187, July 5, 2017]

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

[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).

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) Beneficiaries.

(c) *Merit system.* Subprofessional positions must be subject to merit system 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 beneficiaries; 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

Sec.

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AUTHORITY: 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), 1905(b), 1905(y), and 1905(z) 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:

State Share = [(State per capita income)^2/(National per capita income)^2] × 45 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 × 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.

(6)(i) *Newly eligible FMAP*. Beginning January 1, 2014, under section 1905(y) of the Act, the FMAP for a State that is one of the 50 States or the District of Columbia, including a State that meets the definition of expansion State in § 433.204(b), for amounts expended by such State for medical assistance for newly eligible individuals, as defined in § 433.204(a)(1), will be an increased FMAP equal to:

(A) 100 percent, for calendar quarters in calendar years (CYs) 2014 through 2016;

(B) 95 percent, for calendar quarters in CY 2017;

(C) 94 percent, for calendar quarters in CY 2018;

(D) 93 percent, for calendar quarters in CY 2019;

(E) 90 percent, for calendar quarters in CY 2020 and all subsequent calendar years.

(ii) The FMAP specified in paragraph (c)(6)(i) of this section will apply to amounts expended by a State for medical assistance for newly eligible individuals in accordance with the requirements of the methodology applied by the State under § 433.206.

(7)(i) *Temporary FMAP increase*. During the period January 1, 2014, through December 31, 2015, under section 1905(z)(1) of the Act for a State described in paragraph (c)(7)(ii) of this section, the FMAP determined under paragraph (b) of this section will be increased by 2.2 percentage points.

(ii) A State qualifies for the targeted increase in the FMAP under paragraph (c)(7)(i) of this section, if the State:

(A) Is an expansion State, as described in § 433.204(b) of this section;

(B) Does not qualify for any payments on the basis of the increased FMAP under paragraph (c)(6) of this section, as determined by the Secretary; and

(C) Has not been approved by the Secretary to divert a portion of the disproportionate share hospital allotment for the State under section 1923(f) of the Act to the costs of providing medical assistance or other health benefits coverage under a demonstration that is in effect on July 1, 2009.

(iii) The increased FMAP under paragraph (c)(7)(i) of this section is available for amounts expended by the State for medical assistance for individuals that are not newly eligible as defined in § 433.204(a)(1).

(8) *Expansion State FMAP*. Beginning January 1, 2014, under section 1905(z)(2)

of the Act, the FMAP for an expansion State defined in § 433.204(b), for amounts expended by such State for medical assistance for individuals described in § 435.119 of this chapter who are not newly eligible as defined in § 433.204(a)(1), and who are nonpregnant childless adults with respect to whom the State may require enrollment in benchmark coverage under section 1937 of the Act, will be determined in accordance with the expansion State FMAP formula in paragraph (c)(8)(i).

$$F + (T \times (N - F))$$

F = The base FMAP for the State determined under paragraph (b) of this section, subject to paragraph (c)(7) of this section.

T = The transition percentage specified in paragraph (c)(8)(ii) of this section.

N = The Newly Eligible FMAP determined under paragraph (c)(6) of this section.

(i) *Expansion State FMAP.*

(ii) *Transition percentage.* For purposes of paragraph (c)(8)(i) of this section, the transition percentage is equal to:

(A) 50 percent, for calendar quarters in CY 2014;

(B) 60 percent, for calendar quarters in CY 2015;

(C) 70 percent, for calendar quarters in CY 2016;

(D) 80 percent, for calendar quarters in CY 2017;

(E) 90 percent, for calendar quarters in CY 2018; and

(F) 100 percent, for calendar quarters in CY 2019 and all subsequent calendar years.

(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; 78 FR 19942, Apr. 2, 2013]

§ 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 consistent with § 438.370(a) of this chapter: 75 percent; consistent with § 438.370(b): 50 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; 81 FR 27853, May 6, 2016]

§ 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 beneficiary'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 beneficiary 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(e) 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 the State interest on FFP when—

(i) CMS has notified the Medicaid agency under § 430.42 of this subpart that a State's claim for FFP is not allowable;

(ii) The agency has requested a reconsideration of the disallowance to the Administrator under § 430.42 of this chapter and has chosen to retain the FFP during the administrative reconsideration process in accordance with paragraph (c)(2) of this section;

(iii)(A) CMS has made a final determination upholding part or all of the disallowance;

(B) The agency has withdrawn its request for administrative reconsideration on all or part of the disallowance; or

(C) The agency has reversed its decision to retain the funds without withdrawing its request for administrative reconsideration and CMS upholds all or part of the disallowance.

(iv) The agency has appealed the disallowance to the Departmental 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.

(v)(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 request for administrative reconsideration or appeal on part of the disallowance and therefore returns only that part of the funds on which it has withdrawn its request for administrative reconsideration or 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 requested administrative reconsideration to CMS or appeal of a disallowance to the Board and wishes to retain the disallowed funds until CMS or the Board issues a final determination, the agency must notify the CMS Regional Office in writing of its decision to do so.

(2) The agency must mail its notice to the CMS Regional Office within 60 days of the date of receipt of the notice of the disallowance, as established by the certified mail receipt accompanying the notice.

(3) If the agency withdraws its decision to retain the FFP or its request for administrative reconsideration or appeal on all or part of the FFP, the agency must notify CMS in writing.

(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 CMS of the administrative reconsideration if the State elects not to

appeal to the Board, or final determination by the Board;

(ii) On the date CMS receives written notice from the State that it is withdrawing its request for administrative reconsideration and elects not to appeal to the Board, or withdraws its appeal to the Board on all of the disallowed funds; or

(iii) If the agency withdraws its request for administrative reconsideration on part of the funds on—

(A) The date CMS receives written notice from the agency that it is withdrawing its request for administrative reconsideration on a specified part of the disallowed funds for the part on which the agency withdraws its request for administrative reconsideration; and

(B) The date of the final determination by CMS on the part for which the agency pursues its administrative reconsideration; or

(iv) 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

(v) If the agency has given CMS written notice of its intent to repay by installment, in the quarter in which the final installment is paid. Interest during the repayment of Federal funds by installments will be at the Current Value of Funds Rate (CVFR); or

(vi) 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, as amended at 77 FR 31510, May 29, 2012]

§ 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) of the Act which requires States to share in the cost of medical assistance expenditures and permit both State and local governments to participate in the financing of the non-Federal portion of medical assistance expenditures.

(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; 75 FR 73975, Nov. 30, 2010]

§ 433.51 Public Funds as the State share of financial participation.

(a) Public Funds 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 public funds are appropriated directly to the State or local Medicaid agency, or are transferred from other public agencies (including Indian tribes) to the State or local agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for FFP under this section.

(c) The public funds are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

[75 FR 73975, Nov. 30, 2010]

§ 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 individuals with intellectual disabilities);

(4) Intermediate care facility services for individuals with intellectual disabilities, and similar services furnished by community-based residences for individuals with intellectual disabilities, 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/IIDs 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 nonpublic 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 nonpublic 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 75, 45 CFR part 95, subpart F, and part 11, State Medicaid Manual; and

(2) Section 1903(r) of the Act, which imposes certain standards and conditions on mechanized claims processing and information retrieval systems (including eligibility determination systems) in order for these systems to be eligible for Federal funding under section 1903(a) of the Act.

(b) [Reserved]

[50 FR 30846, July 30, 1985, as amended at 54 FR 41973, Oct. 13, 1989; 76 FR 21973, Apr. 19, 2011; 80 FR 75841, Dec. 4, 2015]

§ 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'' means:

(1) ''Mechanized claims processing and information retrieval system'' means the system of software and/or hardware used to process claims for medical assistance 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. It may include modules of hardware, software, and other technical capabilities that are used by the Medicaid Single State Agency to manage, monitor, and administer the Medicaid enterprise, including transaction processing, information management, and reporting and data analytics.

(2) ''Mechanized claims processing and information retrieval system'' includes a ''System of Systems.'' Under this definition all modules or systems developed to support a Medicaid Management Information System (MMIS) and Eligibility and Enrollment (E&E) may be implemented as discrete, independent, interoperable elements. Use of a System of Systems requires interoperability between the systems.

(i) The system consists of—

(A) Required modules specified by the Secretary.

(B) Required changes to the system or required module that are specified by the Secretary.

(C) Approved enhancements to the system or module.

(ii) A ''Mechanized claims processing and information retrieval system'' include—s—

(A) An Eligibility and Enrollment (E&E) System which is used to process applications from Medicaid or CHIP applicants and beneficiaries to determine eligibility for enrollment in the Medicaid or CHIP programs, as well as change in circumstance updates and renewals; and

(B) A Medicaid Management Information System (MMIS) which is used to process claims for Medicaid payment from providers of medical care and services furnished to beneficiaries under the medical assistance program and to perform other functions necessary for economic and efficient operations, management, monitoring, and administration of the Medicaid program. The pertinent business areas are those included in the MMIS Certification Toolkit, and they may be applicable to Fee-For-Service, Managed Care, or an Administrative Services Organization (ASO) model.

(c) ''Medicaid Information Technology Architecture (MITA)'' is defined at § 495.302 of this chapter.

(d) ''Open source'' means software that can be used freely, changed, and shared (in modified or unmodified form) by anyone. Open source software is distributed under Open Source Initiative-approved licenses that comply

with an open source framework that allows for free redistribution, provision of the source code, allowance for modifications and derived works, free and open distribution of licenses without restrictions and licenses that are technology-neutral.

(e) ''Proprietary'' means a closed source product licensed under exclusive legal right of the copyright holder with the intent that the licensee is given the right to use the software only under certain conditions, and restricted from other uses, such as modification, sharing, studying, redistribution, or reverse engineering.

(f) ''Service'' means a self-contained unit of functionality that is a discretely invokable operation. Services can be combined to provide the functionality of a large software application.

(g) ''Shared Service'' means the use of a service, including SaaS, by one part of an organization or group, including states, where that service is also made available to other entities of the organization, group or states. Thus the funding and resourcing of the service is shared and the providing department effectively becomes an internal service provider.

(h) ''Module'' means a packaged, functional business process or set of processes implemented through software, data, and interoperable interfaces that are enabled through design principles in which functions of a complex system are partitioned into discrete, scalable, reusable components.

(i) ''Commercial Off the Shelf'' (COTS) software means specialized software (which could be a system, subsystem or module) designed for specific applications that is available for sale or lease to other users in the commercial marketplace, and that can be used with little or no modification.

(j) ''Software-as-a-Service'' (SaaS) means a software delivery model in which software is managed and licensed by its vendor-owner on a pay-for-use or subscription basis, centrally hosted, on-demand, and common to all users.

[51 FR 45330, Dec. 18, 1986, as amended at 54 FR 41973, Oct. 13, 1989; 76 FR 21973, Apr. 19, 2011; 80 FR 75841, Dec. 4, 2015]

§ 433.112 FFP for design, development, installation or enhancement of mechanized processing and information retrieval systems.

(a) Subject to paragraph (c) of this section, 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 E&E or claims system described in an APD if certain conditions are met. The conditions that a system must meet are:

(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, standards and conditions, 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 75, subpart E.

(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.

(10) Use a modular, flexible approach to systems development, including the use of open interfaces and exposed application programming interfaces; the separation of business rules from core programming, available in both human and machine readable formats.

(11) Align to, and advance increasingly, in MITA maturity for business, architecture, and data.

(12) The agency ensures alignment with, and incorporation of, industry standards adopted by the Office of the National Coordinator for Health IT in accordance with 45 CFR part 170, subpart B: The HIPAA privacy, security and transaction standards; accessibility standards established under section 508 of the Rehabilitation Act, or standards that provide greater accessibility for individuals with disabilities, and compliance with Federal civil rights laws; standards adopted by the Secretary under section 1104 of the Affordable Care Act; and standards and protocols adopted by the Secretary under section 1561 of the Affordable Care Act.

(13) Promote sharing, leverage, and reuse of Medicaid technologies and systems within and among States.

(14) Support accurate and timely processing and adjudications/eligibility determinations and effective communications with providers, beneficiaries, and the public.

(15) Produce transaction data, reports, and performance information that would contribute to program evaluation, continuous improvement in business operations, and transparency and accountability.

(16) The system supports seamless coordination and integration with the Marketplace, the Federal Data Services Hub, and allows interoperability with health information exchanges, public health agencies, human services programs, and community organizations providing outreach and enrollment assistance services as applicable.

(17) For E&E systems, the State must have delivered acceptable MAGI-based system functionality, demonstrated by performance testing and results based on critical success factors, with limited mitigations and workarounds.

(18) The State must submit plans that contain strategies for reducing the operational consequences of failure to meet applicable requirements for all major milestones and functionality.

(19) The agency, in writing through the APD, must identify key state personnel by name, type and time commitment assigned to each project.

(20) Systems and modules developed, installed or improved with 90 percent match must include documentation of components and procedures such that the systems could be operated by a variety of contractors or other users.

(21) For software systems and modules developed, installed or improved with 90 percent match, the State must consider strategies to minimize the costs and difficulty of operating the software on alternate hardware or operating systems.

(22) Other conditions for compliance with existing statutory and regulatory requirements, issued through formal guidance procedures, determined by the Secretary to be necessary to update and ensure proper implementation of those existing requirements.

(c)(1) FFP is available at 90 percent of a State's expenditures for the design, development, installation or enhancement of an E&E system that meets the requirements of this subpart and only for costs incurred for goods and services provided on or after April 19, 2011.

(2) Design, development, installation, or enhancement costs include costs for initial licensing of commercial off the shelf (COTS) software, and the minimum necessary costs to analyze the suitability of COTS software, install, configure and integrate the COTS software, and modify non-COTS software to ensure coordination of operations. The nature and extent of such costs must be expressly described in the approved APD.

[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; 76 FR 21973, Apr. 19, 2011; 80 FR 75842, Dec. 4, 2015; 81 FR 3011, Jan. 20, 2016]

§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 (i).

(b) If CMS disapproves the system, the notice will include all of the following information:

(1) The findings of fact upon which the determination was made.

(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; 76 FR 21974, Apr. 19, 2011]

§433.116 FFP for operation of mechanized claims processing and information retrieval systems.

(a) Subject to paragraph (j) of this section, 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 enhanced FFP for system operations if the conditions specified in paragraphs (c) through (i) of this section are met.

(c) The conditions of §433.112(b)(1) through (22) must be met at the time of approval.

(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.)

(i) The standards and conditions of §433.112(b)(10) through (b)(16) of this subpart must be met.

(j) Beginning, and no earlier than, April 19, 2011, FFP is available at 75 percent of a State's expenditures for the operation of an E&E system that meets the requirements of this subpart. FFP is not available for E&E systems that do not meet the standards and conditions.

[45 FR 14213, Mar. 5, 1980. Redesignated and amended at 50 FR 30847, July 30, 1985; 55 FR 4375, Feb. 7, 1990; 76 FR 21974, Apr. 19, 2011; 80 FR 75842, Dec. 4, 2015]

§433.117 Initial approval of replacement systems.

(a) A replacement system must meet all standards and 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 (j), 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, as amended at 76 FR 21974, Apr. 19, 2011]

§ 433.119 Conditions for reapproval; notice of decision.

(a) CMS periodically reviews each system operation initially approved under § 433.114 of this subpart and reapproves it for FFP at 75 percent of expenditures if the following standards and conditions are met:

(1) The system meets the requirements of § 433.112(b)(1), (3), (4), and (7) through (22).

(2) The system meets the conditions of § 433.116 (d) through (j).

(3) The system meets the standards, conditions, and performance standards for reapproval and the system requirements in part 11 of the State Medicaid Manual as periodically amended.

(4) A State system must meet all of the requirements of this subpart within the appropriate period CMS determines should apply as required by § 433.123(b) of this subpart.

(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) After performing the review under paragraph (a) of this section, CMS will issue to the Medicaid agency a written notice informing the agency whether the system is reapproved or disapproved. If the system is disapproved, the notice will include the following information:

(1) CMS's decision to reduce FFP for system operations from 75 percent to 50 percent of expenditures, beginning with the first day of the first calendar quarter after CMS issues the written notice to the State.

(2) The findings of fact upon which the determination was made.

(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; 76 FR 21974, Apr. 19, 2011; 80 FR 75843, Dec. 4, 2015]

§ 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 for reapproval in § 433.119, CMS may reduce FFP for certain expenditures for system operations.

(b) CMS may reduce FFP from 75 percent to 50 percent for expenditures related to the operations of non-compliant functionality or system components.

[80 FR 75843, Dec. 4, 2015]

§ 433.121 Reconsideration of the decision to reduce FFP after reapproval review.

(a) The State Medicaid agency may appeal (to the Departmental Appeals Board under 45 CFR part 16) a disallowance concerning a reduction in FFP claimed for system operations caused by a disapproval of the State's system.

(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; 76 FR 21974, Apr. 19, 2011]

§ 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]

§ 433.131 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.

(c) *Waiver of deadline*. In no case will CMS waive the December 31, 2015 deadlines referenced in § 433.112(c) and § 433.116(j).

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989; 76 FR 21975, Apr. 19, 2011]

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 beneficiary 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 beneficiary, 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 beneficiary 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 beneficiary 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 beneficiaries 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)(1) of this chapter, the agency must—

(i) Use the information that identifies Medicaid beneficiaries 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 beneficiaries 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)(2) of this chapter, from the State title IV–A agency, information not previously reported that identifies those Medicaid beneficiaries who 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 beneficiaries and, (if their names and SSNs were available to the

agency under paragraph (c) of this section) absent or custodial parents of Medicaid beneficiaries with employment-related injuries or illnesses; and

(ii) From State Motor Vehicle accident report files, information that identifies those Medicaid beneficiaries 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.* Except as specified under paragraph (l) of this section, the agency must take action to identify those paid claims for Medicaid beneficiaries that contain diagnosis codes that are indicative of trauma, or injury, poisoning, and other consequences of external causes, 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).

(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 (3) of this section, 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) Within 45 days, the agency must follow up (if appropriate) on such information 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; 81 FR 27853, May 6, 2016; 81 FR 86449, Nov. 30, 2016]

§ 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) [Reserved]

(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 for preventive pediatric services, including early and periodic screening, diagnosis and treatment services provided for under part

441, subpart B, of this chapter, that are 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) For child support enforcement services beginning February 9, 2018, the provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited 100 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 beneficiary'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; 85 FR 87100, Dec. 31, 2020]

§ 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 beneficiary 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 the identity of a child's parents and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in § 435.116 of this chapter (pregnant women), who are exempt from cooperating in establishing the identity of a child's parents and obtaining medical support and payments from, or derived from, the non-custodial parent of a child; 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 beneficiary 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; 81 FR 86450, Nov. 30, 2016]

§ 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 the identity of a child's parents 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) Except as exempt under § 433.145(a)(2), establishing the identity of a child's parents and obtaining medical support and payments for himself or herself and any other person for whom the individual can legally assign rights; 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) For establishing the identity of a child's parents 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 that cooperation is against the best interests of the child.

(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.

[45 FR 8984, Feb. 11, 1980, as amended at 55 FR 48606, Nov. 21, 1990; 58 FR 4907, Jan. 19, 1993; 81 FR 86450, Nov. 30, 2016]

§ 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 beneficiary who—

(1) Refuses to assign his own rights or those of any other individual for whom he can legally make an assignment; or

(2) In the case of an applicant, does not attest to willingness to cooperate, and in the case of a beneficiary, refuses to cooperate in establishing the identity of a child's parents, obtaining medical child support and pursuing liable third parties, 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.

[45 FR 8984, Feb. 11, 1980, as amended at 81 FR 86450, Nov. 30, 2016]

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:

(1) The Medicaid agency may not refer a case for medical support enforcement when the following criteria have been met:

(i) The Medicaid referral is based solely upon health care services provided through an Indian Health Program (as defined at 25 U.S.C. 1603(12)), including through the Purchased/Referred Care program, to a child who is eligible for health care services from the Indian Health Service (IHS).

(ii) [Reserved]

(2) The Medicaid agency will 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, as amended at 81 FR 93560, Dec. 20, 2016]

§ 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 beneficiary, 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—Methodologies for Determining Federal Share of Medicaid Expenditures for Adult Eligibility Group

SOURCE: 78 FR 19942, Apr. 2, 2013, unless otherwise noted.

§ 433.202 Scope.

This subpart sets forth the requirements and procedures that are applicable to support State claims for the increased FMAP specified at § 433.10(c)(6) for the medical assistance expenditures for individuals determined eligible as specified in § 435.119 of this chapter who meet the definition of newly eligible individual specified in § 433.204(a)(1). These procedures will also identify individuals determined eligible as specified in § 435.119 of this chapter for whom the State may claim the regular FMAP rate specified at § 433.10(b) or the increased FMAP rate specified at § 433.10(c)(7) or (8), as applicable.

§ 433.204 Definitions.

(a)(1) *Newly eligible individual* means an individual determined eligible for Medicaid in accordance with the requirements of the adult group described in § 435.119 of this chapter, and who, as determined by the State in accordance with the requirements of § 433.206, would not have been eligible for Medicaid under the State's eligibility standards and methodologies for the Medicaid State plan, waiver or demonstration programs in effect in the State as of December 1, 2009, for full benefits or for benchmark coverage described in § 440.330(a), (b), or (c) of this chapter or benchmark equivalent coverage described in § 440.335 of this chapter that has an aggregate actuarial value that is at least actuarially equivalent to benchmark coverage described in § 440.330(a), (b), or (c) of this chapter, or would have been eligible but not enrolled (or placed on a waiting list) for such benefits or coverage through a waiver under the plan that had a capped or limited enrollment that was full.

(2) *Full benefits* means, for purposes of paragraph (a)(1) of this section, with respect to an adult individual, medical assistance for all services covered under the State plan under Title XIX of the Act that is not less in amount, duration, or scope, or is determined by the Secretary to be substantially equivalent, to the medical assistance available for an individual described in section 1902(a)(10)(A)(i) of the Act.

(3) For purposes of establishing under paragraphs (a)(1) and (2) of this section whether an individual would not have been eligible for full benefits, benchmark coverage, or benchmark equivalent coverage under a waiver or demonstration program in effect on December 1, 2009, the State must provide CMS with its analysis, in accordance with guidance issued by CMS, about whether the benefits available under such waiver or demonstration constituted full benefits, benchmark coverage, or benchmark equivalent coverage. CMS will review such analysis and confirm the applicable FMAP. Individuals for whom such benefits or coverage would have been available under such waiver or demonstration are not newly eligible individuals.

(b)(1) *Expansion State* means a State that, as of March 23, 2010, offered health benefits coverage statewide to parents and nonpregnant, childless adults whose income is at least 100 percent of the Federal Poverty Level. A State that offers health benefits coverage to only parents or only nonpregnant childless adults described in the preceding sentence will not be considered to be an expansion State. Such health benefits coverage must:

(i) Have included inpatient hospital services;

(ii) Not have been dependent on access to employer coverage, employer contribution, or employment; and

(iii) Not have been limited to premium assistance, hospital-only benefits, a high deductible health plan, or benefits under a demonstration program authorized under section 1938 of the Act.

(2) For purposes of paragraph (b)(1) of this section and for § 433.10(c)(8), a nonpregnant childless adult means an individual who is not eligible based on pregnancy and does not meet the definition of a caretaker relative in § 435.4 of this chapter.

§ 433.206 Threshold methodology.

(a) *Overview*. Effective January 1, 2014, States must apply the threshold methodology described in this paragraph for purposes of determining the appropriate claiming for the Federal share of expenditures at the applicable FMAP rates described in § 433.10(b) and (c) for medical assistance provided with respect to individuals who have been determined eligible for the Medicaid program under § 435.119 of this chapter. Subject to the provisions of this paragraph, States must apply the CMS-approved State specific threshold methodology to determine and distinguish such individuals as newly or not newly eligible individuals in accordance with the definition in § 433.204(a)(1), and in accordance with States' Medicaid eligibility criteria as in effect on December 1, 2009 and to attribute their associated medical expenditures with the appropriate FMAP. The threshold methodology must not be applied by States for the purpose of determining the applicable FMAP for individuals under any other eligibility category other than § 435.119 of this chapter.

(b) *General principles*. The threshold methodology should:

(1) Not impact the timing or approval of an individual's eligibility for Medicaid.

(2) Not be biased in such a manner as to inappropriately establish the numbers of, or medical assistance expenditures for, individuals determined to be newly or not newly eligible.

(3) Provide a valid and accurate accounting of individuals who would have been eligible in accordance with the December 1, 2009 eligibility standards and applicable eligibility categories for the benefits described in § 433.204(a)(1), and subject to paragraphs (d), (e), and (g) of this section, by incorporating simplified assessments of resources, enrollment cap requirements in place at that time, and other special circumstances as approved by CMS, respectively.

(4) Operate efficiently, without further review once an individual has been determined not to be newly eligible based on the December 1, 2009 standards for any eligibility category.

(c) *Components of the threshold methodology*. Subject to the submission of a threshold methodology State plan amendment as specified in paragraph (h) of this section, the provisions of the threshold methodology consist of two components, the individual income-based determination and population-based non-income adjustments to reflect resource criteria, enrollment caps in effect on December 1, 2009, and other factors in accordance with paragraph (g) of this section.

(1) *Scope*. The threshold methodology shall apply with respect to the population, and the associated expenditures for such population, which has been determined eligible for Medicaid under section 1902(a)(10)(A)(i)(VIII) of the Act and in accordance with § 435.119 of this chapter. This population and associated expenditures must not include individuals who have been determined eligible for Medicaid under any other mandatory or optional eligibility category.

(2) *Benefit criteria for newly eligible*. An individual eligible for and enrolled under § 435.119 of this chapter is considered newly eligible if, with respect to the applicable eligibility category in effect on December 1, 2009, the benefits did not meet the criteria described in the newly eligible definition at § 433.204(a)(1).

(3) *Individual income-based determination*. The individual income-based determination shall be a comparison of the individual's MAGI-based income to the income standard in effect on December 1, 2009, as converted to an

equivalent MAGI-based income standard for each applicable eligibility category as in effect on that date, as follows.

(i) The amount of an individual's income under the threshold methodology is the MAGI-based income determined in accordance with § 435.603 of this chapter.

(ii) For each individual, the equivalent MAGI-based income eligibility standard is the applicable income eligibility standard for the applicable category of eligibility as in effect on December 1, 2009 that is converted to an equivalent MAGI-based income standard. For example, as applicable, a separate MAGI-based income standard will be applied for individuals determined to be disabled who would have been eligible under an optional eligibility category in effect on December 1, 2009 that was based on disability. For these purposes, the applicable equivalent MAGI-based standard is the standard as submitted by the State and approved by CMS in accordance with CMS guidance.

(iii) With respect to income eligibility criteria, if the individual's MAGI-based income is at or below the applicable converted MAGI-based income standard for the relevant eligibility category or group, then the individual is included in the population that is not newly eligible;

(iv) With respect to income eligibility criteria, if the individual's MAGI-based income is greater than the applicable converted MAGI-based income standard for the relevant eligibility category or group, then the individual is included in the population that is newly eligible;

(v) *Treatment of spend-down programs.* Treatment of medically needy or spend-down programs under the threshold methodology is described in paragraph (f) of this section.

(vi) For purposes of comparing the individual's MAGI-based income to the applicable converted MAGI-based income standard in effect on December 1, 2009, an individual will not be considered disabled absent an actual disability determination for the individual that is in accordance with the disability definition applicable for the State under Title XIX of the Act.

(4) *Treatment of disability.* For purposes of applying the appropriate FMAP under § 433.10(b) or (c) for the medical assistance expenditures of an individual in applying the definition of newly eligible under § 433.204(a)(1), for eligibility categories or groups as in effect on December 1, 2009 for which disability was an eligibility criteria:

(i) *During the period of a disability determination.* During the period for which a disability determination is pending, including during the period of any appeal process, and absent an actual disability determination for the individual that is in accordance with the disability definition applicable for the State under Title XIX of the Act, the individual is not considered to be disabled.

(ii) *Following a disability determination.* With respect to an individual for which a disability determination was pending, following the actual determination of disability, the individual will be considered disabled effective with the date of the disability determination, or, if later, the disability onset date, as determined.

(5) *Population-based adjustments to the populations of newly eligible and not newly eligible.* (i) The State may elect a resource criteria proxy adjustment described in paragraph (d) of this section.

(ii) States that had a waiver or demonstration program with an enrollment cap in effect as of December 1, 2009 must apply an adjustment based on enrollment caps, subject to the definition of newly eligible individual in § 433.204(a)(1) and paragraph (e) of this section.

(iii) States that have special circumstances may need to submit associated proxy methodologies to CMS for approval by CMS as described in paragraph (g) of this section.

(6) *Application of FMAP rates to adult group expenditures.* Subject to population adjustments under paragraphs (d), (e), or (g) of this section, federal funding for a State's expenditures for medical assistance provided to individuals determined eligible under § 435.119 of this chapter, including individuals determined eligible under that eligibility group during the evaluation for another eligibility category, must be

claimed using the applicable FMAP as follows:

(i) The newly eligible FMAP under § 433.10(c)(6) is applicable for the medical assistance expenditures for individuals determined to be newly eligible, as defined in § 433.204(a)(1).

(ii) The applicable FMAP under § 433.10(b) or § 433.10(c)(7) or (8) is applicable for the medical assistance expenditures for individuals determined not to be newly eligible.

(7) *Status as newly or not newly eligible.* Under the threshold methodology States must provide that once individuals are determined under the threshold methodology to be either newly or not newly eligible individuals in accordance with the applicable December 1, 2009 eligibility criteria, the State would apply that determination until a new determination of MAGI-based income has been made in accordance with § 435.916 of this chapter, or the individual has been otherwise determined not to be covered under the adult group set forth at § 435.119 of this chapter.

(d) *Optional resource criteria proxy adjustment*—(1) *General.* Under an election under this paragraph (d), the State may use a resource proxy methodology for purposes of adjusting the claims for the expenditures of the population enrolled under § 435.119 of this chapter to account for individuals who would not have been eligible for Medicaid because of the application of resource criteria as in effect for such population as of December 1, 2009, and therefore would meet the newly eligible individual definition at § 433.204(a)(1). Under this paragraph (d), a State may elect to apply a resource proxy methodology with respect to the resource criteria as in effect on December 1, 2009 and applied to the expenditures for a specific eligibility category or categories of individuals as in effect on December 1, 2009, or applied to the expenditures of the entire population enrolled under § 435.119 of this chapter. As provided in paragraph (d)(4) of this section, the State must indicate any resource proxy election in the threshold methodology State plan amendment submitted under paragraph (h) of this section. The use of a resource proxy methodology must not delay or interfere with the eligibility determination for an individual.

(2) A State's resource proxy methodology must:

(i) Describe each eligibility group or groups for which an individual eligible under § 435.119 would have been eligible on December 1, 2009, subject to resource criteria, and a methodology to apply those resource criteria as an adjustment to the total expenditures to adjust determinations of the newly eligible population under paragraph (c) of this section.

(ii) Be auditable.

(iii) Be based on statistically valid data, which is either:

(A) Existing State data from and for periods before January 1, 2014 on the resources of individuals who had applied and received a determination with respect to Medicaid eligibility, including resource eligibility under the State's applicable December 1, 2009 eligibility criteria. The existing State data must be specifically related to resource eligibility determinations, indicate the number and types of individuals for whom resource determinations were made, and establish the denial rates specifically identified as due to excess resources; or

(B) Post-eligibility State data on the resources of individuals described in paragraph (d)(2)(iii)(B)(*1*) and (*2*) of this section, based on and obtained through a post-eligibility statistically valid sample of such individuals with respect to the applicable Medicaid eligibility categories and resource eligibility criteria under the State's applicable December 1, 2009 eligibility criteria:

(*1*) State data from and for periods before January 1, 2014 must be for individuals in eligibility categories relevant to § 435.119 of this chapter who apply and receive a determination with respect to Medicaid eligibility, including both approvals and denials, to establish denial rates specifically due to excess resources and identify numbers and types of individuals.

(*2*) State data from and for periods on or after January 1, 2014 must only be for individuals determined eligible and enrolled under § 435.119 of this chapter, must compare individuals' resources to the applicable December 1, 2009 resource criteria to establish denial rates

specifically due to excess resources, and identify numbers and types of individuals.

(iv) Describe the State data on individuals' resources used and the application of such data. Whether such State data is based on data described in paragraph (d)(2)(iii)(A) or (B) of this section, such State data must represent sampling results for a period of sufficient length to be statistically valid.

(v) Provide that the resource proxy methodology will account for the treatment of resources in a statistically valid manner when there is a lack of sufficient information to make a resource determination for a particular individual in a sampled population.

(vi) Describe the application of the resource proxy methodology in establishing the amount and submission of claims for Federal funding by the State for the medical assistance expenditures of the applicable eligibility group(s). Such claims submitted under the resource proxy methodology must reflect the appropriate FMAP for the medical assistance expenditures of the affected eligibility group(s).

(vii) As appropriate, describe and demonstrate the statistical validity of the resource proxy methodology and the use of data under such methodology.

(3) *Effective date for application of resource proxy*. The resource proxy shall not be effective prior to the beginning of the quarter in which such resource proxy is submitted to CMS under the threshold methodology State plan in paragraph (h) of this section.

(4) *One time election for resource proxy*. The election, application, and description of a resource proxy methodology under this paragraph for individuals determined eligible under § 435.119 must be included in a one-time submission of a State plan amendment submitted under paragraph (h) of this section no later than one year from the first day of the quarter in which eligibility for individuals under § 435.119 of this chapter is initially effective for the State.

(e) *Enrollment caps adjustment*—(1) *Scope*. Certain States may have applied enrollment caps, limits, or waiting lists in their Medicaid programs as in effect on December 1, 2009. Under the definition of newly eligible individual in § 433.204(a)(1), such States must consider as newly eligible those individuals eligible under § 435.119 of this chapter who would otherwise be eligible for full benefits, benchmark coverage, or benchmark equivalent coverage provided through a demonstration under the State plan effective December 1, 2009, but would not have been enrolled (or would have been on a waiting list) based on the application of an enrollment cap or limit determined in accordance with the approved demonstration as in effect on that date. Such States must only apply such enrollment cap, limit or waiting list provisions with respect to eligibility category or categories for which such provisions were applicable (for example, nonpregnant childless adults or parents/caretaker relatives) and in effect under the State's Medicaid program on December 1, 2009. For this purpose, individuals who would have been on a waiting list are considered as not enrolled under the demonstration.

(2) A State for which multiple enrollment caps or limits were in effect under its December 1, 2009 Medicaid program may elect to combine such enrollment caps or limits, unless such treatment would preclude claiming of Federal funding at the applicable FMAP rate required under § 433.10(b) or (c) (for example, to distinguish claims for childless adults and parents in an expansion State) for the medical assistance expenditures of individuals determined eligible and enrolled under § 435.119 of this chapter; a State with enrollment cap or limit provisions that would preclude combining enrollment caps or limit provisions must use separate caps; or, the State, at its option, may elect to use separate caps.

(3) For purposes of claiming Federal funding, with respect to each claiming period for which the State claims Federal funding for an eligibility category for which an enrollment cap or limit is applicable and in effect on December 1, 2009, the State must account for:

(i) The total unduplicated number of individuals eligible and enrolled under § 435.119 of this chapter for the applicable claiming period.

(ii) The total State medical assistance expenditures for individuals eligible and enrolled under § 435.119 of this chapter for the applicable claiming period.

(iii) The enrollment cap or limit in effect on December 1, 2009 for the eligibility category, determined in accordance with the approved demonstration as in effect on December 1, 2009.

(A) For States that elect under paragraph (e)(2) of this section to combine the enrollment caps, the enrollment cap is the sum of the enrollment caps for each eligibility group which is being combined.

(B) For States that elect to treat the enrollment caps separately under paragraph (e)(2) of this section, each enrollment cap will be accounted for separately.

(C) The level of the enrollment cap will be as authorized under the demonstration in effect on December 1, 2009; or, if the State had affirmatively set the cap at a lower level consistent with flexibility provided by the demonstration terms and conditions, the State may elect to apply the lower cap as in effect in the State on December 1, 2009. If a State elects to use such an alternate State-specified enrollment cap, the State will provide CMS with evidence, in its State plan amendment submitted to CMS under paragraph (h) of this section, that it had affirmatively implemented such a cap. Whether the State uses the authorized cap or a lower, verifiable cap as in effect in the State consistent with the demonstration special terms and conditions, the amount of expenditures up to the proportion of the 2009 enrollment cap to the total number of currently enrolled people in the group would not be claimed at the newly eligible FMAP.

(4) States for which an enrollment cap, limit, or waiting list was applicable under their Medicaid programs as in effect on December 1, 2009, must describe the treatment of such provision or provisions in the submission to CMS for approval by CMS in accordance with the State plan requirements outlined in § 433.206(h).

(f) *Application of spend-down income eligibility criteria*—(1) *General.* Certain States' Medicaid programs as in effect on December 1, 2009 may have included eligibility categories for which deduction of incurred medical expenses from income (referred to as spend-down) under the provisions of sections 1902(a)(10)(C) or 1902(f) of the Act was applied in determining individuals' Medicaid eligibility. Paragraphs (f)(2) and (3) of this section apply, for purposes of determining whether an individual enrolled under § 435.119 of this chapter meets the definition of newly eligible under § 433.204(a)(1), and for purposes of applying the appropriate FMAP under § 433.10(b) or (c) for the medical assistance expenditures of the individual for which a spend-down eligibility category of a State effective on December 1, 2009 is applicable.

(2) *Not newly eligible individual.* For purposes of a State's spend-down provision, an individual enrolled under § 435.119 of this chapter whose income before the deduction of incurred medical expenses is less than or equal to the applicable December 1, 2009 State spend-down eligibility income level that would have resulted in full benefits is considered not newly eligible. The FMAP applicable for the medical assistance expenditures of such an individual is the appropriate FMAP under § 433.10(b) and (c) as applicable for an individual who is not newly eligible.

(3) *Newly eligible individual.* For purposes of a State's spend-down provision, an individual enrolled under § 435.119 of this chapter whose income before the deduction of incurred medical expenses is greater than the applicable State spend-down eligibility income level is considered newly eligible. The FMAP applicable for the medical assistance expenditures of such an individual is the appropriate FMAP under § 433.10(b) and (c) as applicable for an individual who is newly eligible.

(g) *Special circumstances.* States may submit additional proxy methodologies to CMS for approval by CMS in accordance with the State plan requirements outlined in § 433.206(h).

(h) *Threshold methodology State plan requirements.* To claim expenditures at the increased FMAPs described in § 433.210(c)(6) or (c)(8), the State must amend its State plan under the provisions of subpart B of part 430 to reflect the threshold methodology the State implements in accordance with the

provisions of this section. The threshold methodology will be included as an attachment to the State plan and, explicitly and by reference, must:

(1) Specify that the threshold methodology the State implements is in accordance with this section;

(2) Specify that the threshold methodology the State implements accounts for the individuals determined eligible under the adult group in § 435.119 of this chapter as a newly eligible individual or not newly eligible individual; and, on that basis, the State implements appropriate tracking for purpose of claiming Federal Medicaid funding for the associated medical assistance expenditures.

(3) Reference the converted MAGI-based December 1, 2009 income eligibility standards and the associated eligibility groups, describe how the State will apply such standards and methodologies, and include other relevant criteria in the assignment of FMAP.

(4) Indicate any required provisions, or options and alternatives the State elects, with respect to:

(i) Treatment of resources, in accordance with paragraph (d) of this section;

(ii) Treatment of enrollment caps or waiting lists, in accordance with paragraph (e) of this section; and

(iii) Special circumstances as approved by CMS in accordance with paragraph (g) of this section.

[78 FR 19942, Apr. 2, 2013, as amended at 78 FR 32991, June 3, 2013]

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 1 year 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 1-year period, 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.

[54 FR 5460, Feb. 3, 1989, as amended at 77 FR 31511, May 29, 2012]

§ 433.302 Scope of subpart.

This subpart sets forth the requirements and procedures under which States have 1 year 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.

[77 FR 31511, May 29, 2012]

§ 433.304 Definitions.

As used in this subpart—

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.

Final written notice means that written communication, immediately preceding the first level of formal administrative or judicial proceedings, from a Medicaid agency official or other State official that notifies the provider of the State's overpayment determination and allows the provider to contest that determination, or that notifies the State Medicaid agency of the filing of a civil or criminal action.

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, as amended at 77 FR 31511, May 29, 2012]

§ 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 beneficiaries, 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 State Medicaid agency has 1 year 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 State Medicaid agency must refund the Federal share of overpayments at the end of the 1-year 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.

[54 FR 5460, Feb. 3, 1989, as amended at 77 FR 31511, May 29, 2012]

§ 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 1-year period allowed for 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*. An overpayment resulting from a situation other than fraud 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*. (1) An overpayment that results from fraud is discovered on the date of the final written notice (as defined in § 433.304 of this subchapter) of the State's overpayment determination.

(2) When the State is unable to recover a debt which represents an overpayment (or any portion thereof) resulting from fraud within 1 year of discovery because no final determination of the amount of the overpayment has been made under an administrative or judicial process (as applicable), including as a result of a judgment being under appeal, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or any portion thereof) until 30 days after the date on which a final judgment (including, if applicable, a final determination on an appeal) is made.

(3) The Medicaid agency may treat an overpayment made to a Medicaid provider as resulting from fraud under subsection (d) of this section only if it has referred a provider's case to the Medicaid fraud control unit, or appropriate law enforcement agency in States with no certified Medicaid fraud control unit, as required by § 455.15, § 455.21, or § 455.23 of this chapter, and the Medicaid fraud control unit or appropriate law enforcement agency has provided the Medicaid agency with written notification of acceptance of the case; or if the Medicaid fraud control unit or appropriate law enforcement agency has filed a civil or criminal action against a provider and has notified the State Medicaid agency.

(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 1-year 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 1-year recovery period:

(1) A downward adjustment in the amount of an overpayment subject to recovery that occurs after discovery does not change the original 1-year recovery period for the outstanding balance.

(2) An upward adjustment in the amount of an overpayment subject to recovery that occurs during the 1-year period following discovery does not change the 1-year recovery period for the original overpayment amount. A new 1-year 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 1-year period following discovery does not change the 1-year recovery period for the balance of 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, as amended at 77 FR 31511, May 29, 2012]

§ 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 1-year 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 1-year 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 1-year 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 1-year 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 1-year 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 1-year 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 1-year 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 of this subpart.

[54 FR 5460, Feb. 3, 1989; 54 FR 8435, Feb. 28, 1989, as amended at 77 FR 31512, May 29, 2012]

§ 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 agency must credit CMS with the Federal share of overpayments subject to recovery on the earlier of—

(i) The Form CMS–64 submission due to CMS for the quarter in which the State recovers the overpayment from the provider; or

(ii) The Form CMS–64 due to CMS for the quarter in which the 1-year 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.

(4) If the State does not refund the Federal share of such overpayment as indicated in paragraph (a)(2) of this section, the State will be liable for interest on the amount equal to the Federal share of the non-recovered, non-refunded overpayment amount. Interest during this period will be at the Current Value of Funds Rate (CVFR), and will accrue beginning on the day after the end of the 1-year period following discovery until the last day of the quarter for which the State submits a CMS–64 report refunding the Federal share of the overpayment.

(b) *Effect of reporting collections and submitting reduced expenditure claims.* (1) The State is not required to refund the Federal share of an overpayment at the end of the 1-year period if the State has already reported a collection or submitted an expenditure claim reduced by a discrete amount to recover the overpayment prior to the end of the 1-year 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 1-year recovery period.* If an overpayment has not been determined uncollectable in accordance with the requirements of § 433.318 of this subpart at the end of the 1-year 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 1-year 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 1-year 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 1-year 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.

[54 FR 5460, Feb. 3, 1989, as amended at 77 FR 31512, May 29, 2012]

§ 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 75.361 through 75.370.

[77 FR 31512, May 29, 2012, as amended at 81 FR 3011, Jan. 20, 2016]

Subpart G—Temporary FMAP Increase During the Public Health Emergency for COVID–19

SOURCE: 85 FR 71197, Nov. 6, 2020, unless otherwise noted.

§ 433.400 Continued enrollment for temporary FMAP increase.

(a) *Statutory basis*. This subpart interprets and implements section 6008(b)(3) of the Families First Coronavirus Response Act (FFCRA) and section 1902(a)(4) and (a)(19) of the Social Security Act.

(b) *Definitions*. For purposes of this subpart—

COVID–19 means Coronavirus Disease 2019.

Medicare Savings Program means the coverage of Medicare premiums and cost sharing furnished to individuals described in, and determined by the state to be eligible under, section 1902(a)(10)(E)(i), 1902(a)(10)(E)(iii), or 1902(a)(10)(E)(iv) of the Act.

Minimum essential coverage (MEC) has the meaning provided under section 5000A(f)(1) of the Internal Revenue Code and implementing regulations at

26 CFR 1.5000A–2 and includes minimum essential coverage determined by the Secretary under 26 CFR 1.5000A–2(f).

Public Health Emergency for COVID–19 has the same definition provided in § 400.200 of this chapter.

Temporary FMAP increase means the 6.2 percentage point increase in the State's Federal medical assistance percentage (FMAP) that is authorized under section 6008(a) of the FFCRA through the end of the fiscal quarter in which the Public Health Emergency for COVID–19 ends.

Validly enrolled means that the beneficiary was enrolled in Medicaid based on a determination of eligibility. A beneficiary is not validly enrolled if the agency determines the eligibility was erroneously granted at the most recent determination, redetermination, or renewal of eligibility (if such last redetermination or renewal was completed prior to March 18, 2020) because of agency error or fraud (as evidenced by a fraud conviction) or abuse (as determined following the completion of an investigation pursuant to §§ 455.15 and 455.16 of this chapter) attributed to the beneficiary or the beneficiary's representative, which was material to the determination of eligibility. Individuals receiving medical assistance during a presumptive eligibility period in accordance with part 435, subpart L, of this chapter have not received a determination of eligibility by the state under the state plan and are not considered validly enrolled beneficiaries for purposes of this section.

(c) *General requirements.* (1) In order to claim the temporary FMAP increase for:

(i) The quarter in which November 2, 2020, falls, a state must meet the requirements described in paragraph (c)(2) of this section from November 2, 2020, through the end of the quarter.

(ii) Any quarter beginning after November 2, 2020, through the quarter in which the public health emergency for COVID–19, including any extensions, ends, a state must meet the requirements described in paragraphs (c)(2) of this section.

(2) Except as provided in paragraph (d) of this section, for all beneficiaries validly enrolled for benefits under the state plan, a waiver of such plan, or a demonstration project under section 1115(a) of the Act as of or after March 18, 2020, the state must maintain the beneficiary's enrollment as follows, through the end of the month in which the public health emergency for COVID–19 ends:

(i)(A) For beneficiaries whose Medicaid coverage meets the definition of MEC in paragraph (b) of this section as of or after March 18, 2020, the state must continue to provide Medicaid coverage that meets the definition of MEC, except as provided in paragraph (c)(2)(i)(B) of this section.

(B) For beneficiaries described in paragraph (c)(2)(i)(A) whom the state subsequently determines are eligible for coverage under a Medicare Savings Program eligibility group, the state satisfies the requirement described in paragraph (c)(2) of this section if it furnishes the medical assistance available through the Medicare Savings Program.

(ii) For beneficiaries whose Medicaid coverage as of or after March 18, 2020 does not meet the definition of MEC in paragraph (b) of this section but does include coverage for testing services and treatments for COVID–19, including vaccines, specialized equipment, and therapies, the state must continue to provide Medicaid coverage that includes such testing services and treatments.

(iii) For beneficiaries not described in paragraph (c)(2)(i) or (ii) of this section, the state must continue to provide at least the same level of medical assistance as was provided as of or after March 18, 2020.

(iv) If a state determines that a validly enrolled beneficiary is no longer eligible for Medicaid, including on a procedural basis, the state meets the requirements described in paragraph (c)(2)(i), (ii), or (iii) of this section by continuing to provide the same Medicaid coverage that the beneficiary would have received absent the determination of ineligibility.

(3) Otherwise permissible changes to beneficiary coverage, cost sharing, and post-eligibility treatment of income, including both changes affecting an individual beneficiary and approved changes to the state plan, a section

1115 demonstration and/or a waiver authorized under section 1915 of the Act impacting multiple beneficiaries, will not impact a state's ability to claim the temporary FMAP increase provided that any such changes do not violate the requirement to maintain beneficiary enrollment described at paragraph (c)(2) of this section or the requirement in section 6008(b)(4) of the FFCRA.

(d) *Exceptions.* (1) Consistent with the condition to claim the temporary FMAP increase described in paragraph (c)(2) of this section, a state may terminate a beneficiary's Medicaid enrollment prior to the first day of the month after the public health emergency for COVID–19 ends in the following circumstances:

(i) The beneficiary or the beneficiary's representative requests a voluntary termination of eligibility;

(ii) The beneficiary ceases to be a resident of the state; or

(iii) The beneficiary dies.

(2) States which have elected the option under section 1903(v)(4) of the Act to provide full benefits to lawfully residing children or pregnant women must limit coverage for such beneficiaries if they no longer meet the definition of a lawfully residing child or pregnant woman under such section to services necessary for treatment of an emergency medical condition, as defined in section 1903(v)(3) of the Act.

(3)(i) For purposes of paragraph (d)(1)(i) of this section, a beneficiary may request a voluntary termination of eligibility from the Medicaid coverage in which the beneficiary is enrolled to transition to other Medicaid coverage for which the beneficiary is eligible, even if the transition to the new Medicaid coverage would not be consistent with paragraph (c)(2) of this section.

(ii) For purposes of paragraph (d)(1)(ii) of this section, beneficiaries who were identified through a data match with the Public Assistance Reporting Information System in accordance with §435.945(d) of this chapter indicating simultaneous enrollment in two or more states, and who fail to respond to a request for information to verify their residency, may be treated as not being a state resident for purposes of paragraph (d)(1)(ii) of this section, provided that the state takes all reasonably available measures to attempt to verify the beneficiary's state residency. If a beneficiary's enrollment is terminated under the exception at paragraph (d)(1)(ii) of this section based on a PARIS data match and the state subsequently obtains information verifying residency, the state must reinstate the beneficiary's Medicaid enrollment retroactive to the date of termination.

PART 434—CONTRACTS

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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 beneficiaries.

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 include all of the following:

(1) Include provisions that define a sound and complete procurement contract, as required by 45 CFR part 75.

(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 beneficiaries.

(8) Provide that the contractor safeguards information about beneficiaries 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.

(11) Provide that any subcontracts meet the requirements of paragraph (b) of this section.

(12) Specify the following:

(i) No payment will be made by the contractor to a provider for provider-preventable conditions, as identified in the State plan.

(ii) The contractor will require that all providers agree to comply with the reporting requirements in § 447.26(d) of this subchapter as a condition of payment from the contractor.

(iii) The contractor will comply with such reporting requirements to the extent the contractor directly furnishes services.

(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; 76 FR 32837, June 6, 2011; 81 FR 3011, Jan. 20, 2016]

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 beneficiary 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 beneficiaries 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 75; 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, as amended at 81 FR 3011, Jan. 20, 2016]

§ 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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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 beneficiaries 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 beneficiaries.
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 beneficiaries.
1902(a)(34) Three-month retroactive eligibility.
1902(a)(46)(B) Requirement to verify citizenship.
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 beneficiary 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.
1902(ee) Option to verify citizenship through electronic data sharing with the Social Security Administration.
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 non-citizens.
1905(a) Definition of medical assistance.
1905(a) (clause following (21)) Prohibitions against providing Medicaid to certain institutionalized individuals.
1905(a) (second sentence) Definition of essential person.
1905(a) Definition of medical assistance.
1905(a)(i)–(viii) List of eligible individuals.
1905(d)(2) Definition of resident of an intermediate care facility for individuals with intellectual disabilities.
1905(j) Definition of State supplementary payment.
1905(k) Eligibility of essential spouses of eligible individuals.
1905(n) Definition of qualified pregnant woman and child.
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 beneficiaries 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; 81 FR 86450, Nov. 30, 2016]

§ 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;

Advance payments of the premium tax credit (APTC) has the meaning given the term in 45 CFR 155.20.

AFDC means aid to families with dependent children under title IV-A of the Act;

Affordable Care Act means the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), as amended by the Three Percent Withholding Repeal and Job Creation Act (Pub. L. 112–56).

Affordable Insurance Exchanges (Exchanges) has the meaning given the term ''Exchanges'' in 45 CFR 155.20.

Agency means a single State agency designated or established by a State in accordance with § 431.10(b) of this subchapter.

Applicable modified adjusted gross income (MAGI) standard has the meaning provided in § 435.911(b)(1) of this part.

Applicant means an individual who is seeking an eligibility determination for himself or herself through an application submission or a transfer from another agency or insurance affordability program.

Application means the single streamlined application described at § 435.907(b) of this part or an application described in § 435.907(c)(2) of this part submitted by or on behalf of an individual.

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Beneficiary means an individual who has been determined eligible and is currently receiving Medicaid.

Caretaker relative means a relative of a dependent child by blood, adoption, or marriage with whom the child is living, who assumes primary responsibility for the child's care (as may, but is not required to, be indicated by claiming the child as a tax dependent for Federal income tax purposes), and who is one of the following—

(1) The child's father, mother, grandfather, grandmother, brother, sister, stepfather, stepmother, stepbrother, stepsister, uncle, aunt, first cousin, nephew, or niece.

(2) The spouse of such parent or relative, even after the marriage is terminated by death or divorce.

(3) At State option, another relative of the child based on blood (including those of half-blood), adoption, or marriage; the domestic partner of the parent or other caretaker relative; or an adult with whom the child is living and who assumes primary responsibility for the dependent child's care.

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.

Citizenship includes status as a ''national of the United States,'' and includes both citizens of the United States and non-citizen nationals of the United States described in 8 U.S.C. 1101(a)(22).

Combined eligibility notice means an eligibility notice that informs an individual or multiple family members of a household of eligibility for each of the insurance affordability programs and enrollment in a qualified health plan through the Exchange, for which a determination or denial of eligibility was made, as well as any right to request a fair hearing or appeal related to the determination made for each program. A combined notice must meet the requirements of § 435.917(a) and contain the content described in § 435.917(b) and (c), except that information described in § 435.917(b)(1)(iii) and (iv) may be included in a combined notice issued by another insurance affordability program or in a supplemental notice provided by the agency. A combined eligibility notice must be issued in accordance with the agreement(s) consummated by the agency in accordance with § 435.1200(b)(3).

Coordinated content means information included in an eligibility notice regarding, if applicable –

(1) The transfer of an individual's or household's electronic account to another insurance affordability program;

(2) Any notice sent by the agency to another insurance affordability program regarding an individual's eligibility for Medicaid;

(3) The potential impact, if any, of—

(i) The agency's determination of eligibility or ineligibility for Medicaid on eligibility for another insurance affordability program; or

(ii) A determination of eligibility for, or enrollment in, another insurance affordability program on an individual's eligibility for Medicaid; and

(4) The status of household members on the same application or renewal form whose eligibility is not yet determined.

Dependent child means a child who meets both of the following criteria:

(1) Is under the age of 18, or, at State option, is age 18 and a full-time student in secondary school (or equivalent vocational or technical training), if before attaining age 19 the child may reasonably be expected to complete such school or training.

(2) Is deprived of parental support by reason of the death, absence from the home, physical or mental incapacity, or unemployment of at least one parent, unless the State has elected in its State plan to eliminate such deprivation requirement. A parent is considered to be unemployed if he or she is working less than 100 hours per month, or such higher number of hours as the State may elect in its State plan.

Effective income level means the income standard applicable under the State plan for an eligibility group, after taking into consideration any disregard of a block of income applied in determining financial eligibility for such group.

Electronic account means an electronic file that includes all information collected and generated by the agency regarding each individual's Medicaid eligibility and enrollment, including all documentation required under § 435.914 and including any information collected or generated as part of a fair hearing process conducted under subpart E of this part, the Exchange appeals process conducted under 45 CFR part 155, subpart F or other insurance affordability program appeals process.

Eligibility determination means an approval or denial of eligibility in accordance with § 435.911 as well as a renewal or termination of eligibility in accordance with § 435.916 of this part.

Family size has the meaning provided in § 435.603(b) of this part.

Federal poverty level (FPL) means the Federal poverty level updated periodically in the FEDERAL REGISTER by the

Secretary of Health and Human Services under the authority of 42 U.S.C. 9902(2), as in effect for the applicable budget period used to determine an individual's eligibility in accordance with § 435.603(h) of this part.

Household income has the meaning provided in § 435.603(d) of this part.

Insurance affordability program means a program that is one of the following:

(1) A State Medicaid program under title XIX of the Act.

(2) A State children's health insurance program (CHIP) under title XXI of the Act.

(3) A State basic health program established under section 1331 of the Affordable Care Act.

(4) A program that makes coverage in a qualified health plan through the Exchange with advance payments of the premium tax credit established under section 36B of the Internal Revenue Code available to qualified individuals.

(5) A program that makes available coverage in a qualified health plan through the Exchange with cost-sharing reductions established under section 1402 of the Affordable Care Act.

MAGI-based income has the meaning provided in § 435.603(e) of this part.

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.);

Minimum essential coverage means coverage defined in section 5000A(f) of subtitle D of the Internal Revenue Code, as added by section 1401 of the Affordable Care Act, and implementing regulations of such section issued by the Secretary of the Treasury.

Modified adjusted gross income (MAGI) has the meaning provided at 26 CFR 1.36B–1(e)(2).

Non-applicant means an individual who is not seeking an eligibility determination for himself or herself and is included in an applicant's or beneficiary's household to determine eligibility for such applicant or beneficiary.

Non-citizen has the same meaning as the term ''alien,'' as defined at 8 U.S.C. 1101(a)(3) and includes any individual who is not a citizen or national of the United States, defined at 8 U.S.C. 1101(a)(22).

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 household 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 household 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.

Pregnant woman means a woman during pregnancy and the post partum period, which begins on the date the pregnancy ends, extends 60 days, and then ends on the last day of the month in which the 60-day period ends.

Qualified non-citizen includes the term ''qualified alien'' as defined at 8 U.S.C. 1641(b) and (c).

Secure electronic interface means an interface which allows for the exchange of data between Medicaid and other insurance affordability programs and adheres to the requirements in part 433, subpart C of this chapter.

Shared eligibility service means a common or shared eligibility system or service used by a State to determine individuals' eligibility for insurance affordability programs.

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.

Tax dependent has the same meaning as the term ''dependent'' under section 152 of the Internal Revenue Code, as an individual for whom another individual claims a deduction for a personal exemption under section 151 of the Internal Revenue Code for a taxable year.

[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; 77 FR 17203, Mar. 23, 2012; 81 FR 86450, Nov. 30, 2016]

§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

§435.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

MANDATORY COVERAGE OF FAMILIES AND CHILDREN

§435.110 Parents and other caretaker relatives.

(a) *Basis.* This section implements sections 1931(b) and (d) of the Act.

(b) *Scope.* The agency must provide Medicaid to parents and other caretaker relatives, as defined in §435.4, and, if living with such parent or other caretaker relative, his or her spouse, whose household income is at or below the income standard established by the

agency in the State plan, in accordance with paragraph (c) of this section.

(c) *Income standard*. The agency must establish in its State plan the income standard as follows:

(1) The minimum income standard is a State's AFDC income standard in effect as of May 1, 1988 for the applicable family size converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

(2) The maximum income standard is the higher of—

(i) The effective income level in effect for section 1931 low-income families under the Medicaid State plan or waiver of the State plan as of March 23, 2010 or December 31, 2013, if higher, converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act; or

(ii) A State's AFDC income standard in effect as of July 16, 1996 for the applicable family size, increased by no more than the percentage increase in the Consumer Price Index for all urban consumers between July 16, 1996 and the effective date of such increase.

[77 FR 17204, Mar. 23, 2012, as amended at 78 FR 42302, July 15, 2013]

§ 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]

§ 435.115 Families with Medicaid eligibility extended because of increased collection of spousal support.

(a) *Basis*. This section implements sections 408(a)(11)(B) and 1931(c)(1) of the Act.

(b) *Eligibility*. (1) The extended eligibility period is for 4 months.

(2) The agency must provide coverage during an extended eligibility period to a parent or other caretaker relative who was eligible and enrolled for Medicaid under § 435.110, and any dependent child of such parent or other caretaker relative who was eligible and enrolled under § 435.118, in at least 3 out of the 6 months immediately preceding the month that eligibility for the parent or other caretaker relative under § 435.110 is lost due to increased collection of spousal support under title IV–D of the Act.

[81 FR 86451, Nov. 30, 2016]

MANDATORY COVERAGE OF PREGNANT WOMEN, CHILDREN UNDER 19, AND NEWBORN CHILDREN

§ 435.116 Pregnant women.

(a) *Basis*. This section implements sections 1902(a)(10)(A)(i)(III) and (IV); 1902(a)(10)(A)(ii)(I), (IV), and (IX); and 1931(b) and (d) of the Act.

(b) *Scope*. The agency must provide Medicaid to pregnant women whose household income is at or below the income standard established by the agency in its State plan, in accordance with paragraph (c) of this section.

(c) *Income standard*. The agency must establish in its State plan the income standard as follows:

(1) The minimum income standard is the higher of:

(i) 133 percent FPL for the applicable family size; or

(ii) Such higher income standard up to 185 percent FPL, if any, as the State had established as of December 19, 1989 for determining eligibility for pregnant women, or, as of July 1, 1989, had authorizing legislation to do so.

(2) The maximum income standard is the higher of—

(i) The highest effective income level in effect under the Medicaid State plan for coverage under the sections specified at paragraph (a) of this section, or waiver of the State plan covering pregnant women, as of March 23, 2010 or December 31, 2013, if higher, converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act; or

(ii) 185 percent FPL.

(d) *Covered services.* (1) Pregnant women are covered under this section for the full Medicaid coverage described in paragraph (d)(2) of this section, except that the agency may provide only pregnancy-related services described in paragraph (d)(3) of this section for pregnant women whose income exceeds the applicable income limit established by the agency in its State plan, in accordance with paragraph (d)(4) of this section.

(2) Full Medicaid coverage consists of all services which the State is required to cover under §440.210(a)(1) of this subchapter and all services which it has opted to cover under §440.225 and §440.250(p) of this subchapter.

(3) Pregnancy-related services consists of services covered under the State plan consistent with §440.210(a)(2) and §440.250(p) of this subchapter.

(4) *Applicable income limit for full Medicaid coverage of pregnant women.* For purposes of paragraph (d)(1) of this section—

(i) The minimum applicable income limit is the State's AFDC income standard in effect as of May 1, 1988 for the applicable family size converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

(ii) The maximum applicable income limit is the highest effective income level for coverage under section 1902(a)(10)(A)(i)(III) of the Act or under section 1931(b) and (d) of the Act in effect under the Medicaid State plan or waiver of the State plan as of March 23, 2010 or December 31, 2013, if higher, converted to a MAGI-equivalent standard.

[77 FR 17204, Mar. 23, 2012, as amended at 78 FR 42302, July 15, 2013]

§435.117 Deemed newborn children.

(a) *Basis.* This section implements sections 1902(e)(4) and 2112(e) of the Act.

(b) *Eligibility.* (1) The agency must provide Medicaid to children from birth until the child's first birthday without application if, for the date of the child's birth, the child's mother was eligible for and received covered services under—

(i) The Medicaid State plan (including during a period of retroactive eligibility under §435.915) regardless of whether payment for services for the mother is limited to services necessary to treat an emergency medical condition, as defined in section 1903(v)(3) of the Act; or

(ii) The CHIP State plan as a targeted low-income pregnant woman in accordance with section 2112 of the Act, with household income at or below the income standard established by the agency under §435.118 for infants under age 1.

(2) The agency may provide coverage under this section to children from birth until the child's first birthday without application who are not described in (b)(1) of this section if, for the date of the child's birth, the child's mother was eligible for and received covered services under—

(i) The Medicaid State plan of any State (including during a period of retroactive eligibility under §435.915); or

(ii) Any of the following, provided that household income of the child's mother at the time of the child's birth is at or below the income standard established by the agency under §435.118 for infants under age 1:

(A) The State's separate CHIP State plan as a targeted low-income child;

(B) The CHIP State plan of any State as a targeted low-income pregnant woman or child; or

(C) A Medicaid or CHIP demonstration project authorized under section 1115 of the Act.

(3) The child is deemed to have applied and been determined eligible under the Medicaid State plan effective

as of the date of birth, and remains eligible regardless of changes in circumstances until the child's first birthday, unless the child dies or ceases to be a resident of the State or the child's representative requests a voluntary termination of eligibility.

(c) *Medicaid identification number*. (1) The Medicaid identification number of the mother serves as the child's identification number, and all claims for covered services provided to the child may be submitted and paid under such number, unless and until the State issues the child a separate identification number.

(2) The State must issue a separate Medicaid identification number for the child prior to the effective date of any termination of the mother's eligibility or prior to the date of the child's first birthday, whichever is sooner, except that the State must issue a separate Medicaid identification number in the case of a child born to a mother:

(i) Whose coverage is limited to services necessary for the treatment of an emergency medical condition, consistent with § 435.139 or § 435.350;

(ii) Covered under the State's separate CHIP; or

(iii) Who received Medicaid in another State on the date of birth.

(d) *Renewal of eligibility*. 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, as amended at 81 FR 86451, Nov. 30, 2016]

MANDATORY COVERAGE OF QUALIFIED FAMILY MEMBERS

§ 435.118 Infants and children under age 19.

(a) *Basis*. This section implements sections 1902(a)(10)(A)(i)(III), (IV), (VI), and (VII); 1902(a)(10)(A)(ii)(IV) and (IX); and 1931(b) and (d) of the Act.

(b) *Scope*. The agency must provide Medicaid to children under age 19 whose household income is at or below the income standard established by the agency in its State plan, in accordance with paragraph (c) of this section.

(c) *Income standard*. (1) The minimum income standard is the higher of—

(i) 133 percent FPL for the applicable family size; or

(ii) For infants under age 1, such higher income standard up to 185 percent FPL, if any, as the State had established as of December 19, 1989 for determining eligibility for infants, or, as of July 1, 1989 had authorizing legislation to do so.

(2) The maximum income standard for each of the age groups of infants under age 1, children age 1 through age 5, and children age 6 through age 18 is the higher of—

(i) 133 percent FPL;

(ii) The highest effective income level for each age group in effect under the Medicaid State plan for coverage under the applicable sections of the Act listed at paragraph (a) of this section or waiver of the State plan covering such age group as of March 23, 2010 or December 31, 2013, if higher, converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act; or

(iii) For infants under age 1, 185 percent FPL.

[77 FR 17205, Mar. 23, 2012]

MANDATORY COVERAGE FOR INDIVIDUALS AGE 19 THROUGH 64

§ 435.119 Coverage for individuals age 19 or older and under age 65 at or below 133 percent FPL.

(a) *Basis*. This section implements section 1902(a)(10)(A)(i)(VIII) of the Act.

(b) *Eligibility*. Effective January 1, 2014, the agency must provide Medicaid to individuals who:

(1) Are age 19 or older and under age 65;

(2) Are not pregnant;

(3) Are not entitled to or enrolled for Medicare benefits under part A or B of title XVIII of the Act;

(4) Are not otherwise eligible for and enrolled for mandatory coverage under a State's Medicaid State plan in accordance with subpart B of this part; and

(5) Have household income that is at or below 133 percent FPL for the applicable family size.

(c) *Coverage for dependent children.* (1) A State may not provide Medicaid under this section to a parent or other caretaker relative living with a dependent child if the child is under the age specified in paragraph (c)(2) of this section, unless such child is receiving benefits under Medicaid, the Children's Health Insurance Program under subchapter D of this chapter, or otherwise is enrolled in minimum essential coverage as defined in § 435.4 of this part.

(2) For the purpose of paragraph (c)(1) of this section, the age specified is under age 19, unless the State had elected as of March 23, 2010 to provide Medicaid to individuals under age 20 or 21 under § 435.222 of this part, in which case the age specified is such higher age.

[58 FR 48614, Sept. 17, 1993, as amended at 77 FR 17205, Mar. 23, 2012; 78 FR 42302, July 15, 2013]

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 beneficiaries, 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 beneficiaries.

(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 beneficiaries (including individuals deemed to be SSI beneficiaries under §§ 435.135, 435.137, and 435.138), eligible spouses of SSI beneficiaries, State supplement beneficiaries, 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 beneficiaries, eligible spouses of SSI beneficiaries, State supplement beneficiaries, 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 § 447.52, § 447.53, or § 447.54 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, as amended at 78 FR 42302, July 15, 2013]

§ 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 beneficiaries 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 beneficiaries 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 with adoption assistance, foster care, or guardianship care under title IV–E.

(a) *Basis*. This section implements sections 1902(a)(10)(A)(i)(I) and 473(b)(3) of the Act.

(b) *Eligibility*. The agency must provide Medicaid to individuals for whom—

(1) An adoption assistance agreement is in effect with a State or Tribe under title IV–E of the Act, regardless of whether adoption assistance is being provided or an interlocutory or other

judicial decree of adoption has been issued; or

(2) Foster care or kinship guardianship assistance maintenance payments are being made by a State or Tribe under title IV–E of the Act.

[81 FR 86451, Nov. 30, 2016]

§ 435.150 Former foster care children.

(a) *Basis*. This section implements section 1902(a)(10)(A)(i)(IX) of the Act.

(b) *Eligibility*. The agency must provide Medicaid to individuals who:

(1) Are under age 26;

(2) Are not eligible and enrolled for mandatory coverage under §§ 435.110 through 435.118 or §§ 435.120 through 435.145; and

(3) Were in foster care under the responsibility of the State or a Tribe within the State and enrolled in Medicaid under the State's Medicaid State plan or under a section 1115 demonstration project upon attaining:

(i) Age 18; or

(ii) A higher age at which the State's or such Tribe's foster care assistance ends under title IV–E of the Act.

(c) *Options*. At the State option, the agency may provide Medicaid to individuals who meet the requirements at paragraphs (b)(1) and (2) of this section, were in foster care under the responsibility of the State or Tribe within the State upon attaining either age described in paragraph (b)(3)(i) or (ii) of this section, and were:

(1) Enrolled in Medicaid under the State's Medicaid State plan or under a section 1115 demonstration project at some time during the period in foster care during which the individual attained such age; or

(2) Placed by the State or Tribe in another State and, while in such placement, were enrolled in the other State's Medicaid State plan or under a section 1115 demonstration project:

(i) Upon attaining either age described in paragraph (b)(3)(i) or (ii) of this section; or

(ii) At state option, at some time during the period in foster care during which the individual attained such age.

[81 FR 86451, Nov. 30, 2016]

MANDATORY COVERAGE OF SPECIAL GROUPS

§ 435.170 Pregnant women eligible for extended or continuous eligibility.

(a) *Basis*. This section implements sections 1902(e)(5) and 1902(e)(6) of the Act.

(b) *Extended eligibility for pregnant women*. For a pregnant woman who was eligible and enrolled under subpart B, C, or D of this part on the date her pregnancy ends, the agency must provide coverage described in paragraph (d) of this section through the last day of the month in which the 60-day postpartum period ends.

(c) *Continuous eligibility for pregnant women*. For a pregnant woman who was eligible and enrolled under subpart B, C, or D of this part and who, because of a change in household income, will not otherwise remain eligible, the agency must provide coverage described in paragraph (d) of this section through the last day of the month in which the 60-day post-partum period ends.

(d) *Covered Services*. The coverage described in this paragraph (d) consists of—

(1) Full Medicaid coverage, as described in § 435.116(d)(2); or

(2) Pregnancy-related services described in § 435.116(d)(3), if the agency has elected to establish an income limit under § 435.116(d)(4), above which pregnant women enrolled for coverage under § 435.116 receive pregnancy-related services described in § 435.116(d)(3).

(e) *Presumptive Eligibility*. This section does not apply to pregnant women covered during a presumptive eligibility period under section 1920 of the Act.

[81 FR 86452, Nov. 30, 2016]

§ 435.172 Continuous eligibility for hospitalized children.

(a) *Basis*. This section implements section 1902(e)(7) of the Act.

(b) *Requirement*. The agency must provide Medicaid to an individual eligible and enrolled under § 435.118 until the end of an inpatient stay for which inpatient services are furnished, if the individual:

(1) Was receiving inpatient services covered by Medicaid on the date the individual is no longer eligible under § 435.118 based on the child's age; and

(2) Would remain eligible but for attaining such age.

[81 FR 86452, Nov. 30, 2016]

Subpart C—Options for Coverage

§ 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; and

(5) Parents and other caretaker relatives (as defined in § 435.4).

(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, as amended at 81 FR 86452, Nov. 30, 2016]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN AND THE AGED, BLIND, AND DISABLED

§ 435.210 Optional eligibility for individuals who meet the income and resource requirements of the cash assistance programs.

(a) *Basis*. This section implements section 1902(a)(10)(A)(ii)(I) of the Act.

(b) *Eligibility*. The agency may provide Medicaid to any group or groups of individuals specified in § 435.201(a)(1) through (3) who meet the income and resource requirements of SSI or an optional State supplement program in States that provide Medicaid to optional State supplement recipients.

[81 FR 86452, Nov. 30, 2016]

§ 435.211 Optional eligibility for individuals who would be eligible for cash assistance if they were not in medical institutions.

(a) *Basis*. This section implements section 1902(a)(10)(A)(ii)(IV) of the Act.

(b) *Eligibility*. The agency may provide Medicaid to any group or groups of individuals specified in § 435.201(a)(1) through (3) who are institutionalized in a title XIX reimbursable medical institution and who:

(1) Are ineligible for the SSI or an optional State supplement program 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

(2) Would be eligible for aid or assistance under SSI or an optional State supplement program (as specified in § 435.232 or § 435.234) if they were not institutionalized.

[81 FR 86452, Nov. 30, 2016]

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a beneficiary 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 beneficiary 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]

§ 435.213 Optional eligibility for individuals needing treatment for breast or cervical cancer.

(a) *Basis.* This section implements sections 1902(a)(10)(A)(ii)(XVIII) and 1902(aa) of the Act.

(b) *Eligibility.* The agency may provide Medicaid to individuals who—

(1) Are under age 65;

(2) Are not eligible and enrolled for mandatory coverage under the State's Medicaid State plan in accordance with subpart B of this part;

(3) Have been screened under the Centers for Disease Control and Prevention (CDC) breast and cervical cancer early detection program (BCCEDP), established in accordance with the requirements of section 1504 of the Public Health Service Act, and found to need treatment for breast or cervical cancer; and

(4) Do not otherwise have creditable coverage, as defined in section 2704(c) of the Public Health Service Act, for treatment of the individual's breast or cervical cancer. An individual is not considered to have creditable coverage just because the individual may:

(i) Receive medical services provided by the Indian Health Service, a tribal organization, or an Urban Indian organization; or

(ii) Obtain health insurance coverage after a waiting period of uninsurance.

(c) *Need for treatment.* An individual is considered to need treatment for breast or cervical cancer if the initial screen under BCCEDP or, subsequent to the initial period of eligibility, the individual's treating health professional determines that:

(1) Definitive treatment for breast or cervical cancer is needed, including treatment of a precancerous condition or early stage cancer, and including diagnostic services as necessary to determine the extent and proper course of treatment; and

(2) More than routine diagnostic services or monitoring services for a precancerous breast or cervical condition are needed.

[81 FR 86452, Nov. 30, 2016]

§ 435.214 Eligibility for Medicaid limited to family planning and related services.

(a) *Basis.* This section implements sections 1902(a)(10)(A)(ii)(XXI) and 1902(ii) and clause (XVI) in the matter following section 1902(a)(10)(G) of the Act.

(b) *Eligibility.* (1) The agency may provide Medicaid limited to the services described in paragraph (d) of this section to individuals (of any gender) who—

(i) Are not pregnant; and

(ii) Meet the income eligibility requirements at paragraph (c) of this section.

(2) [Reserved]

(c) *Income standard.* (1) The income standard established in the State plan may not exceed the higher of the income standard for pregnant women in effect under—

(i) The Medicaid State plan in accordance with § 435.116.

(ii) A Medicaid demonstration under section 1115 of the Act.

(iii) The CHIP State plan under section 2112 of the Act.

(iv) A CHIP demonstration under section 1115 of the Act.

(2) The individual's household income is determined in accordance with § 435.603. The agency must indicate in its State plan the options selected by it under § 435.603(k).

(d) *Covered services.* Individuals eligible under this section are covered for family planning and family planning-related benefits as described in clause (XVI) of the matter following section 1902(a)(10)(G) of the Act.

[81 FR 86453, Nov. 30, 2016]

§ 435.215 Individuals infected with tuberculosis.

(a) *Basis.* This section implements sections 1902(a)(10)(A)(ii)(XII) and 1902(z)(1) of the Act.

(b) *Eligibility.* The agency may provide Medicaid to individuals who—

(1) Are infected with tuberculosis;

(2) Are not eligible for full coverage under the State's Medicaid State plan (that is, all services which the State is

required to cover under § 440.210(a)(1) of this chapter and all services which it has opted to cover under § 440.225 of this chapter, or which the State covers under an approved alternative benefits plan under § 440.325 of this chapter), including coverage for tuberculosis treatment as elected by the State for this group; and

(3) Have household income that does not exceed the income standard established by the State in its State plan, which standard must not exceed the higher of—

(i) The maximum income standard applicable to disabled individuals for mandatory coverage under subpart B of this part; or

(ii) The effective income level for coverage of individuals infected with tuberculosis under the State plan in effect as of March 23, 2010, or December 31, 2013, if higher, converted, at State option, to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

(c) *Covered Services*. Individuals eligible under this section are covered for the following services related to the treatment of infection with tuberculosis:

(1) Prescribed drugs, described in § 440.120 of this chapter;

(2) Physician's services, described in § 440.50 of this chapter;

(3) Outpatient hospital and rural health clinic described in § 440.20 of this chapter, and Federally-qualified health center services;

(4) Laboratory and x-ray services (including services to confirm the presence of the infection), described in § 440.30 of this chapter;

(5) Clinic services, described in § 440.90 of this chapter;

(6) Case management services defined in § 440.169 of this chapter; and

(7) Services other than room and board designated to encourage completion of regimens of prescribed drugs by outpatients including services to observe directly the intake of prescription drugs.

[81 FR 86453, Nov. 30, 2016]

§ 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/IID; 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]

§ 435.218 Individuals with MAGI-based income above 133 percent FPL.

(a) *Basis*. This section implements section 1902(a)(10)(A)(ii)(XX) of the Act.

(b) *Eligibility*—(1) *Criteria*. The agency may provide Medicaid to individuals who:

(i) Are under age 65;

(ii) Are not eligible for and enrolled for mandatory coverage under a State's Medicaid State plan in accordance with subpart B of this part;

(iii) Are not otherwise eligible for and enrolled for optional coverage under a State's Medicaid State plan in accordance with section 1902(a)(10)(A)(ii)(I) through (XIX) of the Act and subpart C of this part, based on information available to the State from the application filed by or on behalf of the individual; and

(iv) Have household income that exceeds 133 percent FPL but is at or below the income standard elected by the agency and approved in its Medicaid State plan, for the applicable family size.

(2) *Limitations*. (i) A State may not, except as permitted under an approved phase-in plan adopted in accordance with paragraph (b)(3) of this section, provide Medicaid to higher income individuals described in paragraph (b)(1) of this section without providing Medicaid to lower income individuals described in such paragraph.

(ii) The limitation on eligibility of parents and other caretaker relatives specified in § 435.119(c) of this section also applies to eligibility under this section.

(3) *Phase-in plan*. A State may phase in coverage to all individuals described in paragraph (b)(1) of this section under a phase-in plan submitted in a State plan amendment to and approved by the Secretary.

[77 FR 17205, Mar. 23, 2012]

§ 435.219 Individuals receiving State plan home and community-based services.

If the agency provides State plan home and community-based services to individuals described in section 1915(i)(1), the agency, under its State plan, may, in addition, provide Medicaid to individuals in the community who are described in one or both of paragraphs (a) or (b) of this section.

(a) Individuals who—

(1) Are not otherwise eligible for Medicaid;

(2) Have income that does not exceed 150 percent of the Federal poverty line (FPL);

(3) Meet the needs-based criteria under § 441.715 of this chapter; and

(4) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(b) Individuals who—

(1) Would be determined eligible by the agency under an existing waiver or demonstration project under sections 1915(c), 1915(d), 1915(e) or 1115 of the Act, but are not required to receive services under such waivers or demonstration projects;

(2) Have income that does not exceed 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR); and

(3) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(c) For purposes of determining eligibility under paragraph (a) of this section, the agency may not take into account an individual's resources and must use income standards that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in the best interests of the beneficiary. Income methodologies may include use of existing income methodologies, such as the SSI program rules. However, subject to the Secretary's approval, the agency may use other income methodologies that meet the requirements of this paragraph.

[79 FR 3028, Jan. 16, 2014]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

§ 435.220 Optional eligibility for parents and other caretaker relatives.

(a) *Basis*. This section implements section 1902(a)(10)(A)(ii)(I) of the Act for optional eligibility of parents and other caretaker relatives as defined at § 435.4.

(b) *Eligibility*. The agency may provide Medicaid to parents and other caretaker relatives defined in § 435.4 and, if living with such parent or other caretaker relative, his or her spouse, whose household income is at or below the income standard established by the agency in its State plan, in accordance with paragraph (c) of this section.

(c) *Income standard*. The income standard under this section—

(1) Must exceed the income standard established by the agency under § 435.110(c); and

(2) May not exceed the higher of the State's AFDC payment standard in effect as of July 16, 1996, or the State's highest effective income level for eligibility of parents and other caretaker relatives in effect under the Medicaid State plan or demonstration program under section 1115 of the Act as of March 23, 2010, or December 31, 2013, if higher, converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

[81 FR 86453, Nov. 30, 2016]

§ 435.221 [Reserved]

§ 435.222 Optional eligibility for reasonable classifications of individuals under age 21.

(a) *Basis*. This section implements sections 1902(a)(10)(A)(ii)(I) and (IV) of the Act for optional eligibility of individuals under age 21.

(b) *Eligibility*. The agency may provide Medicaid to all—or to one or more

reasonable classifications, as defined in the State plan, of—individuals under age 21 (or, at State option, under age 20, 19 or 18) who have household income at or below the income standard established by the agency in its State plan in accordance with paragraph (c) of this section.

(c) *Income standard*. The income standard established under this section may not exceed the higher of the State's AFDC payment standard in effect as of July 16, 1996, or the State's highest effective income level, if any, for such individuals under the Medicaid State plan or a demonstration program under section 1115 of the Act as of March 23, 2010, or December 31, 2013, if higher, converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

[81 FR 86453, Nov. 30, 2016]

§ 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]

§ 435.226 Optional eligibility for independent foster care adolescents.

(a) *Basis*. This section implements section 1902(a)(10)(A)(ii)(XVII) of the Act.

(b) *Eligibility*. The agency may provide Medicaid to individuals under age 21 (or, at State option, under age 20 or 19) who were in foster care under the responsibility of a State or Tribe (or, at State or Tribe option, only to such individuals for whom Federal foster care assistance under title IV–E of the Act was being provided) on the individual's 18th birthday and have household income at or below the income standard, if any, established by the agency in its State plan in accordance with paragraph (c) of this section.

(c) *Income standard*. (1) The income standard established under this section may not be lower than the State's income standard established under § 435.110.

(2) The State may elect to have no income standard for eligibility under this section.

[81 FR 86453, Nov. 30, 2016]

§ 435.227 Optional eligibility for individuals under age 21 who are under State adoption assistance agreements.

(a) *Basis*. This section implements section 1902(a)(10)(A)(ii)(VIII) of the Act.

(b) *Eligibility*. The agency may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18):

(1) For whom an adoption assistance agreement (other than an agreement under title IV–E of the Act) between a State and the adoptive parent(s) is in effect;

(2) Who the State agency which entered into the adoption agreement determined could not be placed for adoption without Medicaid coverage because the child has special needs for medical or rehabilitative care; and

(3) Who, prior to the adoption agreement being entered into—

(i) Were eligible under the Medicaid State plan of the State with the adoption assistance agreement; or

(ii) Had household income at or below the income standard established by the

agency in its State plan in accordance with paragraph (c) of this section.

(c) *Income standard*. The income standard established under this section may not exceed the effective income level (converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act) under the State plan or under a demonstration program under section 1115 of the Act as of March 23, 2010 or December 31, 2013, whichever is higher, that was applied by the State to the household income of a child prior to the execution of an adoption assistance agreement for purposes of determining eligibility of children described in paragraphs (b)(1) and (2) of this section.

(d) *Limit Eligibility* The agency may limit eligibility under this section to children for whom the State, or another State identified in the State plan, has entered into an adoption assistance agreement.

[81 FR 86454, Nov. 30, 2016]

§ 435.229 Optional targeted low-income children.

(a) *Basis*. This section implements section 1902(a)(10)(A)(ii)(XIV) of the Act.

(b) *Eligibility*. The agency may provide Medicaid to individuals under age 19, or at State option within a range of ages under age 19 established in the State plan, who meet the definition of an optional targeted low-income child in § 435.4 and have household income at or below the income standard established by the agency in its State plan in accordance with paragraph (c) of this section.

(c) *Income standard*. The income standard established under this section may not exceed the higher of—

(1) 200 percent of the Federal poverty level (FPL);

(2) A percentage of the FPL which exceeds the State's Medicaid applicable income level, defined at § 457.10 of this chapter, by no more than 50 percentage points (converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act); and

(3) The highest effective income level for coverage of such individuals under the Medicaid State plan or demonstration program under section 1115 of the Act or for coverage of targeted low-income children, defined in § 457.10 of this chapter, under the CHIP State plan or demonstration program under section 1115 of the Act, as of March 23, 2010, or December 31, 2013, converted to a MAGI-equivalent standard in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act.

[81 FR 86454, Nov. 30, 2016]

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 beneficiaries 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) 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) Parents and other caretaker relatives (§ 435.310).

(iii) Aged (§§ 435.320 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; 81 FR 86454, Nov. 30, 2016]

§ 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 individuals with intellectual disabilities.

(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 parents and other caretaker relatives.

If the agency provides Medicaid for the medically needy, it may provide Medicaid to parents and other caretaker relatives who meet:

(a) The definition of ''caretaker relative'' at § 435.4, or are the spouse of a parent or caretaker relative; and

(b) The medically needy income and resource requirements at subpart I of this part.

[81 FR 86454, Nov. 30, 2016]

§ 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 beneficiaries 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) [Reserved]

(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.

[43 FR 45204, Sept. 29, 1978, as amended at 81 FR 86454, Nov. 30, 2016]

§ 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 Intellectual Disability 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 intellectual disability.

(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 age 21 and over.* Except as provided in paragraph (f) of this section, with respect to individuals age 21 and over —

(1) For an individual not residing in an institution as defined in paragraph (b) of this section, the State of residence is the State where the individual is living and—

(i) Intends to reside, including without a fixed address; or

(ii) Has entered the State with a job commitment or seeking employment (whether or not currently employed).

(2) For an individual not residing in an institution as defined in paragraph (b) of this section who is not capable of stating intent, the State of residency is the State where the individual is living.

(3) 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.

(4) 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.

(5) For any other institutionalized individual, the State of residence is the State where the individual is living and intends to reside.

(i) *Individuals under age 21.* For an individual under age 21 who is not eligible for Medicaid based on receipt of assistance under title IV–E of the Act, as addressed in paragraph (g) of this section, and is not receiving a State supplementary payment, as addressed in paragraph (f) of this section, the State of residence is as follows:

(1) For an individual who is capable of indicating intent and who is emancipated from his or her parent or who is married, the State of residence is determined in accordance with paragraph (h)(1) of this section.

(2) For an individual not described in paragraph (i)(1) of this section, not living in an institution as defined in paragraph (b) of this section and not eligible for Medicaid based on receipt of assistance under title IV–E of the Act, as addressed in paragraph (g) of this section, and is not receiving a State supplementary payment, as addressed in paragraph (f) of this section, the State of residence is:

(i) The State where the individual resides, including without a fixed address; or

(ii) The State of residency of the parent or caretaker, in accordance with paragraph (h)(1) of this section, with whom the individual resides.

(3) 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.

(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 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.

(l) *Continued Medicaid for institutionalized beneficiaries.* If an agency is providing Medicaid to an institutionalized beneficiary 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 beneficiary 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 (i) 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; 77 FR 17206, Mar. 23, 2012]

§ 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 non-citizen eligibility.

(a) The agency must provide Medicaid to otherwise eligible individuals who are—

(1) Citizens and nationals of the United States, provided that—

(i) The individual has made a declaration of United States citizenship, as defined in § 435.4, or an individual described in paragraph (a)(3) of this section has made such declaration on the individual's behalf, and such status is verified in accordance with paragraph (c) of this section; and

(ii) For purposes of the declaration and citizenship verification requirements discussed in paragraphs (a)(1)(i) of this section, an individual includes applicants under a section 1115 demonstration (including a family planning demonstration project) for which a State receives Federal financial participation in its expenditures.

(iii) The following groups of individuals are exempt from the requirement to provide documentation to verify citizenship in paragraph (c) 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 beneficiaries of foster care maintenance or adoption assistance payments under Title IV–E of the Act.

(E)(*1*) Individuals who are or were deemed eligible for Medicaid in the State under § 435.117 or § 457.360 of this chapter on or after July 1, 2006, based on being born to a pregnant woman eligible under the State's Medicaid or CHIP state plan or waiver of such plan;

(*2*) At State option, individuals who were deemed eligible for coverage under § 435.117 or § 457.360 of this chapter in another State on or after July 1, 2006, provided that the agency verifies such deemed eligibility.

(2)(i) Except as specified in 8 U.S.C. 1612(b)(1) (permitting States an option with respect to coverage of certain qualified non-citizens), qualified non-citizens as described in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1641) (including qualified non-citizens subject to the 5-year bar) who have provided satisfactory documentary evidence of Qualified Non-Citizen 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 beneficiary is an non-citizen in a satisfactory immigration status.

(ii) The eligibility of qualified non-citizens 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.

(3) For purposes of paragraphs (a)(1) and (2), of this section, a declaration of citizenship or satisfactory immigration status may be provided, in writing and under penalty of perjury, by an adult member of the individual's household, an authorized representative, as defined in § 435.923, or if the applicant is a minor or incapacitated, someone acting responsibly for the applicant provided that such individual attests to having knowledge of the individual's status.

(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 non-citizens subject to the 5-year bar or who are non-qualified non-citizens who meet all Medicaid eligibility criteria, except non-qualified non-citizens need not present a social security number or document immigration status.

(c) The agency must verify the declaration of citizenship or satisfactory immigration status under paragraph (a)(1) or (2) of this section in accordance with § 435.956.

[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; 81 FR 86454, Nov. 30, 2016]

§ 435.407 Types of acceptable documentary evidence of citizenship.

(a) *Stand-alone evidence of citizenship.* The following must be accepted as sufficient documentary evidence of citizenship:

(1) A U.S. passport, including a U.S. Passport Card issued by the Department of State, without regard to any expiration date as long as such passport or Card was issued without limitation.

(2) A Certificate of Naturalization.

(3) A Certificate of U.S. Citizenship.

(4) A valid State-issued driver's license if the State issuing the license requires proof of U.S. citizenship, or obtains and verifies a SSN from the applicant who is a citizen before issuing such license.

(5)(i) Documentary evidence issued by a Federally recognized Indian Tribe identified in the FEDERAL REGISTER by the Bureau of Indian Affairs within the U.S. Department of the Interior, and including Tribes located in a State that has an international border, which—

(A) Identifies the Federally recognized Indian Tribe that issued the document;

(B) Identifies the individual by name; and

(C) Confirms the individual's membership, enrollment, or affiliation with the Tribe.

(ii) Documents described in paragraph (a)(5)(i) of this section include, but are not limited to:

(A) A Tribal enrollment card;

(B) A Certificate of Degree of Indian Blood;

(C) A Tribal census document;

(D) Documents on Tribal letterhead, issued under the signature of the appropriate Tribal official, that meet the requirements of paragraph (a)(5)(i) of this section.

(6) A data match with the Social Security Administration.

(b) *Evidence of citizenship*. If an applicant does not provide documentary evidence from the list in paragraph (a) of this section, the following must be accepted as satisfactory evidence to establish citizenship if also accompanied by an identity document listed in paragraph (c) of this section—

(1) A U.S. public birth certificate showing birth in one of the 50 States, the District of Columbia, Guam, American Samoa, Swain's Island, Puerto Rico (if born on or after January 13, 1941), the Virgin Islands of the U.S. or the CNMI (if born after November 4, 1986, (CNMI local time)). The birth record document may be issued by a State, Commonwealth, Territory, or local jurisdiction. If the document shows the individual was born in Puerto Rico or the Northern Mariana Islands before the applicable date referenced in this paragraph, the individual may be a collectively naturalized citizen. The following will establish U.S. citizenship for collectively naturalized individuals:

(i) *Puerto Rico:* Evidence of birth in Puerto Rico 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.

(ii) *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);

(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);

(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). 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) At State option, a cross match with a State vital statistics agency documenting a record of birth.

(3) A Certification of Report of Birth, issued to U.S. citizens who were born outside the U.S.

(4) A Report of Birth Abroad of a U.S. Citizen.

(5) A Certification of birth in the United States.

(6) A U.S. Citizen I.D. card.

(7) A Northern Marianas Identification Card issued by the U.S. Department of Homeland Security (or predecessor agency).

(8) A final adoption decree showing the child's name and U.S. place of birth, or if an adoption is not final, a Statement from a State-approved

adoption agency that shows the child's name and U.S. place of birth.

(9) Evidence of U.S. Civil Service employment before June 1, 1976.

(10) U.S. Military Record showing a U.S. place of birth.

(11) A data match with the SAVE Program or any other process established by DHS to verify that an individual is a citizen.

(12) Documentation that a child meets the requirements of section 101 of the Child Citizenship Act of 2000 as amended (8 U.S.C. 1431).

(13) Medical records, including, but not limited to, hospital, clinic, or doctor records or admission papers from a nursing facility, skilled care facility, or other institution that indicate a U.S. place of birth.

(14) Life, health, or other insurance record that indicates a U.S. place of birth.

(15) Official religious record recorded in the U.S. showing that the birth occurred in the U.S.

(16) School records, including preschool, Head Start and daycare, showing the child's name and U.S. place of birth.

(17) Federal or State census record showing U.S. citizenship or a U.S. place of birth.

(18) If the applicant does not have one of the documents listed in paragraphs (a) or (b)(1) through (17) of this section, he or she may submit an affidavit signed by another individual under penalty of perjury who can reasonably attest to the applicant's citizenship, and that contains the applicant's name, date of birth, and place of U.S. birth. The affidavit does not have to be notarized.

(c) *Evidence of identity*. (1) The agency must accept the following as proof of identity, provided such document has a photograph or other identifying information sufficient to establish identity, including, but not limited to, name, age, sex, race, height, weight, eye color, or address:

(i) Identity documents listed at 8 CFR 274a.2 (b)(1)(v)(B)(1), except a driver's license issued by a Canadian government authority.

(ii) Driver's license issued by a State or Territory.

(iii) School identification card.

(iv) U.S. military card or draft record.

(v) Identification card issued by the Federal, State, or local government.

(vi) Military dependent's identification card.

(vii) U.S. Coast Guard Merchant Mariner card.

(viii) For children under age 19, a clinic, doctor, hospital, or school record, including preschool or day care records.

(ix) A finding of identity from an Express Lane agency, as defined in section 1902(e)(13)(F) of the Act.

(x) Two other documents containing consistent information that corroborates an applicant's identity. Such documents include, but are not limited to, employer identification cards; high school, high school equivalency and college diplomas; marriage certificates; divorce decrees; and property deeds or titles.

(2) Finding of identity from a Federal or State governmental agency. The agency may accept as proof of identity a finding of identity from a Federal agency or another State agency (not described in paragraph (c)(1)(ix) of this section), including but not limited to a public assistance, law enforcement, internal revenue or tax bureau, or corrections agency, if the agency has verified and certified the identity of the individual.

(3) If the applicant does not have any document specified in paragraph (c)(1) of this section and identity is not verified under paragraph (c)(2) of this section, the agency must accept an affidavit signed, under penalty of perjury, by a person other than the applicant who can reasonably attest to the applicant's identity. Such affidavit must contain the applicant's name and other identifying information establishing identity, as described in paragraph (c)(1) of this section. The affidavit does not have to be notarized.

(d) *Verification of citizenship by a Federal agency or another State*. The agency may rely, without further documentation of citizenship or identity, on a verification of citizenship made by a Federal agency or another State agency, if such verification was done on or after July 1, 2006.

(e) *Assistance with obtaining documentation*. States must provide assistance to individuals who need assistance in securing satisfactory documentary evidence of citizenship in a timely manner.

(f) *Documentary evidence*. A photocopy, facsimile, scanned or other copy of a document must be accepted to the same extent as an original document under this section, unless information on the copy submitted is inconsistent with other information available to the agency or the agency otherwise has reason to question the validity of, or the information in, the document.

[81 FR 86455, Nov. 30, 2016]

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.

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]

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 § 435.912 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 beneficiary 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 beneficiary, 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 beneficiary 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; 77 FR 17206, Mar. 23, 2012]

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 non-MAGI financial methodologies.* (1) This section only applies to individuals excepted from application of MAGI-based methods in accordance with § 435.603(j).

(2) Except as specified in paragraphs (c) and (d) of this section or in § 435.121 or as permitted under § 435.831(b)(1), in determining financial eligibility of individuals as categorically or 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 (5) of this section, the agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies or methodologies permitted under § 435.831(b)(1) in determining eligibility for the following groups:

(i) Qualified Medicare beneficiaries specified in sections 1902(a)(10)(E) and 1905(p) of the Act;

(ii) Optional categorically needy individuals under groups established under subpart C of this part and section 1902(a)(10)(A)(ii) of the Act;

(iii) Medically needy individuals under groups established under subpart

D of this part and section 1902(a)(10)(C)(i)(III) of the Act; and

(iv) 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; 81 FR 86456, Nov. 30, 2016]

§ 435.602 Financial responsibility of relatives and other individuals.

(a)(1) This section only applies to individuals excepted from application of MAGI-based methods in accordance with § 435.603(j).

(2) *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:

(i) 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.

(ii) 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 will be considered if the individual under age 21 were dependent under the State's approved State plan under title IV–A of the Act in effect as of July 16, 1996, whether or not they are actually contributed, except as specified under paragraph (c) of this section. These requirements and methodologies must be applied in accordance with the provisions of the State's approved title IV–A State plan as of July 16, 1996.

(iii) 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.

(iv) 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; 81 FR 86456, Nov. 30, 2016]

§ 435.603 Application of modified adjusted gross income (MAGI).

(a) *Basis, scope, and implementation.* (1) This section implements section 1902(e)(14) of the Act.

(2) Effective January 1, 2014, the agency must apply the financial methodologies set forth in this section in determining the financial eligibility of all individuals for Medicaid, except for individuals identified in paragraph (j) of this section and as provided in paragraph (a)(3) of this section.

(3) In the case of determining ongoing eligibility for beneficiaries determined eligible for Medicaid coverage to begin on or before December 31, 2013, application of the financial methodologies set forth in this section will not be applied until March 31, 2014 or the next regularly-scheduled renewal of eligibility for such individual under § 435.916 of this part, whichever is later.

(b) *Definitions.* For purposes of this section—

Child means a natural or biological, adopted or step child.

Code means the Internal Revenue Code.

Family size means the number of persons counted as members of an individual's household. In the case of determining the family size of a pregnant woman, the pregnant woman is counted as herself plus the number of children she is expected to deliver. In the case of determining the family size of other individuals who have a pregnant woman in their household, the pregnant woman is counted, at State option, as either 1 or 2 person(s) or as herself plus the number of children she is expected to deliver.

Parent means a natural or biological, adopted or step parent.

Sibling means natural or biological, adopted, half, or step sibling.

Tax dependent has the meaning provided in § 435.4 of this part.

(c) *Basic rule.* Except as specified in paragraph (i), (j), and (k) of this section, the agency must determine financial eligibility for Medicaid based on ''household income'' as defined in paragraph (d) of this section.

(d) *Household income*—(1) *General rule.* Except as provided in paragraphs (d)(2) through (d)(4) of this section, household income is the sum of the MAGI-based income, as defined in paragraph (e) of this section, of every individual included in the individual's household.

(2) *Income of children and tax dependents.* (i) The MAGI-based income of an individual who is included in the household of his or her natural, adopted or step parent and is not expected to be required to file a tax return under section 6012(a)(1) of the Code for the taxable year in which eligibility for Medicaid is being determined, is not included in household income whether or not the individual files a tax return.

(ii) The MAGI-based income of a tax dependent described in paragraph (f)(2)(i) of this section who is not expected to be required to file a tax return under section 6012(a)(1) of the Code for the taxable year in which eligibility for Medicaid is being determined is not included in the household

income of the taxpayer whether or not such tax dependent files a tax return.

(3) In the case of individuals described in paragraph (f)(2)(i) of this section, household income may, at State option, also include actually available cash support, exceeding nominal amounts, provided by the person claiming such individual as a tax dependent.

(4) Effective January 1, 2014, in determining the eligibility of an individual using MAGI-based income, a state must subtract an amount equivalent to 5 percentage points of the Federal poverty level for the applicable family size only to determine the eligibility of an individual for medical assistance under the eligibility group with the highest income standard using MAGI-based methodologies in the applicable Title of the Act, but not to determine eligibility for a particular eligibility group.

(e) *MAGI-based income*. For the purposes of this section, MAGI-based income means income calculated using the same financial methodologies used to determine modified adjusted gross income as defined in section 36B(d)(2)(B) of the Code, with the following exceptions—

(1) An amount received as a lump sum is counted as income only in the month received.

(2) Scholarships, awards, or fellowship grants used for education purposes and not for living expenses are excluded from income.

(3) *American Indian/Alaska Native exceptions*. The following are excluded from income:

(i) Distributions from Alaska Native Corporations and Settlement Trusts;

(ii) Distributions from any property held in trust, subject to Federal restrictions, located within the most recent boundaries of a prior Federal reservation, or otherwise under the supervision of the Secretary of the Interior;

(iii) Distributions and payments from rents, leases, rights of way, royalties, usage rights, or natural resource extraction and harvest from—

(A) Rights of ownership or possession in any lands described in paragraph (e)(3)(ii) of this section; or

(B) Federally protected rights regarding off-reservation hunting, fishing, gathering, or usage of natural resources;

(iv) Distributions resulting from real property ownership interests related to natural resources and improvements—

(A) Located on or near a reservation or within the most recent boundaries of a prior Federal reservation; or

(B) Resulting from the exercise of federally-protected rights relating to such real property ownership interests;

(v) Payments resulting from ownership interests in or usage rights to items that have unique religious, spiritual, traditional, or cultural significance or rights that support subsistence or a traditional lifestyle according to applicable Tribal Law or custom;

(vi) Student financial assistance provided under the Bureau of Indian Affairs education programs.

(f) *Household*—(1) *Basic rule for taxpayers not claimed as a tax dependent*. In the case of an individual who expects to file a tax return for the taxable year in which an initial determination or renewal of eligibility is being made, and who does not expect to be claimed as a tax dependent by another taxpayer, the household consists of the taxpayer and, subject to paragraph (f)(5) of this section, all persons whom such individual expects to claim as a tax dependent.

(2) *Basic rule for individuals claimed as a tax dependent*. In the case of an individual who expects to be claimed as a tax dependent by another taxpayer for the taxable year in which an initial determination or renewal of eligibility is being made, the household is the household of the taxpayer claiming such individual as a tax dependent, except that the household must be determined in accordance with paragraph (f)(3) of this section in the case of—

(i) Individuals other than a spouse or child who expect to be claimed as a tax dependent by another taxpayer; and

(ii) Individuals under the age specified by the State under paragraph (f)(3)(iv) of this section who expect to be claimed by one parent as a tax dependent and are living with both parents but whose parents do not expect to file a joint tax return; and

(iii) Individuals under the age specified by the State under paragraph (f)(3)(iv) of this section who expect to be claimed as a tax dependent by a non-custodial parent. For purposes of this section—

(A) A court order or binding separation, divorce, or custody agreement establishing physical custody controls; or

(B) If there is no such order or agreement or in the event of a shared custody agreement, the custodial parent is the parent with whom the child spends most nights.

(3) *Rules for individuals who neither file a tax return nor are claimed as a tax dependent.* In the case of individuals who do not expect to file a Federal tax return and do not expect to be claimed as a tax dependent for the taxable year in which an initial determination or renewal of eligibility is being made, or who are described in paragraph (f)(2)(i), (f)(2)(ii), or (f)(2)(iii) of this section, the household consists of the individual and, if living with the individual—

(i) The individual's spouse;

(ii) The individual's children under the age specified in paragraph (f)(3)(iv) of this section; and

(iii) In the case of individuals under the age specified in paragraph (f)(3)(iv) of this section, the individual's parents and siblings under the age specified in paragraph (f)(3)(iv) of this section.

(iv) The age specified in this paragraph is either of the following, as elected by the agency in the State plan—

(A) Age 19; or

(B) Age 19 or, in the case of full-time students, age 21.

(4) *Married couples.* In the case of a married couple living together, each spouse will be included in the household of the other spouse, regardless of whether they expect to file a joint tax return under section 6013 of the Code or whether one spouse expects to be claimed as a tax dependent by the other spouse.

(5) For purposes of paragraph (f)(1) of this section, if, consistent with the procedures adopted by the State in accordance with § 435.956(f) of this part, a taxpayer cannot reasonably establish that another individual is a tax dependent of the taxpayer for the tax year in which Medicaid is sought, the inclusion of such individual in the household of the taxpayer is determined in accordance with paragraph (f)(3) of this section.

(g) *No resource test or income disregards.* In the case of individuals whose financial eligibility for Medicaid is determined in accordance with this section, the agency must not—

(1) Apply any assets or resources test; or

(2) Apply any income or expense disregards under sections 1902(r)(2) or 1931(b)(2)(C), or otherwise under title XIX of the Act, except as provided in paragraph (d)(1) of this section.

(h) *Budget period*—(1) *Applicants and new enrollees.* Financial eligibility for Medicaid for applicants, and other individuals not receiving Medicaid benefits at the point at which eligibility for Medicaid is being determined, must be based on current monthly household income and family size.

(2) *Current beneficiaries.* For individuals who have been determined financially-eligible for Medicaid using the MAGI-based methods set forth in this section, a State may elect in its State plan to base financial eligibility either on current monthly household income and family size or income based on projected annual household income and family size for the remainder of the current calendar year.

(3) In determining current monthly or projected annual household income and family size under paragraphs (h)(1) or (h)(2) of this section, the agency may adopt a reasonable method to include a prorated portion of reasonably predictable future income, to account for a reasonably predictable increase or decrease in future income, or both, as evidenced by a signed contract for employment, a clear history of predictable fluctuations in income, or other clear indicia of such future changes in income. Such future increase or decrease in income or family size must be verified in the same manner as other income and eligibility factors, in accordance with the income and eligibility verification requirements at § 435.940 through § 435.965, including by self-attestation if reasonably compatible with other electronic data obtained by the agency in accordance with such sections.

(i) If the household income of an individual determined in accordance with this section results in financial ineligibility for Medicaid and the household

income of such individual determined in accordance with 26 CFR 1.36B–1(e) is below 100 percent FPL, Medicaid financial eligibility will be determined in accordance with 26 CFR 1.36B–1(e).

(j) *Eligibility Groups for which MAGI-based methods do not apply*. The financial methodologies described in this section are not applied in determining the Medicaid eligibility of individuals described in this paragraph. The agency must use the financial methods described in § 435.601 and § 435.602 of this subpart.

(1) Individuals whose eligibility for Medicaid does not require a determination of income by the agency, including, but not limited to, individuals receiving Supplemental Security Income (SSI) eligible for Medicaid under § 435.120 of this part, individuals deemed to be receiving SSI and eligible for Medicaid under § 435.135, § 435.137 or § 435.138 of this part and individuals for whom the State relies on a finding of income made by an Express Lane agency, in accordance with section 1902(e)(13) of the Act.

(2) Individuals who are age 65 or older when age is a condition of eligibility.

(3) Individuals whose eligibility is being determined on the basis of being blind or disabled, or on the basis of being treated as being blind or disabled, including, but not limited to, individuals eligible under § 435.121, § 435.232 or § 435.234 of this part or under section 1902(e)(3) of the Act, but only for the purpose of determining eligibility on such basis.

(4) Individuals who request coverage for long-term care services and supports for the purpose of being evaluated for an eligibility group under which long-term care services and supports not covered for individuals determined eligible using MAGI-based financial methods are covered, or for individuals being evaluated for an eligibility group for which being institutionalized, meeting an institutional level of care or satisfying needs-based criteria for home and community based services is a condition of eligibility. For purposes of this paragraph, ''long-term care services and supports'' include nursing facility services, a level of care in any institution equivalent to nursing facility services; and home and community-based services furnished under a waiver or State plan under sections 1915 or 1115 of the Act; home health services as described in sections 1905(a)(7) of the Act and personal care services described in sections 1905(a)(24) of the Act.

(5) Individuals who are being evaluated for eligibility for Medicare cost sharing assistance under section 1902(a)(10)(E) of the Act, but only for purposes of determining eligibility for such assistance.

(6) Individuals who are being evaluated for coverage as medically needy under subparts D and I of this part, but only for the purpose of determining eligibility on such basis.

(k) *Eligibility*. In the case of an individual whose eligibility is being determined under § 435.214, the agency may—

(1) Consider the household to consist of only the individual for purposes of paragraph (f) of this section;

(2) Count only the MAGI-based income of the individual for purposes of paragraph (d) of this section.

(3) Increase the family size of the individual, as defined in paragraph (b) of the section, by one.

[77 FR 17206, Mar. 23, 2012, as amended at 78 FR 42302, July 15, 2013; 81 FR 86456, Nov. 30, 2016]

§ 435.604 [Reserved]

§ 435.606 [Reserved]

§ 435.608 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and beneficiaries 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) Consistent with §§ 433.145 through 433.148 of this chapter, as a condition of eligibility, the agency must require legally able applicants and beneficiaries to:

(1) Assign rights to the Medicaid agency to medical support and to payment for medical care from any third party;

(2) In the case of applicants, attest that they will cooperate, and, in the case of beneficiaries, cooperate with the agency in—

(i) Establishing the identity of a child's parents and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating or is a pregnant woman described in § 435.116; and

(ii) 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.

(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.

[55 FR 48609, Nov. 21, 1990, as amended at 58 FR 4907, Jan. 19, 1993. Redesignated at 58 FR 4931, Jan. 19, 1993, as amended at 81 FR 86457, Nov. 30, 2016]

§ 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 Individuals with Intellectual Disabilities 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 individuals with intellectual disabilities), 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 beneficiaries 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 beneficiaries 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 § 435.915. 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.* For purposes of determining medically needy eligibility under this part, the agency must determine an individual's countable income as follows:

(1) For individuals under age 21, pregnant women, and parents and other caretaker relatives, the agency may apply—

(i) The AFDC methodologies in effect in the State as of August 16, 1996, consistent with §435.601 (relating to financial methodologies for non-MAGI eligibility determinations) and §435.602 (relating to financial responsibility of relatives and other individuals for non-MAGI eligibility determinations); or

(ii) The MAGI-based methodologies defined in §435.603(b) through (f). If the agency applies the MAGI-based methodologies defined in §435.603(b) through (f), the agency must comply with the terms of §435.602, except that in applying §435.602(a)(2)(ii) to individuals under age 21, the agency may, at State option, include all parents as defined in §435.603(b) (including stepparents) who are living with the individual in the individual's household for purposes of determining household income and family size, without regard to whether the parent's income and resources would be counted under the State's approved State plan under title IV–A of the Act in effect as of July 16, 1996, if the individual were a dependent child under such State plan.

(2) For aged, blind, or disabled individuals in States covering all SSI beneficiaries, 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 that applicable income standard under §435.814, 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), 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, as amended at 77 FR 17208, Mar. 23, 2012; 81 FR 86457, Nov. 30, 2016]

§ 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 beneficiaries 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 providing information to applicants and beneficiaries and 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, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, section 1557 of the Affordable Care Act, and all other relevant provisions of Federal and State laws and their respective implementing regulations.

[81 FR 86457, Nov. 30, 2016]

§ 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 beneficiary.

[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)(1) 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 and accessibility of program information.

(a) The agency must furnish the following information in electronic and paper formats (including through the Internet Web site described in § 435.1200(f) of this part), and orally as appropriate, to all applicants and other individuals who request it:

(1) The eligibility requirements;

(2) Available Medicaid services; and

(3) The rights and responsibilities of applicants and beneficiaries.

(b) Such information must be provided to applicants and beneficiaries in plain language and in a manner that is accessible and timely to—

(1) Individuals who are limited English proficient through the provision of language services at no cost to the individual including, oral interpretation and written translations;

(2) Individuals living with disabilities through the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act; and

(3) Individuals must be informed of the availability of the accessible information and language services described in this paragraph and how to access such information and services, at a minimum through providing taglines in non-English languages indicating the availability of language services.

[77 FR 17208, Mar. 23, 2012, as amended at 81 FR 86457, Nov. 30, 2016]

§ 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 Application.

(a) *Basis and implementation.* In accordance with section 1413(b)(1)(A) of the Affordable Care Act, the agency must accept an application from the applicant, an adult who is in the applicant's household, as defined in § 435.603(f), or family, as defined in section 36B(d)(1) of the Code, an authorized representative, or if the applicant is a minor or incapacitated, someone acting responsibly for the applicant, and any documentation required to establish eligibility—

(1) Via the internet Web site described in § 435.1200(f) of this part;

(2) By telephone;

(3) Via mail;

(4) In person; and

(5) Through other commonly available electronic means.

(b) The application must be—

(1) The single, streamlined application for all insurance affordability programs developed by the Secretary; or

(2) An alternative single, streamlined application for all insurance affordability programs, which may be no more burdensome on the applicant than the application described in paragraph (b)(1) of this section, approved by the Secretary.

(c) For individuals applying, or who may be eligible, for assistance on a basis other than the applicable MAGI standard in accordance with § 435.911(c)(2) of this part, the agency may use either—

(1) An application described in paragraph (b) of this section and supplemental forms to collect additional information needed to determine eligibility on such other basis; or

(2) An application designed specifically to determine eligibility on a basis other than the applicable MAGI standard. Such application must minimize burden on applicants.

(3) Any MAGI-exempt applications and supplemental forms in use by the agency must be submitted to the Secretary.

(d) The agency may not require an in-person interview as part of the application process for a determination of eligibility using MAGI-based income.

(e) *Limits on information.* (1) The agency may only require an applicant to provide the information necessary to make an eligibility determination or for a purpose directly connected to the administration of the State plan.

(2) The agency may request information necessary to determine eligibility for other insurance affordability or benefit programs.

(3) The agency may request a non-applicant's SSN provided that—

(i) Provision of such SSN is voluntary;

(ii) Such SSN is used only to determine an applicant's or beneficiary's eligibility for Medicaid or other insurance affordability program or for a purpose directly connected to the administration of the State plan; and

(iii) At the time such SSN is requested, the agency provides clear notice to the individual seeking assistance, or person acting on such individual's behalf, that provision of the non-applicant's SSN is voluntary and information regarding how the SSN will be used.

(f) The agency must require that all initial applications are signed under penalty of perjury. Electronic, including telephonically recorded, signatures and handwritten signatures transmitted via any other electronic transmission must be accepted.

(g) Any application or supplemental form must be accessible to persons who are limited English proficient and persons who have disabilities, consistent with § 435.905(b) of this subpart.

(h) *Reinstatement of withdrawn applications.* (1) In the case of individuals described in paragraph (h)(2) of this section, the agency must reinstate the application submitted by the individual, effective as of the date the application was first received by the Exchange.

(2) Individuals described in this paragraph are individuals who—

(i) Submitted an application described in paragraph (b) of this section to the Exchange;

(ii) Withdrew their application for Medicaid in accordance with 45 CFR 155.302(b)(4)(A);

(iii) Are assessed as potentially eligible for Medicaid by the Exchange appeals entity.

[77 FR 17208, Mar. 23, 2012, as amended at 78 FR 42302, July 15, 2013]

§ 435.908 Assistance with application and renewal.

(a) The agency must provide assistance to any individual seeking help with the application or renewal process in person, over the telephone, and online, and in a manner that is accessible to individuals with disabilities and those who are limited English proficient, consistent with § 435.905(b) of this subpart.

(b) The agency must allow individual(s) of the applicant or beneficiary's choice to assist in the application process or during a renewal of eligibility.

(c) *Certified Application Counselors.* (1) At State option, the agency may certify staff and volunteers of State-designated organizations to act as application assisters, authorized to provide assistance to applicants and beneficiaries with the application process and during renewal of eligibility. To be certified, application assisters must be—

(i) Authorized and registered by the agency to provide assistance at application and renewal;

(ii) Effectively trained in the eligibility and benefits rules and regulations governing enrollment in a QHP through the Exchange and all insurance affordability programs operated in the State, as implemented in the State; and

(iii) Trained in and adhere to all rules regulations relating to the safeguarding and confidentiality of information and prohibiting conflict of interest, including regulations set forth at part 431, subpart F of this chapter, and at 45 CFR 155.260(f), regulations relating to the prohibition against reassignment of provider claims specified in § 447.10 of this chapter, and all other State and Federal laws concerning conflicts of interest and confidentiality of information.

(2) For purposes of this section, assistance includes providing information on insurance affordability programs and coverage options, helping individuals complete an application or renewal, working with the individual to provide required documentation, submitting applications and renewals to the agency, interacting with the

agency on the status of such applications and renewals, assisting individuals with responding to any requests from the agency, and managing their case between the eligibility determination and regularly scheduled renewals. Application assisters may be certified by the agency to act on behalf of applicants and beneficiaries for one, some or all of the permitted assistance activities.

(3) If the agency elects to certify application assisters, it must establish procedures to ensure that—

(i) Applicants and beneficiaries are informed of the functions and responsibilities of certified application assisters;

(ii) Individuals are able to authorize application assisters to receive confidential information about the individual's application for or renewal of Medicaid; and

(iii) The agency does not disclose confidential applicant or beneficiary information to an application assister unless the applicant or beneficiary has authorized the application assister to receive such information.

(4) Application assisters may not impose, accept or receive payment or compensation in any form from applicants or beneficiaries for application assistance.

[77 FR 17208, Mar. 23, 2012, as amended at 78 FR 42302, July 15, 2013]

§ 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) [Reserved]

(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 beneficiaries of optional supplements under § 435.230.

[44 FR 17937, Mar. 23, 1979, as amended at 81 FR 86457, Nov. 30, 2016]

§ 435.910 Use of social security number.

(a) Except as provided in paragraph (h) of this section, the agency must require, as a condition of eligibility, that each individual (including children) seeking Medicaid furnish each of his or her Social Security numbers (SSN).

(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 individual pending issuance or verification of the individual's SSN by SSA or if the individual meets one of the exceptions in paragraph (h) of this section.

(g) The agency must verify the SSN furnished by an applicant or beneficiary with SSA to ensure the SSN was issued to that individual, and to determine whether any other SSNs were issued to that individual.

(h) *Exception.* (1) The requirement of paragraph (a) of this section does not apply and a State may give a Medicaid identification number to an individual who—

(i) Is not eligible to receive an SSN;

(ii) Does not have an SSN and may only be issued an SSN for a valid non-work reason in accordance with 20 CFR 422.104; or

(iii) Refuses to obtain an SSN because of well-established religious objections.

(2) The identification number may be either an SSN obtained by the State on the applicant's behalf or another unique identifier.

(3) 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.

(4) 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; 77 FR 17209, Mar. 23, 2012; 81 FR 86457, Nov. 30, 2016]

DETERMINATION OF MEDICAID ELIGIBILITY

§ 435.911 Determination of eligibility.

(a) *Statutory basis*. This section implements sections 1902(a)(4), (a)(8), (a)(10)(A), (a)(19), and (e)(14) and section 1943 of the Act.

(b)(1) Except as provided in paragraph (b)(2) of this section, applicable modified adjusted gross income standard means 133 percent of the Federal poverty level or, if higher –

(i) In the case of parents and other caretaker relatives described in § 435.110(b), the income standard established in accordance with § 435.110(c) or § 435.220(c);

(ii) In the case of pregnant women, the income standard established in accordance with § 435.116(c) of this part;

(iii) In the case of individuals under age 19, the income standard established in accordance with § 435.118(c) of this part;

(iv) The income standard established under § 435.218(b)(1)(iv) of this part, if the State has elected to provide coverage under such section and, if applicable, coverage under the State's phase-in plan has been implemented for the individual whose eligibility is being determined.

(2) In the case of individuals who have attained at least age 65 and individuals who have attained at least age 19 and who are entitled to or enrolled for Medicare benefits under part A or B or title XVIII of the Act, there is no applicable modified adjusted gross income standard, except that in the case of such individuals—

(i) Who are also pregnant, the applicable modified adjusted gross income standard is the standard established under paragraph (b)(1) of this section; or

(ii) Who are also a parent or caretaker relative, as described in § 435.4, the applicable modified adjusted gross income standard is the higher of the income standard established in accordance with § 435.110(c) or § 435.220(c).

(c) For each individual who has submitted an application described in § 435.907 or whose eligibility is being renewed in accordance with § 435.916 and who meets the non-financial requirements for eligibility (or for whom the agency is providing a reasonable opportunity to verify citizenship or immigration status in accordance with § 435.956(b)) of this chapter, the State Medicaid agency must comply with the following—

(1) The agency must, promptly and without undue delay consistent with timeliness standards established under § 435.912, furnish Medicaid to each such individual whose household income is at or below the applicable modified adjusted gross income standard.

(2) For each individual described in paragraph (d) of this section, the agency must collect such additional information as may be needed consistent with § 435.907(c), to determine whether such individual is eligible for Medicaid on any basis other than the applicable modified adjusted gross income standard, and furnish Medicaid on such basis.

(3) For individuals not eligible on the basis of the applicable modified adjusted gross income standard, the agency must comply with the requirements set forth in § 435.1200(e) of this part.

(d) For purposes of paragraph (c)(2) of this section, individuals described in this paragraph include:

(1) Individuals whom the agency identifies, on the basis of information contained in an application described in § 435.907(b) of this part, or renewal form described in § 435.916(a)(3) of this part, or on the basis of other information available to the State, as potentially eligible on a basis other than the applicable MAGI standard;

(2) Individuals who submit an alternative application described in § 435.907(c) of this part; and

(3) Individuals who otherwise request a determination of eligibility on a basis other than the applicable MAGI standard as described in § 435.603(j) of this part.

[77 FR 17209, Mar. 23, 2012, as amended at 81 FR 86457, Nov. 30, 2016]

§ 435.912 Timely determination of eligibility.

(a) For purposes of this section—

(1) ''Timeliness standards'' refer to the maximum period of time in which every applicant is entitled to a determination of eligibility, subject to the exceptions in paragraph (e) of this section.

(2) ''Performance standards'' are overall standards for determining eligibility in an efficient and timely manner across a pool of applicants, and include standards for accuracy and consumer satisfaction, but do not include standards for an individual applicant's determination of eligibility.

(b) Consistent with guidance issued by the Secretary, the agency must establish in its State plan timeliness and performance standards for, promptly and without undue delay—

(1) Determining eligibility for Medicaid for individuals who submit applications to the single State agency or its designee.

(2) Determining potential eligibility for, and transferring individuals' electronic accounts to, other insurance affordability programs pursuant to § 435.1200(e) of this part.

(3) Determining eligibility for Medicaid for individuals whose accounts are transferred from other insurance affordability programs, including at initial application as well as at a regularly-scheduled renewal or due to a change in circumstances.

(c)(1) The timeliness and performance standards adopted by the agency under paragraph (b) of this section must cover the period from the date of application or transfer from another insurance affordability program to the date the agency notifies the applicant of its decision or the date the agency transfers the individual to another insurance affordability program in accordance with § 435.1200(e) of this part, and must comply with the requirements of paragraph (c)(2) of this section, subject to additional guidance issued by the Secretary to promote accountability and consistency of high quality consumer experience among States and between insurance affordability programs.

(2) Timeliness and performance standards included in the State plan must account for—

(i) The capabilities and cost of generally available systems and technologies;

(ii) The general availability of electronic data matching and ease of connections to electronic sources of authoritative information to determine and verify eligibility;

(iii) The demonstrated performance and timeliness experience of State Medicaid, CHIP and other insurance affordability programs, as reflected in data reported to the Secretary or otherwise available; and

(iv) The needs of applicants, including applicant preferences for mode of application (such as through an internet Web site, telephone, mail, in-person, or other commonly available electronic means), as well as the relative complexity of adjudicating the eligibility determination based on household, income or other relevant information.

(3) Except as provided in paragraph (e) of this section, the determination of eligibility for any applicant may not exceed—

(i) Ninety days for applicants who apply for Medicaid on the basis of disability; and

(ii) Forty-five days for all other applicants.

(d) The agency must inform applicants of the timeliness standards

adopted in accordance with this section.

(e) 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.

(f) The agency must document the reasons for delay in the applicant's case record.

(g) 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. Redesignated and amended at 77 FR 17209, Mar. 23, 2012]

§ 435.914 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.

[44 FR 17937, Mar. 23, 1979. Redesignated at 77 FR 17209, Mar. 23, 2012]

§ 435.915 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.

[44 FR 17937, Mar. 23, 1979. Redesignated at 77 FR 17209, Mar. 23, 2012]

REDETERMINATIONS OF MEDICAID ELIGIBILITY

§ 435.916 Periodic renewal of Medicaid eligibility.

(a) *Renewal of individuals whose Medicaid eligibility is based on modified adjusted gross income methods (MAGI).* (1) Except as provided in paragraph (d) of this section, the eligibility of Medicaid beneficiaries whose financial eligibility is determined using MAGI-based income must be renewed once every 12 months, and no more frequently than once every 12 months.

(2) Renewal on basis of information available to agency. The agency must make a redetermination of eligibility without requiring information from the individual if able to do so based on reliable information contained in the individual's account or other more current information available to the agency, including but not limited to information accessed through any data bases accessed by the agency under §§ 435.948, 435.949 and 435.956 of this part. If the agency is able to renew eligibility based on such information, the agency must, consistent with the requirements of this subpart and subpart E of part 431 of this chapter, notify the individual—

(i) Of the eligibility determination, and basis; and

(ii) That the individual must inform the agency, through any of the modes permitted for submission of applications under § 435.907(a) of this subpart, if any of the information contained in such notice is inaccurate, but that the individual is not required to sign and return such notice if all information provided on such notice is accurate.

(3) Use of a pre-populated renewal form. If the agency cannot renew eligibility in accordance with paragraph (a)(2) of this section, the agency must—

(i) Provide the individual with—

(A) A renewal form containing information, as specified by the Secretary, available to the agency that is needed to renew eligibility.

(B) At least 30 days from the date of the renewal form to respond and provide any necessary information through any of the modes of submission specified in § 435.907(a) of this part, and to sign the renewal form in a manner consistent with § 435.907(f) of the part;

(C) Notice of the agency's decision concerning the renewal of eligibility in accordance with this subpart and subpart E of part 431 of this chapter;

(ii) Verify any information provided by the beneficiary in accordance with §§ 435.945 through 435.956 of this part;

(iii) Reconsider in a timely manner the eligibility of an individual who is terminated for failure to submit the renewal form or necessary information, if the individual subsequently submits the renewal form within 90 days after the date of termination, or a longer period elected by the State, without requiring a new application;

(iv) Not require an individual to complete an in-person interview as part of the renewal process.

(b) *Redetermination of individuals whose Medicaid eligibility is determined on a basis other than modified adjusted gross income.* The agency must redetermine the eligibility of Medicaid beneficiaries excepted from modified adjusted gross income under § 435.603(j) of this part, for circumstances that may change, at least every 12 months. The agency must make a redetermination of eligibility in accordance with the provisions of paragraph (a)(2) of this section, if sufficient information is available to do so. The agency may adopt the procedures described at § 435.916(a)(3) for individuals whose eligibility cannot be renewed in accordance with paragraph (a)(2) of this section.

(1) The agency may consider blindness as continuing until the reviewing physician under § 435.531 of this part determines that a beneficiary'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 of this part, determines that a beneficiary's disability no longer meets the definition of disability contained in the plan.

(c) *Procedures for reporting changes.* The agency must have procedures designed to ensure that beneficiaries make timely and accurate reports of any change in circumstances that may affect their eligibility and that such changes may be reported through any of the modes for submission of applications described in § 435.907(a) of this part.

(d) *Agency action on information about changes.* (1) Consistent with the requirements of § 435.952 of this part, the agency must promptly redetermine eligibility between regular renewals of eligibility described in paragraphs (b) and (c) of this section whenever it receives information about a change in a beneficiary's circumstances that may affect eligibility.

(i) For renewals of Medicaid beneficiaries whose financial eligibility is determined using MAGI-based income, the agency must limit any requests for additional information from the individual to information relating to such change in circumstance.

(ii) If the agency has enough information available to it to renew eligibility with respect to all eligibility criteria, the agency may begin a new 12-month renewal period under paragraphs (a) or (b) of this section.

(2) If the agency has information about anticipated changes in a beneficiary's circumstances that may affect his or her eligibility, it must redetermine eligibility at the appropriate time based on such changes.

(e) The agency may request from beneficiaries only the information needed to renew eligibility. Requests for non-applicant information must be conducted in accordance with § 435.907(e) of this part.

(f) Determination of ineligibility and transmission of data pertaining to individuals no longer eligible for Medicaid.

(1) Prior to making a determination of ineligibility, the agency must consider all bases of eligibility, consistent with § 435.911 of this part.

(2) For individuals determined ineligible for Medicaid, the agency must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in § 435.1200(e) of this part.

(g) Any renewal form or notice must be accessible to persons who are limited English proficient and persons with disabilities, consistent with § 435.905(b) of this subpart.

[77 FR 17210, Mar. 23, 2012]

§ 435.917 Notice of agency's decision concerning eligibility, benefits, or services.

(a) *Notice of eligibility determinations.* Consistent with §§ 431.206 through 431.214 of this chapter, the agency must provide all applicants and beneficiaries with timely and adequate written notice of any decision affecting their eligibility, including an approval, denial, termination or suspension of eligibility, or a denial or change in benefits and services. Such notice must—

(1) Be written in plain language;

(2) Be accessible to persons who are limited English proficient and individuals with disabilities, consistent with § 435.905(b), and

(3) If provided in electronic format, comply with § 435.918(b).

(b) *Content of eligibility notice*—(1) *Notice of approved eligibility*. Any notice of an approval of Medicaid eligibility must include, but is not limited to, clear statements containing the following information—

(i) The basis and effective date of eligibility;

(ii) The circumstances under which the individual must report, and procedures for reporting, any changes that may affect the individual's eligibility;

(iii) If applicable, the amount of medical expenses which must be incurred to establish eligibility in accordance with § 435.121 or § 435.831.

(iv) Basic information on the level of benefits and services available based on the individual's eligibility, including, if applicable—

(A) The differences in coverage available to individuals enrolled in benchmark or benchmark-equivalent coverage or in an Alternative Benefits Plan and coverage available to individuals described in § 440.315 of this chapter (relating to exemptions from mandatory enrollment in benchmark or benchmark-equivalent coverage);

(B) A description of any premiums and cost sharing required under Part 447 Subpart A of this chapter;

(C) An explanation of how to receive additional detailed information on benefits and financial responsibilities; and

(D) An explanation of any right to appeal the eligibility status or level of benefits and services approved.

(2) Notice of adverse action including denial, termination or suspension of eligibility or change in benefits or services. Any notice of denial, termination or suspension of Medicaid eligibility or change in benefits or services must be consistent with § 431.210 of this chapter.

(c) *Eligibility*. Whenever an approval, denial, or termination of eligibility is based on an applicant's or beneficiary's having household income at or below the applicable modified adjusted gross income standard in accordance with § 435.911, the eligibility notice must contain—

(1) Information regarding bases of eligibility other than the applicable modified adjusted gross income standard and the benefits and services afforded to individuals eligible on such other bases, sufficient to enable the individual to make an informed choice as to whether to request a determination on such other bases; and

(2) Information on how to request a determination on such other bases;

(d) *Combined Eligibility Notice*. The agency's responsibility to provide notice under this section is satisfied by a combined eligibility notice, as defined in § 435.4, provided by the Exchange or other insurance affordability program in accordance with an agreement between the agency and such program consummated in accordance with § 435.1200(b)(3), except that, if the information described in paragraph (b)(1)(iii) and (iv) of this section is not included in such combined eligibility notice, the agency must provide the individual with a supplemental notice of

such information, consistent with this section.

[81 FR 86458, Nov. 30, 2016]

§ 435.918 Use of electronic notices.

(a) Effective no earlier than October 1, 2013 and no later than January 1, 2015, the agency must provide individuals with a choice to receive notices and information required under this part or subpart E of part 431 of this chapter in electronic format or by regular mail and must be permitted to change such election.

(b) If the individual elects to receive communications from the agency electronically, the agency must—

(1) Ensure that the individual's election to receive notices electronically is confirmed by regular mail.

(2) Ensure that the individual is informed of his or her right to change such election to receive notices through regular mail.

(3) Post notices to the individual's electronic account within 1 business day of notice generation.

(4) Send an email or other electronic communication alerting the individual that a notice has been posted to his or her account. The agency may not include confidential information in the email or electronic alert.

(5) Send a notice by regular mail within three business days of the date of a failed electronic communication if an electronic communication is undeliverable.

(6) At the individual's request, provide through regular mail any notice posted to the individual's electronic account.

[78 FR 42303, July 15, 2013]

§ 435.920 Verification of SSNs.

(a) In redetermining eligibility, the agency must review case records to determine whether they contain the beneficiary'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 beneficiary to furnish them and meet other requirements of § 435.910.

(c) For any beneficiary 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]

§ 435.923 Authorized representatives.

(a)(1) The agency must permit applicants and beneficiaries to designate an individual or organization to act responsibly on their behalf in assisting with the individual's application and renewal of eligibility and other ongoing communications with the agency. Such a designation must be in accordance with paragraph (f) of this section, including the applicant's signature, and must be permitted at the time of application and at other times.

(2) Authority for an individual or entity to act on behalf of an applicant or beneficiary accorded under state law, including but not limited to, a court order establishing legal guardianship or a power of attorney, must be treated as a written designation by the applicant or beneficiary of authorized representation.

(b) Applicants and beneficiaries may authorize their representatives to—

(1) Sign an application on the applicant's behalf;

(2) Complete and submit a renewal form;

(3) Receive copies of the applicant or beneficiary's notices and other communications from the agency;

(4) Act on behalf of the applicant or beneficiary in all other matters with the agency.

(c) The power to act as an authorized representative is valid until the applicant or beneficiary modifies the authorization or notifies the agency that the representative is no longer authorized to act on his or her behalf, or the authorized representative informs the agency that he or she no longer is acting in such capacity, or there is a change in the legal authority upon which the individual or organization's authority was based. Such notice must be in accordance with paragraph (f) of this section and should include the applicant or authorized representative's signature as appropriate.

(d) The authorized representative—

(1) Is responsible for fulfilling all responsibilities encompassed within the scope of the authorized representation, as described in paragraph (b)(2) of this section, to the same extent as the individual he or she represents;

(2) Must agree to maintain, or be legally bound to maintain, the confidentiality of any information regarding the applicant or beneficiary provided by the agency.

(e) The agency must require that, as a condition of serving as an authorized representative, a provider or staff member or volunteer of an organization must affirm that he or she will adhere to the regulations in part 431, subpart F of this chapter and at 45 CFR 155.260(f) (relating to confidentiality of information), § 447.10 of this chapter (relating to the prohibition against reassignment of provider claims as appropriate for a facility or an organization acting on the facility's behalf), as well as other relevant State and Federal laws concerning conflicts of interest and confidentiality of information.

(f) For purposes of this section, the agency must accept electronic, including telephonically recorded, signatures and handwritten signatures transmitted by facsimile or other electronic transmission. Designations of authorized representatives must be accepted through all of the modalities described in § 435.907(a).

[78 FR 42303, July 15, 2013]

§ 435.926 Continuous eligibility for children.

(a) *Basis*. This section implements section 1902(e)(12) of the Act.

(b) *Eligibility*. The agency may provide continuous eligibility for the period specified in paragraph (c) of this section for an individual who is:

(1) Under age 19 or under a younger age specified by the agency in its State plan; and

(2) Eligible and enrolled for mandatory or optional coverage under the State plan in accordance with subpart B or C of this part.

(c) *Continuous eligibility period*. (1) The agency must specify in the State plan the length of the continuous eligibility period, not to exceed 12 months.

(2) A continuous eligibility period begins on the effective date of the individual's eligibility under § 435.915 or most recent redetermination or renewal of eligibility under § 435.916 and ends after the period specified by the agency under paragraph (c)(1) of this section.

(d) *Applicability*. A child's eligibility may not be terminated during a continuous eligibility period, regardless of any changes in circumstances, unless:

(1) The child attains the maximum age specified in accordance with paragraph (b)(1) of this section;

(2) The child or child's representative requests a voluntary termination of eligibility;

(3) The child ceases to be a resident of the State;

(4) The agency determines that eligibility was erroneously granted at the most recent determination, redetermination or renewal of eligibility because of agency error or fraud, abuse, or perjury attributed to the child or the child's representative; or

(5) The child dies.

[81 FR 86458, Nov. 30, 2016]

FURNISHING MEDICAID

§ 435.930 Furnishing Medicaid.

The agency must—

(a) Furnish Medicaid promptly to beneficiaries 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 beneficiaries 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.

The income and eligibility verification requirements set forth at §§ 435.940 through 435.960 are based on sections 1137, 1902(a)(4), 1902(a)(19), 1902(a)(46)(B), 1902(ee), 1903(r)(3), 1903(x), and 1943(b)(3) of the Act, and section

1413 of the Affordable Care Act. Nothing in the regulations in this subpart should be construed as limiting the State's program integrity measures or affecting the State's obligation to ensure that only eligible individuals receive benefits, consistent with parts 431 and 455 of this subchapter, or its obligation to provide for methods of administration that are in the best interest of applicants and beneficiaries and are necessary for the proper and efficient operation of the plan, consistent with § 431.15 of this subchapter and section 1902(a)(19) of the Act.

[77 FR 17211, Mar. 23, 2012, as amended at 81 FR 86459, Nov. 30, 2016]

§ 435.945 General requirements.

(a) Except where the law requires other procedures (such as for citizenship and immigration status information), the agency may accept attestation of information needed to determine the eligibility of an individual for Medicaid (either self-attestation by the individual or attestation by an adult who is in the applicant's household, as defined in § 435.603(f) of this part, or family, as defined in section 36B(d)(1) of the Internal Revenue Code, an authorized representative, or, if the individual is a minor or incapacitated, someone acting responsibly for the individual) without requiring further information (including documentation) from the individual.

(b) The agency must request and use information relevant to verifying an individual's eligibility for Medicaid in accordance with §§ 435.948 through 435.956 of this subpart.

(c) The agency must furnish, in a timely manner, income and eligibility information, subject to regulations at part 431 subpart F of this chapter, needed for verifying eligibility to the following programs:

(1) To other agencies in the State and other States and to the Federal programs both listed in § 435.948(a) of this subpart and identified in section 1137(b) of the Act;

(2) Other insurance affordability programs;

(3) The child support enforcement program under part D of title IV of the Act; and

(4) SSA for OASDI under title II and for SSI benefits under title XVI of the Act.

(d) All State eligibility determination systems must conduct data matching through the Public Assistance Reporting Information System (PARIS).

(e) The agency must, as required under section 1137(a)(7) of the Act, and upon request, reimburse another agency listed in § 435.948(a) of this subpart or paragraph (c) of this section for reasonable costs incurred in furnishing information, including new developmental costs.

(f) Prior to requesting information for an applicant or beneficiary from another agency or program under this subpart, the agency must inform the individual that the agency will obtain and use information available to it under this subpart to verify income and eligibility or for other purposes directly connected to the administration of the State plan.

(g) Consistent with § 431.16 of this subchapter, the agency must report information as prescribed by the Secretary for purposes of determining compliance with § 431.305 of this subchapter, subpart P of part 431, §§ 435.910 and 435.940 through 435.965 and of evaluating the effectiveness of the income and eligibility verification system.

(h) Information exchanged electronically between the State Medicaid agency and any other agency or program must be sent and received via secure electronic interfaces as defined in § 435.4 of this part.

(i) The agency must execute written agreements with other agencies before releasing data to, or requesting data from, those agencies. Such agreements must provide for appropriate safeguards limiting the use and disclosure of information as required by Federal or State law or regulations.

(j) *Verification plan.* The agency must develop, and update as modified, and submit to the Secretary, upon request, a verification plan describing the verification policies and procedures adopted by the State agency to implement the provisions set forth in §§ 435.940 through 435.956 of this subpart in a format and manner prescribed by the Secretary.

(k) *Flexibility in information collection and verification.* Subject to approval by the Secretary, the agency may request and use information from a source or sources alternative to those listed in § 435.948(a) of this subpart, or through a mechanism other than the electronic service described in § 435.949(a) of this subpart, provided that such alternative source or mechanism will reduce the administrative costs and burdens on individuals and States while maximizing accuracy, minimizing delay, meeting applicable requirements relating to the confidentiality, disclosure, maintenance, or use of information, and promoting coordination with other insurance affordability programs.

[77 FR 17211, Mar. 23, 2012, as amended at 81 FR 86459, Nov. 30, 2016]

§ 435.948 Verifying financial information.

(a) The agency must in accordance with this section request the following information relating to financial eligibility from other agencies in the State and other States and Federal programs to the extent the agency determines such information is useful to verifying the financial eligibility of an individual:

(1) Information related to wages, net earnings from self-employment, unearned income and resources from the State Wage Information Collection Agency (SWICA), the Internal Revenue Service (IRS), the Social Security Administration (SSA), the agencies administering the State unemployment compensation laws, the State-administered supplementary payment programs under section 1616(a) of the Act, and any State program administered under a plan approved under Titles I, X, XIV, or XVI of the Act; and

(2) Information related to eligibility or enrollment from the Supplemental Nutrition Assistance Program, the State program funded under part A of title IV of the Act, and other insurance affordability programs.

(b) To the extent that the information identified in paragraph (a) of this section is available through the electronic service established in accordance with § 435.949 of this subpart, the agency must obtain the information through such service.

(c) The agency must request the information by SSN, or if an SSN is not available, using other personally identifying information in the individual's account, if possible.

[77 FR 17211, Mar. 23, 2012]

§ 435.949 Verification of information through an electronic service.

(a) The Secretary will establish an electronic service through which States may verify certain information with, or obtain such information from, Federal agencies and other data sources, including SSA, the Department of Treasury, and the Department of Homeland Security.

(b) To the extent that information related to eligibility for Medicaid is available through the electronic service established by the Secretary, States must obtain the information through such service, subject to the requirements in subpart C of part 433 of this chapter, except as provided for in § 435.945(k) of this subpart.

[77 FR 17212, Mar. 23, 2012]

§ 435.952 Use of information and requests of additional information from individuals.

(a) The agency must promptly evaluate information received or obtained by it in accordance with regulations under § 435.940 through § 435.960 of this subpart to determine whether such information may affect the eligibility of an individual or the benefits to which he or she is entitled.

(b) If information provided by or on behalf of an individual (on the application or renewal form or otherwise) is reasonably compatible with information obtained by the agency in accordance with § 435.948, § 435.949 or § 435.956 of this subpart, the agency must determine or renew eligibility based on such information.

(c) An individual must not be required to provide additional information or documentation unless information needed by the agency in accordance with § 435.948, § 435.949 or § 435.956 of this subpart cannot be obtained electronically or the information obtained electronically is not reasonably compatible, as provided in the verification

plan described in § 435.945(j) with information provided by or on behalf of the individual.

(1) Income information obtained through an electronic data match shall be considered reasonably compatible with income information provided by or on behalf of an individual if both are either above or at or below the applicable income standard or other relevant income threshold.

(2) If information provided by or on behalf of an individual is not reasonably compatible with information obtained through an electronic data match, the agency must seek additional information from the individual, including—

(i) A statement which reasonably explains the discrepancy; or

(ii) Other information (which may include documentation), provided that documentation from the individual is permitted only to the extent electronic data are not available and establishing a data match would not be effective, considering such factors as the administrative costs associated with establishing and using the data match compared with the administrative costs associated with relying on paper documentation, and the impact on program integrity in terms of the potential for ineligible individuals to be approved as well as for eligible individuals to be denied coverage;

(iii) The agency must provide the individual a reasonable period to furnish any additional information required under paragraph (c) of this section.

(3) *Exception for special circumstances.* The agency must establish an exception to permit, on a case-by-case basis, self-attestation of individuals for all eligibility criteria when documentation does not exist at the time of application or renewal, or is not reasonably available, such as in the case of individuals who are homeless or have experienced domestic violence or a natural disaster. This exception does not apply if documentation is specifically required under title XI or XIX, such as requirements for verifying citizenship and immigration status, as implemented at § 435.956(a).

(d) The agency may not deny or terminate eligibility or reduce benefits for any individual on the basis of information received in accordance with regulations under § 435.940 through § 435.960 of this subpart unless the agency has sought additional information from the individual in accordance with paragraph (c) of this section, and provided proper notice and hearing rights to the individual in accordance with this subpart and subpart E of part 431.

[77 FR 17212, Mar. 23, 2012, as amended at 81 FR 86459, Nov. 30, 2016]

§ 435.956 Verification of other non-financial information.

(a) *Citizenship and immigration status.* (1)(i) The agency must—

(A) Verify citizenship status through the electronic service established in accordance with § 435.949 or alternative mechanism authorized in accordance with § 435.945(k), if available; and

(B) Promptly attempt to resolve any inconsistencies, including typographical or other clerical errors, between information provided by the individual and information from an electronic data source, and resubmit corrected information through such electronic service or alternative mechanism.

(ii) If the agency is unable to verify citizenship status in accordance with paragraph (a)(1)(i) of this section, the agency must verify citizenship either—

(A) Through a data match with the Social Security Administration; or

(B) In accordance with § 435.407.

(2) The agency must—

(i) Verify immigration status through the electronic service established in accordance with § 435.949, or alternative mechanism authorized in accordance with § 435.945(k);

(ii) Promptly attempt to resolve any inconsistencies, including typographical or other clerical errors, between information provided by the individual and information from an electronic data source, and resubmit corrected information through such electronic service or alternative mechanism.

(3) For purposes of the exemption from the five-year waiting period described in 8 U.S.C. 1613, the agency must verify that an individual is an honorably discharged veteran or in active military duty status, or the spouse or unmarried dependent child of such

person, as described in 8 U.S.C. 1612(b)(2) through the electronic service described in § 435.949 or alternative mechanism authorized in accordance with § 435.945(k). If the agency is unable to verify such status through such service the agency may accept self-attestation of such status.

(4)(i) The agency must maintain a record of having verified citizenship or immigration status for each individual, in a case record or electronic database in accordance with the State's record retention policies in accordance with § 431.17(c) of this chapter.

(ii) Unless the individual reports a change in citizenship or the agency has received information indicating a potential change in the individual's citizenship, the agency may not re-verify or require an individual to re-verify citizenship at a renewal of eligibility under § 435.916 of this subpart, or upon a subsequent application following a break in coverage.

(5) If the agency cannot promptly verify the citizenship or satisfactory immigration status of an individual in accordance with paragraph (a)(1) or (2) of this section, the agency—

(i) Must provide a reasonable opportunity in accordance with paragraph (b) of this section; and

(ii) May not delay, deny, reduce or terminate benefits for an individual whom the agency determines to be otherwise eligible for Medicaid during such reasonable opportunity period, in accordance with § 435.911(c).

(iii) If a reasonable opportunity period is provided, the agency may begin to furnish benefits to otherwise eligible individuals, effective the date of application, or the first day of the month of application, consistent with the agency's election under § 435.915(b).

(b) *Reasonable opportunity period.* (1) The agency must provide a reasonable opportunity period to individuals who have made a declaration of citizenship or satisfactory immigration status in accordance with § 435.406(a), and for whom the agency is unable to verify citizenship or satisfactory immigration status in accordance with paragraph (a) of this section. During the reasonable opportunity period, the agency must continue efforts to complete verification of the individual's citizenship or satisfactory immigration status, or request documentation if necessary. The agency must provide notice of such opportunity that is accessible to persons who have limited English proficiency and individuals with disabilities, consistent with § 435.905(b). During such reasonable opportunity period, the agency must, if relevant to verification of the individual's citizenship or satisfactory immigration status—

(i) In the case of individuals declaring citizenship who do not have an SSN at the time of such declaration, assist the individual in obtaining an SSN in accordance with § 435.910, and attempt to verify the individual's citizenship in accordance with paragraph (a)(1) of this section once an SSN has been obtained and verified;

(ii) Promptly provide the individual with information on how to contact the electronic data source described in paragraph (a) of this section so that he or she can attempt to resolve any inconsistencies defeating electronic verification directly with such source, and pursue verification of the individual's citizenship or satisfactory immigration status if the individual or source informs the agency that the inconsistencies have been resolved; and

(iii) Provide the individual with an opportunity to provide other documentation of citizenship or satisfactory immigration status, in accordance with section 1137(d) of the Act and § 435.406 or § 435.407.

(2) The reasonable opportunity period—

(i) Begins on the date on which the notice described in paragraph (b)(1) of this section is received by the individual. The date on which the notice is received is considered to be 5 days after the date on the notice, unless the individual shows that he or she did not receive the notice within the 5-day period.

(ii)(A) Ends on the earlier of the date the agency verifies the individual's citizenship or satisfactory immigration status or determines that the individual did not verify his or her citizenship or satisfactory immigration status in accordance with paragraph (a)(2) of this section, or 90 days after the date

described in paragraph (b)(2)(i) of this section, except that,

(B) The agency may extend the reasonable opportunity period beyond 90 days for individuals declaring to be in a satisfactory immigration status if the agency determines that the individual is making a good faith effort to obtain any necessary documentation or the agency needs more time to verify the individual's status through other available electronic data sources or to assist the individual in obtaining documents needed to verify his or her status.

(3) If, by the end of the reasonable opportunity period, the individual's citizenship or satisfactory immigration status has not been verified in accordance with paragraph (a) of this section, the agency must take action within 30 days to terminate eligibility in accordance with part 431 subpart E (relating to notice and appeal rights) of this chapter, except that §§ 431.230 and 431.231 of this chapter (relating to maintaining and reinstating services) may be applied at State option.

(4)(i) The agency may establish in its State plan reasonable limits on the number of reasonable opportunity periods during which medical assistance is furnished which a given individual may receive once denied eligibility for Medicaid due to failure to verify citizenship or satisfactory immigration status, provided that the conditions in paragraph (b)(4)(ii) of this section are met.

(ii) Prior to implementing any limits under paragraph (b)(4)(i) of this section, the agency must—

(A) Demonstrate that the lack of limits jeopardizes program integrity; and

(B) Receive approval of a State plan amendment prior to implementing limits.

(c) *State residency*. (1) The agency may verify State residency in accordance with § 435.945(a) of this subpart or through other reasonable verification procedures consistent with the requirements in § 435.952 of this subpart.

(2) Evidence of immigration status may not be used to determine that an individual is not a State resident.

(d) *Social Security numbers*. The agency must verify Social Security numbers (SSNs) in accordance with § 435.910 of this subpart.

(e) *Pregnancy*. The agency must accept self-attestation of pregnancy unless the State has information that is not reasonably compatible with such attestation, subject to the requirements of § 435.952 of this subpart.

(f) *Age, date of birth and household size*. The agency may verify date of birth and the individuals that comprise an individual's household, as defined in § 435.603(f) of this part, in accordance with § 435.945(a) of this subpart or through other reasonable verification procedures consistent with the requirements in § 435.952 of this subpart.

[77 FR 17212, Mar. 23, 2012, as amended at 81 FR 86459, Nov. 30, 2016]

§ 435.960 Standardized formats for furnishing and obtaining information to verifying income and eligibility.

(a) The agency must maintain for all applicants and beneficiaries 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) Administering presumptive eligibility.

(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; 81 FR 86460, Nov. 30, 2016]

§ 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 beneficiaries whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to beneficiaries who were eligible for Medicaid in the month in which the medical care or services were provided except that, for beneficiaries who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the beneficiary's liability. (See §§ 435.915 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) During a presumptive eligibility period to individuals who are determined to be presumptively eligible for Medicaid in accordance with subpart L of this part;

(2) During a period of presumptive eligibility;

(3) By a provider that is eligible for payment under the plan; and

(4) Regardless of whether such individuals file an application for a full eligibility determination or 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; 77 FR 17212, Mar. 23, 2012; 81 FR 86460, Nov. 30, 2016]

§ 435.1003 FFP for redeterminations.

(a) If the Social Security Administration (SSA) notifies an agency that a beneficiary has been determined ineligible for SSI, FFP is available in Medicaid expenditures for services to the beneficiary 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 beneficiary 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 beneficiary requests a hearing under subpart E, part 431 of this subchapter.

(3) If a beneficiary 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 beneficiaries, 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 Beneficiaries overcoming certain conditions of eligibility.

(a) FFP is available, as specified in paragraph (b) of this section, in expenditures for services provided to beneficiaries 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 SSI or an optional State supplement continues to receive cash payments while these conditions are being overcome; or

(2) For beneficiaries, eligible for Medicaid only and recipients of SSI or an optional State supplement who do not continue to receive cash payments, the second month following the month in which the beneficiary's Medicaid coverage will have been terminated.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 81 FR 86460, Nov. 30, 2016]

LIMITATIONS ON FFP

§ 435.1005 Beneficiaries in institutions eligible under a special income standard.

For beneficiaries 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 Beneficiaries 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 beneficiaries, medically needy beneficiaries, 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 beneficiaries 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 citizenship or nationality or satisfactory immigration status.

(a) This section implements sections 1137 and 1902(a)(46)(B) of the Act.

(b) Except as provided in paragraph (c) of this section, FFP is not available to a State for expenditures for medical assistance furnished to individuals unless the State has verified citizenship or immigration status in accordance with § 435.956.

(c) FFP is available to States for otherwise eligible individuals whose declaration of U.S. citizenship or satisfactory immigration status in accordance with section 1137(d) of the Act and § 435.406(c) has been verified in accordance with § 435.956, who are exempt from the requirements to verify citizenship under § 435.406(a)(1)(iii), or for whom benefits are provided during a reasonable opportunity period to verify citizenship, nationality, or satisfactory immigration status in accordance with section § 435.956(b), including the time period during which an appeal is pending if the State has elected the option under § 435.956(b)(3).

[81 FR 86460, Nov. 30, 2016]

§ 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 individuals with intellectual disabilities means treatment that meets the requirements specified in the standard concerning active treatment for intermediate care facilities for persons with Intellectual Disability 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 Individuals with Intellectual Disabilities is not an institution for mental diseases.

Institution for Individuals with Intellectual Disabilities 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 Individuals with Intellectual Disabilities 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 Intellectual Disability 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 individuals with intellectual disabilities.

[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]

FFP FOR PREMIUM ASSISTANCE

§ 435.1015 FFP for premium assistance for plans in the individual market.

(a) FFP is available for payment of the costs of insurance premiums on behalf of an eligible individual for a health plan offered in the individual market that provides the individual with benefits for which the individual is covered under the State plan, subject to the following conditions:

(1) The insurer is obligated to pay primary to Medicaid for all health care items and services for which the insurer is legally and contractually responsible under the individual health plan, as required under part 433 subpart D of this chapter;

(2) The agency furnishes all benefits for which the individual is covered under the State plan that are not available through the individual health plan;

(3) The individual does not incur any cost sharing charges in excess of any amounts imposed by the agency under subpart A of part 447; and

(4) The total cost of purchasing such coverage, including administrative expenditures, the costs of paying all cost sharing charges in excess of the amounts imposed by the agency under subpart A of part 447, and the costs of providing benefits as required by (a)(2) of this section, must be comparable to the cost of providing direct coverage under the State plan.

(b) A State may not require an individual to receive benefits through premium assistance under this section, and a State must inform an individual that it is the individual's choice to receive either direct coverage under the Medicaid State plan or coverage through premium assistance for an individual health plan. A State must require that an individual who elects premium assistance obtain through the insurance coverage all benefits for which the insurer is responsible and must provide the individual with information on how to access any additional

benefits and cost sharing assistance not provided by the insurer.

[78 FR 42303, July 15, 2013]

Subpart L—Options for Coverage of Special Groups under Presumptive Eligibility

SOURCE: 66 FR 2667, Jan. 11, 2001, unless otherwise noted.

§ 435.1100 Basis for presumptive eligibility.

This subpart implements sections 1920, 1920A, 1920B, 1920C, and 1902(a)(47)(B) of the Act.

[81 FR 86460, Nov. 30, 2016]

§ 435.1101 Definitions related to presumptive eligibility.

For the purposes of this subpart, the following definitions apply:

Application means, consistent with the definition at § 435.4, the single streamlined application adopted by the agency under § 435.907(a); and

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.*);

(10) Is a health facility operated by the Indian Health Service, a Tribe or Tribal organization under the Indian Self Determination and Education Assistance Act (25 U.S.C. 450 *et seq.*), or an Urban Indian Organization under title V of the Indian Health Care Improvement Act (25 U.S.C. 1651 *et seq.*).

(11) 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; 81 FR 86460, Nov. 30, 2016]

§ 435.1102 Children covered under presumptive eligibility.

(a) The agency may elect to provide Medicaid services for children under age 19 or a younger age specified by the State during a presumptive eligibility period following a determination by a qualified entity, on the basis of preliminary information, that the individual has gross income (or, at state option, a reasonable estimate of household income, as defined in § 435.603 of this part, determined using simplified methods prescribed by the agency) at or below the income standard established by the State for the age of the child under § 435.118(c) or under § 435.229 if applicable and higher.

(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.

(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

(vi) Do not delegate the authority to determine presumptive eligibility to another entity.

(3) Establish oversight mechanisms to ensure that presumptive eligibility determinations are being made consistent with the statute and regulations.

(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.

(d) The agency—

(1) May require, for purposes of making a presumptive eligibility determination under this section, that the individual has attested to being, or another person who attests to having reasonable knowledge of the individual's status has attested to the individual being, a—

(i) Citizen or national of the United States or in satisfactory immigration status; or

(ii) Resident of the State; and

(2) May not—

(i) Impose other conditions for presumptive eligibility not specified in this section; or

(ii) Require verification of the conditions for presumptive eligibility.

(e) Notice and fair hearing regulations in subpart E of part 431 of this chapter do not apply to determinations of presumptive eligibility under this section.

[43 FR 45204, Sept. 29, 1978, as amended at 77 FR 17212, Mar. 23, 2012; 78 FR 42304, July 15, 2013]

§ 435.1103 Presumptive eligibility for other individuals.

(a) The terms of §§ 435.1101 and 435.1102 apply to pregnant women such that the agency may provide Medicaid to pregnant women during a presumptive eligibility period following a determination by a qualified entity that the pregnant woman has income at or below the income standard established by the State under § 435.116(c), except that coverage of services provided to such women is limited to ambulatory prenatal care and the number of presumptive eligibility periods that may be authorized for pregnant women is one per pregnancy.

(b) If the agency provides Medicaid during a presumptive eligibility period to children under § 435.1102 or to pregnant women under paragraph (a) of this section, the agency may also apply the terms of §§ 435.1101 and 435.1102 to the individuals described in one or more of the following sections of this part, based on the income standard established by the state for such individuals and providing the benefits covered under that section: §§ 435.110 (parents and caretaker relatives), 435.119 (individuals aged 19 or older and under age 65), 435.150 (former foster care children), and 435.218 (individuals under age 65 with income above 133 percent FPL).

(c)(1) The terms of §§ 435.1101 and 435.1102 apply to individuals who may be eligible under § 435.213 of this part (relating to individuals with breast or cervical cancer) or § 435.214 of this part (relating to eligibility for limited family planning benefits) such that the agency may provide Medicaid during a presumptive eligibility period following a determination by a qualified entity described in paragraph (c)(2) of this section that—

(i) The individual meets the eligibility requirements of § 435.213; or

(ii) The individual meets the eligibility requirements of § 435.214, except that coverage provided during a presumptive eligibility period to such individuals is limited to the services described in § 435.214(d).

(2) Qualified entities described in this paragraph include qualified entities which participate as providers under the State plan and which the agency determines are capable of making presumptive eligibility determinations.

[78 FR 42304, July 15, 2013]

§ 435.1110 Presumptive eligibility determined by hospitals.

(a) *Basic rule.* The agency must provide Medicaid during a presumptive eligibility period to individuals who are determined by a qualified hospital, on the basis of preliminary information, to be presumptively eligible subject to the same requirements as apply to the State options under §§ 435.1102 and 435.1103, but regardless of whether the agency provides Medicaid during a presumptive eligibility period under such sections.

(b) *Qualified hospitals.* A qualified hospital is a hospital that—

(1) Participates as a provider under the State plan or a demonstration under section 1115 of the Act, notifies the agency of its election to make presumptive eligibility determinations under this section, and agrees to make presumptive eligibility determinations consistent with State policies and procedures;

(2) At State option, assists individuals in completing and submitting the full application and understanding any documentation requirements; and

(3) Has not been disqualified by the agency in accordance with paragraph (d) of this section.

(c) *State options for bases of presumptive eligibility.* The agency may—

(1) Limit the determinations of presumptive eligibility which hospitals may elect to make under this section to determinations based on income for all of the populations described in §§ 435.1102 and 435.1103; or

(2) Permit hospitals to elect to make presumptive eligibility determinations on additional bases approved under the State plan or an 1115 demonstration.

(d) *Disqualification of hospitals.* (1) The agency may establish standards for qualified hospitals related to the proportion of individuals determined presumptively eligible for Medicaid by the hospital who:

(i) Submit a regular application, as described in § 435.907, before the end of the presumptive eligibility period; or

(ii) Are determined eligible for Medicaid by the agency based on such application.

(2) The agency must take action, including, but not limited to, disqualification of a hospital as a qualified hospital under this section, if the agency determines that the hospital is not—

(i) Making, or is not capable of making, presumptive eligibility determinations in accordance with applicable state policies and procedures; or

(ii) Meeting the standard or standards established by the agency under paragraph (d)(1) of this section.

(3) The agency may disqualify a hospital as a qualified hospital under this paragraph only after it has provided the hospital with additional training or taken other reasonable corrective action measures to address the issue.

[78 FR 42304, July 15, 2013]

Subpart M—Coordination of Eligibility and Enrollment Between Medicaid, CHIP, Exchanges and Other Insurance Affordability Programs

SOURCE: 77 FR 17212, Mar. 23, 2012, unless otherwise noted.

§ 435.1200 Medicaid agency responsibilities for a coordinated eligibility and enrollment process with other insurance affordability programs.

(a) *Statutory basis, purpose, and definitions.*

(1) *Statutory basis and purpose.* This section implements section 1943(b)(3) of the Act as added by section 2201 of the Affordable Care Act to ensure coordinated eligibility and enrollment among insurance affordability programs.

(2) *Definitions.* (i) *Combined eligibility notice* has the meaning as provided in § 435.4.

(ii) *Coordinated content* has the meaning as provided in § 435.4.

(iii) *Joint fair hearing request* has the meaning provided in § 431.201 of this chapter.

(b) *General requirements and definitions.* The State Medicaid agency must—

(1) Fulfill the responsibilities set forth in paragraphs (d) through (h) of this section and, if applicable, paragraph (c) of this section.

(2) Certify for the Exchange and other insurance affordability programs the criteria applied in determining Medicaid eligibility.

(3) Enter into and, upon request, provide to the Secretary one or more agreements with the Exchange, Exchange appeals entity and the agencies administering other insurance affordability programs as are necessary to fulfill the requirements of this section, including a clear delineation of the responsibilities of each program to—

(i) Minimize burden on individuals seeking to obtain or renew eligibility or to appeal a determination of eligibility for enrollment in a QHP or for one or more insurance affordability program;

(ii) Ensure compliance with paragraphs (d) through (h) of this section and, if applicable, paragraph (c) of this section;

(iii) Ensure prompt determinations of eligibility and enrollment in the appropriate program without undue delay, consistent with timeliness standards established under § 435.912, based on the date the application is submitted to any insurance affordability program;

(iv) Provide for a combined eligibility notice and opportunity to submit a joint fair hearing request, consistent with paragraphs (g) and (h) of this section; and

(v) If the agency has delegated authority to conduct fair hearings to the Exchange or Exchange appeals entity under § 431.10(c)(1)(ii) of this chapter, provide for a combined appeals decision by the Exchange or Exchange appeals entity for individuals who requested an appeal of an Exchange-related determination in accordance with 45 CFR part155 subpart F and a fair hearing of a denial of Medicaid eligibility which is conducted by the Exchange or Exchange appeals entity.

(c) *Provision of Medicaid for individuals found eligible for Medicaid by another insurance affordability program.* If the agency has entered into an agreement in accordance with § 431.10(d) of this chapter under which the Exchange or other insurance affordability program makes final determinations of

Medicaid eligibility, for each individual determined so eligible by the Exchange (including as a result of a decision made by the Exchange or Exchange appeals entity in accordance with paragraph (g)(6) or (7)(i)(A) of this section) or other program, the agency must—

(1) Establish procedures to receive, via secure electronic interface, the electronic account containing the determination of Medicaid eligibility;

(2) Comply with the provisions of §435.911 of this part to the same extent as if the application had been submitted to the Medicaid agency; and

(3) Comply with the provisions of §431.10 of this subchapter to ensure it maintains oversight for the Medicaid program.

(d) *Transfer from other insurance affordability programs to the State Medicaid agency*. For individuals for whom another insurance affordability program has not made a determination of Medicaid eligibility, but who have been assessed by such program (including as a result of a decision made by the Exchange appeals entity) as potentially Medicaid eligible, and for individuals not so assessed, but who otherwise request a full determination by the Medicaid agency, the agency must—

(1) Accept, via secure electronic interface, the electronic account for the individual and notify such program of the receipt of the electronic account;

(2) Not request information or documentation from the individual in the individual's electronic account, or provided to the agency by another insurance affordability program or appeals entity;

(3) Promptly and without undue delay, consistent with timeliness standards established under §435.912, determine the Medicaid eligibility of the individual, in accordance with §435.911, without requiring submission of another application and, for individuals determined not eligible for Medicaid, comply with paragraph (e) of this section as if the individual had submitted an application to the agency;

(4) Accept any finding relating to a criterion of eligibility made by such program or appeals entity, without further verification, if such finding was made in accordance with policies and procedures which are the same as those applied by the agency or approved by it in the agreement described in paragraph (b)(3) of this section; and

(5) Notify such program of the final determination of the individual's eligibility or ineligibility for Medicaid.

(e) *Evaluation of eligibility for other insurance affordability programs*—(1) *Individuals determined not eligible for Medicaid*. For each individual who submits an application or renewal to the agency which includes sufficient information to determine Medicaid eligibility, or whose eligibility is being renewed in accordance to a change in circumstance in accordance with §435.916(d), and whom the agency determines is not eligible for Medicaid, and for each individual determined ineligible for Medicaid in accordance with a fair hearing under subpart E of part 431 of this chapter, the agency must promptly and without undue delay, consistent with timeliness standards established under §435.912, determine potential eligibility for, and, as appropriate, transfer via a secure electronic interface the individual's electronic account to, other insurance affordability programs.

(2) *Individuals undergoing a Medicaid eligibility determination on a basis other than MAGI*. In the case of an individual with household income greater than the applicable MAGI standard and for whom the agency is determining eligibility in accordance with §435.911(c)(2) of this part, the agency must promptly and without undue delay, consistent with timeliness standards established under §435.912 of this part, determine potential eligibility for, and as appropriate transfer via secure electronic interface the individual's electronic account to, other insurance affordability programs and provide timely notice to such other program—

(i) That the individual is not Medicaid eligible on the basis of the applicable MAGI standard, but that a final determination of Medicaid eligibility is still pending; and

(ii) Of the agency's final determination of eligibility or ineligibility for Medicaid.

(3) The agency may enter into an agreement with the Exchange to make

determinations of eligibility for enrollment in a QHP through the Exchange, advance payments of the premium tax credit and cost-sharing reductions, consistent with 45 CFR 155.110(a)(2).

(f) *Internet Web site.* (1) The State Medicaid agency must make available to current and prospective Medicaid applicants and beneficiaries a Web site that—

(i) Operates in conjunction with or is linked to the Web site described in § 457.340(a) of this subchapter and to the Web site established by the Exchange under 45 CFR 155.205; and

(ii) Supports applicant and beneficiary activities, including accessing information on the insurance affordability programs available in the State, applying for and renewing coverage, and other activities as appropriate.

(2) Such Web site, any interactive kiosks and other information systems established by the State to support Medicaid information and enrollment activities must be in plain language and be accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this subpart.

(g) *Coordination involving appeals entities.* The agency must—

(1) Include in the agreement into which the agency has entered under paragraph (b)(3) of this section that, if the Exchange or other insurance affordability program provides an applicant or beneficiary with a combined eligibility notice including a determination that the individual is not eligible for Medicaid, the Exchange or Exchange appeals entity (or other insurance affordability program or other program's appeals entity) will—

(i) Provide the applicant or beneficiary with an opportunity to submit a joint fair hearing request, including an opportunity to a request expedited review of his or her fair hearing request consistent with § 431.221(a)(1)(ii) of this chapter; and

(ii) Notify the Medicaid agency of any joint fair hearing request and transmit to the agency the electronic account of the individual who made such request, unless the fair hearing will be conducted by the Exchange or Exchange appeals entity in accordance to a delegation of authority under § 431.10(c)(1)(ii) of this chapter; and

(2) Beginning on the applicability date described in paragraph (i) of this section, establish a secure electronic interface the through which—

(i) The Exchange or Exchange appeals entity (or other insurance affordability program or appeals entity) can notify the agency that an individual has submitted a joint fair hearing request in accordance with paragraph (g)(1)(ii) of this section;

(ii) The individual's electronic account, including any information provided by the individual as part of an appeal to either the agency or Exchange appeals entity (or other insurance affordability program or appeals entity), can be transferred from one program or appeals entity to the other; and

(iii) The agency can notify the Exchange, Exchange appeals entity (or other insurance affordability program or appeals entity) of the information described in paragraphs (g)(5)(i)(A), (B) and (C) of this section.

(3) Accept and act on a joint fair hearing request submitted to the Exchange or Exchange appeals entity and transferred to the agency as if the request for fair hearing had been submitted directly to the agency in accordance with § 431.221 of this chapter;

(4) In conducting a fair hearing in accordance with subpart E or part 431 of this chapter, minimize to the maximum extent possible, consistent with guidance issued by the Secretary, any requests for information or documentation from the individual included in the individual's electronic account or provided to the agency by the Exchange or Exchange appeals entity.

(5)(i) In the case of individuals described in paragraph (g)(5)(ii) of this section who submit a request a fair hearing under subpart E of part 431 of this chapter to the agency or who submit a joint fair hearing request to the Exchange or Exchange appeals entity (or other insurance affordability program or appeals entity), if the fair hearing is conducted by the Medicaid agency, transmit, through the electronic interface established under paragraph (g)(1) of this section, to the Exchange, Exchange appeals entity (or

other insurance affordability program or appeals entity), as appropriate and necessary to enable such other entity to fulfill its responsibilities under 45 CFR part 155, 42 CFR part 457 or 42 CFR part 600—

(A) Notice that the individual has requested a fair hearing;

(B) Whether Medicaid benefits will be furnished pending final administrative action on such fair hearing request in accordance with §431.230 or §431.231 of this chapter; and

(C) The hearing decision made by the agency.

(ii) Individuals described in this paragraph include individuals determined ineligible for Medicaid—

(A) By the Exchange; or

(B) By the agency and transferred to the Exchange or other insurance affordability program in accordance with paragraph (e)(1) or (2) of this section.

(6)(i) In the case of individuals described in paragraph (g)(6)(ii) of this section, if the agency has delegated authority under §431.10(c)(1)(i) to the Exchange to make Medicaid eligibility determinations, the agency must accept a determination of Medicaid eligibility made by the Exchange appeals entity and comply with paragraph (c) of this section in the same manner as if the determination of Medicaid eligibility had been made by the Exchange.

(ii) Individuals described in this paragraph are individuals who were determined ineligible for Medicaid by the Exchange in accordance with 45 CFR 155.305(c), who did not request a fair hearing of such determination, and whom the Exchange appeals entity determines are eligible for Medicaid in deciding an appeal requested by the individual in accordance with 45 CFR part 155 subpart F.

(7)(i) In the case of individuals described in paragraph (g)(7)(ii) of this section, the agency must either—

(A) Accept a determination of Medicaid eligibility made by the Exchange appeals entity and comply with paragraph (c) of this section in the same manner as if the determination of Medicaid eligibility had been made by the Exchange; or

(B) Accept a determination of Medicaid eligibility made by the Exchange appeals entity as an assessment of Medicaid eligibility made by the Exchange and make a determination of eligibility in accordance with paragraph (d) of this section, taking into account any additional information provided to or obtained by the Exchange appeals entity in conducting the Exchange-related appeal.

(ii) Individuals described in this paragraph are individuals who were determined ineligible for Medicaid by the Medicaid agency in accordance with paragraph (e) of the section, who did not request a fair hearing of such determination of Medicaid ineligibility, and whom the Exchange appeals entity determines are eligible for Medicaid in deciding an appeal requested by the individual in accordance with 45 CFR part 155 subpart F.

(h) *Coordination of eligibility notices.* The agency must—

(1) Include in the agreement into which the agency has entered under paragraph (b)(3) of this section that, to the maximum extent feasible, the agency, Exchange or other insurance affordability program will provide a combined eligibility notice, as defined in §435.4, to individuals, as well as to multiple members of the same household included on the same application or renewal form.

(2) For individuals and other household members who will not receive a combined eligibility notice, include appropriate coordinated content, as defined in §435.4, in any notice provided by the agency in accordance with §435.917.

(3) For individuals determined ineligible for Medicaid based on having household income above the applicable MAGI standard, but who are undergoing a Medicaid eligibility determination on a basis other than MAGI in accordance with (e)(2) of this section, the agency must—

(i) Provide notice to the individual, consistent with §435.917—

(A) That the agency—

(*1*) Has determined the individual ineligible for Medicaid due to household income over the applicable MAGI standard; and

(*2*) Is continuing to evaluate Medicaid eligibility on other bases, including a plain language explanation of the other bases being considered.

(B) Include in such notice coordinated content that the agency has transferred the individual's electronic account to the other insurance affordability program (as required under paragraph (e)(2) of this section) and an explanation that eligibility for or enrollment in such other program will not affect the determination of Medicaid eligibility on a non-MAGI basis; and

(i) Provide the individual with notice, consistent with § 435.917, of the final determination of eligibility on all bases, including coordinated content regarding, as applicable—

(A) The notice being provided to the Exchange or other program in accordance with paragraph (e)(2)(ii) of this section;

(B) Any impact that approval of Medicaid eligibility may have on the individual's eligibility for such other program; and

(C) The transfer of the individual's electronic account to the Exchange in accordance with paragraph (e)(1) of this section.

(i) *Notice of applicability date.* The date described in this paragraph is 6 months from the date of a published FEDERAL REGISTER document alerting States of the requirement to comply with paragraphs (g)(2) of this section and §§ 431.221(a)(1)(i), 431.244(f)(3)(i) and (ii) of this chapter. The earliest we will publish such notice will be May 30, 2017, which would result in an earliest effective date of November 30, 2017.

[77 FR 17212, Mar. 23, 2012, as amended at 81 FR 86461, Nov. 30, 2016]

§ 435.1205 Alignment with exchange initial open enrollment period.

(a) *Definitions.* For purposes of this section—

Eligibility based on MAGI means Medicaid eligibility based on the eligibility requirements which will be effective under the State plan, or waiver of such plan, as of January 1, 2014, consistent with §§ 435.110 through 435.119, 435.218 and 435.603.

(b) *Medicaid agency responsibilities to achieve coordinated open enrollment.* For the period beginning October 1, 2013 through December 31, 2013, the agency must

(1) Accept all of the following:

(i) The single streamlined application described in § 435.907.

(ii) Via secure electronic interface, an electronic account transferred from another insurance affordability program.

(2) For eligibility based on MAGI, comply with the terms of § 435.1200 of this part, such that—

(i) For each electronic account transferred to the agency under paragraph (c)(1)(ii) of this section, the agency consistent with either of the following:

(A) Section 435.1200(c), accepts a determination of Medicaid eligibility based on MAGI, made by another insurance affordability program.

(B) Section 435.1200(d), determines eligibility for Medicaid based on MAGI.

(ii) Consistent with § 435.1200(e), for each single streamlined application submitted directly to the agency under paragraph (b)(1)(i) of this section—

(A) Determine eligibility based on MAGI; and

(B) For each individual determined not Medicaid eligible based on MAGI, determine potential eligibility for other insurance affordability programs, based on the requirements which will be effective for each program, and transfer the individual's electronic account to such program via secure electronic interface.

(iii) Provide notice and fair hearing rights, in accordance with § 435.917 of this part, part 431 subpart E of this chapter, and § 435.1200 for those determined ineligible for Medicaid.

(3) For each individual determined eligible based on MAGI in accordance with paragraph (c)(2) of this section—

(i) Provide notice, including the effective date of eligibility, to such individual, consistent with § 435.917 of this part, and furnish Medicaid.

(ii) Apply the terms of § 435.916 (relating to beneficiary responsibility to inform the agency of any changes in circumstances that may affect eligibility) and § 435.952 (regarding use of information received by the agency). The first renewal under § 435.916 of this part may, at State option, be scheduled to occur anytime between 12 months from the date of application and 12 months from January 1, 2014.

(4) For eligibility effective in 2013, for all applicants—

(i) Consistent with the requirements of subpart J of this part, and applying the eligibility requirements in effect under the State plan, or waiver of such plan, as of the date the individual submits an application to any insurance affordability program—

(A) Determine the individual's eligibility based on the information provided on the application or in the electronic account; or

(B) Request additional information from the individual needed by the agency to determine eligibility based on the eligibility requirements in effect on such date, including on a basis excepted from application of MAGI-based methods, as described in § 435.603, and determine such eligibility if such information is provided; and

(C) Furnish Medicaid to individuals determined eligible under this clause or provide notice and fair hearing rights in accordance with part 431 subpart E of this part if eligibility effective in 2013 is denied; or

(ii) Notify the individual of the opportunity to submit a separate application for coverage effective in 2013 and information on how to obtain and submit such application.

[78 FR 42305, July 15, 2013]

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

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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 beneficiaries 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 beneficiaries.
1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
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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 beneficiaries.
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 beneficiaries 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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1915(d) Home and 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. 96–272, section 310(b)(1) Continued eligibility of certain beneficiaries 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 beneficiary 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/IID; 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]

§ 436.219 Individuals receiving State plan home and community-based services.

If the agency provides State plan home and community-based services to individuals described in section 1915(i)(1) of the Act, the agency, under its State plan, may, in addition, provide Medicaid to of individuals in the community who are described in one or both of paragraphs (a) or (b) of this section.

(a) Individuals who—

(1) Are not otherwise eligible for Medicaid;

(2) Have income that does not exceed 150 percent of the Federal poverty line (FPL);

(3) Meet the needs-based criteria under § 441.715 of this chapter; and

(4) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(b) Individuals who—

(1) Would be determined eligible by the agency under an existing waiver or demonstration project under sections 1915(c), 1915(d), 1915(e) or 1115 of the Act, but are not required to receive services under such waivers or demonstration projects;

(2) Have income that does not exceed 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR); and

(3) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(c) For purposes of determining eligibility under paragraph (a) of this section, the agency may not take into account an individual's resources and must use income standards that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in the best interests of the beneficiary. Income methodologies may include use of existing income methodologies, such as the rules of the OAA, AB, APTD or AABD programs. However, subject to the Secretary's approval, the agency may use other income methodologies that meet the requirements of this paragraph.

[79 FR 3029, Jan. 16, 2014]

§ 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 individuals with intellectual disabilities.

(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 individuals with intellectual disabilities.

(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 Intellectual Disability 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 intellectual disability.

(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 beneficiaries.* An agency is providing Medicaid to an institutionalized beneficiary 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 beneficiary 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 beneficiaries 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 beneficiaries 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 beneficiary 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 beneficiary 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 beneficiary 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, beneficiary 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 beneficiary'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 beneficiary. Neither of the two individuals can be the applicant or beneficiary.

(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/beneficiary 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 beneficiary, 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 beneficiaries 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 75.361.

(k) *Reasonable opportunity to present satisfactory documentary evidence of citizenship.* States must give an applicant or beneficiary 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; 81 FR 3011, Jan. 20, 2016]

§ 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 beneficiary'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 beneficiaries 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 beneficiaries 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 § 447.52, § 447.53, or § 447.54 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, as amended at 78 FR 42305, July 15, 2013]

§ 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 beneficiaries whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to beneficiaries who were eligible for Medicaid in the month in which the medical care or services were provided, except that, for beneficiaries who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the beneficiary'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 beneficiaries overcoming certain conditions of eligibility.

FFP is available for a temporary period specified in the State plan in expenditures for services provided to beneficiaries 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: 42 U.S.C. 1302.

SOURCE: 67 FR 41095, June 14, 2002, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following statutory sections:

(1) Section 1902(a)(4) of the Act 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) of the Act.

(2) Section 1903(i)(25) of the Act prohibits payment to a State unless a State provides enrollee encounter data required by CMS.

(3) Section 1903(m) of the Act contains requirements that apply to comprehensive risk contracts.

(4) Section 1903(m)(2)(H) of the Act 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.

(5) Section 1905(t) of the Act contains requirements that apply to PCCMs.

(6) Section 1932 of the Act—

(i) Provides that, with specified exceptions, a State may require Medicaid beneficiaries 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.

(vii) Specifies rules for Indian enrollees, Indian health care providers, and Indian managed care entities.

(viii) 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, PCCMs and PCCM entities. 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—

Abuse means as the term is defined in § 455.2 of this chapter.

Actuary means an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board. In this part, Actuary refers to an individual who is acting on behalf of the State when used in reference to the development and certification of capitation rates.

Capitation payment means a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on

the actuarially sound capitation rate for the provision of services under the State plan. The State makes the payment regardless of whether the particular beneficiary receives services during the period covered by the payment.

Choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions; it includes answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP.

Comprehensive risk contract means a risk contract between the State and an MCO 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) Federally Qualified Health Center (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.

Enrollee means a Medicaid beneficiary who is currently enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity in a given managed care program.

Enrollee encounter data means the information relating to the receipt of any item(s) or service(s) by an enrollee under a contract between a State and a MCO, PIHP, or PAHP that is subject to the requirements of §§ 438.242 and 438.818.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

Fraud means as the term is defined in § 455.2 of this chapter.

Health insuring organization (HIO) means a county operated entity, that in exchange for capitation payments, covers services for beneficiaries—

(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(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990 and section 205 of the Medicare Improvements for Patients and Providers Act of 2008).

Long-term services and supports (LTSS) means services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

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 by the Secretary 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 beneficiaries within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Managed care program means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act.

Material adjustment means an adjustment that, using reasonable actuarial judgment, has a significant impact on the development of the capitation payment such that its omission or

misstatement could impact a determination whether the development of the capitation rate is consistent with generally accepted actuarial principles and practices.

Network provider means any provider, group of providers, or entity that has a network provider agreement with a MCO, PIHP, or PAHP, or a subcontractor, and receives Medicaid funding directly or indirectly to order, refer or render covered services as a result of the state's contract with an MCO, PIHP, or PAHP. A network provider is not a subcontractor by virtue of the network provider agreement.

Nonrisk contract means a contract between the State and a PIHP or PAHP 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.

Overpayment means any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled to under Title XIX of the Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not entitled to under Title XIX of the Act.

Potential enrollee means a Medicaid beneficiary who is subject to mandatory enrollment or may voluntarily elect to enroll in a given MCO, PIHP, PAHP, PCCM or PCCM entity, but is not yet an enrollee of a specific MCO, PIHP, PAHP, PCCM, or PCCM entity.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of 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 services to enrollees under contract with the State, and on the basis of 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, pediatrician, or other licensed practitioner as authorized by the State Medicaid program, 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:

(1) A primary care case manager (PCCM) contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid beneficiaries; or

(2) A PCCM entity contracts with the State to provide a defined set of functions.

Primary care case management entity (PCCM entity) means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

(1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

(2) Development of enrollee care plans.

(3) Execution of contracts with and/or oversight responsibilities for the activities of FFS providers in the FFS program.

(4) Provision of payments to FFS providers on behalf of the State.

(5) Provision of enrollee outreach and education activities.

(6) Operation of a customer service call center.

(7) Review of provider claims, utilization and practice patterns to conduct

provider profiling and/or practice improvement.

(8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

(9) Coordination with behavioral health systems/providers.

(10) Coordination with long-term services and supports systems/providers.

Primary care case manager (PCCM) means a physician, a physician group practice or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.

Rate cell means a set of mutually exclusive categories of enrollees that is defined by one or more characteristics for the purpose of determining the capitation rate and making a capitation payment; such characteristics may include age, gender, eligibility category, and region or geographic area. Each enrollee should be categorized in one of the rate cells for each unique set of mutually exclusive benefits under the contract.

Rating period means a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a).

Risk contract means a contract between the State an MCO, PIHP or PAHP 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.

State means the Single State agency as specified in § 431.10 of this chapter.

Subcontractor means an individual or entity that has a contract with an MCO, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCO's, PIHP's, PAHP's, or PCCM entity's obligations under its contract with the State. A network provider is not a subcontractor by virtue of the network provider agreement with the MCO, PIHP, or PAHP.

§ 438.3 Standard contract requirements.

(a) *CMS review*. The CMS 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. Proposed final contracts must be submitted in the form and manner established by CMS. For States seeking approval of contracts prior to a specific effective date, proposed final contracts must be submitted to CMS for review no later than 90 days prior to the effective date of the contract.

(b) *Entities eligible for comprehensive risk contracts*. A State 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 amended by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payment*. The following requirements apply to the final capitation rate and the receipt of capitation payments under the contract:

(1) The final capitation rate for each MCO, PIHP or PAHP must be:

(i) Specifically identified in the applicable contract submitted for CMS review and approval.

(ii) The final capitation rates must be based only upon services covered under the State plan and additional

services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

(2) Capitation payments may only be made by the State and retained by the MCO, PIHP or PAHP for Medicaid-eligible enrollees.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must provide as follows:

(1) The MCO, PIHP, PAHP, PCCM or PCCM entity accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), 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, PCCM or PCCM entity 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, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.

(e) *Services that may be covered by an MCO, PIHP, or PAHP.* (1) An MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the State plan as follows:

(i) Any services that the MCO, PIHP or PAHP voluntarily agree to provide, although the cost of these services cannot be included when determining the payment rates under paragraph (c) of this section.

(ii) Any services necessary for compliance by the MCO, PIHP, or PAHP with the requirements of subpart K of this part and only to the extent such services are necessary for the MCO, PIHP, or PAHP to comply with § 438.910.

(2) An MCO, PIHP, or PAHP may cover, for enrollees, services or settings that are in lieu of services or settings covered under the State plan as follows:

(i) The State determines that the alternative service or setting is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the alternative service or setting;

(iii) The approved in lieu of services are authorized and identified in the MCO, PIHP, or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP, or PAHP; and

(iv) The utilization and actual cost of in lieu of services is taken into account in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise.

(f) *Compliance with applicable laws and conflict of interest safeguards.* All contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities 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; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in § 438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(g) *Provider-preventable condition requirements.* All contracts with MCOs, PIHPs and PAHPs must comply with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this chapter. MCOs, PIHPs,

and PAHPs, must report all identified provider-preventable conditions in a form and frequency as specified by the State.

(h) *Inspection and audit of records and access to facilities.* All contracts must provide that the State, CMS, the Office of the Inspector General, the Comptroller General, and their designees may, at any time, inspect and audit any records or documents of the MCO, PIHP, PAHP, PCCM or PCCM entity, or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(i) *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 ''MA organization,'' ''CMS,'' and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP,'' ''State,'' and ''Medicaid beneficiaries,'' respectively.

(j) *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, as if such regulation applied directly to MCOs and PIHPs.

(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 as if such regulation applied directly to PAHPs 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 the requirements of this paragraph (j) 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.

(k) *Subcontracts.* All subcontracts must fulfill the requirements of this part for the service or activity delegated under the subcontract in accordance with §438.230.

(l) *Choice of network provider.* The contract must allow each enrollee to choose his or her network provider to the extent possible and appropriate.

(m) *Audited financial reports.* The contract must require MCOs, PIHPs, and PAHPs to submit audited financial reports specific to the Medicaid contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(n) *Parity in mental health and substance use disorder benefits.* (1) All MCO contracts, and any PIHP and PAHP contracts providing services to MCO enrollees, must provide for services to be delivered in compliance with the requirements of subpart K of this part insofar as those requirements are applicable.

(2) Any State providing any services to MCO enrollees using a delivery system other than the MCO delivery system must provide documentation of how the requirements of subpart K of this part are met with the submission of the MCO contract for review and approval under paragraph (a) of this section.

(o) *LTSS contract requirements.* Any contract with an MCO, PIHP or PAHP that includes LTSS as a covered benefit must require that any services covered under the contract that could be authorized through a waiver under section 1915(c) of the Act or a State plan amendment authorized through sections 1915(i) or 1915(k) of the Act be delivered in settings consistent with §441.301(c)(4) of this chapter.

(p) *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 (b) of this section.

(q) *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 beneficiaries who reside sufficiently near one of the PCCM'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 beneficiary's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll in accordance with § 438.56(c).

(r) *Additional rules for contracts with PCCM entities.* In addition to the requirements in paragraph (q) of this section, States must submit PCCM entity contracts to CMS for review and approval to ensure compliance with the provisions of this paragraph (r); § 438.10; and § 438.310(c)(2).

(s) *Requirements for MCOs, PCCMs, PIHPs, or PAHPs that provide covered outpatient drugs.* Contracts that obligate MCOs, PCCMs, PIHPs, or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

(1) The MCO, PIHP or PAHP provides coverage of covered outpatient drugs as defined in section 1927(k)(2) of the Act, that meets the standards for such coverage imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP.

(2) The MCO, PIHP, or PAHP reports drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period. Such utilization information must include, at a minimum, information on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

(3) The MCO, PIHP or PAHP establishes procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section when states do not require submission of managed care drug claims data from covered entities directly.

(4) The MCO, PCCM, PIHP, or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and part 456, subpart K, of this chapter, as if such requirement applied to the MCO, PCCM, PIHP, or PAHP instead of the State.

(5) The MCO, PCCM, PIHP, or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

(6) The MCO, PIHP or PAHP must conduct a prior authorization program that complies with the requirements of section 1927(d)(5) of the Act, as if such requirements applied to the MCO, PIHP, or PAHP instead of the State.

(t) *Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.* In a State that enters into a Coordination of Benefits Agreement (COBA) with Medicare for Medicaid, an MCO, PIHP, or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must specify the methodology by which the State ensures that the appropriate MCO, PIHP, or PAHP receives all applicable crossover claims for which the MCO, PIHP, or PAHP is responsible. If the State elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the State's remittance advice that the State has not denied payment and that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

(u) *Recordkeeping requirements.* MCOs, PIHPs, and PAHPs must retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in § 438.416, base data in § 438.5(c), MLR reports in § 438.8(k), and the data, information, and documentation specified in §§ 438.604, 438.606, 438.608, and 438.610 for a period of no less than 10 years.

(v) *Applicability date.* Sections 438.3(h) and (q) apply to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.6(g) and (k) contained in the 42 CFR, parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 85 FR 37243, June 19, 2020; 85 FR 72837, Nov. 13, 2020; 85 FR 87101, Dec. 31, 2020]

§ 438.4 Actuarial soundness.

(a) *Actuarially sound capitation rates defined.* Actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements in paragraph (b) of this section.

(b) *CMS review and approval of actuarially sound capitation rates.* Capitation rates for MCOs, PIHPs, and PAHPs must be reviewed and approved by CMS as actuarially sound. To be approved by CMS, capitation rates must:

(1) Have been developed in accordance with the standards specified in § 438.5 and generally accepted actuarial principles and practices. Any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations must be based on valid rate development standards that represent actual cost differences in providing covered services to the covered populations. Any differences in the assumptions, methodologies, or factors used to develop capitation rates must not vary with the rate of Federal financial participation (FFP) associated with the covered populations in a manner that increases Federal costs. The determination that differences in the assumptions, methodologies, or factors used to develop capitation rates for MCOs, PIHPs, and PAHPs increase Federal costs and vary with the rate of FFP associated with the covered populations must be evaluated for the entire managed care program and include all managed care contracts for all covered populations. CMS may require a State to provide written documentation and justification that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

(2) Be appropriate for the populations to be covered and the services to be furnished under the contract.

(3) Be adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208.

(4) Be specific to payments for each rate cell under the contract.

(5) Payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell.

(6) Be certified by an actuary as meeting the applicable requirements of this part, including that the rates have been developed in accordance with the requirements specified in § 438.3(c)(1)(ii) and (e).

(7) Meet any applicable special contract provisions as specified in § 438.6.

(8) Be provided to CMS in a format and within a timeframe that meets requirements in § 438.7.

(9) Be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard, as calculated under § 438.8, of at least 85 percent for the rate year. The capitation rates may be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard greater than 85 percent, as calculated under § 438.8, as long as the capitation rates are adequate for reasonable, appropriate, and attainable non-benefit costs.

(c) *Option to develop and certify a rate range.* (1) Notwithstanding the provision at paragraph (b)(4) of this section, the State may develop and certify a range of capitation rates per rate cell as actuarially sound, when all of the following conditions are met:

(i) The rate certification identifies and justifies the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range.

(ii) Both the upper and lower bounds of the rate range must be certified as actuarially sound consistent with the requirements of this part.

(iii) The upper bound of the rate range does not exceed the lower bound of the rate range multiplied by 1.05.

(iv) The rate certification documents the State's criteria for paying MCOs, PIHPs, and PAHPs at different points within the rate range.

(v) The State does not use as a criterion for paying MCOs, PIHPs, and PAHPs at different points within the rate range any of the following:

(A) The willingness or agreement of the MCOs, PIHPs, or PAHPs or their network providers to enter into, or adhere to, intergovernmental transfer (IGT) agreements; or

(B) The amount of funding the MCOs, PIHPs, or PAHPs or their network providers provide through IGT agreements.

(2) When a State develops and certifies a range of capitation rates per rate cell as actuarially sound consistent with the requirements of this paragraph (c), the State must:

(i) Document the capitation rates, prior to the start of the rating period, for the MCOs, PIHPs, and PAHPs at points within the rate range, consistent with the criteria in paragraph (c)(1)(iv) of this section.

(ii) Not modify the capitation rates under § 438.7(c)(3).

(iii) Not modify the capitation rates within the rate range, unless the State is increasing or decreasing the capitation rate per rate cell within the rate range up to 1 percent during the rating period. However, any changes of the capitation rate within the permissible 1 percent range must be consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at paragraph (b)(1) of this section. Any modification to the capitation rates within the rate range greater than the permissible 1 percent range will require the State to provide a revised rate certification for CMS approval, which demonstrates that—

(A) The criteria in paragraph (c)(1)(iv) of this section, as described in the initial rate certification, were not applied accurately;

(B) There was a material error in the data, assumptions, or methodologies used to develop the initial rate certification and that the modifications are necessary to correct the error; or

(C) Other adjustments are appropriate and reasonable to account for programmatic changes.

(iv) Post on the website required in § 438.10(c)(3) the following information prior to executing a managed care contract or contract amendment that includes or modifies a rate range:

(A) The upper and lower bounds of each rate cell;

(B) A description of all assumptions that vary between the upper and lower bounds of each rate cell, including for the assumptions that vary, the specific assumptions used for the upper and lower bounds of each rate cell; and

(C) A description of the data and methodologies that vary between the upper and lower bounds of each rate cell, including for the data and methodologies that vary, the specific data and methodologies used for the upper and lower bounds of each rate cell.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72837, Nov. 13, 2020; 85 FR 72837, Nov. 13, 2020]

§ 438.5 Rate development standards.

(a) *Definitions.* As used in this section and § 438.7(b), the following terms have the indicated meanings:

Budget neutral means a standard for any risk sharing mechanism that recognizes both higher and lower expected costs among contracted MCOs, PIHPs, or PAHPs under a managed care program and does not create a net aggregate gain or loss across all payments under that managed care program.

Prospective risk adjustment means a methodology to account for anticipated variation in risk levels among contracted MCOs, PIHPs, or PAHPs

that is derived from historical experience of the contracted MCOs, PIHPs, or PAHPs and applied to rates for the rating period for which the certification is submitted.

Retrospective risk adjustment means a methodology to account for variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from experience concurrent with the rating period of the contracted MCOs, PIHPs, or PAHPs subject to the adjustment and calculated at the expiration of the rating period.

Risk adjustment is a methodology to account for the health status of enrollees via relative risk factors when predicting or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the State.

(b) *Process and requirements for setting actuarially sound capitation rates.* In setting actuarially sound capitation rates, the State must follow the steps below, in an appropriate order, in accordance with this section, or explain why they are not applicable:

(1) Consistent with paragraph (c) of this section, identify and develop the base utilization and price data.

(2) Consistent with paragraph (d) of this section, develop and apply trend factors, including cost and utilization, to base data that are developed from actual experience of the Medicaid population or a similar population in accordance with generally accepted actuarial practices and principles.

(3) Consistent with paragraph (e) of this section, develop the non-benefit component of the rate to account for reasonable expenses related to MCO, PIHP, or PAHP administration; taxes; licensing and regulatory fees; contribution to reserves; risk margin; cost of capital; and other operational costs associated with the MCO's, PIHP's, or PAHP's provision of State plan services to Medicaid enrollees.

(4) Consistent with paragraph (f) of this section, make appropriate and reasonable adjustments to account for changes to the base data, programmatic changes, non-benefit components, and any other adjustment necessary to establish actuarially sound rates.

(5) Take into account the MCO's, PIHP's, or PAHP's past medical loss ratio, as calculated and reported under §438.8, in the development of the capitation rates, and consider the projected medical loss ratio in accordance with §438.4(b)(9).

(6) Consistent with paragraph (g) of this section, if risk adjustment is applied, select a risk adjustment methodology that uses generally accepted models and apply it in a budget neutral manner across all MCOs, PIHPs, or PAHPs in the program to calculate adjustments to the payments as necessary.

(c) *Base data.* (1) States must provide all the validated encounter data, FFS data (as appropriate), and audited financial reports (as defined in §438.3(m)) that demonstrate experience for the populations to be served by the MCO, PIHP, or PAHP to the actuary developing the capitation rates for at least the three most recent and complete years prior to the rating period.

(2) States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates. Such base data must be derived from the Medicaid population, or, if data on the Medicaid population is not available, derived from a similar population and adjusted to make the utilization and price data comparable to data from the Medicaid population. Data must be in accordance with actuarial standards for data quality and an explanation of why that specific data is used must be provided in the rate certification.

(3) *Exception.* (i) States that are unable to base their rates on data meeting the qualifications in paragraph (c)(2) of this section that the basis of the data be no older than from the 3 most recent and complete years prior to the rating period may request approval for an exception; the request must describe why an exception is necessary and describe the actions the state intends to take to come into compliance with those requirements.

(ii) States that request an exception from the base data standards established in this section must set forth a corrective action plan to come into compliance with the base data standards no later than 2 years after the last day of the rating period for which the deficiency was identified.

(d) *Trend*. Each trend must be reasonable and developed in accordance with generally accepted actuarial principles and practices. Trend must be developed primarily from actual experience of the Medicaid population or from a similar population.

(e) *Non-benefit component of the rate*. The development of the non-benefit component of the rate must include reasonable, appropriate, and attainable expenses related to MCO, PIHP, or PAHP administration, taxes, licensing and regulatory fees, contribution to reserves, risk margin, cost of capital, and other operational costs associated with the provision of services identified in § 438.3(c)(1)(ii) to the populations covered under the contract.

(f) *Adjustments*. Each adjustment must reasonably support the development of an accurate base data set for purposes of rate setting, address appropriate programmatic changes, reflect the health status of the enrolled population, or reflect non-benefit costs, and be developed in accordance with generally accepted actuarial principles and practices.

(g) *Risk adjustment*. Prospective or retrospective risk adjustment methodologies must be developed in a budget neutral manner consistent with generally accepted actuarial principles and practices.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72837, Nov. 13, 2020]

§ 438.6 Special contract provisions related to payment.

(a) *Definitions*. As used in this part, the following terms have the indicated meanings:

Base amount is the starting amount, calculated according to paragraph (d)(2) of this section, available for pass-through payments to hospitals in a given contract year subject to the schedule in paragraph (d)(3) of this section.

Incentive arrangement means any payment mechanism under which a MCO, PIHP, or PAHP may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

Pass-through payment is any amount required by the State to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate, between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for the following purposes: A specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under paragraphs (c)(1)(i) through (iii) of this section for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments.

Risk corridor means a risk sharing mechanism in which States and MCOs, PIHPs, or PAHPs may share in profits and losses under the contract outside of a predetermined threshold amount.

State plan approved rates means amounts calculated for specific services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan. Supplemental payments contained in a State plan are not, and do not constitute, State plan approved rates.

Supplemental payments means amounts paid by the State in its FFS Medicaid delivery system to providers that are described and approved in the State plan or under a demonstration or waiver thereof and are in addition to State plan approved rates. Disproportionate share hospital (DSH) and graduate medical education (GME) payments are not, and do not constitute, supplemental payments.

Withhold arrangement means any payment mechanism under which a portion of a capitation rate is withheld from an MCO, PIHP, or PAHP and a portion of or all of the withheld amount will be paid to the MCO, PIHP, or PAHP for meeting targets specified in the contract. The targets for a withhold arrangement are distinct from

general operational requirements under the contract. Arrangements that withhold a portion of a capitation rate for noncompliance with general operational requirements are a penalty and not a withhold arrangement.

(b) *Basic requirements.* (1) If used in the payment arrangement between the State and the MCO, PIHP, or PAHP, all applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be documented in the contract and rate certification documents for the rating period prior to the start of the rating period, and must be developed in accordance with § 438.4, the rate development standards in § 438.5, and generally accepted actuarial principles and practices. Risk-sharing mechanisms may not be added or modified after the start of the rating period.

(2) 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. For all incentive arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the incentive arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition MCO, PIHP, or PAHP participation in the incentive arrangement on the MCO, PIHP, or PAHP entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy at § 438.340.

(3) Contracts that provide for a withhold arrangement must ensure that the capitation payment minus any portion of the withhold that is not reasonably achievable is actuarially sound as determined by an actuary. The total amount of the withhold, achievable or not, must be reasonable and take into consideration the MCO's, PIHP's or PAHP's financial operating needs accounting for the size and characteristics of the populations covered under the contract, as well as the MCO's, PIHP's or PAHP's capital reserves as measured by the risk-based capital level, months of claims reserve, or other appropriate measure of reserves. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable must be submitted as part of the documentation required under § 438.7(b)(6). For all withhold arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the withhold arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition MCO, PIHP, or PAHP participation in the withhold arrangement on the MCO, PIHP, or PAHP entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy under § 438.340.

(c) *Delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts*—(1) *General rule.* Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation implementing a Title XIX provision related to payments to providers, that is applicable to managed care programs, the State may not direct the MCO's, PIHP's or PAHP's expenditures under the contract.

(i) The State may require the MCO, PIHP or PAHP to implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.

(ii) The State may require MCOs, PIHPs, or PAHPs to participate in a

multi-payer or Medicaid-specific delivery system reform or performance improvement initiative.

(iii) The State may require the MCO, PIHP, or PAHP to:

(A) Adopt a minimum fee schedule for network providers that provide a particular service under the contract using State plan approved rates as defined in paragraph (a) of this section.

(B) Adopt a minimum fee schedule for network providers that provide a particular service under the contract using rates other than the State plan approved rates defined in paragraph (a) of this section.

(C) Provide a uniform dollar or percentage increase for network providers that provide a particular service under the contract.

(D) Adopt a maximum fee schedule for network providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(2) *Process for approval.* (i) All contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

(ii) Contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(B) through (D) of this section must have written approval prior to implementation. Contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraph (c)(1)(iii)(A) of this section do not require written approval prior to implementation but are required to meet the criteria in paragraphs (c)(2)(ii)(A) through (F) of this section. To obtain written approval, a State must demonstrate, in writing, that the arrangement—

(A) Is based on the utilization and delivery of services;

(B) Directs expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;

(C) Expects to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the quality strategy in § 438.340;

(E) Does not condition provider participation in contract arrangements under paragraphs (c)(1)(i) through (iii) of this section on the provider entering into or adhering to intergovernmental transfer agreements; and

(F) May not be renewed automatically.

(iii) Any contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraph (c)(1)(i) or (ii) of this section must also demonstrate, in writing, that the arrangement—

(A) Must make participation in the value-based purchasing initiative, delivery system reform or performance improvement initiative available, using the same terms of performance, to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) Must use a common set of performance measures across all of the payers and providers;

(C) May not set the amount or frequency of the expenditures; and

(D) Does not allow the State to recoup any unspent funds allocated for these arrangements from the MCO, PIHP, or PAHP.

(3) *Approval timeframes.* (i) Approval of a payment arrangement under paragraphs (c)(1)(i) and (ii) of this section is for one rating period unless a multi-year approval is requested and meets all of the following criteria:

(A) The State has explicitly identified and described the payment arrangement in the contract as a multi-year payment arrangement, including a description of the payment arrangement by year, if the payment arrangement varies by year.

(B) The State has developed and described its plan for implementing a multi-year payment arrangement, including the State's plan for multi-year evaluation, and the impact of a multi-year payment arrangement on the

State's goals and objectives in the State's quality strategy in §438.340.

(C) The State has affirmed that it will not make any changes to the payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year payment arrangement without CMS prior approval. If the State determines that changes to the payment methodology, or magnitude of the payment, are necessary, the State must obtain prior approval of such changes under paragraph (c)(2) of this section.

(ii) Approval of a payment arrangement under paragraph (c)(1)(iii) of this section is for one rating period.

(d) *Pass-through payments under MCO, PIHP, and PAHP contracts*—(1) *General rule.* States may continue to require MCOs, PIHPs, and PAHPs to make pass-through payments (as defined in paragraph (a) of this section) to network providers that are hospitals, physicians, or nursing facilities under the contract, provided the requirements of this paragraph (d) are met. States may not require MCOs, PIHPs, and PAHPs to make pass-through payments other than those permitted under this paragraph (d).

(i) In order to use a transition period described in this paragraph (d), a State must demonstrate that it had pass-through payments for hospitals, physicians, or nursing facilities in:

(A) Managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016, and were submitted for CMS review and approval on or before July 5, 2016; or

(B) If the managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016 had not been submitted to CMS on or before July 5, 2016, the managed care contract(s) and rate certification(s) for a rating period before July 5, 2016 that had been most recently submitted for CMS review and approval as of July 5, 2016.

(ii) CMS will not approve a retroactive adjustment or amendment, notwithstanding the adjustments to the base amount permitted in paragraph (d)(2) of this section, to managed care contract(s) and rate certification(s) to add new pass-through payments or increase existing pass-through payments defined in paragraph (a) of this section.

(2) *Calculation of the base amount.* The base amount of pass-through payments is the sum of the results of paragraphs (d)(2)(i) and (ii) of this section.

(i) For inpatient and outpatient hospital services that will be provided to eligible populations through the MCO, PIHP, or PAHP contracts for the rating period that includes pass-through payments and that were provided to the eligible populations under MCO, PIHP, or PAHP contracts two years prior to the rating period, the State must determine reasonable estimates of the aggregate difference between:

(A) The amount Medicare FFS would have paid for those inpatient and outpatient hospital services utilized by the eligible populations under the MCO, PIHP, or PAHP contracts for the 12-month period immediately two years prior to the rating period that will include pass-through payments; and

(B) The amount the MCOs, PIHPs, or PAHPs paid (not including pass through payments) for those inpatient and outpatient hospital services utilized by the eligible populations under MCO, PIHP, or PAHP contracts for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments.

(ii) For inpatient and outpatient hospital services that will be provided to eligible populations through the MCO, PIHP, or PAHP contracts for the rating period that includes pass-through payments and that were provided to the eligible populations under Medicaid FFS for the 12-month period immediately 2 years prior to the rating period, the State must determine reasonable estimates of the aggregate difference between:

(A) The amount Medicare FFS would have paid for those inpatient and outpatient hospital services utilized by the eligible populations under Medicaid FFS for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments; and

(B) The amount the State paid under Medicaid FFS (not including pass through payments) for those inpatient and outpatient hospital services utilized by the eligible populations for the

12-month period immediately 2 years prior to the rating period that will include pass-through payments.

(iii) The base amount must be calculated on an annual basis and is recalculated annually.

(iv) States may calculate reasonable estimates of the aggregate differences in paragraphs (d)(2)(i) and (ii) of this section in accordance with the upper payment limit requirements in 42 CFR part 447.

(3) *Schedule for the reduction of the base amount of pass-through payments for hospitals under the MCO, PIHP, or PAHP contract and maximum amount of permitted pass-through payments for each year of the transition period.* For States that meet the requirement in paragraph (d)(1)(i) of this section, pass-through payments for hospitals may continue to be required under the contract but must be phased out no longer than on the 10-year schedule, beginning with rating periods for contract(s) that start on or after July 1, 2017. For rating periods for contract(s) beginning on or after July 1, 2027, the State cannot require pass-through payments for hospitals under a MCO, PIHP, or PAHP contract. Until July 1, 2027, the total dollar amount of pass-through payments to hospitals may not exceed the lesser of:

(i) A percentage of the base amount, beginning with 100 percent for rating periods for contract(s) beginning on or after July 1, 2017, and decreasing by 10 percentage points each successive year; or

(ii) The total dollar amount of pass-through payments to hospitals identified in the managed care contract(s) and rate certification(s) used to meet the requirement of paragraph (d)(1)(i) of this section.

(4) *Documentation of the base amount for pass-through payments to hospitals.* All contract arrangements that direct pass-through payments under the MCO's, PIHP's or PAHP's contract for hospitals must document the calculation of the base amount in the rate certification required in § 438.7. The documentation must include the following:

(i) The data, methodologies, and assumptions used to calculate the base amount;

(ii) The aggregate amounts calculated for paragraphs (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(ii)(A), (d)(2)(ii)(B) of this section; and

(iii) The calculation of the applicable percentage of the base amount available for pass-through payments under the schedule in paragraph (d)(3) of this section.

(5) *Pass-through payments to physicians or nursing facilities.* For States that meet the requirement in paragraph (d)(1)(i) of this section, rating periods for contract(s) beginning on or after July 1, 2017 through rating periods for contract(s) beginning on or after July 1, 2021, may continue to require pass-through payments to physicians or nursing facilities under the MCO, PIHP, or PAHP contract of no more than the total dollar amount of pass-through payments to physicians or nursing facilities, respectively, identified in the managed care contract(s) and rate certification(s) used to meet the requirement of paragraph (d)(1)(i) of this section. For rating periods for contract(s) beginning on or after July 1, 2022, the State cannot require pass-through payments for physicians or nursing facilities under a MCO, PIHP, or PAHP contract.

(6) *Pass-through payments for States transitioning services and populations from a fee-for-service delivery system to a managed care delivery system.* Notwithstanding the restrictions on pass-through payments in paragraphs (d)(1), (3), and (5) of this section, a State may require the MCO, PIHP, or PAHP to make pass-through payments to network providers that are hospitals, nursing facilities, or physicians under the contract, for each rating period of the transition period for up to 3 years, when Medicaid populations or services are initially transitioning from a fee-for-service (FFS) delivery system to a managed care delivery system, provided the following requirements are met:

(i) The services will be covered for the first time under a managed care contract and were previously provided in a FFS delivery system prior to the first rating period of the transition period.

(ii) The State made supplemental payments, as defined in paragraph (a)

of this section, to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first year of the transition period.

(iii) The aggregate amount of the pass-through payments that the State requires the MCO, PIHP, or PAHP to make is less than or equal to the amounts calculated in paragraph (d)(6)(iii)(A), (B), or (C) of this section for the relevant provider type for each rating period of the transition period. In determining the amount of each component for the calculations contained in paragraphs (d)(6)(iii)(A) through (C), the State must use the amounts paid for services during the 12-month period immediately 2 years prior to the first rating period of the transition period.

(A) *Hospitals.* For inpatient and outpatient hospital services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for hospital services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through state plan approved rates for hospital services made in the State's FFS delivery system. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(B) *Nursing facilities.* For nursing facility services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through state plan approved rates for nursing facility services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for nursing facility services made in the State's FFS delivery system. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(C) *Physicians.* For physician services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through state plan approved rates for physician services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for physician services made in the State's FFS delivery system. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(iv) The State may require the MCO, PIHP, or PAHP to make pass-through payments for Medicaid populations or services that are initially transitioning from a FFS delivery system to a managed care delivery system for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP.

(e) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease.* The State may make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21–64 receiving inpatient treatment in an Institution for Mental Diseases, as defined in §435.1010 of this chapter, so long as the facility is a hospital providing psychiatric or substance use disorder inpatient care or a sub-acute facility providing psychiatric or substance use disorder crisis residential services, and length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. The provision of inpatient psychiatric or substance use disorder treatment in an IMD must meet the requirements for in lieu of services at §438.3(e)(2)(i) through (iii). For purposes of rate setting, the state may use the utilization of services provided to an enrollee under this section when developing the inpatient psychiatric or substance use disorder component of the capitation rate, but must price utilization at the cost of the same services through providers included under the State plan.

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§ 438.7 Rate certification submission.

(a) *CMS review and approval of the rate certification.* States must submit to CMS for review and approval, all MCO, PIHP, and PAHP rate certifications concurrent with the review and approval process for contracts as specified in § 438.3(a).

(b) *Documentation.* The rate certification must contain the following information:

(1) *Base data.* A description of the base data used in the rate setting process (including the base data requested by the actuary, the base data that was provided by the State, and an explanation of why any base data requested was not provided by the State) and of how the actuary determined which base data set was appropriate to use for the rating period.

(2) *Trend.* Each trend factor, including trend factors for changes in the utilization and price of services, applied to develop the capitation rates must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(i) The calculation of each trend used for the rating period and the reasonableness of the trend for the enrolled population.

(ii) Any meaningful difference in how a trend differs between the rate cells, service categories, or eligibility categories.

(3) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense that is included in the rate and evaluate the reasonableness of the cost assumptions underlying each expense. The actuary may document the non-benefit costs according to the types of non-benefit costs under § 438.5(e).

(4) *Adjustments.* All adjustments used to develop the capitation rates must be adequately described with enough detail so that CMS, or an actuary applying generally accepted actuarial principles and practices, can understand and evaluate all of the following:

(i) How each material adjustment was developed and the reasonableness of the material adjustment for the enrolled population.

(ii) The cost impact of each material adjustment and the aggregate cost impact of non-material adjustments.

(iii) Where in the rate setting process the adjustment was applied.

(iv) A list of all non-material adjustments used in the rate development process.

(5) *Risk adjustment.* (i) All prospective risk adjustment methodologies must be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The data, and any adjustments to that data, to be used to calculate the adjustment.

(B) The model, and any adjustments to that model, to be used to calculate the adjustment.

(C) The method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk factors of the respective populations.

(D) The magnitude of the adjustment on the capitation rate per MCO, PIHP, or PAHP.

(E) An assessment of the predictive value of the methodology compared to prior rating periods.

(F) Any concerns the actuary has with the risk adjustment process.

(ii) All retrospective risk adjustment methodologies must be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The party calculating the risk adjustment.

(B) The data, and any adjustments to that data, to be used to calculate the adjustment.

(C) The model, and any adjustments to that model, to be used to calculate the adjustment.

(D) The timing and frequency of the application of the risk adjustment.

(E) Any concerns the actuary has with the risk adjustment process.

(iii) Application of an approved risk adjustment methodology to capitation

rates does not require a revised rate certification because payment of capitation rates as modified by the approved risk adjustment methodology must be within the scope of the original rate certification. The State must provide to CMS the payment terms updated by the application of the risk adjustment methodology consistent with § 438.3(c).

(6) *Special contract provisions.* A description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract.

(c) *Rates paid under risk contracts.* The State, through its actuary, must certify the final capitation rate paid per rate cell under each risk contract and document the underlying data, assumptions and methodologies supporting that specific capitation rate.

(1) The State may pay each MCO, PIHP or PAHP a capitation rate under the contract that is different than the capitation rate paid to another MCO, PIHP or PAHP, so long as each capitation rate per rate cell that is paid is independently developed and set in accordance with this part.

(2) If the State determines that a retroactive adjustment to the capitation rate is necessary, the retroactive adjustment must be supported by a rationale for the adjustment and the data, assumptions and methodologies used to develop the magnitude of the adjustment must be adequately described with enough detail to allow CMS or an actuary to determine the reasonableness of the adjustment. These retroactive adjustments must be certified by an actuary in a revised rate certification and submitted as a contract amendment to be approved by CMS. All such adjustments are also subject to Federal timely claim filing requirements.

(3) The State may increase or decrease the capitation rate per rate cell, as required in paragraph (c) of this section and § 438.4(b)(4), up to 1.5 percent during the rating period without submitting a revised rate certification, as required under paragraph (a) of this section. However, any changes of the capitation rate within the permissible range must be consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at § 438.4(b)(1). Notwithstanding the provisions in paragraph (c) of this section, CMS may require a State to provide documentation that modifications to the capitation rate comply with the requirements in §§ 438.3(c) and (e) and 438.4(b)(1).

(d) *Provision of additional information.* The State must, upon CMS' request, provide additional information, whether part of the rate certification or additional supplemental materials, if CMS determines that information is pertinent to the approval of the certification under this part. The State must identify whether the information provided in addition to the rate certification is proffered by the State, the actuary, or another party.

(e) *Provision of additional guidance.* CMS will issue guidance, at least annually, which includes all of the following:

(1) The Federal standards for capitation rate development.

(2) The documentation required to determine that the capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms.

(3) The documentation required to determine that the capitation rates have been developed in accordance with the requirements of this part.

(4) Any updates or developments in the rate review process to reduce State burden and facilitate prompt actuarial reviews.

(5) The documentation necessary to demonstrate that capitation rates competitively bid through a procurement process have been established consistent with the requirements of §§ 438.4 through 438.8.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72839, Nov. 13, 2020]

§ 438.8 Medical loss ratio (MLR) standards.

(a) *Basic rule.* The State must ensure, through its contracts starting on or after July 1, 2017, that each MCO, PIHP, and PAHP calculate and report a MLR in accordance with this section. For multi-year contracts that do not start in 2017, the State must require the MCO, PIHP, or PAHP to calculate and report a MLR for the rating period that begins in 2017.

(b) *Definitions*. As used in this section, the following terms have the indicated meanings:

Credibility adjustment means an adjustment to the MLR for a partially credible MCO, PIHP, or PAHP to account for a difference between the actual and target MLRs that may be due to random statistical variation.

Full credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR with a minimal chance that the difference between the actual and target medical loss ratio is not statistically significant. An MCO, PIHP, or PAHP that is assigned full credibility (or is fully credible) will not receive a credibility adjustment to its MLR.

Member months mean the number of months an enrollee or a group of enrollees is covered by an MCO, PIHP, or PAHP over a specified time period, such as a year.

MLR reporting year means a period of 12 months consistent with the rating period selected by the State.

No credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be insufficient for the calculation of a MLR. An MCO, PIHP, or PAHP that is assigned no credibility (or is non-credible) will not be measured against any MLR requirements.

Non-claims costs means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e)(2) of this section); expenditures on activities that improve health care quality (as defined in paragraph (e)(3) of this section); or licensing and regulatory fees, or Federal and State taxes (as defined in paragraph (f)(2) of this section).

Partial credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR but with a non-negligible chance that the difference between the actual and target medical loss ratios is statistically significant. An MCO, PIHP, or PAHP that is assigned partial credibility (or is partially credible) will receive a credibility adjustment to its MLR.

(c) *MLR requirement*. If a State elects to mandate a minimum MLR for its MCOs, PIHPs, or PAHPs, that minimum MLR must be equal to or higher than 85 percent (the standard used for projecting actuarial soundness under § 438.4(b)) and the MLR must be calculated and reported for each MLR reporting year by the MCO, PIHP, or PAHP, consistent with this section.

(d) *Calculation of the MLR*. The MLR experienced for each MCO, PIHP, or PAHP in a MLR reporting year is the ratio of the numerator (as defined in paragraph (e) of this section) to the denominator (as defined in paragraph (f) of this section). A MLR may be increased by a credibility adjustment, in accordance with paragraph (h) of this section.

(e) *Numerator*—(1) *Required elements*. The numerator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year is the sum of the MCO's, PIHP's, or PAHP's incurred claims (as defined in (e)(2) of this section); the MCO's, PIHP's, or PAHP's expenditures for activities that improve health care quality (as defined in paragraph (e)(3) of this section); and fraud prevention activities (as defined in paragraph (e)(4) of this section).

(2) *Incurred claims*. (i) Incurred claims must include the following:

(A) Direct claims that the MCO, PIHP, or PAHP paid to providers (including under capitated contracts with network providers) for services or supplies covered under the contract and services meeting the requirements of § 438.3(e) provided to enrollees.

(B) Unpaid claims liabilities for the MLR reporting year, including claims reported that are in the process of being adjusted or claims incurred but not reported.

(C) Withholds from payments made to network providers.

(D) Claims that are recoverable for anticipated coordination of benefits.

(E) Claims payments recoveries received as a result of subrogation.

(F) Incurred but not reported claims based on past experience, and modified to reflect current conditions, such as changes in exposure or claim frequency or severity.

(G) Changes in other claims-related reserves.

(H) Reserves for contingent benefits and the medical claim portion of lawsuits.

(ii) Amounts that must be deducted from incurred claims include the following:

(A) Overpayment recoveries received from network providers.

(B) Prescription drug rebates received and accrued.

(iii) Expenditures that must be included in incurred claims include the following:

(A) The amount of incentive and bonus payments made, or expected to be made, to network providers.

(B) The amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses. The amount of fraud reduction expenses must not include activities specified in paragraph (e)(4) of this section.

(iv) Amounts that must either be included in or deducted from incurred claims include, respectively, net payments or receipts related to State mandated solvency funds.

(v) Amounts that must be excluded from incurred claims:

(A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:

(*1*) Amounts paid to third party vendors for secondary network savings.

(*2*) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.

(*3*) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in § 438.3(e) and provided to an enrollee.

(*4*) Fines and penalties assessed by regulatory authorities.

(B) Amounts paid to the State as remittance under paragraph (j) of this section.

(C) Amounts paid to network providers under to § 438.6(d).

(vi) Incurred claims paid by one MCO, PIHP, or PAHP that is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no incurred claims for that MLR reporting year may be reported by the ceding MCO, PIHP, or PAHP.

(3) *Activities that improve health care quality*. Activities that improve health care quality must be in one of the following categories:

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(b) and is not excluded under 45 CFR 158.150(c).

(ii) An MCO, PIHP, or PAHP activity related to any EQR-related activity as described in § 438.358(b) and (c).

(iii) Any MCO, PIHP, or PAHP expenditure that is related to Health Information Technology and meaningful use, meets the requirements placed on issuers found in 45 CFR 158.151, and is not considered incurred claims, as defined in paragraph (e)(2) of this section.

(4) *Fraud prevention activities*. MCO, PIHP, or PAHP expenditures on activities related to fraud prevention consistent with regulations adopted for the private market at 45 CFR part 158. Expenditures under this paragraph must not include expenses for fraud reduction efforts in paragraph (e)(2)(iii)(B) of this section.

(f) *Denominator*—(1) *Required elements*. The denominator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year must equal the adjusted premium revenue. The adjusted premium revenue is the MCO's, PIHP's, or PAHP's premium revenue (as defined in paragraph (f)(2) of this section) minus the MCO's, PIHP's, or PAHP's Federal, State, and local taxes and licensing and regulatory fees (as defined in paragraph (f)(3) of this section) and is aggregated in accordance with paragraph (i) of this section.

(2) *Premium revenue*. Premium revenue includes the following for the MLR reporting year:

(i) State capitation payments, developed in accordance with § 438.4, to the MCO, PIHP, or PAHP for all enrollees under a risk contract approved under § 438.3(a), excluding payments made under § 438.6(d).

(ii) State-developed one time payments, for specific life events of enrollees.

(iii) Other payments to the MCO, PIHP, or PAHP approved under § 438.6(b)(3).

(iv) Unpaid cost-sharing amounts that the MCO, PIHP, or PAHP could have collected from enrollees under the contract, except those amounts the MCO, PIHP, or PAHP can show it made a reasonable, but unsuccessful, effort to collect.

(v) All changes to unearned premium reserves.

(vi) Net payments or receipts related to risk sharing mechanisms developed in accordance with § 438.5 or § 438.6.

(3) *Federal, State, and local taxes and licensing and regulatory fees.* Taxes, licensing and regulatory fees for the MLR reporting year include:

(i) Statutory assessments to defray the operating expenses of any State or Federal department.

(ii) Examination fees in lieu of premium taxes as specified by State law.

(iii) Federal taxes and assessments allocated to MCOs, PIHPs, and PAHPs, excluding Federal income taxes on investment income and capital gains and Federal employment taxes.

(iv) State and local taxes and assessments including:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State or locality directly.

(B) Guaranty fund assessments.

(C) Assessments of State or locality industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State or locality income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

(E) State or locality premium taxes plus State or locality taxes based on reserves, if in lieu of premium taxes.

(v) Payments made by an MCO, PIHP, or PAHP that are otherwise exempt from Federal income taxes, for community benefit expenditures as defined in 45 CFR 158.162(c), limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by the MCO's, PIHP's, or PAHP's earned premium in the State.

(4) *Denominator when MCO, PIHP, or PAHP is assumed.* The total amount of the denominator for a MCO, PIHP, or PAHP which is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no amount under this paragraph for that year may be reported by the ceding MCO, PIHP, or PAHP.

(g) *Allocation of expense*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.

(ii) Expenditures that benefit multiple contracts or populations, or contracts other than those being reported, must be reported on a pro rata basis.

(2) *Methods used to allocate expenses.* (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.

(iii) Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.

(h) *Credibility adjustment.* (1) A MCO, PIHP, or PAHP may add a credibility adjustment to a calculated MLR if the MLR reporting year experience is partially credible. The credibility adjustment is added to the reported MLR calculation before calculating any remittances, if required by the State as described in paragraph (j) of this section.

(2) A MCO, PIHP, or PAHP may not add a credibility adjustment to a calculated MLR if the MLR reporting year experience is fully credible.

(3) If a MCO's, PIHP's, or PAHP's experience is non-credible, it is presumed to meet or exceed the MLR calculation standards in this section.

(4) On an annual basis, CMS will publish base credibility factors for MCOs,

PIHPs, and PAHPs that are developed according to the following methodology:

(i) CMS will use the most recently available and complete managed care encounter data or FFS claims data, and enrollment data, reported by the states to CMS. This data may cover more than 1 year of experience.

(ii) CMS will calculate the credibility adjustment so that a MCO, PIHP, or PAHP receiving a capitation payment that is estimated to have a medical loss ratio of 85 percent would be expected to experience a loss ratio less than 85 percent 1 out of every 4 years, or 25 percent of the time.

(iii) The minimum number of member months necessary for a MCO's, PIHP's, or PAHP's medical loss ratio to be determined at least partially credible will be set so that the credibility adjustment would not exceed 10 percent for any partially credible MCO, PIHP, or PAHP. Any MCO, PIHP, or PAHP with enrollment less than this number of member months will be determined non-credible.

(iv) The minimum number of member months necessary for an MCO's, PIHP's, or PAHP's medical loss ratio to be determined fully credible will be set so that the minimum credibility adjustment for any partially credible MCO, PIHP, or PAHP would be greater than 1 percent. Any MCO, PIHP, or PAHP with enrollment greater than this number of member months will be determined to be fully credible.

(v) A MCO, PIHP, or PAHP with a number of enrollee member months between the levels established for non-credible and fully credible plans will be deemed partially credible, and CMS will develop adjustments, using linear interpolation, based on the number of enrollee member months.

(vi) CMS may adjust the number of enrollee member months necessary for a MCO's, PIHP's, or PAHP's experience to be non-credible, partially credible, or fully credible so that the standards are rounded for the purposes of administrative simplification. The number of member months will be rounded to 1,000 or a different degree of rounding as appropriate to ensure that the credibility thresholds are consistent with the objectives of this regulation.

(i) *Aggregation of data.* MCOs, PIHPs, or PAHPs will aggregate data for all Medicaid eligibility groups covered under the contract with the State unless the State requires separate reporting and a separate MLR calculation for specific populations.

(j) *Remittance to the State if specific MLR is not met.* If required by the State, a MCO, PIHP, or PAHP must provide a remittance for an MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 85 percent or higher if set by the State as described in paragraph (c) of this section.

(k) *Reporting requirements.* (1) The State, through its contracts, must require each MCO, PIHP, or PAHP to submit a report to the State that includes at least the following information for each MLR reporting year:

(i) Total incurred claims.

(ii) Expenditures on quality improving activities.

(iii) Fraud prevention activities as defined in paragraph (e)(4) of this section.

(iv) Non-claims costs.

(v) Premium revenue.

(vi) Taxes, licensing and regulatory fees.

(vii) Methodology(ies) for allocation of expenditures.

(viii) Any credibility adjustment applied.

(ix) The calculated MLR.

(x) Any remittance owed to the State, if applicable.

(xi) A comparison of the information reported in this paragraph with the audited financial report required under §438.3(m).

(xii) A description of the aggregation method used under paragraph (i) of this section.

(xiii) The number of member months.

(2) A MCO, PIHP, or PAHP must submit the report required in paragraph (k)(1) of this section in a timeframe and manner determined by the State, which must be within 12 months of the end of the MLR reporting year.

(3) MCOs, PIHPs, or PAHPs must require any third party vendor providing claims adjudication activities to provide all underlying data associated with MLR reporting to that MCO, PIHP, or PAHP within 180 days of the

end of the MLR reporting year or within 30 days of being requested by the MCO, PIHP, or PAHP, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting.

(l) *Newer experience.* A State, in its discretion, may exclude a MCO, PIHP, or PAHP that is newly contracted with the State from the requirements in this section for the first year of the MCO's, PIHP's, or PAHP's operation. Such MCOs, PIHPs, or PAHPs must be required to comply with the requirements in this section during the next MLR reporting year in which the MCO, PIHP, or PAHP is in business with the State, even if the first year was not a full 12 months.

(m) *Recalculation of MLR.* In any instance where a State makes a retroactive change to the capitation payments for a MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.

(n) *Attestation.* MCOs, PIHPs, and PAHPs must attest to the accuracy of the calculation of the MLR in accordance with requirements of this section when submitting the report required under paragraph (k) of this section.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 85 FR 72840, Nov. 13, 2020]

§ 438.9 Provisions that apply to non-emergency medical transportation PAHPs.

(a) For purposes of this section, Non-Emergency Medical Transportation (NEMT) PAHP means an entity that provides only NEMT services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(b) Unless listed in this paragraph (b), a requirement of this part does not apply to NEMT PAHPs, NEMT PAHP contracts, or States in connection with a NEMT PAHP. The following requirements and options apply to NEMT PAHPs, NEMT PAHP contracts, and States in connection with NEMT PAHPs, to the same extent that they apply to PAHPs, PAHP contracts, and States in connection with PAHPs.

(1) All contract provisions in § 438.3 except requirements for:

(i) Physician incentive plans at § 438.3(i).

(ii) Advance directives at § 438.3(j).

(iii) LTSS requirements at § 438.3(o).

(iv) MHPAEA at § 438.3(n).

(2) The actuarial soundness requirements in § 438.4, except § 438.4(b)(9).

(3) The information requirements in § 438.10.

(4) The provision against provider discrimination in § 438.12.

(5) The State responsibility provisions in §§ 438.56, 438.58, 438.60, 438.62(a), and 438.818.

(6) The provisions on enrollee rights and protections in subpart C of this part except for §§ 438.110 and 438.114.

(7) The PAHP standards in §§ 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242.

(8) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(9) Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in § 438.610.

(10) Requirements relating to contracts involving Indians, Indian Health Care Providers, and Indian managed care entities in § 438.14.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020]

§ 438.10 Information requirements.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Limited English proficient (LEP) means potential enrollees and enrollees who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English may be LEP and may be eligible to receive language assistance for a particular type of service, benefit, or encounter.

Prevalent means a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient.

Readily accessible means electronic information and services which comply with modern accessibility standards

such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.

(b) *Applicability*. The provisions of this section apply to all managed care programs which operate under any authority in the Act.

(c) *Basic rules*. (1) Each State, enrollment broker, MCO, PIHP, PAHP, PCCM, and PCCM entity must provide all required information in this section to enrollees and potential enrollees in a manner and format that may be easily understood and is readily accessible by such enrollees and potential enrollees.

(2) The State must utilize its beneficiary support system required in § 438.71.

(3) The State must operate a Web site that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity Web sites, specified in paragraphs (g), (h), and (i) of this section.

(4) For consistency in the information provided to enrollees, the State must develop and require each MCO, PIHP, PAHP and PCCM entity to use:

(i) Definitions for managed care terminology, including appeal, co-payment, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services and devices, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, medically necessary, network, non-participating provider, physician services, plan, preauthorization, participating provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, rehabilitation services and devices, skilled nursing care, specialist, and urgent care; and

(ii) Model enrollee handbooks and enrollee notices.

(5) The State must ensure, through its contracts, that each MCO, PIHP, PAHP and PCCM entity provides the required information in this section to each enrollee.

(6) Enrollee information required in this section may not be provided electronically by the State, MCO, PIHP, PAHP, PCCM, or PCCM entity unless all of the following are met:

(i) The format is readily accessible;

(ii) The information is placed in a location on the State, MCO's, PIHP's, PAHP's, or PCCM's, or PCCM entity's Web site that is prominent and readily accessible;

(iii) The information is provided in an electronic form which can be electronically retained and printed;

(iv) The information is consistent with the content and language requirements of this section; and

(v) The enrollee is informed that the information is available in paper form without charge upon request and provides it upon request within 5 business days.

(7) Each MCO, PIHP, PAHP, and PCCM entity must have in place mechanisms to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(d) *Language and format*. The State must:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area.

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. Written materials that are critical to obtaining services for potential enrollees must include taglines in the prevalent non-English languages in the State, explaining the availability of written translations or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously-visible font size.

(3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, available in the prevalent non-English languages

in its particular service area. Written materials that are critical to obtaining services must also be made available in alternative formats upon request of the potential enrollee or enrollee at no cost, include taglines in the prevalent non-English languages in the State and in a conspicuously visible font size explaining the availability of written translation or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and include the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's, or PCCM entity's member/customer service unit. Auxiliary aids and services must also be made available upon request of the potential enrollee or enrollee at no cost.

(4) Make interpretation services available to each potential enrollee and require each MCO, PIHP, PAHP, and PCCM entity to make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language. Oral interpretation requirements apply to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify potential enrollees, and require each MCO, PIHP, PAHP, and PCCM entity to notify its enrollees—

(i) That oral interpretation is available for any language and written translation is available in prevalent languages;

(ii) That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

(iii) How to access the services in paragraphs (d)(5)(i) and (ii) of this section.

(6) Provide, and require MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities to provide, all written materials for potential enrollees and enrollees consistent with the following:

(i) Use easily understood language and format.

(ii) Use a font size no smaller than 12 point.

(iii) Be available in alternative formats and through the provision of auxiliary aids and services in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

(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, either in paper or electronic form as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary managed care program, or is first required to enroll in a mandatory managed care program; and

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities.

(2) The information for potential enrollees must include, at a minimum, all of the following:

(i) Information about the potential enrollee's right to disenroll consistent with the requirements of § 438.56 and which explains clearly the process for exercising this disenrollment right, as well as the alternatives available to the potential enrollee based on their specific circumstance;

(ii) The basic features of managed care;

(iii) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program. For mandatory and voluntary populations, the length of the enrollment period and all disenrollment opportunities available to the enrollee must also be specified;

(iv) The service area covered by each MCO, PIHP, PAHP, PCCM, or PCCM entity;

(v) Covered benefits including:

(A) Which benefits are provided by the MCO, PIHP, or PAHP; and

(B) Which, if any, benefits are provided directly by the State.

(C) For a counseling or referral service that the MCO, PIHP, or PAHP does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service;

(vi) The provider directory and formulary information required in paragraphs (h) and (i) of this section;

(vii) Any cost-sharing that will be imposed by the MCO, PIHP, PAHP,

PCCM, or PCCM entity consistent with those set forth in the State plan;

(viii) The requirements for each MCO, PIHP or PAHP to provide adequate access to covered services, including the network adequacy standards established in § 438.68;

(ix) The MCO, PIHP, PAHP, PCCM and PCCM entity's responsibilities for coordination of enrollee care; and

(x) To the extent available, quality and performance indicators for each MCO, PIHP, PAHP and PCCM entity, including enrollee satisfaction.

(f) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: General requirements.* (1) The MCO, PIHP, PAHP, and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider. Notice to the enrollee must be provided by the later of 30 calendar days prior to the effective date of the termination, or 15 calendar days after receipt or issuance of the termination notice.

(2) The State must notify all enrollees of their right to disenroll consistent with the requirements of § 438.56 at least annually. Such notification must clearly explain the process for exercising this disenrollment right, as well as the alternatives available to the enrollee based on their specific circumstance. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 calendar days before the start of each enrollment period.

(3) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity must make available, upon request, any physician incentive plans in place as set forth in § 438.3(i).

(g) *Information for enrollees of MCOs, PIHPs, PAHPs and PCCM entities—Enrollee handbook.* (1) Each MCO, PIHP, PAHP and PCCM entity must provide each enrollee an enrollee handbook, within a reasonable time after receiving notice of the beneficiary's enrollment, which serves a similar function as the summary of benefits and coverage described in 45 CFR 147.200(a).

(2) The content of the enrollee handbook must include information that enables the enrollee to understand how to effectively use the managed care program. This information must include at a minimum:

(i) Benefits provided by the MCO, PIHP, PAHP or PCCM entity.

(ii) How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided.

(A) In the case of a counseling or referral service that the MCO, PIHP, PAHP, or PCCM entity does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM entity must inform enrollees that the service is not covered by the MCO, PIHP, PAHP, or PCCM entity.

(B) The MCO, PIHP, PAHP, or PCCM entity must inform enrollees how they can obtain information from the State about how to access the services described in paragraph (g)(2)(ii)(A) of this section.

(iii) 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.

(iv) Procedures for obtaining benefits, including any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(v) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes an emergency medical condition and emergency services.

(B) The fact that prior authorization is not required for emergency services.

(C) 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.

(vi) Any restrictions on the enrollee's freedom of choice among network providers.

(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services and supplies from out-of-network providers. This includes an explanation that the MCO, PIHP, or PAHP cannot require

an enrollee to obtain a referral before choosing a family planning provider.

(viii) Cost sharing, if any is imposed under the State plan.

(ix) Enrollee rights and responsibilities, including the elements specified in § 438.100.

(x) The process of selecting and changing the enrollee's primary care provider.

(xi) Grievance, appeal, and fair hearing procedures and timeframes, consistent with subpart F of this part, in a State-developed or State-approved description. Such information must include:

(A) The right to file grievances and appeals.

(B) The requirements and timeframes for filing a grievance or appeal.

(C) The availability of assistance in the filing process.

(D) The right to request a State fair hearing after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee.

(E) The fact that, when requested by the enrollee, benefits that the MCO, PIHP, or PAHP seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing, and that the enrollee may, consistent with state policy, be required to pay the cost of services furnished while the appeal or state fair hearing is pending if the final decision is adverse to the enrollee.

(xii) How to exercise an advance directive, as set forth in § 438.3(j). For PAHPs, information must be provided only to the extent that the PAHP includes any of the providers described in § 489.102(a) of this chapter.

(xiii) How to access auxiliary aids and services, including additional information in alternative formats or languages.

(xiv) The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees.

(xv) Information on how to report suspected fraud or abuse;

(xvi) Any other content required by the State.

(3) Information required by this paragraph to be provided by a MCO, PIHP, PAHP or PCCM entity will be considered to be provided if the MCO, PIHP, PAHP or PCCM entity:

(i) Mails a printed copy of the information to the enrollee's mailing address;

(ii) Provides the information by email after obtaining the enrollee's agreement to receive the information by email;

(iii) Posts the information on the Web site of the MCO, PIHP, PAHP or PCCM entity and advises the enrollee in paper or electronic form that the information is available on the Internet and includes the applicable Internet address, provided that enrollees with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or

(iv) Provides the information by any other method that can reasonably be expected to result in the enrollee receiving that information.

(4) The MCO, PIHP, PAHP, or PCCM entity must give each enrollee notice of any change that the State defines as significant in the information specified in this paragraph (g), at least 30 days before the intended effective date of the change.

(h) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities—Provider Directory.* (1) Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in paper form upon request and electronic form, the following information about its network providers:

(i) The provider's name as well as any group affiliation.

(ii) Street address(es).

(iii) Telephone number(s).

(iv) Web site URL, as appropriate.

(v) Specialty, as appropriate.

(vi) Whether the provider will accept new enrollees.

(vii) The provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office.

(viii) Whether the provider's office/facility has accommodations for people with physical disabilities, including offices, exam room(s) and equipment.

(2) The provider directory must include the information in paragraph (h)(1) of this section for each of the following provider types covered under the contract:

(i) Physicians, including specialists;

(ii) Hospitals;

(iii) Pharmacies;

(iv) Behavioral health providers; and

(v) LTSS providers, as appropriate.

(3) Information included in—

(i) A paper provider directory must be updated at least—

(A) Monthly, if the MCO, PIHP, PAHP, or PCCM entity does not have a mobile-enabled, electronic directory; or

(B) Quarterly, if the MCO, PIHP, PAHP, or PCCM entity has a mobile-enabled, electronic provider directory.

(ii) An electronic provider directory must be updated no later than 30 calendar days after the MCO, PIHP, PAHP, or PCCM entity receives updated provider information.

(4) Provider directories must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

(i) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: Formulary.* Each MCO, PIHP, PAHP, and when appropriate, PCCM entity, must make available in electronic or paper form, the following information about its formulary:

(1) Which medications are covered (both generic and name brand).

(2) What tier each medication is on.

(3) Formulary drug lists must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

(j) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.10 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 85 FR 72840, Nov. 13, 2020]

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate in 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 provider network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with network providers, 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.

§ 438.14 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs).

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Indian means any individual defined at 25 U.S.C. 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. 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 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 issued 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.

Indian health care provider (IHCP) 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).

Indian managed care entity (IMCE) means a MCO, PIHP, PAHP, PCCM, or PCCM entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C) of the Act) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of one or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

(b) *Network and coverage requirements.* All contracts between a State and a MCO, PIHP, PAHP, and PCCM entity, to the extent that the PCCM entity has a provider network, which enroll Indians must:

(1) Require the MCO, PIHP, PAHP, or PCCM entity to demonstrate that there are sufficient IHCPs participating in the provider network of the MCO, PIHP, PAHP, or PCCM entity to ensure timely access to services available under the contract from such providers for Indian enrollees who are eligible to receive services.

(2) Require that IHCPs, whether participating or not, be paid for covered services provided to Indian enrollees who are eligible to receive services from such providers as follows:

(i) At a rate negotiated between the MCO, PIHP, PAHP, or PCCM entity, and the IHCP, or

(ii) In the absence of a negotiated rate, at a rate not less than the level and amount of payment that the MCO, PIHP, PAHP, or PCCM entity would make for the services to a participating provider which is not an IHCP; and

(iii) Make payment to all IHCPs in its network in a timely manner as required for payments to practitioners in individual or group practices under 42 CFR 447.45 and 447.46.

(3) Permit any Indian who is enrolled in a MCO, PIHP, PAHP, PCCM or PCCM entity that is not an IMCE and eligible to receive services from a IHCP primary care provider participating as a network provider, to choose that IHCP as his or her primary care provider, as long as that provider has capacity to provide the services.

(4) Permit Indian enrollees to obtain services covered under the contract between the State and the MCO, PIHP, PAHP, or PCCM entity from out-of-network IHCPs from whom the enrollee is otherwise eligible to receive such services.

(5) In a State where timely access to covered services cannot be ensured due to few or no IHCPs, an MCO, PIHP, PAHP and PCCM entity will be considered to have met the requirement in paragraph (b)(1) of this section if—

(i) Indian enrollees are permitted by the MCO, PIHP, PAHP, or PCCM entity to access out-of-State IHCPs; or

(ii) If this circumstance is deemed to be good cause for disenrollment from both the MCO, PIHP, PAHP, or PCCM entity and the State's managed care program in accordance with § 438.56(c).

(6) MCOs, PIHPs, PAHPs, and PCCM entities, to the extent the PCCM entity has a provider network, must permit an out-of-network IHCP to refer an Indian enrollee to a network provider.

(c) *Payment requirements.* (1) When an IHCP is enrolled in Medicaid as a FQHC but not a participating provider of the MCO, PIHP, PAHP or PCCM entity, it

must be paid an amount equal to the amount the MCO, PIHP, PAHP, or PCCM entity would pay a FQHC that is a network provider but is not an IHCP, including any supplemental payment from the State to make up the difference between the amount the MCO, PIHP, PAHP or PCCM entity pays and what the IHCP FQHC would have received under FFS.

(2) When an IHCP is not enrolled in Medicaid as a FQHC, regardless of whether it participates in the network of an MCO, PIHP, PAHP and PCCM entity or not, it has the right to receive its applicable encounter rate published annually in the FEDERAL REGISTER by the Indian Health Service, or in the absence of a published encounter rate, the amount it would receive if the services were provided under the State plan's FFS payment methodology.

(3) When the amount a IHCP receives from a MCO, PIHP, PAHP, or PCCM entity is less than the amount required by paragraph (c)(2) of this section, the State must make a supplemental payment to the IHCP to make up the difference between the amount the MCO, PIHP, PAHP, or PCCM entity pays and the amount the IHCP would have received under FFS or the applicable encounter rate.

(d) *Enrollment in IMCEs.* An IMCE may restrict its enrollment to Indians in the same manner as Indian Health Programs, as defined in 25 U.S.C. 1603(12), may restrict the delivery of services to Indians, without being in violation of the requirements in § 438.3(d).

Subpart B—State Responsibilities

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid beneficiaries to enroll in MCOs, PCCMs, or PCCM 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(a) 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 FFS or capitation).

(3) Whether it contracts on a comprehensive risk basis.

(4) The process the State uses to involve the public in both design and initial implementation of the managed care 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 or PCCM entity contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring beneficiaries to receive their benefits through managed care entities.

(4) This part, for MCOs, PCCMs, and PCCM entities.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.4, 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, PCCM or PCCM entity:

(1) Beneficiaries who are also eligible for Medicare.

(2) Indians as defined in § 438.14(a), except as permitted under § 438.14(d).

(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.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid beneficiaries to:

(1) Enroll in an MCO, PIHP, or PAHP, must give those beneficiaries a choice of at least two MCOs, PIHPs, or PAHPs.

(2) Enroll in a primary care case management system, must give those beneficiaries a choice from at least two primary care case managers employed or contracted with the State.

(3) Enroll in a PCCM entity, may limit a beneficiary to a single PCCM entity. Beneficiaries must be permitted to choose from at least two primary care case managers employed by or contracted with the PCCM entity.

(b) *Exception for rural area residents.* (1) Under any managed care program authorized by any of the following, 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, or PAHP:

(i) A State plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115(a) of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) To comply with this paragraph (b), a State, must permit the beneficiary—

(i) To choose from at least two primary care providers; 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, or PAHP network.

(B) The provider is not part of the network, but is the main source of a service to the beneficiary, provided that—

(*1*) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, or PAHP 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 calendar days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the beneficiary does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The beneficiary's primary care provider or other provider determines that the beneficiary needs related services that would subject the beneficiary 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 (b), ''rural area'' is any county designated as ''micro,'' ''rural,'' or ''County with Extreme Access Considerations (CEAC)'' in the Medicare Advantage Health Services Delivery (HSD) Reference file for the applicable calendar year.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit beneficiaries 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 beneficiary 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).

§ 438.54 Managed care enrollment.

(a) *Applicability.* The provisions of this section apply to all Medicaid managed care programs which operate under any authority in the Act.

(b) *General rule.* The State must have an enrollment system for its managed

care programs, voluntary and mandatory, as appropriate.

(1) Voluntary managed care programs are those where one or more groups of beneficiaries as enumerated in section of 1905(a) of the Act have the option to either enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity, or remain enrolled in FFS to receive Medicaid covered benefits.

(2) Mandatory managed care programs are those where one or more groups of beneficiaries as enumerated in section 1905(a) of the Act must enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity to receive covered Medicaid benefits.

(3) States must provide the demographic information listed in § 438.340(b)(6) for each Medicaid enrollee to the individual's MCO, PIHP, PAHP, or PCCM entity at the time of enrollment.

(c) *Voluntary managed care programs.* (1) States that have a voluntary managed care program must have an enrollment system that:

(i) Provides an enrollment choice period during which potential enrollees may make an active choice of delivery system and, if needed, choice of an MCO, PIHP, PAHP, PCCM or PCCM entity before enrollment is effectuated; or

(ii) Employs a passive enrollment process in which the State enrolls the potential enrollee into a MCO, PIHP, PAHP, PCCM or PCCM entity and simultaneously provides a period of time for the enrollee to make an active choice of delivery system and, if needed, to maintain enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity passively assigned or to select a different MCO, PIHP, PAHP, PCCM or PCCM entity.

(2) A State must provide potential enrollees the opportunity to actively elect to receive covered services through the managed care or FFS delivery system. If the potential enrollee elects to receive covered services through the managed care delivery system, the potential enrollee must then also select a MCO, PIHP, PAHP, PCCM, or PCCM entity.

(i) If the State does not use a passive enrollment process and the potential enrollee does not make an active choice during the period allowed by the state, then the potential enrollee will continue to receive covered services through the FFS delivery system.

(ii) If the State uses a passive enrollment process, the potential enrollee must select either to accept the MCO, PIHP, PAHP, PCCM, or PCCM entity selected for them by the State's passive enrollment process, select a different MCO, PIHP, PAHP, PCCM, or PCCM entity, or elect to receive covered services through the FFS delivery system. If the potential enrollee does not make an active choice during the time allowed by the state, the potential enrollee will remain enrolled with the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the passive enrollment process.

(3) The State must provide informational notices to each potential enrollee at the time the potential enrollee first becomes eligible to enroll in a managed care program and within a timeframe that enables the potential enrollee to use the information in choosing among available delivery system and/or managed care plan options. The notices must:

(i) Clearly explain (as relevant to the State's managed care program) the implications to the potential enrollee of: not making an active choice between managed care and FFS; selecting a different MCO, PIHP, PAHP, PCCM or PCCM entity; and accepting the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State;

(ii) Identify the MCOs, PIHPs, PAHPs, PCCMs or PCCM entities available to the potential enrollee should they elect the managed care delivery system;

(iii) Provide clear instructions for how to make known to the State the enrollee's selection of the FFS delivery system or a MCO, PIHP, PAHP, PCCM or PCCM entity;

(iv) Provide a comprehensive explanation of the length of the enrollment period, the 90 day without cause disenrollment period, and all other disenrollment options as specified in § 438.56;

(v) Include the contact information for the beneficiary support system in § 438.71; and

(vi) Comply with the information requirements in § 438.10.

(4) The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) If a State elects to use a passive enrollment process, the process must assign beneficiaries to a qualified MCO, PIHP, PAHP, PCCM or PCCM entity. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(6) A passive enrollment process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An ''existing provider-beneficiary relationship'' is one in which the provider was a main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have ''traditionally served'' Medicaid beneficiaries if it has experience in serving the Medicaid population.

(7) If the approach in paragraph (c)(6) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM, or PCCM entity from being considered.

(ii) The State may consider additional criteria to conduct the passive enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria that support the objectives of the managed care program.

(8) If a passive enrollment process is used and the enrollee does not elect to be enrolled into the FFS delivery system, the State must send a notice to the enrollee:

(i) Confirming that the enrollee's time to elect to enroll in the FFS delivery system has ended and that the enrollee will remain enrolled in the managed care delivery system for the remainder of the enrollment period unless one of the disenrollment reasons specified in § 438.56 applies.

(ii) Clearly and fully explaining the enrollee's right, and process to follow, to disenroll from the passively assigned MCO, PIHP, PAHP, PCCM or PCCM entity and select a different MCO, PIHP, PAHP, PCCM or PCCM entity within 90 days from the effective date of the enrollment or for any reason specified in § 438.56(d)(2).

(iii) Within 5 calendar days of the end of the time allowed for making the delivery system selection.

(d) *Mandatory managed care programs.* (1) States must have an enrollment system for a mandatory managed care program that includes the elements specified in paragraphs (d)(2) through (8) of this section.

(2) The State's enrollment system must implement enrollment in a MCO, PIHP, PAHP, PCCM, or PCCM entity as follows:

(i) If the State does not use a passive enrollment process and the potential enrollee does not make an active choice of a MCO, PIHP, PAHP, PCCM, or PCCM entity during the period allowed by the State, the potential enrollee will be enrolled into a MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State's default process.

(ii) If the State uses a passive enrollment process, the potential enrollee must either accept the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State's passive enrollment process or select a different MCO, PIHP, PAHP, PCCM, or PCCM entity. If the potential enrollee does not make an active choice during the time allowed by the State, the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the passive enrollment process will remain effective.

(3) A State must provide informational notices to each potential enrollee at the time the potential enrollee first becomes eligible to enroll in a managed care program and within a timeframe that enables the potential enrollee to use the information in choosing among available managed care plans. The notices must:

(i) Include the MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities available to the potential enrollee;

(ii) Provide clear instructions for how to make known to the State the enrollee's selection of a MCO, PIHP, PAHP, PCCM, or PCCM entity;

(iii) Clearly explain the implications to the potential enrollee of not making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity as well as the implications of making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity;

(iv) Provide a comprehensive explanation of the length of the enrollment period, the 90 day without cause disenrollment period, and all other disenrollment options as specified in § 438.56;

(v) Include the contact information for the beneficiary support system in § 438.71; and

(vi) Comply with the information requirements in § 438.10.

(4) *Priority for enrollment*. The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) *Enrollment by default*. For potential enrollees that do not select an MCO, PIHP, PAHP, PCCM or PCCM entities during the period allowed by the state, the State must have a default enrollment process for assigning those beneficiaries to qualified MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(6) *Passive enrollment*. For States that use a passive enrollment process, the process must assign potential enrollees to qualified MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(7) The passive and default enrollment processes must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An ''existing provider-beneficiary relationship'' is one in which the provider was a main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have ''traditionally served'' Medicaid beneficiaries if it has experience in serving the Medicaid population.

(8) If the approach in paragraph (d)(7) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities available to enroll them.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered; and

(ii) The State may consider additional criteria to conduct the default enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria related to a beneficiary's experience with the Medicaid program.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020]

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability*. The provisions of this section apply to all managed care

programs whether enrollment is mandatory or voluntary and whether the contract is with an MCO, PIHP, PAHP, PCCM, or PCCM entity.

(b) *Disenrollment requested by the MCO, PIHP, PAHP, PCCM, or PCCM entity.* All MCO, PIHP, PAHP, PCCM and PCCM entity contracts must:

(1) Specify the reasons for which the MCO, PIHP, PAHP, PCCM, or PCCM entity may request disenrollment of an enrollee.

(2) Provide that the MCO, PIHP, PAHP, PCCM, or PCCM entity 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, PCCM or PCCM entity seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees).

(3) Specify the methods by which the MCO, PIHP, PAHP, PCCM, or PCCM entity 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, PCCM, and PCCM entity contracts must provide that a beneficiary 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 beneficiary's initial enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity, or during the 90 days following the date the State sends the beneficiary notice of that 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 beneficiary to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(4).

(d) *Procedures for disenrollment*—(1) *Request for disenrollment.* The beneficiary (or his or her representative) must submit an oral or written request, as required by the State—

(i) To the State (or its agent); or

(ii) To the MCO, PIHP, PAHP, PCCM, or PCCM entity, if the State permits MCOs, PIHP, PAHPs, PCCMs, and PCCM entities 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, PCCM's, or PCCM entity'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 provider 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) For enrollees that use MLTSS, the enrollee would have to change their residential, institutional, or employment supports provider based on that provider's change in status from an in-network to an out-of-network provider with the MCO, PIHP, or PAHP and, as a result, would experience a disruption in their residence or employment.

(v) Other reasons, including 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 care needs.

(3) *MCO, PIHP, PAHP, PCCM, or PCCM entity action on request.* (i) When the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's contract with the State permits the MCO, PIHP, PAHP, PCCM, or PCCM entity to process disenrollment requests, the MCO, PIHP, PAHP, PCCM, or PCCM entity may either approve a request for disenrollment by or on behalf of an enrollee or the MCO, PIHP, PAHP, PCCM, or PCCM entity must refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or State agency (whichever is responsible) fails to make a disenrollment determination so that the beneficiary 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 beneficiary, or one referred by the MCO, PIHP, PAHP, PCCM, or PCCM entity, 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, PCCM, or PCCM entity at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO's, PIHP's, PAHP's grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO's, PHIP's, or PAHP'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 paragraph (e)(1) of this section.

(iii) If, as a result of the grievance process, the MCO, PIHP, or PAHP approves the disenrollment, the State agency is not required to make a determination in accordance with paragraph (d)(4) of this section.

(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 requests disenrollment or the MCO, PIHP, PAHP, PCCM, or PCCM entity refers the request to the State.

(2) If the MCO, PIHP, PAHP, PCCM, PCCM entity, 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 for the effective date that would have been established had the State or MCO, PIHP, PAHP, PCCM, PCCM entity complied with paragraph (e)(1) of this section.

(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. The notice must include an explanation of all of the enrollee's disenrollment rights as specified in this section.

(2) Ensure timely 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 beneficiary who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020]

§ 438.58 Conflict of interest safeguards.

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 enrollment processes specified in § 438.54(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 Prohibition of additional payments for services covered under MCO, PIHP or PAHP contracts.

The State agency must ensure that no payment is made to a network provider other than by the MCO, PIHP, or PAHP for services covered under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are specifically required to be made by the State in Title XIX of the Act, in 42 CFR chapter IV, or when the State agency makes direct payments to network providers for graduate medical education costs approved under the State plan.

§ 438.62 Continued services to enrollees.

(a) The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, PCCM, or PCCM entity the contract of which is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, PCCM, or PCCM entity for any reason other than ineligibility for Medicaid.

(b) The State must have in effect a transition of care policy to ensure continued access to services during a transition from FFS to a MCO, PIHP, PAHP, PCCM or PCCM entity or transition from one MCO, PIHP, PAHP, PCCM or PCCM entity to another when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization.

(1) The transition of care policy must include the following:

(i) The enrollee has access to services consistent with the access they previously had, and is permitted to retain their current provider for a period of time if that provider is not in the MCO, PIHP or PAHP network.

(ii) The enrollee is referred to appropriate providers of services that are in the network.

(iii) The State, in the case of FFS, PCCM, or PCCM entity, or the MCO, PIHP or PAHP that was previously serving the enrollee, fully and timely complies with requests for historical utilization data from the new MCO, PIHP, PAHP, PCCM, or PCCM entity in compliance with Federal and State law.

(iv) Consistent with Federal and State law, the enrollee's new provider(s) are able to obtain copies of the enrollee's medical records, as appropriate.

(v) Any other necessary procedures as specified by the Secretary to ensure continued access to services to prevent serious detriment to the enrollee's health or reduce the risk of hospitalization or institutionalization.

(vi) A process for the electronic exchange of, at a minimum, the data classes and elements included in the content standard adopted at 45 CFR 170.213. Such information received by the MCO, PIHP, or PAHP must be incorporated into the MCO's, PIHP's, or PAHP's records about the current enrollee. With the approval and at the direction of a current or former enrollee or the enrollee's personal representative, the MCO, PIHP, or PAHP must:

(A) Receive all such data for a current enrollee from any other payer that has provided coverage to the enrollee within the preceding 5 years;

(B) At any time the enrollee is currently enrolled in the MCO, PIHP, or PAHP and up to 5 years after disenrollment, send all such data to any other payer that currently covers the enrollee or a payer the enrollee or the enrollee's personal representative specifically requests receive the data; and

(C) Send data received from another payer under this paragraph in the electronic form and format it was received.

(vii) Applicability.

(A) The MCO, PIHP, or PAHP must comply with the requirements in paragraph (b)(1)(vi) of this section beginning January 1, 2022 with regard to data:

(*1*) With a date of service on or after January 1, 2016; and

(*2*) That are maintained by the MCO, PIHP, or PAHP.

(B) [Reserved]

(2) The State must require by contract that MCOs, PIHPs, and PAHPs implement a transition of care policy consistent with the requirements in paragraph (b)(1) of this section and at least meets the State defined transition of care policy.

(3) The State must make its transition of care policy publicly available and provide instructions to enrollees and potential enrollees on how to access continued services upon transition. At a minimum, the transition of care policy must be described in the quality strategy, under § 438.340, and explained to individuals in the materials to enrollees and potential enrollees, in accordance with § 438.10.

(c) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2018. Until that applicability date, states are required to continue to comply with § 438.62 contained

in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 85 FR 25635, May 1, 2020]

§ 438.66 State monitoring requirements.

(a) *General requirement.* The State agency must have in effect a monitoring system for all managed care programs.

(b) The State's system must address all aspects of the managed care program, including the performance of each MCO, PIHP, PAHP, and PCCM entity (if applicable) in at least the following areas:

(1) Administration and management.

(2) Appeal and grievance systems.

(3) Claims management.

(4) Enrollee materials and customer services, including the activities of the beneficiary support system.

(5) Finance, including medical loss ratio reporting.

(6) Information systems, including encounter data reporting.

(7) Marketing.

(8) Medical management, including utilization management and case management.

(9) Program integrity.

(10) Provider network management, including provider directory standards.

(11) Availability and accessibility of services, including network adequacy standards.

(12) Quality improvement.

(13) Areas related to the delivery of LTSS not otherwise included in paragraphs (b)(1) through (12) of this section as applicable to the managed care program.

(14) All other provisions of the contract, as appropriate.

(c) The State must use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:

(1) Enrollment and disenrollment trends in each MCO, PIHP, or PAHP.

(2) Member grievance and appeal logs.

(3) Provider complaint and appeal logs.

(4) Findings from the State's External Quality Review process.

(5) Results from any enrollee or provider satisfaction survey conducted by the State or MCO, PIHP, or PAHP.

(6) Performance on required quality measures.

(7) Medical management committee reports and minutes.

(8) The annual quality improvement plan for each MCO, PIHP, PAHP, or PCCM entity.

(9) Audited financial and encounter data submitted by each MCO, PIHP, or PAHP.

(10) The medical loss ratio summary reports required by § 438.8.

(11) Customer service performance data submitted by each MCO, PIHP, or PAHP and performance data submitted by the beneficiary support system.

(12) Any other data related to the provision of LTSS not otherwise included in paragraphs (c)(1) through (11) of this section as applicable to the managed care program.

(d)(1) The State must assess the readiness of each MCO, PIHP, PAHP or PCCM entity with which it contracts as follows:

(i) Prior to the State implementing a managed care program, whether the program is voluntary or mandatory.

(ii) When the specific MCO, PIHP, PAHP, or PCCM entity has not previously contracted with the State.

(iii) When any MCO, PIHP, PAHP, or PCCM entity currently contracting with the State will provide or arrange for the provision of covered benefits to new eligibility groups.

(2) The State must conduct a readiness review of each MCO, PIHP, PAHP, or PCCM entity with which it contracts as follows:

(i) Started at least 3 months prior to the effective date of the events described in paragraph (d)(1) of this section.

(ii) Completed in sufficient time to ensure smooth implementation of an event described in paragraph (d)(1) of this section.

(iii) Submitted to CMS for CMS to make a determination that the contract or contract amendment associated with an event described in paragraph (d)(1) of this section is approved under § 438.3(a).

(3) Readiness reviews described in paragraphs (d)(1)(i) and (ii) of this section must include both a desk review of documents and on-site reviews of each MCO, PIHP, PAHP, or PCCM entity. Readiness reviews described in paragraph (d)(1)(iii) of this section must include a desk review of documents and may, at the State's option, include an on-site review. On-site reviews must include interviews with MCO, PIHP, PAHP, or PCCM entity staff and leadership that manage key operational areas.

(4) A State's readiness review must assess the ability and capacity of the MCO, PIHP, PAHP, and PCCM entity (if applicable) to perform satisfactorily for the following areas:

(i) Operations/Administration, including—

(A) Administrative staffing and resources.

(B) Delegation and oversight of MCO, PIHP, PAHP or PCCM entity responsibilities.

(C) Enrollee and provider communications.

(D) Grievance and appeals.

(E) Member services and outreach.

(F) Provider Network Management.

(G) Program Integrity/Compliance.

(ii) Service delivery, including—

(A) Case management/care coordination/service planning.

(B) Quality improvement.

(C) Utilization review.

(iii) Financial management, including—

(A) Financial reporting and monitoring.

(B) Financial solvency.

(iv) Systems management, including—

(A) Claims management.

(B) Encounter data and enrollment information management.

(e)(1) The State must submit to CMS no later than 180 days after each contract year, a report on each managed care program administered by the State, regardless of the authority under which the program operates.

(i) The initial report will be due after the contract year following the release of CMS guidance on the content and form of the report.

(ii) For States that operate their managed care program under section 1115(a) of the Act authority, submission of an annual report that may be required by the Special Terms and Conditions of the section 1115(a) demonstration program will be deemed to satisfy the requirement of this paragraph (e)(1) provided that the report includes the information specified in paragraph (e)(2) of this section.

(2) The program report must provide information on and an assessment of the operation of the managed care program on, at a minimum, the following areas:

(i) Financial performance of each MCO, PIHP, and PAHP, including MLR experience.

(ii) Encounter data reporting by each MCO, PIHP, or PAHP.

(iii) Enrollment and service area expansion (if applicable) of each MCO, PIHP, PAHP, and PCCM entity.

(iv) Modifications to, and implementation of, MCO, PIHP, or PAHP benefits covered under the contract with the State.

(v) Grievance, appeals, and State fair hearings for the managed care program.

(vi) Availability and accessibility of covered services within the MCO, PIHP, or PAHP contracts, including network adequacy standards.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance.

(viii) Results of any sanctions or corrective action plans imposed by the State or other formal or informal intervention with a contracted MCO, PIHP, PAHP, or PCCM entity to improve performance.

(ix) Activities and performance of the beneficiary support system.

(x) Any other factors in the delivery of LTSS not otherwise addressed in (e)(2)(i)–(ix) of this section as applicable.

(3) The program report required in this section must be:

(i) Posted on the Web site required under § 438.10(c)(3).

(ii) Provided to the Medical Care Advisory Committee, required under § 431.12 of this chapter.

(iii) Provided to the stakeholder consultation group specified in § 438.70, to

the extent that the managed care program includes LTSS.

(f) *Applicability*. States will not be held out of compliance with the requirements of paragraphs (a) through (d) of this section prior to the rating period for contracts starting on or after July 1, 2017, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.66 contained in the 42 CFR, parts 430 to 481, edition revised as of October 1, 2015.

§ 438.68 Network adequacy standards.

(a) *General rule*. A State that contracts with an MCO, PIHP or PAHP to deliver Medicaid services must develop and enforce network adequacy standards consistent with this section.

(b) *Provider-specific network adequacy standards*.–(1) *Provider types*. At a minimum, a State must develop a quantitative network adequacy standard for the following provider types, if covered under the contract:

(i) Primary care, adult and pediatric.

(ii) OB/GYN.

(iii) Behavioral health (mental health and substance use disorder), adult and pediatric.

(iv) Specialist (as designated by the State), adult, and pediatric.

(v) Hospital.

(vi) Pharmacy.

(vii) Pediatric dental.

(2) *LTSS*. States with MCO, PIHP, or PAHP contracts which cover LTSS must develop a quantitative network adequacy standard for LTSS provider types.

(3) *Scope of network adequacy standards*. Network standards established in accordance with paragraphs (b)(1) and (2) of this section must include all geographic areas covered by the managed care program or, if applicable, the contract between the State and the MCO, PIHP or PAHP. States are permitted to have varying standards for the same provider type based on geographic areas.

(c) *Development of network adequacy standards*. (1) States developing network adequacy standards consistent with paragraph (b)(1) of this section must consider, at a minimum, the following elements:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services.

(iii) The characteristics and health care needs of specific Medicaid populations covered in the MCO, PIHP, and PAHP contract.

(iv) The numbers and types (in terms of training, experience, and specialization) of network providers required to furnish the contracted Medicaid services.

(v) The numbers of network providers who are not accepting new Medicaid patients.

(vi) The geographic location of network providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees.

(vii) The ability of network providers to communicate with limited English proficient enrollees in their preferred language.

(viii) The ability of network providers to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(ix) The availability of triage lines or screening systems, as well as the use of telemedicine, e-visits, and/or other evolving and innovative technological solutions.

(2) States developing standards consistent with paragraph (b)(2) of this section must consider the following:

(i) All elements in paragraphs (c)(1)(i) through (ix) of this section.

(ii) Elements that would support an enrollee's choice of provider.

(iii) Strategies that would ensure the health and welfare of the enrollee and support community integration of the enrollee.

(iv) Other considerations that are in the best interest of the enrollees that need LTSS.

(d) *Exceptions process*. (1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must be:

(i) Specified in the MCO, PIHP or PAHP contract.

(ii) Based, at a minimum, on the number of providers in that specialty

practicing in the MCO, PIHP, or PAHP service area.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to a MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66.

(e) *Publication of network adequacy standards.* States must publish the standards developed in accordance with paragraphs (b)(1) and (2) of this section on the Web site required by § 438.10. Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020]

§ 438.70 Stakeholder engagement when LTSS is delivered through a managed care program.

The State must ensure the views of beneficiaries, individuals representing beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of a State's managed LTSS program. The composition of the stakeholder group and frequency of meetings must be sufficient to ensure meaningful stakeholder engagement.

§ 438.71 Beneficiary support system.

(a) *General requirement.* The State must develop and implement a beneficiary support system that provides support to beneficiaries both prior to and after enrollment in a MCO, PIHP, PAHP, PCCM or PCCM entity.

(b) *Elements of the support system.* (1) A State beneficiary support system must include at a minimum:

(i) Choice counseling for all beneficiaries.

(ii) Assistance for enrollees in understanding managed care.

(iii) Assistance as specified for enrollees who use, or express a desire to receive, LTSS in paragraph (d) of this section.

(2) The beneficiary support system must perform outreach to beneficiaries and/or authorized representatives and be accessible in multiple ways including phone, Internet, in-person, and via auxiliary aids and services when requested.

(c) *Choice counseling.* (1) Choice counseling, as defined in § 438.2, must be provided to all potential enrollees and enrollees who disenroll from a MCO, PIHP, PAHP, PCCM or PCCM entity for reasons specified in § 438.56(b) and (c).

(2) If an individual or entity provides choice counseling on the State's behalf under a memorandum of agreement or contract, it is considered an enrollment broker as defined in § 438.810(a) and must meet the independence and freedom from conflict of interest standards in § 438.810(b)(1) and (2).

(3) An entity that receives non-Medicaid funding to represent beneficiaries at hearings may provide choice counseling on behalf of the State so long as the State requires firewalls to ensure that the requirements for the provision of choice counseling are met.

(d) *Functions specific to LTSS activities.* At a minimum, the beneficiary support system must provide the following support to enrollees who use, or express a desire to receive, LTSS:

(1) An access point for complaints and concerns about MCO, PIHP, PAHP, PCCM, and PCCM entity enrollment, access to covered services, and other related matters.

(2) Education on enrollees' grievance and appeal rights within the MCO, PIHP or PAHP; the State fair hearing process; enrollee rights and responsibilities; and additional resources outside of the MCO, PIHP or PAHP.

(3) Assistance, upon request, in navigating the grievance and appeal process within the MCO, PIHP or PAHP, as well as appealing adverse benefit determinations by the MCO, PIHP, or PAHP to a State fair hearing. The system may not provide representation to the enrollee at a State fair hearing but may refer enrollees to sources of legal representation.

(4) Review and oversight of LTSS program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.

§ 438.74 State oversight of the minimum MLR requirement.

(a) *State reporting requirement.* (1) The State must annually submit to CMS a summary description of the report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State, according to § 438.8(k), with the rate certification required in § 438.7.

(2) The summary description must include, at a minimum, the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.

(b) *Repayment of Federal share of remittances.* (1) If a State requires a MCO, PIHP, or PAHP to pay remittances through the contract for not meeting the minimum MLR required by the State, the State must reimburse CMS for an amount equal to the Federal share of the remittance, taking into account applicable differences in the Federal matching rate.

(2) If a remittance is owed according to paragraph (b)(1) of this section, the State must submit a separate report describing the methodology used to determine the State and Federal share of the remittance with the report required in paragraph (a) of this section.

Subpart C—Enrollee Rights and Protections

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that:

(1) Each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its employees and contracted providers observe and protect those rights.

(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 (3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, PCCM, or PCCM entity 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(g)(2)(ii)(A) and (B).)

(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, PCCM or PCCM entity and its network 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, PCCM and PCCM entity complies with any other applicable Federal and State laws (including: 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; Title IX of the Education Amendments of 1972 (regarding education programs and activities); Titles II and III of the Americans with Disabilities Act; and section 1557 of the Patient Protection and Affordable Care Act.

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a provider 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 to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or non-treatment.

(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)(i) 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:

(A) To the State—

(*1*) With its application for a Medicaid contract.

(*2*) Whenever it adopts the policy during the term of the contract.

(B) Consistent with the provisions of § 438.10, to enrollees, within 90 days after adopting the policy for any particular service.

(ii) 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(g)(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(g)(2)(ii)(A) and (B), the MCOs, PIHPs, and PAHPs must inform enrollees how they can obtain information from the State about how to access 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.

(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.

§ 438.104 Marketing activities.

(a) *Definitions.* 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, PCCM or PCCM entity with a potential enrollee for the purpose of marketing as defined in this paragraph (a).

Marketing means any communication, from an MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that particular MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product, or either to not enroll in or to disenroll from another MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product. Marketing does not include communication to a Medicaid beneficiary from the issuer of a qualified health plan, as defined in 45 CFR 155.20, about the qualified health plan.

Marketing materials means materials that—

(i) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, PCCM, or PCCM entity; and

(ii) Can reasonably be interpreted as intended to market the MCO, PIHP, PAHP, PCCM, or PCCM entity to potential enrollees.

MCO, PIHP, PAHP, PCCM or PCCM entity include any of the entity's employees, network providers, agents, or contractors.

Private insurance does not include a qualified health plan, as defined in 45 CFR 155.20.

(b) *Contract requirements*. Each contract with an MCO, PIHP, PAHP, PCCM, or PCCM entity 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 beneficiary 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.

(v) Does not, directly or indirectly, engage in door-to-door, telephone, email, texting, or other cold-call marketing activities.

(2) Specify the methods by which the entity ensures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the beneficiaries 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 beneficiary must enroll in the MCO, PIHP, PAHP, PCCM or PCCM entity to obtain benefits or to not lose benefits; or

(ii) The MCO, PIHP, PAHP, PCCM or PCCM entity 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 furnished 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 covered 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 447.82 of this chapter.

§ 438.110 Member advisory committee.

(a) *General rule*. When LTSS are covered under a risk contract between a State and an MCO, PIHP, or PAHP, the contract must provide that each MCO, PIHP or PAHP establish and maintain a member advisory committee.

(b) *Committee composition*. The committee required in paragraph (a) of this section must include at least a reasonably representative sample of the LTSS populations, or other individuals representing those enrollees, covered under the contract with the MCO, PIHP, or PAHP.

§ 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:

(i) Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(ii) Serious impairment to bodily functions.

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

Emergency services means covered inpatient and outpatient services that are as follows:

(i) Furnished by a provider that is qualified to furnish these services under this Title.

(ii) 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 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 State, for managed care programs that contract with PCCMs or PCCM entities

(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, PCCM or PCCM entity; 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, PCCM, or PCCM entity instructs the enrollee to seek emergency services.

(2) A PCCM or PCCM entity must 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.

(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 ''MA organization'' and ''financially responsible'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section, and payment rules governed by Title XIX of the Act and the States.

(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.

§ 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.

Subpart D—MCO, PIHP and PAHP Standards

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 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 in a timely manner. The State must also ensure that MCO, PIHP and PAHP provider networks for services covered under the contract meet the standards developed by the State in accordance with § 438.68.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP, consistent with the scope of its 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 for all enrollees, including those with limited English proficiency or physical or mental disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the provider 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 network provider, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the provider 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's provider network is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO, PIHP, or PAHP for payment and ensures the cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its network providers are credentialed as required by § 438.214.

(7) Demonstrates that its network includes sufficient family planning providers to ensure timely access to covered services.

(c) *Furnishing of services.* The State must ensure that each contract with a MCO, PIHP, and PAHP complies with the following requirements.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its network 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 FFS, 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 network providers.

(v) Monitor network providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply by a network provider.

(2) *Access and 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, disabilities, and regardless of sex.

(3) *Accessibility considerations.* Each MCO, PIHP, and PAHP must ensure that network providers provide physical access, reasonable accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(d) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2018. Until that applicability date, states are required to continue to comply with § 438.206 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 85 FR 37243, June 19, 2020]

§ 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 part, including the standards at § 438.68 and § 438.206(c)(1).

(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, specialty services, and LTSS 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) On an annual basis.

(3) 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 the adequacy of capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area, composition of or payments to its provider network; 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 submit an assurance of compliance to CMS that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in § 438.68 and § 438.206. The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.

(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.

(f) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2018. Until that applicability date, states are required to continue to comply with § 438.207 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (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 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 Advantage Organization (as defined in § 422.2 of this chapter), the State determines to what extent the MCO must meet the identification, assessment, and treatment planning provisions of paragraph (c) of this section for dually eligible individuals.

(ii) The State bases its determination on the needs of the population it requires the MCO to serve.

(b) *Care and coordination of services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver care to and coordinate services 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 care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee. The enrollee must be provided information on how to contact their designated person or entity;

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee:

(i) Between settings of care, including appropriate discharge planning for short term and long-term hospital and institutional stays;

(ii) With the services the enrollee receives from any other MCO, PIHP, or PAHP;

(iii) With the services the enrollee receives in FFS Medicaid; and

(iv) With the services the enrollee receives from community and social support providers.

(3) Provide that the MCO, PIHP or PAHP makes a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful;

(4) Share with the State or other MCOs, PIHPs, and PAHPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities;

(5) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards; and

(6) 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 or who need LTSS*—(1) *Identification.* The State must implement mechanisms to identify persons who need LTSS or 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 strategy under § 438.340.

(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

comprehensively 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 needing LTSS or having special health care needs 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 providers or individuals meeting LTSS service coordination requirements of the State or the MCO, PIHP, or PAHP as appropriate.

(3) *Treatment/service plans.* MCOs, PIHPs, or PAHPs must produce a treatment or service plan meeting the criteria in paragraphs (c)(3)(i) through (v) of this section for enrollees who require LTSS and, if the State requires, must produce a treatment or service plan meeting the criteria in paragraphs (c)(3)(iii) through (v) of this section for enrollees with special health care needs that are determined through assessment to need a course of treatment or regular care monitoring. The treatment or service plan must be:

(i) Developed by an individual meeting LTSS service coordination requirements with enrollee participation, and in consultation with any providers caring for the enrollee;

(ii) Developed by a person trained in person-centered planning using a person-centered process and plan as defined in § 441.301(c)(1) and (2) of this chapter for LTSS treatment or service plans;

(iii) Approved by the MCO, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP;

(iv) In accordance with any applicable State quality assurance and utilization review standards; and

(v) Reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly, or at the request of the enrollee per § 441.301(c)(3) of this chapter.

(4) *Direct access to specialists.* For enrollees with special health care needs determined through an assessment (consistent with paragraph (c)(2) of this section) 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.

(d) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.208 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract between a State and 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 FFS Medicaid, as set forth in § 440.230 of this chapter, and for enrollees under the age of 21, as set forth in subpart B of part 441 of this chapter.

(3) Provide that the MCO, PIHP, or PAHP—

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably 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.

(4) Permit an MCO, PIHP, or PAHP to place appropriate limits on a service—

(i) On the basis of criteria applied under the State plan, such as medical necessity; or

(ii) For the purpose of utilization control, provided that—

(A) The services furnished can reasonably achieve their purpose, as required in paragraph (a)(3)(i) of this section;

(B) The services supporting individuals with ongoing or chronic conditions or who require long-term services and supports are authorized in a manner that reflects the enrollee's ongoing need for such services and supports; and

(C) Family planning services are provided in a manner that protects and enables the enrollee's freedom to choose the method of family planning to be used consistent with §441.20 of this chapter.

(5) Specify what constitutes ''medically necessary services'' in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program, including quantitative and non-quantitative treatment limits, 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 that address:

(A) The prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability.

(B) The ability for an enrollee to achieve age-appropriate growth and development.

(C) The ability for an enrollee to attain, maintain, or regain functional capacity.

(D) The opportunity for an enrollee receiving long-term services and supports to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice.

(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.

(ii) Consult with the requesting provider for medical services when appropriate.

(iii) Authorize LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan.

(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 an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs.

(c) *Notice of adverse benefit determination.* 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, PIHPs, and PAHPs, the enrollee's notice must meet the requirements of §438.404. For Medicaid contracts with an applicable integrated plan, as defined in §422.561 of this chapter, in lieu of the provisions in this paragraph governing notices of adverse benefit determinations, the provisions set forth in §§422.629 through 422.634 of this chapter apply to determinations affecting dually eligible individuals who are also enrolled in a dual eligible special needs plan with exclusively aligned enrollment, as defined in §422.2 of this chapter.

(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 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 72 hours after receipt of the request for service.

(ii) The MCO, PIHP, or PAHP may extend the 72 hour 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.

(3) *Covered outpatient drug decisions.* For all covered outpatient drug authorization decisions, provide notice as described in section 1927(d)(5)(A) of the Act.

(4) For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, timelines for decisions and notices must be compliant with the provisions set forth in §§ 422.629 through 422.634 of this chapter in lieu of §§ 438.404 through 438.424.

(e) *Compensation for utilization management activities.* Each contract between a State and MCO, PIHP, or PAHP must provide that, consistent with §§ 438.3(i), 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.

(f) *Applicability date.* (1) Subject to paragraph (f)(2) of this section, this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States are required to continue to comply with § 438.210 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 84 FR 15843, Apr. 16, 2019]

§ 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 network providers and that those policies and procedures, at a minimum, meet the requirements of this section.

(b) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, behavioral, substance use disorders, and LTSS providers, as appropriate, and requires each MCO, PIHP and PAHP to follow those policies.

(2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing of network providers.

(c) *Nondiscrimination.* MCO, PIHP, and PAHP network 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.* (1) 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.

(2) [Reserved]

(e) *State requirements.* Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

§ 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.

§ 438.228 Grievance and appeal systems.

(a) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP has in effect a grievance and appeal system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO, PIHP, or PAHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO, PIHP, or PAHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

(a) *Applicability*. The requirements of this section apply to any contract or written arrangement that an MCO, PIHP, PAHP, or PCCM entity has with any subcontractor.

(b) *General rule*. The State must ensure, through its contracts with MCOs, PIHPs, PAHPs, and PCCM entities that—

(1) Notwithstanding any relationship(s) that the MCO, PIHP, PAHP, or PCCM entity may have with any subcontractor, the MCO, PIHP, PAHP, or PCCM entity maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the State; and

(2) All contracts or written arrangements between the MCO, PIHP, PAHP, or PCCM entity and any subcontractor must meet the requirements of paragraph (c) of this section.

(c) Each contract or written arrangement described in paragraph (b)(2) of this section must specify that:

(1) If any of the MCO's, PIHP's, PAHP's, or PCCM entity's activities or obligations under its contract with the State are delegated to a subcontractor—

(i) The delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement.

(ii) The subcontractor agrees to perform the delegated activities and reporting responsibilities specified in compliance with the MCO's, PIHP's, PAHP's, or PCCM entity's contract obligations.

(iii) The contract or written arrangement must either provide for revocation of the delegation of activities or obligations, or specify other remedies in instances where the State or the MCO, PIHP, PAHP, or PCCM entity determine that the subcontractor has not performed satisfactorily.

(2) The subcontractor agrees to comply with all applicable Medicaid laws, regulations, including applicable subregulatory guidance and contract provisions;

(3) The subcontractor agrees that—

(i) The State, CMS, the HHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, records, contracts, computer or other electronic systems of the subcontractor, or of the subcontractor's contractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the MCO's, PIHP's, or PAHP's contract with the State.

(ii) The subcontractor will make available, for purposes of an audit, evaluation, or inspection under paragraph (c)(3)(i) of this section, its premises, physical facilities, equipment, books, records, contracts, computer or other electronic systems relating to its Medicaid enrollees.

(iii) The right to audit under paragraph (c)(3)(i) of this section will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(iv) If the State, CMS, or the HHS Inspector General determines that there is a reasonable possibility of fraud or similar risk, the State, CMS, or the HHS Inspector General may inspect, evaluate, and audit the subcontractor at any time.

(d) *Applicability date*. This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.230 contained in the 42

CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.236 Practice guidelines.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, 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 providers in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with network providers.

(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.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72841, Nov. 13, 2020]

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts that each MCO, PIHP, and PAHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this part. The systems must provide information on areas including, but not limited to, utilization, claims, 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, PIHP, and PAHP comply with the following:

(1) Section 6504(a) of the Affordable Care Act, which requires that State claims processing and retrieval systems are able to collect data elements necessary to enable the mechanized claims processing and information retrieval systems in operation by the State to meet the requirements of section 1903(r)(1)(F) of the Act.

(2) Collect data on enrollee and provider characteristics as specified by the State, and on all services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

(3) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data, including data from network providers the MCO, PIHP, or PAHP is compensating on the basis of capitation payments.

(ii) Screening the data for completeness, logic, and consistency.

(iii) Collecting data from providers in standardized formats to the extent feasible and appropriate, including secure information exchanges and technologies utilized for State Medicaid quality improvement and care coordination efforts.

(4) Make all collected data available to the State and upon request to CMS.

(5) Implement an Application Programming Interface (API) as specified in § 431.60 of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP and include—

(i) All encounter data, including encounter data from any network providers the MCO, PIHP, or PAHP is compensating on the basis of capitation payments and adjudicated claims and encounter data from any subcontractors.

(ii) [Reserved]

(6) Implement, by January 1, 2021, and maintain a publicly accessible standards-based API described in § 431.70, which must include all information specified in § 438.10(h)(1) and (2) of this chapter.

(c) *Enrollee encounter data.* Contracts between a State and a MCO, PIHP, or PAHP must provide for:

(1) Collection and maintenance of sufficient enrollee encounter data to identify the provider who delivers any item(s) or service(s) to enrollees.

(2) Submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS

and the State, based on program administration, oversight, and program integrity needs.

(3) Submission of all enrollee encounter data, including allowed amount and paid amount, that the State is required to report to CMS under §438.818.

(4) Specifications for submitting encounter data to the State in standardized ASC X12N 837 and NCPDP formats, and the ASC X12N 835 format as appropriate.

(d) *State review and validation of encounter data*. The State must review and validate that the encounter data collected, maintained, and submitted to the State by the MCO, PIHP, or PAHP, meets the requirements of this section. The State must have procedures and quality assurance protocols to ensure that enrollee encounter data submitted under paragraph (c) of this section is a complete and accurate representation of the services provided to the enrollees under the contract between the State and the MCO, PIHP, or PAHP.

(e) *Applicability date*. This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with §438.242 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 85 FR 25635, May 1, 2020; 85 FR 72841, Nov. 13, 2020]

Subpart E—Quality Measurement and Improvement; External Quality Review

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§438.310 Basis, scope, and applicability.

(a) *Statutory basis*. This subpart is based on sections 1932(c), 1903(a)(3)(C)(ii), 1902(a)(4), and 1902(a)(19) of the Act.

(b) *Scope*. This subpart sets forth:

(1) Specifications for a quality assessment and performance improvement program that States must require each contracting MCO, PIHP, and PAHP to implement and maintain.

(2) Requirements for the State review of the accreditation status of all contracting MCOs, PIHPs, and PAHPs.

(3) Specifications for a Medicaid managed care quality rating system for all States contracting with MCOs, PIHPs, and PAHPs.

(4) Specifications for a Medicaid managed care quality strategy that States contracting with MCOs, PIHPs, PAHPs, and PCCM entities (described in paragraph (c)(2) of this section) must implement to ensure the delivery of quality health care.

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, PAHP and PCCM entity (described in paragraph (c)(2) of this section) including—

(i) Criteria that States must use in selecting entities to perform the reviews.

(ii) Specifications for the activities related to external quality review.

(iii) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews.

(iv) Requirements for making the results of the reviews publicly available.

(c) *Applicability*. (1) The provisions of this subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid.

(2) The provisions of §438.330(b)(2), (b)(3), (c), and (e), §438.340, and §438.350 apply to States contracting with PCCM entities whose contracts with the State provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes.

(d) *Applicability dates*. States will not be held out of compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015:

(1) States must comply with §438.330 and §438.332 no later than the rating period for contracts beginning on or after July 1, 2017.

(2) States must comply with §§438.340, 438.350, 438.354, 438.356, 438.358,

438.360, 438.362, and 438.364 no later than July 1, 2018.

§ 438.320 Definitions.

As used in this subpart—

Access, as it pertains to external quality review, means the timely use of services to achieve optimal outcomes, as evidenced by managed care plans successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under § 438.68 (Network adequacy standards) and § 438.206 (Availability of services).

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, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or their contractors furnish to Medicaid beneficiaries.

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.

Health care services means all Medicaid services provided by an MCO, PIHP, or PAHP under contract with the State Medicaid agency in any setting, including but not limited to medical care, behavioral health care, and long-term services and supports.

Outcomes means changes in patient health, functional status, satisfaction or goal achievement that result from health care or supportive services.

Quality, as it pertains to external quality review, means the degree to which an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) increases the likelihood of desired outcomes of its enrollees through:

(1) Its structural and operational characteristics.

(2) The provision of services that are consistent with current professional, evidenced-based-knowledge.

(3) Interventions for performance improvement.

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.

§ 438.330 Quality assessment and performance improvement program.

(a) *General rules*. (1) The State must require, through its contracts, that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees that includes the elements identified in paragraph (b) of this section.

(2) After consulting with States and other stakeholders and providing public notice and opportunity to comment, CMS may specify performance measures and PIPs, which must be included in the standard measures identified and PIPs required by the State in accordance with paragraphs (c) and (d) of this section. A State may request an exemption from including the performance measures or PIPs established under paragraph (a)(2) of this section, by submitting a written request to CMS explaining the basis for such request.

(3) The State must require, through its contracts, that each PCCM entity described in § 438.310(c)(2) establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees which incorporates, at a minimum, paragraphs (b)(2) and (3) of this section and the performance measures identified by the State per paragraph (c) of this section.

(b) *Basic elements of quality assessment and performance improvement programs*. The comprehensive quality assessment

and performance improvement program described in paragraph (a) of this section must include at least the following elements:

(1) Performance improvement projects in accordance with paragraph (d) of this section.

(2) Collection and submission of performance measurement data in accordance with paragraph (c) of this section.

(3) Mechanisms to detect both underutilization and overutilization of services.

(4) Mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the State in the quality strategy under § 438.340.

(5) For MCOs, PIHPs, or PAHPs providing long-term services and supports:

(i) Mechanisms to assess the quality and appropriateness of care furnished to enrollees using long-term services and supports, including assessment of care between care settings and a comparison of services and supports received with those set forth in the enrollee's treatment/service plan, if applicable; and

(ii) Participate in efforts by the State to prevent, detect, and remediate critical incidents (consistent with assuring beneficiary health and welfare per §§ 441.302 and 441.730(a) of this chapter) that are based, at a minimum, on the requirements on the State for home and community-based waiver programs per § 441.302(h) of this chapter.

(c) *Performance measurement.* The State must—

(1)(i) Identify standard performance measures, including those performance measures that may be specified by CMS under paragraph (a)(2) of this section, relating to the performance of MCOs, PIHPs, and PAHPs; and

(ii) In addition to the measures specified in paragraph (c)(1)(i) of this section, in the case of an MCO, PIHP, or PAHP providing long-term services and supports, identify standard performance measures relating to quality of life, rebalancing, and community integration activities for individuals receiving long-term services and supports.

(2) Require that each MCO, PIHP, and PAHP annually—

(i) Measure and report to the State on its performance, using the standard measures required by the State in paragraph (c)(1) of this section;

(ii) Submit to the State data, specified by the State, which enables the State to calculate the MCO's, PIHP's, or PAHP's performance using the standard measures identified by the State under paragraph (c)(1) of this section; or

(iii) Perform a combination of the activities described in paragraphs (c)(2)(i) and (ii) of this section.

(d) *Performance improvement projects.* (1) The State must require that MCOs, PIHPs, and PAHPs conduct performance improvement projects, including any performance improvement projects required by CMS in accordance with paragraph (a)(2) of this section, that focus on both clinical and nonclinical areas.

(2) Each performance improvement project must be designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction, and must include the following elements:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of interventions to achieve improvement in the access to and quality of care.

(iii) Evaluation of the effectiveness of the interventions based on the performance measures in paragraph (d)(2)(i) of this section.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(3) The State must require each MCO, PIHP, and PAHP to report the status and results of each project conducted per paragraph (d)(1) of this section to the State as requested, but not less than once per year.

(4) The State may permit an MCO, PIHP, or PAHP exclusively serving dual eligibles to substitute an MA Organization quality improvement project conducted under § 422.152(d) of this chapter for one or more of the performance improvement projects otherwise required under this section.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of the quality assessment and performance

improvement program of each MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2). The review must include—

(i) The MCO's, PIHP's, PAHP's, and PCCM entity's performance on the measures on which it is required to report.

(ii) The outcomes and trended results of each MCO's, PIHP's, and PAHP's performance improvement projects.

(iii) The results of any efforts by the MCO, PIHP, or PAHP to support community integration for enrollees using long-term services and supports.

(2) The State may require that an MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2) develop a process to evaluate the impact and effectiveness of its own quality assessment and performance improvement program.

§ 438.332 State review of the accreditation status of MCOs, PIHPs, and PAHPs.

(a) The State must require, through its contracts, that each MCO, PIHP, and PAHP inform the State whether it has been accredited by a private independent accrediting entity.

(b) The State must require, through its contracts, that each MCO, PIHP, and PAHP that has received accreditation by a private independent accrediting entity must authorize the private independent accrediting entity to provide the State a copy of its most recent accreditation review, including:

(1) Accreditation status, survey type, and level (as applicable);

(2) Accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings; and

(3) Expiration date of the accreditation.

(c) The State must—

(1) Make the accreditation status for each contracted MCO, PIHP, and PAHP available on the Web site required under § 438.10(c)(3), including whether each MCO, PIHP, and PAHP has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level; and

(2) Update this information at least annually.

§ 438.334 Medicaid managed care quality rating system.

(a) *General rule.* Each State contracting with an MCO, PIHP or PAHP to furnish services to Medicaid beneficiaries must—

(1) Adopt the Medicaid managed care quality rating system developed by CMS in accordance with paragraph (b) of this section; or

(2) Adopt an alternative Medicaid managed care quality rating system in accordance with paragraph (c) of this section.

(3) Implement such Medicaid managed care quality rating system within 3 years of the date of a final notice published in the FEDERAL REGISTER.

(b) *Quality rating system.* (1) CMS, after consulting with States and other stakeholders and providing public notice and opportunity to comment, will develop a framework for a Medicaid managed care quality rating system (QRS), including the identification of the performance measures, a subset of mandatory performance measures, and a methodology, that aligns where appropriate with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the Medicare Advantage 5-Star Rating System described in subpart D of part 422 of this chapter, and other related CMS quality rating approaches.

(2) CMS, after consulting with States and other stakeholders and providing public notice and opportunity to comment, may periodically update the Medicaid managed care QRS framework developed in accordance with paragraph (b)(1) of this section.

(c) *Alternative quality rating system.*

(1) A state may implement an alternative Medicaid managed care quality rating system that utilizes different performance measures or applies a different methodology from that described in paragraph (b) of this section provided that—

(i) The alternative quality rating system includes the mandatory measures identified in the framework developed under paragraph (b) of this section;

(ii) The ratings generated by the alternative quality rating system yield information regarding MCO, PIHP, and PAHP performance which is substantially comparable to that yielded by

the framework developed under paragraph (b) of this section to the extent feasible, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

(iii) The State receives CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

(2) Prior to submitting a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS, the State must—

(i) Obtain input from the State's Medical Care Advisory Committee established under § 431.12 of this chapter; and

(ii) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(3) In requesting CMS approval, the State must include the following:

(i) The alternative quality rating system framework, including the performance measures and methodology to be used in generating plan ratings; and,

(ii) Documentation of the public comment process specified in paragraphs (c)(2)(i) and (ii) of this section, including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must document any policy revisions or modifications made in response to the comments and rationale for comments not accepted; and,

(iii) Other information specified by CMS to demonstrate compliance with paragraph (c) of this section.

(4) The Secretary, after consulting with States and other stakeholders, shall issue guidance which describes the criteria and process for determining if an alternative QRS system is substantially comparable to the Medicaid managed care quality rating system in paragraph (b) of this section.

(d) *Quality ratings.* Each year, the State must collect data from each MCO, PIHP, and PAHP with which it contracts and issue an annual quality rating for each MCO, PIHP, and PAHP based on the data collected, using the Medicaid managed care quality rating system adopted under this section.

(e) *Availability of information.* The State must prominently display the quality rating given by the State to each MCO, PIHP, or PAHP under paragraph (d) of this section on the Web site required under § 438.10(c)(3) in a manner that complies with the standards in § 438.10(d).

[81 FR 27853, May 6, 2016, as amended at 85 FR 72841, Nov. 13, 2020]

§ 438.340 Managed care State quality strategy.

(a) *General rule.* Each State contracting with an MCO, PIHP, or PAHP as defined in § 438.2 or with a PCCM entity as described in § 438.310(c)(2) must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, PAHP or PCCM entity.

(b) *Elements of the State quality strategy.* At a minimum, the State's quality strategy must include the following:

(1) The State-defined network adequacy and availability of services standards for MCOs, PIHPs, and PAHPs required by §§ 438.68 and 438.206 and examples of evidence-based clinical practice guidelines the State requires in accordance with § 438.236.

(2) The State's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2).

(3) A description of—

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2) with which the State contracts, including but not limited to, the performance measures reported in accordance with § 438.330(c). The State must identify which quality measures and performance outcomes the State will publish at least annually on the website required under § 438.10(c)(3); and,

(ii) The performance improvement projects to be implemented in accordance with § 438.330(d), including a description of any interventions the

State proposes to improve access, quality, or timeliness of care for beneficiaries enrolled in an MCO, PIHP, or PAHP.

(4) Arrangements for annual, external independent reviews, in accordance with § 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)) contract.

(5) A description of the State's transition of care policy required under § 438.62(b)(3).

(6) The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. For purposes of this paragraph (b)(6), ''disability status'' means, at a minimum, whether the individual qualified for Medicaid on the basis of a disability. States must include in this plan the State's definition of disability status and how the State will make the determination that a Medicaid enrollee meets the standard including the data source(s) that the State will use to identify disability status.

(7) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(8) The mechanisms implemented by the State to comply with § 438.208(c)(1) (relating to the identification of persons who need long-term services and supports or persons with special health care needs).

(9) The information required under § 438.360(c) (relating to nonduplication of EQR activities).

(10) The State's definition of a ''significant change'' for the purposes of paragraph (c)(3)(ii) of this section.

(c) *Development, evaluation, and revision.* In drafting or revising its quality strategy, the State must:

(1) Make the strategy available for public comment before submitting the strategy to CMS for review, including:

(i) Obtaining input from the Medical Care Advisory Committee (established by § 431.12 of this chapter), beneficiaries, and other stakeholders.

(ii) If the State enrolls Indians in the MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2), consulting with Tribes in accordance with the State's Tribal consultation policy.

(2) Review and update the quality strategy as needed, but no less than once every 3 years.

(i) This review must include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years.

(ii) The State must make the results of the review available on the Web site required under § 438.10(c)(3).

(iii) Updates to the quality strategy must take into consideration the recommendations provided pursuant to § 438.364(a)(4).

(3) Submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback prior to adopting it in final.

(ii) A copy of the revised strategy whenever significant changes, as defined in the state's quality strategy per paragraph (b)(11) of this section, are made to the document, or whenever significant changes occur within the State's Medicaid program.

(d) *Availability.* The State must make the final quality strategy available on the Web site required under § 438.10(c)(3).

[81 FR 27853, May 6, 2016, as amended at 85 FR 72841, Nov. 13, 2020]

§ 438.350 External quality review.

Each State that contracts with MCOs, PIHPs, or PAHPs, or with PCCM entities (described in § 438.310(c)(2)) must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, PAHP or PCCM entity (described in § 438.310(c)(2)).

(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 or, if applicable, from a Medicare or private accreditation review as described in § 438.360.

(d) For each EQR-related activity, the information gathered for use in the EQR must include the elements described in § 438.364(a)(2)(i) through (iv).

(e) The information provided to the EQRO in accordance with paragraph (b) of this section is obtained through

methods consistent with the protocols established by the Secretary in accordance with § 438.352.

(f) The results of the reviews are made available as specified in § 438.364.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017]

§ 438.352 External quality review protocols.

The Secretary, in coordination with the National Governor's Association, must develop protocols for the external quality reviews required under this subpart. Each protocol issued by the Secretary 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 beneficiaries, 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 must be independent from the State Medicaid agency and from the MCOs, PIHPs, PAHPs, or PCCM entities (described in § 438.310(c)(2)) that they review. To qualify as ''independent''—

(1) If a State agency, department, university, or other State entity:

(i) May not have Medicaid purchasing or managed care licensing authority; and

(ii) Must be governed by a Board or similar body the majority of whose members are not government employees.

(2) An EQRO may not:

(i) Review any MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or a competitor operating in the State, over which the EQRO exerts control or which exerts control over the EQRO (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 beneficiaries;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) services, except for the related activities specified in § 438.358;

(iv) Review any MCO, PIHP, PAHP or PCCM entity (described in § 438.310(c)(2)) for which it is conducting or has conducted an accreditation review within the previous 3 years; or

(v) Have a present, or known future, direct or indirect financial relationship with an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) that it will review as an EQRO.

§ 438.356 State contract options for external quality review.

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities.

(2) May contract with additional EQROs or other entities 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 with an EQRO described in paragraph (a) of this section, the State must follow an open, competitive procurement process that is in accordance with State law and regulations. In addition, the State must comply with 45 CFR part 75 as it applies to State procurement of Medicaid services.

§ 438.358 Activities related to external quality review.

(a) *General rule.* (1) The State, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(2) The data obtained from the mandatory and optional EQR-related activities in this section must be used for the annual EQR in § 438.350 and must include, at a minimum, the elements in § 438.364(a)(2)(i) through (iv).

(b) *Mandatory activities.* (1) For each MCO, PIHP, or PAHP the following EQR-related activities must be performed:

(i) Validation of performance improvement projects required in accordance with § 438.330(b)(1) that were underway during the preceding 12 months.

(ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with § 438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the preceding 12 months.

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D of this part, the disenrollment requirements and limitations described in § 438.56, the enrollee rights requirements described in § 438.100, the emergency and post-stabilization services requirements described in § 438.114, and the quality assessment and performance improvement requirements described in § 438.330.

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months to comply with requirements set forth in § 438.68 and, if the State enrolls Indians in the MCO, PIHP, or PAHP, § 438.14(b)(1).

(2) For each PCCM entity (described in § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section must be performed.

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed by using information derived during the preceding 12 months:

(1) Validation of encounter data reported by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)).

(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, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) and validated by an EQRO in accordance with paragraph (b)(1)(ii) of this section.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) and validated by an EQRO in accordance with paragraph (b)(1)(i) of this section.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with § 438.334.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs, PIHPs, PAHPs, or PCCM entities (described in § 438.310(c)(2)) to assist them in conducting activities related to the

mandatory and optional activities described in this section that provide information for the EQR and the resulting EQR technical report.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 82 FR 12510, Mar. 6, 2017; 85 FR 72841, Nov. 13, 2020]

§ 438.360 Nonduplication of mandatory activities with Medicare or accreditation review.

(a) *General rule.* Consistent with guidance issued by the Secretary under § 438.352, to avoid duplication the State may use information from a Medicare or private accreditation review of an MCO, PIHP, or PAHP to provide information for the annual EQR (described in § 438.350) instead of conducting one or more of the EQR activities described in § 438.358(b)(1)(i) through (iii) (relating to the validation of performance improvement projects, validation of performance measures, and compliance review) if the following conditions are met:

(1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in § 422.158 of this chapter;

(2) The Medicare or private accreditation review standards are comparable to standards established through the EQR protocols (§ 438.352) for the EQR activities described in § 438.358(b)(1)(i) through (iii); and

(3) The MCO, PIHP, or PAHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review activities applicable to the standards for the EQR activities.

(b) *External quality review report.* If the State uses information from a Medicare or private accreditation review in accordance with paragraph (a) of this section, the State must ensure that all such information is furnished to the EQRO for analysis and inclusion in the report described in § 438.364(a).

(c) *Quality strategy.* The State must identify in its quality strategy under § 438.340 the EQR activities for which it has exercised the option described in this section, and explain the rationale for the State's determination that the Medicare review or private accreditation activity is comparable to such EQR activities, consistent with paragraph (a)(2) of this section.

§ 438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO from EQR if the following conditions are met:

(1) The MCO 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 has been subject to EQR under this part, and found to be performing acceptably for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries.

(b) *Information on exempted MCOs.* 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 that it exempts from EQR the most recent Medicare review findings reported on the MCO including—

(i) All data, correspondence, information, and findings pertaining to the MCO'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 performance.

(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 Advantage Organization deeming.* (i) If an exempted MCO has been reviewed by a private accrediting organization,

the State must require the MCO 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.

(c) *Identification of exempted MCOs.* The State must annually identify, on the website required under § 438.10(c)(3) and in the same location where the EQR technical reports are posted in accordance with § 438.364(c)(2)(i), the names of the MCOs exempt from external quality review by the State, including the beginning date of the current exemption period, or that no MCOs are exempt, as appropriate.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020]

§ 438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR results in an annual detailed technical report that summarizes findings on access and quality of care, including:

(1) A description of 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, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)).

(2) For each EQR-related activity conducted in accordance with § 438.358:

(i) Objectives;

(ii) Technical methods of data collection and analysis;

(iii) Description of data obtained, including validated performance measurement data for each activity conducted in accordance with § 438.358(b)(1)(i) and (ii); and

(iv) Conclusions drawn from the data.

(3) An assessment of each MCO's, PIHP's, PAHP's, or PCCM entity's (described in § 438.310(c)(2)) strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) including how the State can target goals and objectives in the quality strategy, under § 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(5) Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities (described in § 438.310(c)(2)), consistent with guidance included in the EQR protocols issued in accordance with § 438.352(e).

(6) An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(7) The names of the MCOs exempt from external quality review by the State, including the beginning date of the current exemption period, or that no MCOs are exempt, as appropriate.

(b) *Revision.* States may not substantively revise the content of the final EQR technical report without evidence of error or omission.

(c) *Availability of information.* (1) The State must contract with a qualified EQRO to produce and submit to the State an annual EQR technical report in accordance with paragraph (a) of this section. The State must finalize the annual technical report by April 30th of each year.

(2) The State must—

(i) Post the most recent copy of the annual EQR technical report on the Web site required under § 438.10(c)(3) by April 30th of each year.

(ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees

and potential enrollees of the MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)), beneficiary advocacy groups, and members of the general public.

(3) The State must make the information specified in paragraph (a) of this section available in alternative formats for persons with disabilities, when requested.

(d) *Safeguarding patient identity*. The information released under paragraph (c) of this section may not disclose the identity or other protected health information of any patient.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020]

§ 438.370 Federal financial participation (FFP).

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and the EQR-related activities set forth in § 438.358 performed on MCOs and 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, and for EQR (including the production of EQR results) and EQR-related activities performed by an EQRO on entities other than MCOs.

(c) Prior to claiming FFP at the 75 percent rate in accordance with paragraph (a) of this section, the State must submit each EQRO contract to CMS for review and approval.

Subpart F—Grievance and Appeal System

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 438.400 Statutory basis, definitions, and applicability.

(a) *Statutory basis*. This subpart is based on the following statutory sections:

(1) Section 1902(a)(3) of the Act 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) of the Act 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) of the Act 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.

(4) Section 1859(f)(8)(B) of the Act requires that the Secretary, to the extent feasible, establish procedures unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for items and services provided, by specialized Medicare Advantage plans for special needs individuals described in section 1859(b)(6)(B)(ii), under Titles XVIII and XIX of the Act.

(b) *Definitions*. As used in this subpart, the following terms have the indicated meanings:

Adverse benefit determination means, in the case of an MCO, PIHP, or PAHP, any of the following:

(1) The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit.

(2) The reduction, suspension, or termination of a previously authorized service.

(3) The denial, in whole or in part, of payment for a service. A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a ''clean claim'' at § 447.45(b) of this chapter is not an adverse benefit determination.

(4) The failure to provide services in a timely manner, as defined by the State.

(5) The failure of an MCO, PIHP, or PAHP to act within the timeframes provided in § 438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals.

(6) For a resident of a rural area with only one MCO, the denial of an enrollee's request to exercise his or her right, under § 438.52(b)(2)(ii), to obtain services outside the network.

(7) The denial of an enrollee's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other enrollee financial liabilities.

Appeal means a review by an MCO, PIHP, or PAHP of an adverse benefit determination.

Grievance means an expression of dissatisfaction about any matter other than an adverse benefit determination. Grievances may 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 regardless of whether remedial action is requested. Grievance includes an enrollee's right to dispute an extension of time proposed by the MCO, PIHP or PAHP to make an authorization decision.

Grievance and appeal system means the processes the MCO, PIHP, or PAHP implements to handle appeals of an adverse benefit determination and grievances, as well as the processes to collect and track information about them.

State fair hearing means the process set forth in subpart E of part 431 of this chapter.

(c) *Applicability*. (1) Subject to paragraph (c)(2) of this section, this subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this part affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

[81 FR 27853, May 6, 2016, as amended at 84 FR 15844, Apr. 16, 2019; 85 FR 72842, Nov. 13, 2020]

§ 438.402 General requirements.

(a) *The grievance and appeal system*. Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to this subpart F. For grievances and appeals at the plan level, an applicable integrated plan as defined in § 422.561 of this chapter is not subject to this subpart F, and is instead subject to the requirements of §§ 422.629 through 422.634 of this chapter. For appeals of integrated reconsiderations, applicable integrated plans are subject to § 438.408(f).

(b) *Level of appeals*. Each MCO, PIHP, and PAHP may have only one level of appeal for enrollees.

(c) *Filing requirements*—(1) *Authority to file*. (i) An enrollee may file a grievance and request an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State fair hearing after receiving notice under § 438.408 that the adverse benefit determination is upheld.

(A) *Deemed exhaustion of appeals processes*. In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(B) *External medical review*. The State may offer and arrange for an external medical review if the following conditions are met.

(*1*) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(*2*) The review must be independent of both the State and MCO, PIHP, or PAHP.

(*3*) The review must be offered without any cost to the enrollee.

(*4*) The review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420.

(ii) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of an enrollee. When the term ''enrollee'' is used throughout subpart F of this part, it includes providers and authorized representatives consistent with this paragraph, with the exception that providers cannot request continuation of benefits as specified in § 438.420(b)(5).

(2) *Timing*—(i) *Grievance*. An enrollee may file a grievance with the MCO, PIHP, or PAHP at any time.

(ii) *Appeal*. Following receipt of a notification of an adverse benefit determination by an MCO, PIHP, or PAHP, an enrollee has 60 calendar days from the date on the adverse benefit determination notice in which to file a request for an appeal to the managed care plan.

(3) *Procedures*—(i) *Grievance*. 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, PIHP, or PAHP.

(ii) *Appeal*. The enrollee may request an appeal either orally or in writing.

[81 FR 27853, May 6, 2016, as amended at 84 FR 15844, Apr. 16, 2019; 85 FR 72842, Nov. 13, 2020]

§ 438.404 Timely and adequate notice of adverse benefit determination.

(a) *Notice*. The MCO, PIHP, or PAHP must give enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below and in § 438.10.

(b) *Content of notice*. The notice must explain the following:

(1) The adverse benefit determination the MCO, PIHP, or PAHP has made or intends to make.

(2) The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

(3) The enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal described at § 438.402(b) and the right to request a State fair hearing consistent with § 438.402(c).

(4) The procedures for exercising the rights specified in this paragraph (b).

(5) The circumstances under which an appeal process can be expedited and how to request it.

(6) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances, consistent with state policy, under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice*. The MCO, PIHP, or PAHP 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, PIHP, or PAHP meets the criteria set forth for extending the timeframe for standard service authorization decisions consistent with § 438.210(d)(1)(ii), 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 benefit determination), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d)(2).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements*. In handling grievances and appeals, each MCO, PIHP, and PAHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(b) *Special requirements*. An MCO's, PIHP's or PAHP's process for handling

enrollee grievances and appeals of adverse benefit determinations must:

(1) Acknowledge receipt of each grievance and appeal.

(2) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) Who, if deciding any of the following, are individuals 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.

(iii) Who take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination.

(3) Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals.

(4) Provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments. The MCO, PIHP, or PAHP must inform the enrollee of the limited time available for this sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c) in the case of expedited resolution.

(5) Provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the MCO, PIHP or PAHP (or at the direction of the MCO, PIHP or PAHP) in connection with the appeal of the adverse benefit determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c).

(6) 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.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020]

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* Each MCO, PIHP, or PAHP must resolve each grievance and 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 resolution of grievances.* For standard resolution of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 calendar days from the day the MCO, PIHP, or PAHP 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 30 calendar days from the day the MCO, PIHP, or PAHP 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 72 hours after the MCO, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes.* (1) The MCO, PIHP, or PAHP 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, PIHP, or PAHP 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, PIHP, or PAHP extends the timeframes not at the request of the enrollee, it must complete all of the following:

(i) Make reasonable efforts to give the enrollee prompt oral notice of the delay.

(ii) Within 2 calendar days 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.

(iii) Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(3) *Deemed exhaustion of appeals processes*. In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(d) *Format of notice*—(1) *Grievances*. The State must establish the method that an MCO, PIHP, and PAHP will use to notify an enrollee of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 438.10.

(2) *Appeals*. (i) For all appeals, the MCO, PIHP, or PAHP must provide written notice of resolution in a format and language that, at a minimum, meet the standards described at § 438.10.

(ii) For notice of an expedited resolution, the MCO, PIHP, or PAHP 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 and receive benefits while the hearing is pending, and how to make the request.

(iii) That the enrollee may, consistent with state policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination.

(f) *Requirements for State fair hearings*—(1) *Availability*. An enrollee may request a State fair hearing only after receiving notice that the MCO, PIHP, or PAHP is upholding the adverse benefit determination.

(i) *Deemed exhaustion of appeals processes*. In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(ii) *External medical review*. The State may offer and arrange for an external medical review if the following conditions are met.

(A) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(B) The review must be independent of both the State and MCO, PIHP, or PAHP.

(C) The review must be offered without any cost to the enrollee.

(D) The review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420.

(2) *State fair hearing*. The enrollee must have no less than 90 calendar days and no more than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution to request a State fair hearing.

(3) *Parties*. The parties to the State fair hearing include the MCO, PIHP, or PAHP, as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020]

§ 438.410 Expedited resolution of appeals.

(a) *General rule*. Each MCO, PIHP, and PAHP must establish and maintain an expedited review process for appeals, when the MCO, PIHP, or PAHP 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, physical or mental health, or ability to attain, maintain, or regain maximum function.

(b) *Punitive action*. The MCO, PIHP, or PAHP must ensure that punitive action is not 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, PIHP, or PAHP 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) Follow the requirements in § 438.408(c)(2).

§ 438.414 Information about the grievance and appeal system to providers and subcontractors.

The MCO, PIHP, or PAHP must provide information specified in § 438.10(g)(2)(xi) about the grievance and appeal system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping requirements.

(a) The State must require MCOs, PIHPs, and PAHPs to maintain records of grievances and appeals and must review the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(b) The record of each grievance or appeal must contain, at a minimum, all of the following information:

(1) A general description of the reason for the appeal or grievance.

(2) The date received.

(3) The date of each review or, if applicable, review meeting.

(4) Resolution at each level of the appeal or grievance, if applicable.

(5) Date of resolution at each level, if applicable.

(6) Name of the covered person for whom the appeal or grievance was filed.

(c) The record must be accurately maintained in a manner accessible to the state and available upon request to CMS.

§ 438.420 Continuation of benefits while the MCO, PIHP, or PAHP appeal and the State fair hearing are pending.

(a) *Definition.* As used in this section—

Timely files means files for continuation of benefits on or before the later of the following:

(i) Within 10 calendar days of the MCO, PIHP, or PAHP sending the notice of adverse benefit determination.

(ii) The intended effective date of the MCO's, PIHP's, or PAHP's proposed adverse benefit determination.

(b) *Continuation of benefits.* The MCO, PIHP, or PAHP must continue the enrollee's benefits if all of the following occur:

(1) The enrollee files the request for an appeal timely in accordance with § 438.402(c)(1)(ii) and (c)(2)(ii);

(2) The appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the MCO, PIHP, or PAHP continues or reinstates the enrollee's benefits while the appeal or state fair hearing is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal or request for state fair hearing.

(2) The enrollee fails to request a state fair hearing and continuation of benefits within 10 calendar days after the MCO, PIHP, or PAHP sends the notice of an adverse resolution to the enrollee's appeal under § 438.408(d)(2).

(3) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Enrollee responsibility for services furnished while the appeal or state fair hearing is pending.* If the final resolution of the appeal or state fair hearing is adverse to the enrollee, that is, upholds the MCO's, PIHP's, or PAHP's adverse benefit determination, the MCO, PIHP, or PAHP may, consistent with the state's usual policy on recoveries under § 431.230(b) of this chapter and as specified in the MCO's, PIHP's, or PAHP's contract, recover the cost of services furnished to the enrollee while the appeal and state fair hearing was pending, to the extent that they were furnished solely because of the requirements of this section.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, 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, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(b) *Services furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, 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, PIHP, or PAHP, or the State must pay for those services, in accordance with State policy and regulations.

Subpart G [Reserved]

Subpart H—Additional Program Integrity Safeguards

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 438.600 Statutory basis, basic rule, and applicability.

(a) *Statutory basis.* This subpart is based on the following statutory sections:

(1) Section 1128 of the Act provides for the exclusion of certain individuals and entities from participation in the Medicaid program.

(2) Section 1128J(d) of the Act requires that persons who have received an overpayment under Medicaid report and return the overpayment within 60 days after the date on which the overpayment was identified.

(3) Section 1902(a)(4) of the Act requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(4) Section 1902(a)(19) of the Act 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 beneficiaries.

(5) Section 1902(a)(27) of the Act requires States to enroll persons or institutions that provide services under the State plan.

(6) Section 1902(a)(68) of the Act requires that any entity that receives or makes annual payments under the State plan of at least $5,000,000 must establish certain minimum written policies relating to the Federal False Claims Act.

(7) Section 1902(a)(77) of the Act requires that States comply with provider and supplier screening, oversight, and reporting requirements described in section 1902(kk)(1) of the Act.

(8) Section 1902(a)(80) of the Act prohibits payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States.

(9) Section 1902(kk)(7) of the Act requires States to enroll physicians or other professionals that order or refer services under the State plan.

(10) Section 1903(i) of the Act prohibits FFP for amounts expended by MCOs or PCCMs for providers excluded by Medicare, Medicaid, or CHIP, except for emergency services.

(11) Section 1903(m) of the Act establishes conditions for payments to the State for contracts with MCOs.

(12) Section 1932(d)(1) of the Act prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals and entities debarred under Federal regulations from participating in specified activities, or with affiliates of those individuals.

(b) *Basic rule.* As a condition for receiving payment under a Medicaid managed care program, an MCO, PIHP, PAHP, PCCM or PCCM entity must comply with the requirements in §§ 438.604, 438.606, 438.608 and 438.610, as applicable.

(c) *Applicability.* States will not be held out compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the CFR, parts 430 to 481, edition revised as of October 1, 2015:

(1) States must comply with §§ 438.602(a), 438.602(c) through (h), 438.604, 438.606, 438.608(a), and 438.608(c) and (d), no later than the rating period for contracts starting on or after July 1, 2017.

(2) States must comply with § 438.602(b) and § 438.608(b) no later than the rating period for contracts beginning on or after July 1, 2018.

§ 438.602 State responsibilities.

(a) *Monitoring contractor compliance.* Consistent with § 438.66, the State must monitor the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's compliance, as applicable, with §§ 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808.

(b) *Screening and enrollment and revalidation of providers.* (1) The State must screen and enroll, and periodically revalidate, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E of this chapter. This requirement extends to PCCMs and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries. This provision does not require the network provider to render services to FFS beneficiaries.

(2) MCOs, PIHPs, and PAHPs may execute network provider agreements pending the outcome of the process in paragraph (b)(1) of this section of up to 120 days, but must terminate a network provider immediately upon notification from the State that the network provider cannot be enrolled, or the expiration of one 120 day period without enrollment of the provider, and notify affected enrollees.

(c) *Ownership and control information.* The State must review the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM or PCCM entity, and any subcontractors as required in § 438.608(c).

(d) *Federal database checks.* Consistent with the requirements at § 455.436 of this chapter, the State must confirm the identity and determine the exclusion status of the MCO, PIHP, PAHP, PCCM or PCCM entity, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the MCO, PIHP, PAHP, PCCM or PCCM entity through routine checks of Federal databases. This includes the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the System for Award Management (SAM), and any other databases as the State or Secretary may prescribe. These databases must be consulted upon contracting and no less frequently than monthly thereafter. If the State finds a party that is excluded, it must promptly notify the MCO, PIHP, PAHP, PCCM, or PCCM entity and take action consistent with § 438.610(c).

(e) *Periodic audits.* The State must periodically, but no less frequently than once every 3 years, conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP or PAHP.

(f) *Whistleblowers.* The State must receive and investigate information from whistleblowers relating to the integrity of the MCO, PIHP, PAHP, PCCM, or PCCM entity, subcontractors, or network providers receiving Federal funds under this part.

(g) *Transparency.* The State must post on its Web site, as required in § 438.10(c)(3), the following documents and reports:

(1) The MCO, PIHP, PAHP, or PCCM entity contract.

(2) The data at § 438.604(a)(5).

(3) The name and title of individuals included in § 438.604(a)(6).

(4) The results of any audits under paragraph (e) of this section.

(h) *Contracting integrity.* The State must have in place conflict of interest safeguards described in § 438.58 and must comply with the requirement described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(i) *Entities located outside of the U.S.* The State must ensure that the MCO, PIHP, PAHP, PCCM, or PCCM entity with which the State contracts under this part is not located outside of the United States and that no claims paid

by an MCO, PIHP, or PAHP to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates.

§ 438.604 Data, information, and documentation that must be submitted.

(a) *Specified data, information, and documentation.* The State must require any MCO, PIHP, PAHP, PCCM or PCCM entity to submit to the State the following data:

(1) Encounter data in the form and manner described in § 438.818.

(2) Data on the basis of which the State certifies the actuarial soundness of capitation rates to an MCO, PIHP or PAHP under § 438.4, including base data described in § 438.5(c) that is generated by the MCO, PIHP or PAHP.

(3) Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in § 438.8.

(4) Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under § 438.116.

(5) Documentation described in § 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in § 438.206.

(6) Information on ownership and control described in § 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by § 438.230.

(7) The annual report of overpayment recoveries as required in § 438.608(d)(3).

(b) *Additional data, documentation, or information.* In addition to the data, documentation, or information specified in paragraph (a) of this section, an MCO, PIHP, PAHP, PCCM or PCCM entity must submit any other data, documentation, or information relating to the performance of the entity's obligations under this part required by the State or the Secretary.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017]

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data, documentation, or information specified in § 438.604, the State must require that the data, documentation or information the MCO, PIHP, PAHP, PCCM or PCCM entity submits to the State be certified by either the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's Chief Executive Officer; Chief Financial Officer; or an individual who reports directly to the Chief Executive Officer or Chief Financial Officer with delegated authority to sign for the Chief Executive Officer or Chief Financial Officer so that the Chief Executive Officer or Chief Financial Officer is ultimately responsible for the certification.

(b) *Content of certification.* The certification provided by the individual in paragraph (a) of this section must attest that, based on best information, knowledge, and belief, the data, documentation, and information specified in § 438.604 is accurate, complete, and truthful.

(c) *Timing of certification.* The State must require the MCO, PIHP, PAHP, PCCM, or PCCM entity to submit the certification concurrently with the submission of the data, documentation, or information required in § 438.604(a) and (b).

§ 438.608 Program integrity requirements under the contract.

(a) *Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse.* The State, through its contract with the MCO, PIHP or PAHP, must require that the MCO, PIHP, or PAHP, or subcontractor to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims under the contract between the State and the MCO, PIHP, or PAHP, implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:

(1) A compliance program that includes, at a minimum, all of the following elements:

(i) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and State requirements.

(ii) The designation of a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the Chief Executive Officer and the board of directors.

(iii) The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.

(iv) A system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.

(v) Effective lines of communication between the compliance officer and the organization's employees.

(vi) Enforcement of standards through well-publicized disciplinary guidelines.

(vii) Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract.

(2) Provision for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.

(3) Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including all of the following:

(i) Changes in the enrollee's residence;

(ii) The death of an enrollee.

(4) Provision for notification to the State when it receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the MCO, PIHP or PAHP.

(5) Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis.

(6) In the case of MCOs, PIHPs, or PAHPs that make or receive annual payments under the contract of at least $5,000,000, provision for written policies for all employees of the entity, and of any contractor or agent, that provide detailed information about the False Claims Act and other Federal and State laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers.

(7) Provision for the prompt referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit.

(8) Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the State determines there is a credible allegation of fraud in accordance with § 455.23 of this chapter.

(b) *Provider screening and enrollment requirements.* The State, through its contracts with a MCO, PIHP, PAHP, PCCM, or PCCM entity must ensure that all network providers are enrolled with the State as Medicaid providers consistent with the provider disclosure, screening and enrollment requirements of part 455, subparts B and E of this chapter. This provision does not require the network provider to render services to FFS beneficiaries.

(c) *Disclosures.* The State must ensure, through its contracts, that each

MCO, PIHP, PAHP, PCCM, PCCM entity, and any subcontractors:

(1) Provides written disclosure of any prohibited affiliation under § 438.610.

(2) Provides written disclosures of information on ownership and control required under § 455.104 of this chapter.

(3) Reports to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the contract.

(d) *Treatment of recoveries made by the MCO, PIHP or PAHP of overpayments to providers.* (1) Contracts with a MCO, PIHP, or PAHP must specify:

(i) The retention policies for the treatment of recoveries of all overpayments from the MCO, PIHP, or PAHP to a provider, including specifically the retention policies for the treatment of recoveries of overpayments due to fraud, waste, or abuse.

(ii) The process, timeframes, and documentation required for reporting the recovery of all overpayments.

(iii) The process, timeframes, and documentation required for payment of recoveries of overpayments to the State in situations where the MCO, PIHP, or PAHP is not permitted to retain some or all of the recoveries of overpayments.

(iv) This provision does not apply to any amount of a recovery to be retained under False Claims Act cases or through other investigations.

(2) Each MCO, PIHP, or PAHP requires and has a mechanism for a network provider to report to the MCO, PIHP or PAHP when it has received an overpayment, to return the overpayment to the MCO, PIHP or PAHP within 60 calendar days after the date on which the overpayment was identified, and to notify the MCO, PIHP or PAHP in writing of the reason for the overpayment.

(3) Each MCO, PIHP, or PAHP must report annually to the State on their recoveries of overpayments.

(4) The State must use the results of the information and documentation collected in paragraph (d)(1) of this section and the report in paragraph (d)(3) of this section for setting actuarially sound capitation rates for each MCO, PIHP, or PAHP consistent with the requirements in § 438.4.

§ 438.610 Prohibited affiliations.

(a) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not knowingly have a relationship of the type described in paragraph (c) of this section with the following:

(1) An individual or entity that 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 or entity who is an affiliate, as defined in the Federal Acquisition Regulation at 48 CFR 2.101, of a person described in paragraph (a)(1) of this section.

(b) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not have a relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Act.

(c) The relationships described in paragraph (a) of this section, are as follows:

(1) A director, officer, or partner of the MCO, PIHP, PAHP, PCCM. or PCCM entity.

(2) A subcontractor of the MCO, PIHP, PAHP, PCCM, or PCCM entity, as governed by § 438.230.

(3) A person with beneficial ownership of 5 percent or more of the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's equity.

(4) A network provider or person with an employment, consulting or other arrangement with the MCO, PIHP, PAHP, PCCM, or PCCM entity for the provision of items and services that are significant and material to the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's obligations under its contract with the State.

(d) If a State finds that an MCO, PIHP, PAHP, PCCM, or PCCM entity 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, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliations.

(4) Nothing in this section must be construed to limit or otherwise affect any remedies available to the U.S. under sections 1128, 1128A or 1128B of the Act.

(e) *Consultation with the Inspector General*. Any action by the Secretary described in paragraphs (d)(2) or (3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM or PCCM entity may, establish intermediate sanctions (which may include those 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 that 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 beneficiary, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by beneficiaries 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 that an MCO, PCCM or PCCM entity 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 that—

(1) An MCO has violated any of the other requirements of sections 1903(m) or 1932 of the Act, or any implementing regulations.

(2) A PCCM or PCCM entity has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act, or any implementing regulations.

(3) For any of the violations under paragraphs (d)(1) and (2) of this section, only the sanctions specified in § 438.702(a)(3), (4), and (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 date the Secretary or the State notifies the MCO of a determination of a violation of any requirement under sections 1903(m) or 1932 of the Act.

(5) Suspension of payment for beneficiaries 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*. If the State imposes civil monetary penalties as provided under § 438.702(a)(1), the maximum civil money penalty the State may impose varies depending on the nature of the MCO's, PCCM or PCCM entity's action or failure to act, as provided in this section.

(b) *Specific limits*. (1) The limit is $25,000 for each determination under § 438.700(b)(1), (5), (6), and (c).

(2) The limit is $100,000 for each determination under § 438.700(b)(3) or (4).

(3) The limit is $15,000 for each beneficiary the State determines was not enrolled because of a discriminatory practice under § 438.700(b)(3). (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*. If the State imposes temporary management under § 438.702(a)(2), the State may do so only if it finds (through onsite surveys, enrollee or other complaints, financial status, or any other source) any of the following:

(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.

(2) There is substantial risk to enrollees' health.

(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.

(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 sections 1903(m) or 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, PCCM or PCCM entity contract.

A State has the authority to terminate an MCO, PCCM or PCCM entity contract and enroll that entity's enrollees in other MCOs, PCCMs or PCCM entities, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO, PCCM or PCCM entity has failed to do either of the following:

(a) Carry out the substantive terms of its contract.

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Notice of sanction and pretermination 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 appeal rights that the State elects to provide.

(b) *Pre-termination hearing*—(1) *General rule*. Before terminating an MCO, PCCM or PCCM entity contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures*. The State must do all of the following:

(i) Give the MCO, PCCM or PCCM entity 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.

(iii) For an affirming decision, give enrollees of the MCO, PCCM or PCCM entity 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, PCCM or PCCM entity 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 CMS written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must adhere to all of the following requirements:

(1) Be given no later than 30 days after the State imposes or lifts a sanction.

(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 § 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs.

(a) *Basis for sanction*. A State 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 (6).

(b) *Effect of an agency determination*. (1) The State's determination becomes CMS' determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the State decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS' 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's determination becomes CMS' determination under paragraph (b)(2) of this section, the State takes all of 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.

(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—

(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.

(iii) Forwards the decision to CMS.

(2) The State's decision under paragraph (d)(1)(ii) of this section becomes CMS' 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 decision, the agency sends the MCO a copy of CMS' 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 MCO 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 (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' denial of payment for new enrollees automatically results in a denial of agency payments to the MCO 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 (c) 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) of this section, the sanction is effective on the date specified in CMS' reconsideration notice.

(ii) If CMS, in consultation with the State, 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 (d)(1)(ii) of this section.

(g) *CMS' role.* (1) CMS retains the right to independently perform the functions assigned to the State under paragraphs (a) through (d) of this section.

(2) At the same time that the State sends notice to the MCO under paragraph (c)(1) 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 (FFP)

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§ 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 all of the following apply:

(1) CMS has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (5) of § 438.3.

(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 provisions of 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 or PIHP, PAHP, PCCM, or PCCM entity contracts under a section 1915(b)(1) of the Act waiver 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 or an individual described in § 438.610(a) and (b).

(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 described in § 438.610(a) and (b).

(ii) Any individual or entity that would provide those services through an individual or entity described in § 438.610(a) and (b).

§ 438.810 Expenditures for enrollment broker services.

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

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone, in person, or through electronic methods of communication.

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

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, PCCM entity 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, PCCM entity or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM, PCCM entity, 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.

§ 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 beneficiaries 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.

§ 438.816 Expenditures for the beneficiary support system for enrollees using LTSS.

State expenditures for the person or entity providing the services outlined in § 438.71(d) are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if all of the following conditions are met:

(a) Costs must be supported by an allocation methodology that appears in the State's approved Public Assistance Cost Allocation Plan in § 433.34 of this chapter.

(b) The costs do not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs.

(c) The person or entity providing the services must meet the requirements in § 438.810(b)(1) and (2).

(d) The initial contract or MOA for services performed has been reviewed and approved by CMS.

§ 438.818 Enrollee encounter data.

(a) FFP is available for expenditures under an MCO, PIHP, or PAHP contract only if the State meets the following conditions for providing enrollee encounter data to CMS:

(1) Enrollee encounter data reports must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security and privacy standards and be submitted in the format required by the Medicaid Statistical Information System or format required by any successor system to the Medicaid Statistical Information System.

(2) States must ensure that enrollee encounter data is validated for accuracy and completeness as required under § 438.242 before submitting data to CMS. States must also validate that the data submitted to CMS is a complete and accurate representation of the information submitted to the State by the MCOs, PIHPs, and PAHPs.

(3) States must cooperate with CMS to fully comply with all encounter data reporting requirements of the Medicaid Statistical Information System or any successor system.

(b) CMS will assess a State's submission to determine if it complies with current criteria for accuracy and completeness.

(c) If, after being notified of compliance issues under paragraph (b) of this section the State is unable to make a data submission compliant, CMS will take appropriate steps to defer and/or disallow FFP on all or part of an MCO, PIHP, or PAHP contract in a manner based on the enrollee and specific service type of the noncompliant data. Any deferral and/or disallowance of FFP will be effectuated utilizing the processes specified in §§ 430.40 and 430.42 of this chapter.

Subpart K—Parity in Mental Health and Substance Use Disorder Benefits

SOURCE: 81 FR 18436, Mar. 30, 2016, unless otherwise noted.

§ 438.900 Meaning of terms.

For purposes of this subpart, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a MCO, PIHP, or PAHP.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a MCO, PIHP, or PAHP.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However,

cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits are benefits defined in section 1905(r) of the Act.

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

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

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

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

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (*See* § 438.910(d)(2) for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

§ 438.905 Parity requirements for aggregate lifetime and annual dollar limits.

(a) *General parity requirement.* Each MCO, PIHP, and PAHP providing services to MCO enrollees must comply with paragraphs (b), (c), or (e) of this section for all enrollees of a MCO in States that cover both medical/surgical benefits and mental health or substance use disorder benefits under the State plan. This section details the application of the parity requirements for aggregate lifetime and annual dollar limits.

(b) *MCOs, PIHPs, or PAHPs with no limit or limits on less than one-third of all medical/surgical benefits.* If a MCO, PIHP, or PAHP does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits provided to enrollees through a contract with the State, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(c) *MCOs, PIHPs, or PAHPs with a limit on at least two-thirds of all medical/surgical benefits.* If a MCO, PIHP, or PAHP includes an aggregate lifetime or annual dollar limit on at least two-

thirds of all medical/surgical benefits provided to enrollees through a contract with the State, it must either—

(1) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(2) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is more restrictive than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits.

(d) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this section, the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits expected to be paid under the MCO, PIHP, or PAHP for a contract year (or for the portion of a contract year after a change in benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the MCOs, PIHPs, and PAHPs will constitute one-third or two-thirds of the dollar amount of all payments for medical/surgical benefits.

(e) *MCO, PIHP, or PAHP not described in this section*—(1) *In general.* A MCO, PIHP, or PAHP that is not described in paragraph (b) or (c) of this section for aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(i) Impose no aggregate lifetime or annual dollar limit, on mental health or substance use disorder benefits; or

(ii) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no more restrictive than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery mechanisms, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (e)(1)(ii). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the contract are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a MCO, PIHP, or PAHP may reasonably be expected to incur for such benefits, taking into account any other applicable restrictions.

(2) *Weighting.* For purposes of this paragraph (e), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (d) of this section for determining one-third or two-thirds of all medical/surgical benefits.

§ 438.910 Parity requirements for financial requirements and treatment limitations.

(a) *Clarification of terms*—(1) *Classification of benefits.* When reference is made in this section to a classification of benefits, the term ''classification'' means a classification as described in paragraph (b)(2) of this section.

(2) *Type of financial requirement or treatment limitation.* When reference is made in this section to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. *See* paragraph (d)(2) of this section for an illustrative list of nonquantitative treatment limitations.

(3) *Level of a type of financial requirement or treatment limitation.* When reference is made in this section to a level of a type of financial requirement or treatment limitation, level refers to

the magnitude of the type of financial requirement or treatment limitation.

(b) *General parity requirement*—(1) *General rule and scope*. Each MCO, PIHP and PAHP providing services to MCO enrollees in a State that covers both medical/surgical benefits and mental health or substance use disorder benefits under the State plan, must not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification furnished to enrollees (whether or not the benefits are furnished by the same MCO, PIHP, or PAHP). Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (b) to financial requirements and quantitative treatment limitations is addressed in paragraph (c) of this section; the application of the rules of this paragraph (b) to nonquantitative treatment limitations is addressed in paragraph (d) of this section.

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

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

(ii) *Outpatient*. Benefits furnished on an outpatient basis. *See* special rules for office visits in paragraph (c)(2) of this section.

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

(iv) *Prescription drugs*. Benefits for prescription drugs. *See* special rules for multi-tiered prescription drug benefits in paragraph (c)(2) of this section.

(c) *Financial requirements and quantitative treatment limitations*—(1) *Determining ''substantially all'' and ''predominant''*—(i) *Substantially all*. For purposes of this section, a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

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

(B) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of

medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the MCO, PIHP, or PAHP may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a MCO, PIHP, or PAHP may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(iii) *Portion based on MCO, PIHP or PAHP payments.* For purposes of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits in the classification expected to be paid under the MCOs, PIHPs, and PAHPs for a contract year (or for the portion of a contract year after a change in benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

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

(v) *Determining the dollar amount of MCO, PIHP, or PAHP payments.* Subject to paragraph (c)(1)(iv) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a MCO, PIHP, or PAHP for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(2) *Special rules*—(i) *Multi-tiered prescription drug benefits.* If a MCO, PIHP, or PAHP applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (d)(1) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the MCO, PIHP, or PAHP satisfies the parity requirements of this section for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(ii) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this section, a MCO, PIHP, or PAHP may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(2)(ii). After the sub-classifications are established, the MCO, PIHP or PAHP may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(1) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists,

are not permitted. The two sub-classifications permitted under this paragraph (c)(2)(ii) are:

(A) Office visits (such as physician visits); and

(B) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

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

(4) *Compliance with other cost-sharing rules.* Each MCO, PIHP, and PAHP must meet the cost-sharing requirements in § 438.108 when applying Medicaid cost-sharing.

(d) *Nonquantitative treatment limitations*—(1) *General rule.* A MCO, PIHP, or PAHP may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the policies and procedures of the MCO, PIHP, or PAHP as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(2) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include –

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

(ii) Formulary design for prescription drugs;

(iii) For MCOs, PIHPs, or PAHPs with multiple network tiers (such as preferred providers and participating providers), network tier design;

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

(v) MCO, PIHP, or PAHP methods for determining usual, customary, and reasonable charges;

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

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

(viii) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the MCO, PIHP, or PAHP; and

(ix) Standards for providing access to out-of-network providers.

(3) *Application to out-of-network providers.* Any MCO, PIHP or PAHP providing access to out-of-network providers for medical/surgical benefits within a classification, must use processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for mental health or substance use disorder benefits that are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for medical/surgical benefits.

§ 438.915 Availability of information.

(a) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations, made by a MCO or by a PIHP or PAHP providing services to an MCO enrollee, for mental health or substance use disorder benefits must be made available by the MCO, PIHP, or PAHP administrator to any enrollee, potential enrollee, or contracting provider upon request. MCOs, PIHPs, and PAHPs operating in compliance with § 438.236(c) will be deemed compliant with the requirements in this paragraph (a).

(b) *Reason for any denial.* The reason for any denial by a MCO, PIHP, or PAHP of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available

by the MCO, PIHP, or PAHP administrator to the enrollee.

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

§ 438.920 Applicability.

(a) *MCOs, PIHPs, and PAHPs.* The requirements of this subpart apply to each MCO, PIHP, and PAHP offering services to enrollees of a MCO, in States covering medical/surgical and mental health or substance use disorder services under the State plan. These requirements regarding coverage for services that must be provided to enrollees of an MCO apply regardless of the delivery system of the medical/surgical, mental health, or substance use disorder services under the State plan.

(b) *State responsibilities.* (1) In any instance where the full scope of medical/surgical and mental health and substance use disorder services are not provided through the MCO, the State must review the mental health and substance use disorder and medical/surgical benefits provided through the MCO, PIHP, PAHP, and fee-for service (FFS) coverage to ensure the full scope of services available to all enrollees of the MCO complies with the requirements in this subpart. The State must provide documentation of compliance with requirements in this subpart to the general public and post this information on the State Medicaid Web site by October 2, 2017. Such documentation must be updated prior to any change in MCO, PIHP, PAHP or FFS State plan benefits.

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

(c) *Scope.* This subpart does not—

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

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

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

§ 438.930 Compliance dates.

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

PART 440—SERVICES: GENERAL PROVISIONS

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AUTHORITY: 42 U.S.C. 1302.

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

Subpart A—Definitions

§ 440.1 Basis and purpose.

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

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

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

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

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

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

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

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

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

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

(a) *Specific definitions.*

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

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

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

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

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

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

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

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

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

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

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

(3) Are furnished in an institution that—

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

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

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

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

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

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

§ 440.20 Outpatient hospital services and rural health clinic services.

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

(1) Are furnished to outpatients;

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

(3) Are furnished by an institution that—

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

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

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

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

(1) Services furnished by a physician within the scope of practice of his profession under State law, if the physician performs the services in the clinic or the services are furnished away from the clinic and the physician has an agreement with the clinic providing

that he will be paid by it for such services.

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

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

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

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

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

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

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

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

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

§ 440.30 Other laboratory and X-ray services.

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

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

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

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

(d) During the Public Health Emergency defined in 42 CFR 400.200 or any future Public Health Emergency resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance (as defined in this paragraph), Medicaid coverage is available for laboratory tests and X-ray services that do not meet conditions specified in paragraph (a) or (b) of this section, if the purpose of such laboratory and X-ray services is to diagnose or detect SARS–CoV–2, antibodies to SARS–CoV–2, COVID–19, or the communicable disease named in the Public Health Emergency or its causes, and if the deviation from the conditions specified in paragraph (a) or (b) of this section is intended to avoid transmission of the communicable disease. For purposes of this paragraph, a period of active surveillance is defined

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

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

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

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

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

(ii) Provided by—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

or dental surgery if the services are services that—

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

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

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

[56 FR 8851, Mar. 1, 1991]

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

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

(b) Chiropractors' services include only services that—

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

(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

§ 440.70 Home health services.

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

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

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

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

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

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

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

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

(iii) Documents the care and services provided; and

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

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

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

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

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

(iii) A beneficiary's need for medical supplies, equipment, and appliances must be reviewed by a physician or, as

defined in § 400.200 of this chapter, an other licensed practitioner of the healing arts acting within the scope of practice authorized under State law, annually.

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

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

(4) Physical therapy, occupational therapy, or speech pathology and audiology services, provided by a home health agency or by a facility licensed by the State to provide medical rehabilitation services. (See § 441.15 of this subchapter.)

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

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

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

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

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

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

(i) Medical evaluation and services; and

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

(2) Is operated under competent medical supervision either—

(i) In connection with a hospital; or

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

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

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

(2) For the initiation of medical equipment, the face-to-face encounter must be related to the primary reason

the beneficiary requires medical equipment and must occur no more than 6 months prior to the start of services.

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

(i) A physician;

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

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

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

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

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

(4) If State law does not allow the non-physician practitioner, as described in paragraphs (f)(3)(ii) through (vi) of this section, to perform the face-to-face encounter independently, the non-physician practitioner must communicate the clinical findings of that face-to-face encounter to the ordering physician. Those clinical findings must be incorporated into a written or electronic document included in the beneficiary's medical record.

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

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

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

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

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

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

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

§ 440.80 Private duty nursing services.

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

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

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

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

(1) His or her own home;

(2) A hospital; or

(3) A skilled nursing facility.

[52 FR 47934, Dec. 17, 1987]

§ 440.90 Clinic services.

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

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

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

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

§ 440.100 Dental services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

doctoral degree in audiology, or a related field; and successfully completed a national examination in audiology approved by the Secretary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Prolong life; and

(3) Promote physical and mental health and efficiency.

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

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

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

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

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

(2) Has been granted a waiver of those utilization review requirements

under section 1903(i)(4) of the Act and subpart H of part 456 of this chapter.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[59 FR 56234, Nov. 10, 1994]

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

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

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

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

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

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

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

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

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

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

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

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

(1) Meets all requirements for a nursing facility;

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

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

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

(5) Is clearly identified; and

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

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

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

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

§ 440.160 Inpatient psychiatric services for individuals under age 21.

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

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

(b) Are provided by—

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

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

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

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

§ 440.165 Nurse-midwife service.

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

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

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

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

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

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

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

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

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

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

(iii) Has successfully completed a formal educational program for preparing

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

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

§ 440.166 Nurse practitioner services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[60 FR 19861, Apr. 21, 1995]

§ 440.167 Personal care services.

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

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

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

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

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

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

[42 FR 47902, Sept. 11, 1997]

§ 440.168 Primary care case management services.

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

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

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

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

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

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

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

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

[67 FR 41115, June 14, 2002]

§ 440.169 Case management services.

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

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

(c) [Reserved]

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

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

(i) Taking client history.

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

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

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

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

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

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

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

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

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

(ii) Services in the care plan are adequate.

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

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

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

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

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

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

(3) ''Travel expenses'' include—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(*2*) Transportation is so specialized that there is no other available Medicaid participating provider or other provider determined by the State to be qualified except the non-governmental broker.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Requires that the reviews be made by a committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

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

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

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

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

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

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

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

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

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

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

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

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

(i) The conditions for participation under Medicare; or

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

(f) [Reserved]

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

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

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

§ 440.180 Home and community-based waiver services.

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

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

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

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

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

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services.

(7) Respite care services.

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) Defined as any combination of special supervisory services, training,

transportation, and adaptive equipment that the State demonstrates are essential for persons to engage in paid employment and that are not normally required for nondisabled persons engaged in competitive employment.

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

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

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

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

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

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

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

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

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

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

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

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Respite care services.

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

[57 FR 29156, June 30, 1992]

§ 440.182 State plan home and community-based services.

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

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

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

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

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

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

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

(7) Respite care services.

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

(i) Day treatment or other partial hospitalization services;

(ii) Psychosocial rehabilitation services;

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

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

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

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

(2) Meals provided as an integral component of a program of adult day health services or another service and consistent with standard procedures in the State for such a program.

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

[79 FR 3029, Jan. 16, 2014]

§ 440.185 Respiratory care for ventilator-dependent individuals.

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

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

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

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

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

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

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

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

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

Subpart B—Requirements and Limits Applicable to All Services

§ 440.200 Basis, purpose, and scope.

(a) This subpart implements the following statutory requirements—

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

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

(3) Section 1903(v)(1), which provides that no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent

residence or otherwise permanently residing in the United States under color of law;

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

(5) Section 1907 on observance of religious beliefs;

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

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

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

[55 FR 36822, Sept. 7, 1990]

§ 440.210 Required services for the categorically needy.

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

(1) The services defined in §§ 440.10 through 440.50, 440.70, and (to the extent nurse-midwives and nurse practitioners are authorized to practice under State law or regulation) the services defined in §§ 440.165 and 440.166, respectively.

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

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

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

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

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

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

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

§ 440.220 Required services for the medically needy.

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

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

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

(i) Individuals under age 18; and

(ii) Groups of individuals entitled to institutional services.

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

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

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

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

(5) For women who, while pregnant, applied for, were eligible as medically

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

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

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

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

§ 440.225 Optional services.

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

[60 FR 19862, Apr. 21, 1995]

§ 440.230 Sufficiency of amount, duration, and scope.

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

(1) The categorically needy; and

(2) Each covered group of medically needy.

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

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

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

[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 beneficiary under the plan are not less in amount, duration, and scope than those services available to a medically needy beneficiary; and

(b) The plan must provide that the services available to any individual in the following groups are equal in amount, duration, and scope for all beneficiaries within the group:

(1) The categorically needy.

(2) A covered medically needy group.

[46 FR 47993, Sept. 30, 1981]

§ 440.250 Limits on comparability of services.

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

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

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

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

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

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

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

contracting organization and who elect to receive services from it.

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

(1) Individuals under age 18; and

(2) Groups of individuals entitled to institutional services.

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

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

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

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

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

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

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

(p) A State may provide a greater amount, duration, or scope of services to pregnant women than it provides under its plan to other individuals who are eligible for Medicaid, under the following conditions:

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

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

(q) [Reserved]

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

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

(2) Targeted groups specified by the State.

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

§ 440.255 Limited services available to certain aliens.

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

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

meet all other requirements for Medicaid will be eligible for the following services—

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

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

(ii) Serious impairment to bodily functions; or

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

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

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

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

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

(ii) Serious impairment to bodily functions; or

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

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

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

§ 440.260 Methods and standards to assure quality of services.

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

§ 440.262 Access and cultural conditions.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.

[85 FR 37243, June 19, 2020]

§ 440.270 Religious objections.

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

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

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

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

§ 440.300 Basis.

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

§ 440.305 Scope.

(a) *General.* This subpart sets out requirements for States that elect to provide medical assistance to certain Medicaid eligible individuals within one or more groups of individuals specified by the State, through enrollment of the

individuals in coverage, identified as ''benchmark'' or ''benchmark-equivalent.'' Groups must be identified by characteristics of individuals rather than the amount or level of FMAP.

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

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

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

§ 440.310 Applicability.

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

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

§ 440.315 Exempt individuals.

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

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

(b) The individual qualifies for medical assistance under the State plan on the basis of being blind or disabled (or being treated as being blind or disabled) without regard to whether the individual is eligible for Supplemental Security Income benefits under title XVI on the basis of being blind or disabled and including an individual who is eligible for medical assistance on the basis of section 1902(e)(3) of the Act.

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

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

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

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

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

(h) The individual is eligible and enrolled for Medicaid under § 435.145 of this chapter based on current eligibility for assistance under title IV–E of

the Act or under § 435.150 of this chapter based on current status as a former foster care child.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 440.325 State plan requirements: Coverage and benefits.

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

(a) Benchmark coverage in accordance with § 440.330.

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

§ 440.330 Benchmark health benefits coverage.

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

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

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

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

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

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

(2) [Reserved]

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

§ 440.335 Benchmark-equivalent health benefits coverage.

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

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

(1) Inpatient and outpatient hospital services.

(2) Physicians' surgical and medical services.

(3) Laboratory and x-ray services.

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

(5) Emergency services.

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

(7) Prescription drugs.

(8) Mental health benefits.

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

(2) If the benchmark coverage package used by the State for purposes of comparison in establishing the aggregate actuarial value of the benchmark-equivalent package includes any of the following four categories of services: Prescription drugs; mental health services; vision services; and hearing services; then the actuarial value of the coverage for each of these categories of

service in the benchmark-equivalent coverage package must be at least 75 percent of the actuarial value of the coverage for that category of service in the benchmark plan used for comparison by the State.

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

§ 440.340 Actuarial report for benchmark-equivalent coverage.

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

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

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

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

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

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

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

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

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

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

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

§ 440.345 EPSDT and other required benefits.

(a) The State must assure access to early and periodic screening, diagnostic and treatment (EPSDT) services through benchmark or benchmark-equivalent plan benefits or as additional benefits provided by the State for any child under 21 years of age eligible under the State plan in a category under section 1902(a)(10)(A) of the Act.

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

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

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

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

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

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

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

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

§ 440.347 Essential health benefits.

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

(1) Ambulatory patient services;

(2) Emergency services;

(3) Hospitalization;

(4) Maternity and newborn care;

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

(6) Prescription drugs;

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

(8) Laboratory services;

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

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

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

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

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

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

[78 FR 42307, July 15, 2013]

§ 440.350 Employer-sponsored insurance health plans.

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

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

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

§ 440.355 Payment of premiums.

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

§ 440.360 State plan requirements for providing additional services.

In addition to the requirements of § 440.345, the State may elect to provide additional coverage to individuals enrolled in Alternative Benefit Plans, except that the coverage for individuals eligible only through section 1902(a)(10)(A)(i)(VIII) of the Act is limited to benchmark or benchmark-equivalent coverage. The State must

describe the populations covered and the payment methodology for these benefits. Additional benefits must be benefits of the type, which are covered in 1 or more of the standard benchmark coverage packages described in § 440.330(a) through (c) or State plan benefits including those described in sections 1905(a), 1915(i), 1915(j), 1915(k) and 1945 of the Act and any other Medicaid State plan benefits enacted under title XIX, or benefits available under base benchmark plans described in 45 CFR 156.100.

[78 FR 42307, July 15, 2013]

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

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

§ 440.370 Economy and efficiency.

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

§ 440.375 Comparability.

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

§ 440.380 Statewideness.

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

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

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

§ 440.386 Public notice.

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

[78 FR 42307, July 15, 2013]

§ 440.390 Assurance of transportation.

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

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

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

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

Alternative Benefit Plans (ABPs) mean benefit packages in one or more of the

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

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

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

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

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

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

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

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

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

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

(ii) *Type of financial requirement or treatment limitation*. When reference is made in this paragraph (b) to a type of financial requirement or treatment limitation, the reference to type means

its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. *See* paragraph (b)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Formulary design for prescription drugs;

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

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

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

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

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

(c) *ABP providing EPSDT benefits.* An ABP that provides EPSDT benefits is deemed to be compliant with the parity requirements for financial requirements and treatment limitations with respect to individuals entitled to such benefits. Annual or lifetime limits are not permissible in EPSDT benefits.

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

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

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

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

(2) *Scope.* This section does not—

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

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance

use disorder benefits under the ABP except as specifically provided in paragraph (b) of this section.

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

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

(ii) [Reserved]

[81 FR 18439, Mar. 30, 2016]

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AUTHORITY: 42 U.S.C. 1302.

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

§ 441.1 Purpose.

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

Subpart A—General Provisions

§ 441.10 Basis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 441.11 Continuation of FFP for institutional services.

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

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

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

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

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

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

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

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

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

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

(1) Inpatient hospital services.

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

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

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

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

(6) Nursing facility services for individuals under 21.

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

[59 FR 56234, Nov. 10, 1994]

§ 441.12 Inpatient hospital tests.

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

[46 FR 48554, Oct. 1, 1981]

§ 441.13 Prohibitions on FFP: Institutionalized individuals.

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

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

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

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

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

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

§ 441.15 Home health services.

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

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

(1) Nursing services;

(2) Home health aide services; and

(3) Medical supplies, equipment, and appliances.

(b) The agency provides home health services to—

(1) Categorically needy beneficiaries age 21 or over;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) For other good cause.

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

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

(i) Has effect only within the State; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(v) Any action by the HHA to—

(A) Cease operation;

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

(C) File for bankruptcy; or

(D) Fail to pay the Surety.

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

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

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

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

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

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

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

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

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

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

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

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

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

this section and the Medicaid agency's instructions.

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

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

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

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

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

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

§ 441.17 Laboratory services.

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

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

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

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

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

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

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

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

§ 441.18 Case management services.

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

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

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

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

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

(5) [Reserved]

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

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

(i) The name of the individual.

(ii) The dates of the case management services.

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

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

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

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

(vii) A timeline for obtaining needed services.

(viii) A timeline for reevaluation of the plan.

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

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

(ii) Identifies the geographic area to be served.

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

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

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

(vi) [Reserved]

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

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

(i) The case management services to be furnished;

(ii) The qualifications of case management providers; or

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

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

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

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

(2) Assessing adoption placements.

(3) Recruiting or interviewing potential foster care parents.

(4) Serving legal papers.

(5) Home investigations.

(6) Providing transportation.

(7) Administering foster care subsidies.

(8) Making placement arrangements.

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

subsequent guidance and reflected in an approved cost allocation plan.

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

§ 441.20 Family planning services.

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

§ 441.21 Nurse-midwife services.

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

[47 FR 21051, May 17, 1982]

§ 441.22 Nurse practitioner services.

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

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

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

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

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

(2) Be paid through the employing provider.

[60 FR 19862, Apr. 21, 1995]

§ 441.25 Prohibition on FFP for certain prescribed drugs.

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

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

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

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

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

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

[46 FR 48554, Oct. 1, 1981]

§ 441.30 Optometric services.

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

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

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

§ 441.35 Organ transplants.

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

(1) Similarly situated individuals are treated alike; and

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

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

[56 FR 8851, Mar. 1, 1991]

§ 441.40 End-stage renal disease.

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

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

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

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

§ 441.50 Basis and purpose.

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

§ 441.55 State plan requirements.

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

§ 441.56 Required activities.

(a) *Informing*. The agency must—

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

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

(i) The benefits of preventive health care;

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

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

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

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

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

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

(i) Comprehensive health and developmental history.

(ii) Comprehensive unclothed physical examination.

(iii) Appropriate vision testing.

(iv) Appropriate hearing testing.

(v) Appropriate laboratory tests.

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

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

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

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

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

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

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

(1) Records and program manuals;

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

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

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

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

§ 441.57 Discretionary services.

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

§ 441.58 Periodicity schedule.

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

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

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

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

§ 441.59 Treatment of requests for EPSDT screening services.

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

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

§ 441.60 Continuing care.

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

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

(2) Maintenance of the beneficiary's consolidated health history, including information received from other providers.

(3) Physicians' services as needed by the beneficiary for acute, episodic or chronic illnesses or conditions.

(4) At the provider's option, provision of dental services required under § 441.56 or direct referral to a dentist to provide dental services required under § 441.56(b)(1)(vi). The provider must specify in the agreement whether dental services or referral for dental services are provided. If the provider does not choose to provide either service, then the provider must refer beneficiaries to the agency to obtain those dental services required under § 441.56.

(5) At the provider's option, provision of all or part of the transportation and scheduling assistance as required under § 441.62. The provider must specify in the agreement the transportation and scheduling assistance to be furnished. If the provider does not choose to provide some or all of the assistance, then the provider must refer beneficiaries to the agency to obtain the transportation and scheduling assistance required under § 441.62.

(b) *Reports*. A continuing care provider must provide to the agency any reports that the agency may reasonably require.

(c) *State monitoring*. If the State plan provides for agreements with continuing care providers, the agency must employ methods described in the State plan to assure the providers' compliance with their agreements.

(d) *Effect of agreement with continuing care providers*. Subject to the requirements of paragraphs (a), (b), and (c) of this section, CMS will deem the agency to meet the requirements of this subpart with respect to all EPSDT eligible beneficiaries formally enrolled with the continuing care provider. To be formally enrolled, a beneficiary or beneficiary's family agrees to use one continuing care provider to be a regular source of the described set of services for a stated period of time. Both the beneficiary and the provider must sign statements that reflect their obligations under the continuing care arrangement.

(e) If the agreement in paragraph (a) of this section does not provide for all or part of the transportation and scheduling assistance required under § 441.62, or for dental service under § 441.56, the agency must provide for those services to the extent they are not provided for in the agreement.

§ 441.61 Utilization of providers and coordination with related programs.

(a) The agency must provide referral assistance for treatment not covered by the plan, but found to be needed as a result of conditions disclosed during screening and diagnosis. This referral assistance must include giving the family or beneficiary the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.

(b) The agency must make available a variety of individual and group providers qualified and willing to provide EPSDT services.

(c) The agency must make appropriate use of State health agencies, State vocational rehabilitation agencies, and Title V grantees (Maternal and Child Health/Crippled Children's Services). Further, the agency should make use of other public health, mental health, and education programs and related programs, such as Head Start, Title XX (Social Services) programs, and the Special Supplemental Food Program for Women, Infants and Children (WIC), to ensure an effective child health program.

§ 441.62 Transportation and scheduling assistance.

The agency must offer to the family or beneficiary, and provide if the beneficiary requests—

(a) Necessary assistance with transportation as required under § 431.53 of this chapter; and

(b) Necessary assistance with scheduling appointments for services.

Subpart C—Medicaid for Individuals Age 65 or Over in Institutions for Mental Diseases

SOURCE: 44 FR 17940, Mar. 23, 1979, unless otherwise noted.

§ 441.100 Basis and purpose.

This subpart implements section 1905(a)(14) of the Act, which authorizes State plans to provide for inpatient hospital services, skilled nursing services, and intermediate care facility services for individuals age 65 or older in an institution for mental diseases, and sections 1902(a)(20)(B) and (C) and 1902(a)(21), which prescribe the conditions a State must meet to offer these services. (See § 431.620 of this subchapter for regulations implementing section 1902(a)(20)(A), which prescribe interagency requirements related to these services.)

§ 441.101 State plan requirements.

A State plan that includes Medicaid for individuals age 65 or older in institutions for mental diseases must provide that the requirements of this subpart are met.

§ 441.102 Plan of care for institutionalized beneficiaries.

(a) The Medicaid agency must provide for a recorded individual plan of treatment and care to ensure that institutional care maintains the beneficiary at, or restores him to, the greatest possible degree of health and independent functioning.

(b) The plan must include—

(1) An initial review of the beneficiary's medical, psychiatric, and social needs—

(i) Within 90 days after approval of the State plan provision for services in institutions for mental disease; and

(ii) After that period, within 30 days after the date payments are initiated for services provided a beneficiary.

(2) Periodic review of the beneficiary's medical, psychiatric, and social needs;

(3) A determination, at least quarterly, of the beneficiary's need for continued institutional care and for alternative care arrangements;

(4) Appropriate medical treatment in the institution; and

(5) Appropriate social services.

§ 441.103 Alternate plans of care.

(a) The agency must develop alternate plans of care for each beneficiary age 65 or older who would otherwise need care in an institution for mental diseases.

(b) These alternate plans of care must—

(1) Make maximum use of available resources to meet the beneficiary's medical, social, and financial needs; and

(2) In Guam, Puerto Rico, and the Virgin Islands, make available appropriate social services authorized under sections 3(a)(4) (i) and (ii) or 1603(a)(4)(A) (i) and (ii) of the Act.

§ 441.105 Methods of administration.

The agency must have methods of administration to ensure that its responsibilities under this subpart are met.

§ 441.106 Comprehensive mental health program.

(a) If the plan includes services in public institutions for mental diseases, the agency must show that the State is making satisfactory progress in developing and implementing a comprehensive mental health program.

(b) The program must—

(1) Cover all ages;

(2) Use mental health and public welfare resources; including—

(i) Community mental health centers;

(ii) Nursing homes; and

(iii) Other alternatives to public institutional care; and

(3) Include joint planning with State authorities.

(c) The agency must submit annual progress reports within 3 months after the end of each fiscal year in which

Medicaid is provided under this subpart.

Subpart D—Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs

§441.150 Basis and purpose.

This subpart specifies requirements applicable if a State provides inpatient psychiatric services to individuals under age 21, as defined in §440.160 of this subchapter and authorized under section 1905 (a)(16) and (h) of the Act.

§441.151 General requirements.

(a) Inpatient psychiatric services for individuals under age 21 must be:

(1) Provided under the direction of a physician;

(2) Provided by—

(i) A psychiatric hospital that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a psychiatric hospital as specified in §482.60 of this chapter, or is accredited by a national organization whose psychiatric hospital accrediting program has been approved by CMS; or a hospital with an inpatient psychiatric program that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a hospital, as specified in part 482 of this chapter, or is accredited by a national accrediting organization whose hospital accrediting program has been approved by CMS.

(ii) A psychiatric facility that is not a hospital and is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children, or by any other accrediting organization with comparable standards that is recognized by the State.

(3) Provided before the individual reaches age 21, or, if the individual was receiving the services immediately before he or she reached age 21, before the earlier of the following—

(i) The date the individual no longer requires the services; or

(ii) The date the individual reaches 22; and

(4) Certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with §441.152.

(b) Inpatient psychiatric services furnished in a psychiatric residential treatment facility as defined in §483.352 of this chapter, must satisfy all requirements in subpart G of part 483 of this chapter governing the use of restraint and seclusion.

(c) *COVID–19 Vaccination of facility staff*. The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the center setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID–19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID–19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

[66 FR 7160, Jan. 22, 2001, as amended at 75 FR 50418, Aug. 16, 2010; 86 FR 61617, Nov. 5, 2021]

§ 441.152 Certification of need for services.

(a) A team specified in § 441.154 must certify that—

(1) Ambulatory care resources available in the community do not meet the treatment needs of the beneficiary;

(2) Proper treatment of the beneficiary's psychiatric condition requires services on an inpatient basis under the direction of a physician; and

(3) The services can reasonably be expected to improve the beneficiary's condition or prevent further regression

so that the services will no longer be needed.

(b) The certification specified in this section and in §441.153 satisfies the utilization control requirement for physician certification in §§456.60, 456.160, and 456.360 of this subchapter.

[43 FR 45229, Sept. 29, 1978, as amended at 61 FR 38398, July 24, 1996]

§441.153 Team certifying need for services.

Certification under §441.152 must be made by terms specified as follows:

(a) For an individual who is a beneficiary when admitted to a facility or program, certification must be made by an independent team that—

(1) Includes a physician;

(2) Has competence in diagnosis and treatment of mental illness, preferably in child psychiatry; and

(3) Has knowledge of the individual's situation.

(b) For an individual who applies for Medicaid while in the facility of program, the certification must be—

(1) Made by the team responsible for the plan of care as specified in §441.156; and

(2) Cover any period before application for which claims are made.

(c) For emergency admissions, the certification must be made by the team responsible for the plan of care (§441.156) within 14 days after admission.

§441.154 Active treatment.

Inpatient psychiatric services must involve ''active treatment'', which means implementation of a professionally developed and supervised individual plan of care, described in §441.155 that is—

(a) Developed and implemented no later than 14 days after admission; and

(b) Designed to achieve the beneficiary's discharge from inpatient status at the earliest possible time.

§441.155 Individual plan of care.

(a) ''Individual plan of care'' means a written plan developed for each beneficiary in accordance with §§456.180 and 456.181 of this chapter, to improve his condition to the extent that inpatient care is no longer necessary.

(b) The plan of care must—

(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the beneficiary's situation and reflects the need for inpatient psychiatric care;

(2) Be developed by a team of professionals specified under §441.156 in consultation with the beneficiary; and his parents, legal guardians, or others in whose care he will be released after discharge;

(3) State treatment objectives;

(4) Prescribe an integrated program of therapies, activities, and experiences designed to meet the objectives; and

(5) Include, at an appropriate time, post-discharge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the beneficiary's family, school, and community upon discharge.

(c) The plan must be reviewed every 30 days by the team specified in §441.156 to—

(1) Determine that services being provided are or were required on an inpatient basis, and

(2) Recommend changes in the plan as indicated by the beneficiary's overall adjustment as an inpatient.

(d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for—

(1) Recertification under §§456.60(b), 456.160(b), and 456.360(b) of this subchapter; and

(2) Establishment and periodic review of the plan of care under §§456.80, 456.180, and 456.380 of this subchapter.

[43 FR 45229, Sept. 29, 1978, as amended at 46 FR 48560, Oct. 1, 1981; 61 FR 38398, July 24, 1996]

§441.156 Team developing individual plan of care.

(a) The individual plan of care under §441.155 must be developed by an interdisciplinary team of physicians and other personnel who are employed by, or provide services to patients in, the facility.

(b) Based on education and experience, preferably including competence in child psychiatry, the team must be capable of—

(1) Assessing the beneficiary's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;

(2) Assessing the potential resources of the beneficiary's family;

(3) Setting treatment objectives; and

(4) Prescribing therapeutic modalities to achieve the plan's objectives.

(c) The team must include, as a minimum, either—

(1) A Board-eligible or Board-certified psychiatrist;

(2) A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or

(3) A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases, and a psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

(d) The team must also include one of the following:

(1) A psychiatric social worker.

(2) A registered nurse with specialized training or one year's experience in treating mentally ill individuals.

(3) An occupational therapist who is licensed, if required by the State, and who has specialized training or one year of experience in treating mentally ill individuals.

(4) A psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

§ 441.180 Maintenance of effort: General rule.

FFP is available only if the State maintains fiscal effort as prescribed under this subpart.

§ 441.181 Maintenance of effort: Explanation of terms and requirements.

(a) For purposes of § 441.182:

(1) The base year is the 4-quarter period ending December 31, 1971.

(2) Quarterly per capita non-Federal expenditures are expenditures for inpatient psychiatric services determined by reimbursement principles under Medicare. (See part 405, subpart D.)

(3) The number of individuals receiving inpatient psychiatric services in the current quarter means—

(i) The number of individuals receiving services for the full quarter; plus

(ii) The full quarter composite number of individuals receiving services for less than a full quarter.

(4) In determining the per capita expenditures for the base year, the Medicaid agency must compute the number of individuals receiving services in a manner similar to that in paragraph (a)(3) of this section.

(5) Non-Federal expenditures means the total amount of funds expended by the State and its political subdivisions, excluding Federal funds received directly or indirectly from any source.

(6) Expenditures for the current calendar quarter exclude Federal funds received directly or indirectly from any source.

(b) As a basis for determining the correct amount of Federal payments, each State must submit estimated and actual cost data and other information necessary for this purpose in the form and at the times specified in this subchapter and by CMS guidelines.

(c) The agency must have on file adequate records to substantiate compliance with the requirements of § 441.182 and to ensure that all necessary adjustments have been made.

(d) Facilities that did not meet the requirements of §§ 441.151–441.156 in the base year, but are providing inpatient psychiatric services under those sections in the current quarter, must be included in the maintenance of effort computation if, during the base year, they were—

(1) Providing inpatient psychiatric services for individuals under age 21; and

(2) Receiving State aid.

§ 441.182 Maintenance of effort: Computation.

(a) For expenditures for inpatient psychiatric services for individuals under age 21, in any calendar quarter, FFP is available only to the extent

that the total State Medicaid expenditures in the current quarter for inpatient psychiatric services and outpatient psychiatric treatment for individuals under age 21 exceed the sum of the following:

(1) The total number of individuals receiving inpatient psychiatric services in the current quarter times the average quarterly per capita non-Federal expenditures for the base year; and

(2) The average non-Federal quarterly expenditures for the base year for outpatient psychiatric services for individuals under age 21.

(b) FFP is available for 100 percent of the increase in expenditures over the base year period, but may not exceed the Federal medical assistance percentage times the expenditures under this subpart for inpatient psychiatric services for individuals under age 21.

§ 441.184 Emergency preparedness.

The Psychiatric Residential Treatment Facility (PRTF) must comply with all applicable Federal, State, and local emergency preparedness requirements. The PRTF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan*. The PRTF must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the PRTF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures*. The PRTF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered residents in the PRTF's care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the PRTF must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the PRTF, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and

role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other PRTFs and other providers to receive residents in the event of limitations or cessation of operations to maintain the continuity of services to PRTF residents.

(8) The role of the PRTF under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan*. The PRTF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other PRTFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the PRTF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the PRTF's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PRTF's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing*. The PRTF must develop and maintain an emergency preparedness training program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program*. The PRTF must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) After initial training, provide emergency preparedness training every 2 years.

(iii) Demonstrate staff knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(v) If the emergency preparedness policies and procedures are significantly updated, the PRTF must conduct training on the updated policies and procedures.

(2) *Testing*. The PRTF must conduct exercises to test the emergency plan twice per year. The PRTF must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or

(B) If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, a facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PRTF's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a PRTF is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the PRTF may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64025, Sept. 16, 2016, as amended at 84 FR 51816, Sept. 30, 2019]

Subpart E—Abortions

§ 441.200 Basis and purpose.

This subpart implements section 402 of Pub. L. 97–12, and subsequent laws that appropriate funds for the Medicaid program, including section 204 of Pub. L. 98–619. All of these laws prohibit the use of Federal funds to pay for abortions except when continuation of the pregnancy would endanger the mother's life.

[52 FR 47935, Dec. 17, 1987]

§ 441.201 Definition.

As used in this subpart, ''physician'' means a doctor of medicine or osteopathy who is licensed to practice in the State.

[52 FR 47935, Dec. 17, 1987]

§ 441.202 General rule.

FFP is not available in expenditures for an abortion unless the conditions specified in §§ 441.203 and 441.206 are met.

[52 FR 47935, Dec. 17, 1987]

§ 441.203 Life of the mother would be endangered.

FFP is available in expenditures for an abortion when a physician has found, and certified in writing to the Medicaid agency, that on the basis of his professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

§§ 441.204–441.205 [Reserved]

§ 441.206 Documentation needed by the Medicaid agency.

FFP is not available in any expenditures for abortions or other medical procedures otherwise provided for under § 441.203 if the Medicaid agency has paid without first having received

the certifications and documentation specified in that section.

[52 FR 47935, Dec. 17, 1987]

§ 441.207 Drugs and devices and termination of ectopic pregnancies.

FFP is available in expenditures for drugs or devices to prevent implantation of the fertilized ovum and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 441.208 Recordkeeping requirements.

Medicaid agencies must maintain copies of the certifications and documentation specified in § 441.203 for 3 years under the recordkeeping requirements at 45 CFR 75.361.

[52 FR 47935, Dec. 17, 1987, as amended at 81 FR 3011, Jan. 20, 2016]

Subpart F—Sterilizations

SOURCE: 43 FR 52171, Nov. 8, 1978, unless otherwise noted.

§ 441.250 Applicability.

This subpart applies to sterilizations and hysterectomies reimbursed under Medicaid.

§ 441.251 Definitions.

As used in this subpart:

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (a) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or (b) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 441.252 State plan requirements.

A State plan must provide that the Medicaid agency will make payment under the plan for sterilization procedures and hysterectomies only if all the requirements of this subpart were met.

§ 441.253 Sterilization of a mentally competent individual aged 21 or older.

FFP is available in expenditures for the sterilization of an individual only if—

(a) The individual is at least 21 years old at the time consent is obtained;

(b) The individual is not a mentally incompetent individual;

(c) The individual has voluntarily given informed consent in accordance with all the requirements precribed in §§ 441.257 and 441.258; and

(d) At least 30 days, but not more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed since he or she gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 441.254 Mentally incompetent or institutionalized individuals.

FFP is not available for the sterilization of a mentally incompetent or institutionalized individual.

§ 441.255 Sterilization by hysterectomy.

(a) FFP is not available in expenditures for a hysterectomy if—

(1) It was performed solely for the purpose of rendering an individual permanently incapable of reproducing; or

(2) If there was more than one purpose to the procedure, it would not have been performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) FFP is available in expenditures for a hysterectomy not covered by paragraph (a) of this section only under the conditions specified in paragraph (c), (d), or (e) of this section.

(c) FFP is available if—

(1) The person who secured authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make the individual permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(d) Effective on March 8, 1979 or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available if—

(1) The individual—

(i) Was already sterile before the hysterectomy; or

(ii) Requires a hysterectomy because of a life-threatening emergency situation in which the physician determines that prior acknowledgment is not possible; and

(2) The physician who performs the hysterectomy—

(i) Certifies in writing that the individual was already sterile at the time of the hysterectomy, and states the cause of the sterility; or

(ii) Certifies in writing that the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

(e) Effective March 8, 1979, or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available for hysterectomies performed during a period of an individual's retroactive Medicaid eligibility if the physician who performed the hysterectomy certifies in writing that—

(1) The individual was informed before the operation that the hysterectomy would make her permanently incapable of reproducing; or

(2) One of the conditions in paragraph (d)(1) of this section was met. The physician must supply the information specified in paragraph (d)(2) of this section.

[47 FR 33702, Aug. 4, 1982]

§441.256 Additional condition for Federal financial participation (FFP).

(a) FFP is not available in expenditures for any sterilization or hysterectomy unless the Medicaid agency, before making payment, obtained documentation showing that the requirements of this subpart were met. This documentation must include a consent from, an acknowledgement of receipt of hysterectomy information or a physician's certification under §441.255(d)(2), as applicable.

(b) With regard to the requirements of §441.255(d) for hysterectomies performed from March 8, 1979 through November 2, 1982, FFP is available in expenditures for those services if the documentation showing that the requirements of that paragraph were met is obtained by the Medicaid agency before submitting a claim for FFP for that procedure.

[47 FR 33702, Aug. 4, 1982]

§441.257 Informed consent.

(a) *Informing the individual.* For purposes of this subpart, an individual has given informed consent only if—

(1) The person who obtained consent for the sterilization procedure offered to answer any questions the individual to be sterilized may have concerning the procedure, provided a copy of the consent form and provided orally all of the following information or advice to the individual to be sterilized:

(i) Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.

(ii) A description of available alternative methods of family planning and birth control.

(iii) Advice that the sterilization procedure is considered to be irreversible.

(iv) A thorough explanation of the specific sterilization procedure to be performed.

(v) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used.

(vi) A full description of the benefits or advantages that may be expected as a result of the sterilization.

(vii) Advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in § 441.253(c).

(2) Suitable arrangements were made to insure that the information specified in paragraph (a)(1) of this section was effectively communicated to any individual who is blind, deaf, or otherwise handicapped;

(3) An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent;

(4) The individual to be sterilized was permitted to have a witness of his or her choice present when consent was obtained;

(5) The consent form requirements of § 441.258 were met; and

(6) Any additional requirement of State or local law for obtaining consent, except a requirement for spousal consent, was followed.

(b) *When informed consent may not be obtained.* Informed consent may not be obtained while the individual to be sterilized is—

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

§ 441.258 Consent form requirements.

(a) *Content of consent form.* The consent form must be a copy of the form appended to this subpart or another form approved by the Secretary.

(b) *Required signatures.* The consent form must be signed and dated by—

(1) The individual to be sterilized;

(2) The interpreter, if one was provided;

(3) The person who obtained the consent; and

(4) The physician who performed the sterilization procedure.

(c) *Required certifications.* (1) The person securing the consent must certify, by signing the consent form, that

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify, by signing the consent form, that:

(i) Shortly before the performance of sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual appeared mentally competent and knowingly and voluntarily consented to be sterilized.

Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed.

(3) In the case of premature delivery or emergency abdominal surgery performed within 30 days of consent, the physician must certify that the sterilization was performed less than 30 days, but not less than 72 hours after informed consent was obtained because of premature delivery or emergency abdominal surgery and—

(i) In the case of premature delivery, must state the expected date of delivery; or

(ii) In the case of abdominal surgery, must describe the emergency.

(4) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally and read the consent

form and explained its contents to the individual to be sterilized and that, to the best of the interpreter's knowledge and belief, the individual understood what the interpreter told him or her.

§ 441.259 Review of regulations.

The Secretary will request public comment on the operation of this subpart not later than 3 years after its effective date.

APPENDIX TO SUBPART F OF PART 441—REQUIRED CONSENT FORM

NOTICE: Your decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving Federal funds.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I understand that the sterilization must be considered permanent and not reversible. I have decided that I do not want to become pregnant, bear children or father children.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by Federally funded programs.

I am at least 21 years of age and was born on (Day) (Month) (Year).

I, _____, hereby consent of my own free will to be sterilized by _____ by a method called _____. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form. (Signature) (Date) (Month) (Day) (Year).

You are requested to supply the following information, but it is not required: (Race and ethnicity designation (please check)) Black (not of Hispanic origin); Hispanic; Asian or Pacific Islander; American Indian or Alaskan native; or White (not of Hispanic origin).

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation. (Interpreter) (Date).

STATEMENT OF PERSON OBTAINING CONSENT

Before (name of individual) signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure. (Signature of person obtaining consent) (Date) (Facility) (Address).

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon (Name of individual to be sterilized) on (Date of sterilization) (operation), I explained to him/her the nature of the sterilization operation (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(*Instructions for use of alternative final paragraphs:* Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested): Premature delivery. Individual's expected date of delivery: _____

☐ Emergency abdominal surgery: (describe circumstances):_____ (Physician) (Date).

Subpart G—Home and Community-Based Services: Waiver Requirements

SOURCE: 46 FR 48541, Oct. 1, 1981, unless otherwise noted.

§ 441.300 Basis and purpose.

Section 1915(c) of the Act permits States to offer, under a waiver of statutory requirements, an array of home and community-based services that an individual needs to avoid institutionalization. Those services are defined in § 440.180 of this subchapter. This subpart describes what the Medicaid agency must do to obtain a waiver.

§ 441.301 Contents of request for a waiver.

(a) A request for a waiver under this section must consist of the following:

(1) The assurances required by § 441.302 and the supporting documentation required by § 441.303.

(2) When applicable, requests for waivers of the requirements of section 1902(a)(1), section 1902(a)(10)(B), or section 1902(a)(10)(C)(i)(III) of the Act, which concern respectively, statewide application of Medicaid, comparability of services, and income and resource rules applicable to medically needy individuals living in the community.

(3) A statement explaining whether the agency will refuse to offer home or community-based services to any beneficiary if the agency can reasonably expect that the cost of the services would exceed the cost of an equivalent level of care provided in—

(i) A hospital (as defined in § 440.10 of this chapter);

(ii) A NF (as defined in section 1919(a) of the Act); or

(iii) An ICF/IID (as defined in § 440.150 of this chapter), if applicable.

(b) If the agency furnishes home and community-based services, as defined in § 440.180 of this subchapter, under a waiver granted under this subpart, the waiver request must—

(1) Provide that the services are furnished—

(i) Under a written person-centered service plan (also called plan of care) that is based on a person-centered approach and is subject to approval by the Medicaid agency.

(ii) Only to beneficiaries who are not inpatients of a hospital, NF, or ICF/IID; and

(iii) Only to beneficiaries who the agency determines would, in the absence of these services, require the Medicaid covered level of care provided in—

(A) A hospital (as defined in § 440.10 of this chapter);

(B) A NF (as defined in section 1919(a) of the Act); or

(C) An ICF/IID (as defined in § 440.150 of this chapter);

(2) Describe the qualifications of the individual or individuals who will be responsible for developing the individual plan of care;

(3) Describe the group or groups of individuals to whom the services will be offered;

(4) Describe the services to be furnished so that each service is separately defined. Multiple services that are generally considered to be separate services may not be consolidated under a single definition. Commonly accepted terms must be used to describe the service and definitions may not be open ended in scope. CMS will, however, allow combined service definitions (bundling) when this will permit more efficient delivery of services and not compromise either a beneficiary's access to or free choice of providers.

(5) Provide that the documentation requirements regarding individual evaluation, specified in §441.303(c), will be met; and

(6) Be limited to one or more of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Individuals with Intellectual or Developmental Disabilities, or both.

(iii) Mentally ill.

(c) A waiver request under this subpart must include the following—

(1) *Person-centered planning process.* The individual will lead the person-centered planning process where possible. The individual's representative should have a participatory role, as needed and as defined by the individual, unless State law confers decision-making authority to the legal representative. All references to individuals include the role of the individual's representative. In addition to being led by the individual receiving services and supports, the person-centered planning process:

(i) Includes people chosen by the individual.

(ii) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(iii) Is timely and occurs at times and locations of convenience to the individual.

(iv) Reflects cultural considerations of the individual and is conducted by providing information in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with §435.905(b) of this chapter.

(v) Includes strategies for solving conflict or disagreement within the process, including clear conflict-of-interest guidelines for all planning participants.

(vi) Providers of HCBS for the individual, or those who have an interest in or are employed by a provider of HCBS for the individual must not provide case management or develop the person-centered service plan, except when the State demonstrates that the only willing and qualified entity to provide case management and/or develop person-centered service plans in a geographic area also provides HCBS. In these cases, the State must devise conflict of interest protections including separation of entity and provider functions within provider entities, which must be approved by CMS. Individuals must be provided with a clear and accessible alternative dispute resolution process.

(vii) Offers informed choices to the individual regarding the services and supports they receive and from whom.

(viii) Includes a method for the individual to request updates to the plan as needed.

(ix) Records the alternative home and community-based settings that were considered by the individual.

(2) *The Person-Centered Service Plan.* The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under the State's 1915(c) HCBS waiver, the written plan must:

(i) Reflect that the setting in which the individual resides is chosen by the individual. The State must ensure that the setting chosen by the individual is integrated in, and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and

work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) Reflect the individual's strengths and preferences.

(iii) Reflect clinical and support needs as identified through an assessment of functional need.

(iv) Include individually identified goals and desired outcomes.

(v) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports are unpaid supports that are provided voluntarily to the individual in lieu of 1915(c) HCBS waiver services and supports.

(vi) Reflect risk factors and measures in place to minimize them, including individualized back-up plans and strategies when needed.

(vii) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her. At a minimum, for the written plan to be understandable, it must be written in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

(viii) Identify the individual and/or entity responsible for monitoring the plan.

(ix) Be finalized and agreed to, with the informed consent of the individual in writing, and signed by all individuals and providers responsible for its implementation.

(x) Be distributed to the individual and other people involved in the plan.

(xi) Include those services, the purpose or control of which the individual elects to self-direct.

(xii) Prevent the provision of unnecessary or inappropriate services and supports.

(xiii) Document that any modification of the additional conditions, under paragraph (c)(4)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(A) Identify a specific and individualized assessed need.

(B) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(C) Document less intrusive methods of meeting the need that have been tried but did not work.

(D) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(E) Include a regular collection and review of data to measure the ongoing effectiveness of the modification.

(F) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(G) Include informed consent of the individual.

(H) Include an assurance that interventions and supports will cause no harm to the individual.

(3) *Review of the Person-Centered Service Plan*. The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

(4) *Home and Community-Based Settings*. Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options including non-disability specific settings and an option for a private unit

in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the qualities at §441.301(c)(4)(i) through (v), the following additional conditions must be met:

(A) The unit or dwelling is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the State, county, city, or other designated entity. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant, and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors.

(*2*) Individuals sharing units have a choice of roommates in that setting.

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time.

(D) Individuals are able to have visitors of their choosing at any time.

(E) The setting is physically accessible to the individual.

(F) Any modification of the additional conditions, under §441.301(c)(4)(vi)(A) through (D), must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(*1*) Identify a specific and individualized assessed need.

(*2*) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(*3*) Document less intrusive methods of meeting the need that have been tried but did not work.

(*4*) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(*5*) Include regular collection and review of data to measure the ongoing effectiveness of the modification.

(*6*) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(*7*) Include the informed consent of the individual.

(*8*) Include an assurance that interventions and supports will cause no harm to the individual.

(5) *Settings that are not Home and Community-Based.* Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for individuals with intellectual disabilities;

(iv) A hospital; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of

individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(6) *Home and Community-Based Settings: Compliance and Transition:*

(i) States submitting new and initial waiver requests must provide assurances of compliance with the requirements of this section for home and community-based settings as of the effective date of the waiver.

(ii) CMS will require transition plans for existing section 1915(c) waivers and approved state plans providing home and community-based services under section 1915(i) to achieve compliance with this section, as follows:

(A) For each approved section 1915(c) HCBS waiver subject to renewal or submitted for amendment within one year after the effective date of this regulation, the State must submit a transition plan at the time of the waiver renewal or amendment request that sets forth the actions the State will take to bring the specific waiver into compliance with this section. The waiver approval will be contingent on the inclusion of the transition plan approved by CMS. The transition plan must include all elements required by the Secretary; and within one hundred and twenty days of the submission of the first waiver renewal or amendment request the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(B) For States that do not have a section 1915(c) HCBS waiver or a section 1915(i) State plan benefit due for renewal or proposed for amendments within one year of the effective date of this regulation, the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. This plan must be submitted no later than one year after the effective date of this regulation. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(iii) A State must provide at least a 30-day public notice and comment period regarding the transition plan(s) that the State intends to submit to CMS for review and consideration, as follows:

(A) The State must at a minimum provide two (2) statements of public notice and public input procedures.

(B) The State must ensure the full transition plan(s) is available to the public for public comment.

(C) The State must consider and modify the transition plan, as the State deems appropriate, to account for public comment.

(iv) A State must submit to CMS, with the proposed transition plan:

(A) Evidence of the public notice required.

(B) A summary of the comments received during the public notice period, reasons why comments were not adopted, and any modifications to the transition plan based upon those comments.

(v) Upon approval by CMS, the State will begin implementation of the transition plans. The State's failure to submit an approvable transition plan as required by this section and/or to comply with the terms of the approved transition plan may result in compliance actions, including but not limited to deferral/disallowance of Federal Financial Participation.

[46 FR 48541, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985; 59 FR 37717, July 25, 1994; 65 FR 60107, Oct. 10, 2000; 79 FR 3029, Jan. 16, 2014]

§ 441.302 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to CMS, CMS will not grant a waiver under this subpart and may terminate a waiver already granted:

(a) *Health and Welfare*—Assurance that necessary safeguards have been taken to protect the health and welfare

of the beneficiaries of the services. Those safeguards must include—

(1) Adequate standards for all types of providers that provide services under the waiver;

(2) Assurance that the standards of any State licensure or certification requirements are met for services or for individuals furnishing services that are provided under the waiver; and

(3) Assurance that all facilities covered by section 1616(e) of the Act, in which home and community-based services will be provided, are in compliance with applicable State standards that meet the requirements of 45 CFR part 1397 for board and care facilities.

(4) Assurance that the State is able to meet the unique service needs of the individuals when the State elects to serve more than one target group under a single waiver, as specified in § 441.301(b)(6).

(i) On an annual basis the State will include in the quality section of the CMS–372 form (or any successor form designated by CMS) data that indicates the State continues to serve multiple target groups in the single waiver and that a single target group is not being prioritized to the detriment of other groups.

(ii) [Reserved]

(5) Assurance that services are provided in home and community based settings, as specified in § 441.301(c)(4).

(b) *Financial accountability*— The agency will assure financial accountability for funds expended for home and community-based services, provide for an independent audit of its waiver program (except as CMS may otherwise specify for particular waivers), and it will maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services provided under the waiver, including reports of any independent audits conducted.

(c) *Evaluation of need*. Assurance that the agency will provide for the following:

(1) *Initial evaluation*. An evaluation of the need for the level of care provided in a hospital, a NF, or an ICF/IID when there is a reasonable indication that a beneficiary might need the services in the near future (that is, a month or less) unless he or she receives home or community-based services. For purposes of this section, ''evaluation'' means a review of an individual beneficiary's condition to determine—

(i) If the beneficiary requires the level of care provided in a hospital as defined in § 440.10 of this subchapter, a NF as defined in section 1919(a) of the Act, or an ICF/IID as defined by § 440.150 of this subchapter; and

(ii) That the beneficiary, but for the provision of waiver services, would otherwise be institutionalized in such a facility.

(2) *Periodic reevaluations*. Reevaluations, at least annually, of each beneficiary receiving home or community-based services to determine if the beneficiary continues to need the level of care provided and would, but for the provision of waiver services, otherwise be institutionalized in one of the following institutions:

(i) A hospital;

(ii) A NF; or

(iii) An ICF/IID.

(d) *Alternatives*—Assurance that when a beneficiary is determined to be likely to require the level of care provided in a hospital, NF, or ICF/IID, the beneficiary or his or her legal representative will be—

(1) Informed of any feasible alternatives available under the waiver; and

(2) Given the choice of either institutional or home and community-based services.

(e) *Average per capita expenditures*. Assurance that the average per capita fiscal year expenditures under the waiver will not exceed 100 percent of the average per capita expenditures that would have been made in the fiscal year for the level of care provided in a hospital, NF, or ICF/IID under the State plan had the waiver not been granted.

(1) These expenditures must be reasonably estimated and documented by the agency.

(2) The estimate must be on an annual basis and must cover each year of the waiver period.

(f) *Actual total expenditures*. Assurance that the agency's actual total expenditures for home and community-based and other Medicaid services under the waiver and its claim for FFP

in expenditures for the services provided to beneficiaries under the waiver will not, in any year of the waiver period, exceed 100 percent of the amount that would be incurred by the State's Medicaid program for these individuals, absent the waiver, in—

(1) A hospital;

(2) A NF; or

(3) An ICF/IID.

(g) *Institutionalization absent waiver.* Assurance that, absent the waiver, beneficiaries in the waiver would receive the appropriate type of Medicaid-funded institutional care (hospital, NF, or ICF/IID) that they require.

(h) *Reporting.* Assurance that annually, the agency will provide CMS with information on the waiver's impact. The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on—

(1) The type, amount, and cost of services provided under the State plan; and

(2) The health and welfare of beneficiaries.

(i) *Habilitation services.* Assurance that prevocational, educational, or supported employment services, or a combination of these services, if provided as habilitation services under the waiver, are—

(1) Not otherwise available to the individual through a local educational agency under section 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730); and

(2) Furnished as part of expanded habilitation services, if the State has requested and received CMS's approval under a waiver or an amendment to a waiver.

(j) *Day treatment or partial hospitalization, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness.* Assurance that FFP will not be claimed in expenditures for waiver services including, but not limited to, day treatment or partial hospitalization, psychosocial rehabilitation services, and clinic services provided as home and community-based services to individuals with chronic mental illnesses if these individuals, in the absence of a waiver, would be placed in an IMD and are—

(1) Age 22 to 64;

(2) Age 65 and older and the State has not included the optional Medicaid benefit cited in § 440.140; or

(3) Age 21 and under and the State has not included the optional Medicaid benefit cited in § 440.160.

[50 FR 10026, Mar. 13, 1985, as amended at 59 FR 37717, July 25, 1994; 65 FR 60107, Oct. 10, 2000; 79 FR 3031, Jan. 16, 2014]

§ 441.303 Supporting documentation required.

The agency must furnish CMS with sufficient information to support the assurances required by § 441.302. Except as CMS may otherwise specify for particular waivers, the information must consist of the following:

(a) A description of the safeguards necessary to protect the health and welfare of beneficiaries. This information must include a copy of the standards established by the State for facilities that are covered by section 1616(e) of the Act.

(b) A description of the records and information that will be maintained to support financial accountability.

(c) A description of the agency's plan for the evaluation and reevaluation of beneficiaries, including—

(1) A description of who will make these evaluations and how they will be made;

(2) A copy of the evaluation form to be used; and if it differs from the form used in placing beneficiaries in hospitals, NFs, or ICFs/IID, a description of how and why it differs and an assurance that the outcome of the new evaluation form is reliable, valid, and fully comparable to the form used for hospital, NF, or ICF/IID placement;

(3) The agency's procedure to ensure the maintenance of written documentation on all evaluations and reevaluations; and

(4) The agency's procedure to ensure reevaluations of need at regular intervals.

(d) A description of the agency's plan for informing eligible beneficiaries of the feasible alternatives available under the waiver and allowing beneficiaries to choose either institutional

services or home and community-based services.

(e) An explanation of how the agency will apply the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in §435.217 of this chapter).

(f) An explanation with supporting documentation satisfactory to CMS of how the agency estimated the average per capita expenditures for services.

(1) The annual average per capita expenditure estimate of the cost of home and community-based and other Medicaid services under the waiver must not exceed the estimated annual average per capita expenditures of the cost of services in the absence of a waiver. The estimates are to be based on the following equation:

$$D + D' \leq G + G'.$$

The symbol ''≤'' means that the result of the left side of the equation must be less than or *equal* to the result of the right side of the equation.

D = the estimated annual average per capita Medicaid cost for home and community-based services for individuals in the waiver program.

D′ = the estimated annual average per capita Medicaid cost for all other services provided to individuals in the waiver program.

G = the estimated annual average per capita Medicaid cost for hospital, NF, or ICF/IID care that would be incurred for individuals served in the waiver, were the waiver not granted.

G′ = the estimated annual average per capita Medicaid costs for all services other than those included in factor G for individuals served in the waiver, were the waiver not granted.

(2) For purposes of the equation, the prime factors include the average per capita cost for all State plan services and expanded EPSDT services provided that are not accounted for in other formula values.

(3) In making estimates of average per capita expenditures for a waiver that applies only to individuals with a particular illness (for example, acquired immune deficiency syndrome) or condition (for example, chronic mental illness) who are inpatients in or who would require the level of care provided in hospitals as defined by §440.10, NFs as defined in section 1919(a) of the Act, or ICFs/IID, the agency may determine the average per capita expenditures for these individuals absent the waiver without including expenditures for other individuals in the affected hospitals, NFs, or ICFs/IID.

(4) In making estimates of average per capita expenditures for a separate waiver program that applies only to individuals identified through the preadmission screening annual resident review (PASARR) process who are developmentally disabled, inpatients of a NF, and require the level of care provided in an ICF/IID as determined by the State on the basis of an evaluation under §441.303(c), the agency may determine the average per capita expenditures that would have been made in a fiscal year for those individuals based on the average per capita expenditures for inpatients in an ICF/IID. When submitting estimates of institutional costs without the waiver, the agency may use the average per capita costs of ICF/IID care even though the deinstitutionalized developmentally disabled were inpatients of NFs.

(5) For persons diverted rather than deinstitutionalized, the State's evaluation process required by §441.303(c) must provide for a more detailed description of their evaluation and screening procedures for beneficiaries to ensure that waiver services will be limited to persons who would otherwise receive the level of care provided in a hospital, NF, or ICF/IID, as applicable.

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver participants in a waiver amendment.

(7) In determining the average per capita expenditures that would have been made in a waiver year, for waiver estimates that apply to persons with Intellectual Disability or related conditions, the agency may include costs of Medicaid residents in ICFs/IID that have been terminated on or after November 5, 1990.

(8) In submitting estimates for waivers that include personal caregivers as a waiver service, the agency may include a portion of the rent and food attributed to the unrelated personal caregiver who resides in the home or residence of the beneficiary covered under the waiver. The agency must submit to CMS for review and approval the method it uses to apportion the costs of rent and food. The method must be explained fully to CMS. A personal caregiver provides a waiver service to meet the beneficiary's physical, social, or emotional needs (as opposed to services not directly related to the care of the beneficiary; that is, housekeeping or chore services). FFP for live-in caregivers is not available if the beneficiary lives in the caregiver's home or in a residence that is owned or leased by the caregiver.

(9) In submitting estimates for waivers that apply to individuals with Intellectual Disability or a related condition, the agency may adjust its estimate of average per capita expenditures to include increases in expenditures for ICF/IID care resulting from implementation of a PASARR program for making determinations for individuals with Intellectual Disability or related conditions on or after January 1, 1989.

(10) For a State that has CMS approval to bundle waiver services, the State must continue to compute separately the costs and utilization of the component services that make up the bundled service to support the final cost and utilization of the bundled service that will be used in the cost-neutrality formula.

(g) The State, at its option, may provide for an independent assessment of its waiver that evaluates the quality of care provided, access to care, and cost-neutrality. The results of the assessment should be submitted to CMS at least 90 days prior to the expiration date of the approved waiver-period and cover the first 24 or 48 months of the waiver. If a State chooses to provide for an independent assessment, FFP is available for the costs attributable to the independent assessment.

(h) For States offering habilitation services that include prevocational, educational, or supported employment services, or a combination of these services, consistent with the provisions of § 440.180(c) of this chapter, an explanation of why these services are not available as special education and related services under sections 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. section 730);

(i) For States offering home and community-based services for individuals diagnosed as chronically mentally ill, an explanation of why these individuals would not be placed in an institution for mental diseases (IMD) absent the waiver, and the age group of these individuals.

[46 FR 48532, Oct. 1, 1981, as amended at 50 FR 10027, Mar. 13, 1985; 50 FR 25080, June 17, 1985; 59 FR 37718, July 25, 1994]

§ 441.304 Duration, extension, and amendment of a waiver.

(a) The effective date for a new waiver of Medicaid requirements to provide home and community-based services approved under this subpart is established by CMS prospectively on or after the date of approval and after consultation with the State agency. The initial approved waiver continues for a 3-year period from the effective date. If the agency requests it, the waiver may be extended for additional periods unless—

(1) CMS's review of the prior waiver period shows that the assurances required by § 441.302 were not met; and

(2) CMS is not satisfied with the assurances and documentation provided by the State in regard to the extension period.

(b) CMS will determine whether a request for extension of an existing waiver is actually an extension request or a request for a new waiver. If a State submits an extension request that would add a new group to the existing group of beneficiaries covered under the waiver (as defined under § 441.301(b)(6)), CMS will consider it to be two requests: One as an extension request for the existing group, and the other as a new waiver request for the new group. Waivers may be extended for additional 5-year periods.

(c) CMS *may* grant a State an extension of its existing waiver for up to 90 days to permit the State to document more fully the satisfaction of statutory and regulatory requirements needed to approve a new waiver request. CMS will consider this option when it requests additional information on a new waiver request submitted by a State to extend its existing waiver or when CMS disapproves a State's request for extension.

(d) The agency may request that waiver modifications be made effective retroactive to the first day of a waiver year, or another date after the first day of a waiver year, in which the amendment is submitted, unless the amendment involves substantive changes as determined by CMS.

(1) Substantive changes include, but are not limited to, revisions to services available under the waiver including elimination or reduction of services, or reduction in the scope, amount, and duration of any service, a change in the qualifications of service providers, changes in rate methodology or a constriction in the eligible population.

(2) A request for an amendment that involves a substantive change as determined by CMS, may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal effect on individuals adversely impacted by the change.

(e) The agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services in accordance with §447.205 of this chapter.

(f) The agency must establish and use a public input process, for any changes in the services or operations of the waiver.

(1) This process must be described fully in the State's waiver application and be sufficient in light of the scope of the changes proposed, to ensure meaningful opportunities for input for individuals served, or eligible to be served, in the waiver.

(2) This process must be completed at a minimum of 30 days prior to implementation of the proposed change or submission of the proposed change to CMS, whichever comes first.

(3) This process must be used for both existing waivers that have substantive changes proposed, either through the renewal or the amendment process, and new waivers.

(4) This process must include consultation with Federally-recognized Tribes, and in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), Indian health programs and Urban Indian Organizations.

(g)(1) If CMS finds that the Medicaid agency is not meeting one or more of the requirements for a waiver contained in this subpart, the agency is given a notice of CMS' findings and an opportunity for a hearing to rebut the findings.

(2) If CMS determines that the agency is substantively out of compliance with this subpart after the notice and any hearing, CMS may employ strategies to ensure compliance as described in paragraph (g)(3) of this section or terminate the waiver.

(3)(i) Strategies to ensure compliance may include the imposition of a moratorium on waiver enrollments, other corrective strategies as appropriate to ensure the health and welfare of waiver participants, or the withholding of a portion of Federal payment for waiver services until such time that compliance is achieved, or other actions as determined by the Secretary as necessary to address non-compliance with 1915(c) of the Act, or termination. When a waiver is terminated, the State must comport with §441.307.

(ii) CMS will provide states with a written notice of the impending strategies to ensure compliance for a waiver program. The notice of CMS' intent to utilize strategies to ensure compliance would include the nature of the non-compliance, the strategy to be employed, the effective date of the compliance strategy, the criteria for removing the compliance strategy and the opportunity for a hearing.

[50 FR 10028, Mar. 13, 1985; 50 FR 25080, June 17, 1985, as amended at 59 FR 37719, July 25, 1994; 79 FR 3032, Jan. 16, 2014]

§ 441.305 Replacement of beneficiaries in approved waiver programs.

(a) *Regular waivers.* A State's estimate of the number of individuals who may receive home and community-based services must include those who will replace beneficiaries who leave the program for any reason. A State may replace beneficiaries who leave the program due to death or loss of eligibility under the State plan without regard to any federally-imposed limit on utilization, but must maintain a record of beneficiaries replaced on this basis.

(b) *Model waivers.* (1) The number of individuals who may receive home and community-based services under a model waiver may not exceed 200 beneficiaries at any one time.

(2) The agency may replace any individuals who die or become ineligible for State plan services to maintain a count up to the number specified by the State and approved by CMS within the 200-maximum limit.

[59 FR 37719, July 25, 1994]

§ 441.306 Cooperative arrangements with the Maternal and Child Health program.

Whenever appropriate, the State agency administering the plan under Medicaid may enter into cooperative arrangements with the State agency responsible for administering a program for children with special health care needs under the Maternal and Child Health program (Title V of the Act) in order to ensure improved access to coordinated services to meet the children's needs.

[59 FR 37720, July 25, 1994]

§ 441.307 Notification of a waiver termination.

(a) If a State chooses to terminate its waiver before the initial 3-year period or 5-year renewal period expires, it must notify CMS in writing 30 days before terminating services to beneficiaries.

(b) If CMS or the State terminates the waiver, the State must notify beneficiaries of services under the waiver in accordance with § 431.210 of this subchapter and notify them 30 days before terminating services.

[46 FR 48541, Oct. 1, 1981. Redesignated at 59 FR 37719, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000]

§ 441.308 Hearings procedures for waiver terminations.

The procedures specified in subpart D of part 430 of this chapter are applicable to State requests for hearings on terminations.

[50 FR 10028, Mar. 13, 1985. Redesignated at 59 FR 37720, July 25, 1994]

§ 441.310 Limits on Federal financial participation (FFP).

(a) FFP for home and community-based services listed in § 440.180 of this chapter is not available in expenditures for the following:

(1) Services provided in a facility subject to the health and welfare requirements described in § 441.302(a) during any period in which the facility is found not to be in compliance with the applicable State standards described in that section.

(2) The cost of room and board except when provided as—

(i) Part of respite care services in a facility approved by the State that is not a private residence; or

(ii) For waivers that allow personal caregivers as providers of approved waiver services, a portion of the rent and food that may be reasonably attributed to the unrelated caregiver who resides in the same household with the waiver beneficiary. FFP for a live-in caregiver is not available if the beneficiary lives in the caregiver's home or in a residence that is owned or leased by the provider of Medicaid services (the caregiver). For purposes of this provision, ''board'' means 3 meals a day or any other full nutritional regimen and does not include meals provided as part of a program of adult day health services as long as the meals provided do not constitute a ''full'' nutritional regimen.

(3) Prevocational, educational, or supported employment services, or any combination of these services, as part of habilitation services that are—

(i) Provided in approved waivers that include a definition of ''habilitation services'' but which have not included

prevocational, educational, and supported employment services in that definition; or

(ii) Otherwise available to the beneficiary under either special education and related services as defined in section 602(16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401(16) and (17)) or vocational rehabilitation services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(4) For waiver applications and renewals approved on or after October 21, 1986, home and community-based services provided to individuals aged 22 through 64 diagnosed as chronically mentally ill who would be placed in an institution for mental diseases. FFP is also not available for such services provided to individuals aged 65 and over and 21 and under as an alternative to institutionalization in an IMD if the State does not include the appropriate optional Medicaid benefits specified at §§440.140 and 440.160 of this chapter in its State plan.

(b) FFP is available for expenditures for expanded habilitation services, as described in §440.180 of this chapter, if the services are included under a waiver or waiver amendment approved by CMS.

[59 FR 37720, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000]

Subpart H—Home and Community-Based Services Waivers for Individuals Age 65 or Older: Waiver Requirements

SOURCE: 57 FR 29156, June 30, 1992, unless otherwise noted.

§441.350 Basis and purpose.

Section 1915(d) of the Act permits States to offer, under a waiver of statutory requirements, home and community-based services not otherwise available under Medicaid to individuals age 65 or older, in exchange for accepting an aggregate limit on the amount of expenditures for which they claim FFP for certain services furnished to these individuals. The home and community-based services that may be furnished are listed in §440.181 of this subchapter. This subpart describes the procedures the Medicaid agency must follow to request a waiver.

§441.351 Contents of a request for a waiver.

A request for a waiver under this section must meet the following requirements:

(a) *Required signatures.* The request must be signed by the Governor, the Director of the Medicaid agency or the Director of the larger State agency of which the Medicaid agency is a component or any official of the Medicaid agency to whom this authority has been delegated. A request from any other agency of State government will not be accepted.

(b) *Assurances and supporting documentation.* The request must provide the assurances required by §441.352 of this part and the supporting documentation required by §441.353.

(c) *Statement for sections of the Act.* The request must provide a statement as to whether waiver of section 1902(a)(1), 1902(a)(10)(B), or 1902(a)(10)(C)(i)(III) of the Act is requested. If the State requests a waiver of section 1902(a)(1) of the Act, the waiver must clearly specify the geographic areas or political subdivisions in which the services will be offered. The State must indicate whether it is requesting a waiver of one or all of these sections. The State may request a waiver of any one of the sections cited above.

(d) *Identification of services.* The request must identify all services available under the approved State plan, which are also included in the APEL and which are identified under §440.181, and any limitations that the State has imposed on the provision of any service. The request must also identify and describe each service specified in §440.181 of this subchapter to be furnished under the waiver, and any additional services to be furnished under the authority of §440.181(b)(7). Descriptions of additional services must explain how each additional service included under §440.181(b)(7) will contribute to the health and well-being of the beneficiaries and to their ability to reside in a community-based setting.

(e) *Beneficiaries served*. The request must provide that the home and community-based services described in § 440.181 of this subchapter, are furnished only to individuals who—

(1) Are age 65 or older;

(2) Are not inpatients of a hospital, NF, or ICF/IID; and

(3) The agency determines would be likely to require the care furnished in a NF under Medicaid.

(f) *Plan of care*. The request must provide that the home and community-based services described in § 440.181 of this subchapter, are furnished under a written plan of care based on an assessment of the individual's health and welfare needs and developed by qualified individuals for each beneficiary under the waiver. The qualifications of the individual or individuals who will be responsible for developing the individual plan of care must be described. Each plan of care must contain, at a minimum, the medical and other services to be provided, their frequency, and the type of provider to furnish them. Plans of care must be subject to the approval of the Medicaid agency.

(g) *Medicaid agency review*. The request must assure that the State agency maintain and exercise its authority to review (at a minimum) a valid statistical sample of each month's plans of care. When the services in a plan do not comport with the stated disabilities and needs of the beneficiary, the agency must implement immediate corrective action procedures to ensure that the needs of the beneficiary are adequately addressed.

(h) *Groups served*. The request must describe the group or groups of individuals to whom the services will be offered.

(i) *Assurances regarding amount expended*. The request must assure that the total amount expended by the State under the plan for individuals age 65 or older during a waiver year for medical assistance with respect to NF, home health, private duty nursing, personal care, and home and community-based services described in §§ 440.180 and 440.181 of this subchapter and furnished as an alternative to NF care will not exceed the aggregate projected expenditure limit (APEL) defined in § 441.354.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.351 was added. This section contains information collection and 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 beneficiaries of services by assuring that the following conditions are met:

(1) Adequate standards for all types of providers that furnish services under the waiver are met. (These standards must be reasonably related to the requirements of the waiver service to be furnished.)

(2) The standards of any State licensure or certification requirements are met for services or for individuals furnishing services under the waiver.

(3) All facilities covered by section 1616(e) of the Act, in which home and community-based services are furnished, are in compliance with applicable State standards that meet the requirements of 45 CFR part 1397 for board and care facilities.

(4) Physician reviews of prescribed psychotropic drugs (when prescribed for purposes of behavior control of waiver beneficiaries) occur at least every 30 days.

(b) *Financial accountability*. The agency must assure financial accountability for funds expended for home and community-based services. The State must provide for an independent audit f its waiver program. The performance of a single financial audit, in accordance with the Single Audit Act of 1984 (Pub. L. 98–502, enacted on October 19, 1984), is deemed to satisfy the requirement for an independent audit. The agency must maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services furnished to individuals age 65 or older under the waiver and the State plan, including reports of any independent audits conducted.

(c) *Evaluation of need*. The agency must provide for an initial evaluation (and periodic reevaluations) of the need for the level of care furnished in a NF when there is a reasonable indication that individuals age 65 or older might need those services in the near future, but for the availability of home and community-based services. The procedures used to assess level of care for a potential waiver beneficiary must be at least as stringent as any existing State procedures applicable to individuals entering a NF. The qualifications of individuals performing the waiver assessment must be as high as those of individuals assessing the need for NF care, and the assessment instrument itself must be the same as any assessment instrument used to establish level of care of prospective inpatients in NFs. A periodic reevaluation of the level of care must be performed. The period of reevaluation of level of care cannot extend beyond 1 year.

(d) *Expenditures*. The agency must assure that the total amount expended by the State for medical assistance with respect to NF, home health, private duty nursing, personal care services, home and community-based services furnished under a section 1915(c) waiver granted under Subpart G of this part to individuals age 65 or older, and the home and community-based services approved and furnished under a section 1915(d) waiver for individuals age 65 or older during a waiver year will not exceed the APEL, calculated in accordance with §441.354.

(e) *Reporting*. The agency must assure that it will provide CMS annually with information on the waiver's impact. The information must be consistent with a reasonable data collection plan designed by CMS and must address the waiver's impact on—

(1) The type, amount, and cost of services furnished under the State plan; and

(2) The health and welfare of beneficiaries of the services described in §440.181 of this chapter.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, §441.352 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§441.353 Supporting documentation required.

The agency must furnish CMS with sufficient information to support the assurances required under §441.352, in order to meet the requirement that the assurances are satisfactory. At a minimum, this information must consist of the following:

(a) *Safeguards*. A description of the safeguards necessary to protect the health and welfare of beneficiaries.

This information must include:

(1) A copy of the standards established by the State for facilities (in which services will be furnished) that are covered by section 1616(e) of the Act.

(2) The minimum educational or professional qualifications of the providers of the services.

(3) A description of the administrative oversight mechanisms established by the State to ensure quality of care.

(b) *Records*. A description of the records and information that are maintained by the agency and by providers of services to support financial accountability, information regarding how the State meets the requirement for financial accountability, and an explanation of how the State assures that there is an audit trail for State and Federal funds expended for section 1915(d) home and community-based waiver services. If the State has an approved Medicaid Management Information System (MMIS), this system must be used to process individual claims data and account for funds expended for services furnished under the waiver.

(c) *Evaluation and reevaluation of beneficiaries*. A description of the agency's plan for the evaluation and reevaluation of beneficiaries' level of care, including the following:

(1) A description of who makes these evaluations and how they are made.

(2) A copy of the evaluation instrument.

(3) The agency's procedure to assure the maintenance of written documentation on all evaluations and reevaluations and copies of the forms. In accordance with regulations at 45 CFR part 75, written documentation of all evaluations and reevaluations must be maintained for a minimum period of 3 years.

(4) The agency's procedure to assure reevaluations of need at regular intervals.

(5) The intervals at which reevaluations occur, which may be no less frequent than for institutionalized individuals at comparable levels of care.

(6) The procedures and criteria used for evaluation and reevaluation of waiver beneficiaries must be the same or more stringent than those used for individuals served in NFs.

(d) *Alternatives available.* A description of the agency's plan for informing eligible beneficiaries of the feasible alternatives available under the waiver and allowing beneficiaries to choose either institutional or home and community-based services must be submitted to CMS. A copy of the forms or documentation used by the agency to verify that this choice has been offered and that beneficiaries of waiver services, or their legal representatives, have been given the free choice of the providers of both waiver and State plan services must also be available for CMS review. The Medicaid agency must provide an opportunity for a fair hearing, under 42 CFR part 431, subpart E, to beneficiaries who are not given the choice of home or community-based services as an alternative to institutional care in a NF or who are denied the service(s) or the providers of their choice.

(e) *Post-eligibility of income.* An explanation of how the agency applies the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in § 435.217 of this subchapter).

[57 FR 29156, June 30, 1992, as amended at 81 FR 3012, Jan. 20, 2016]

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.353 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.354 Aggregate projected expenditure limit (APEL).

(a) *Definitions.* For purposes of this section, the term *base year* means—

(1) Federal fiscal year (FFY) 1987 (that is, October 1, 1986 through September 30, 1987); or

(2) In the case of a State which did not report expenditures on the basis of age categories during FFY 1987, the base year means FFY 1989 (that is, October 1, 1988 through September 30, 1989).

(b) *General.* (1) The total amount expended by the State for medical assistance with respect to NF, home and community-based services under the waiver, home health services, personal care services, private duty nursing services, and services furnished under a waiver under subpart G of this part to individuals age 65 or older furnished as an alternative to care in an SNF or ICF (NF effective October 1, 1990), may not exceed the APEL calculated in accordance with paragraph (c) of this section.

(2) In applying for a waiver under this subpart, the agency must clearly identify the base year it intends to use.

(3) The State may make a preliminary calculation of the expenditure limit at the time of the waiver approval; however, CMS makes final calculations of the aggregate limit after base data have been verified and accepted.

(4) All base year and waiver year data are subject to final cost settlement within 2 years from the end of the base or waiver year involved.

(c) *Formula for calculating APEL.* Except as provided in paragraph (d) of this section, the formula for calculating the APEL follows:

$$APEL = P \times (1 + Y) + V \times (1 + Z), \text{ where}$$

P = The aggregate amount of the State's medical assistance under title XIX for SNF and ICF (NF effective October 1, 1990) services furnished to individuals who have reached age 65, defined as the total medical assistance payments (Federal and State) reported on line 6 of form CMS 64 (as adjusted) for SNF services, ICF-other services, and mental health facility services for the base year, multiplied by the ratio of expenditures for SNF and ICF-other services for the aged to total expenditures for these services as reported on form CMS 2082 for the base year.

Q = The market basket index for SNF and ICF (NF effective October 1, 1990) services for the waiver year involved, defined as the total SNF Input Price Index used

in the Medicare program, identified as the third quarter data available from CMS's Office of National Cost Estimates in August preceding the start of the fiscal year.

R = The SNF Input Price Index for the base year.

S = The number of residents in the State in the waiver year involved who have reached age 65, defined as the number of aged Medicare beneficiaries in the State, equal to the Mid-Period Enrollment in HI or SMI in that State on July 1 preceding the start of the fiscal year.

T = The number of aged Medicare beneficiaries in the State who are enrolled in either the HI or SMI programs in the base year, as defined in S, above.

U = The number of years beginning after the base year and ending on the last day of the waiver year involved.

V = The aggregate amount of the State's medical assistance under title XIX in the base year for home and community-based services for individuals who have reached age 65, defined as the total medical assistance payments (Federal and State) reported on line 6 of form CMS 64 (as adjusted) for home health, personal care, and home and community-based services waivers, which provide services as an alternative to care in a SNF or ICF (NF effective October 1, 1990), increased by an estimate (acceptable to CMS) of expenditures for private duty nursing services, multiplied by the ratio of expenditures for home health services for the aged to total expenditures for home health services, as reported on form CMS 2082, for the base year.

W = The market basket index for home and community-based services for the waiver year involved, defined as the Home Agency Input Price Index, used in the Medicare program identified as the third quarter data available from CMS's Office of National Cost Estimates in August preceding the start of the fiscal year.

X = The Home Health Agency Input Price Index for the base year.

Y = The greater of—

$(U \times .07)$, or $(Q/R)-1 + (S/T)-1 + (U \times .02)$.

Z = The greater of—

$(U \times .07)$, or $(W/X)-1 + (S/T)-1 + + (U \times .02)$.

(d) *Amendment of the APEL.* The State may request amendment of its APEL to reflect an increase in the aggregate amount of medical assistance for NF services and for services included in the calculation of the APEL as required by paragraph (c) of this section when the increase is directly attributable to legislation enacted on or after December 22, 1987, which amends title XIX of the Act. Costs attributable to laws enacted before December 22, 1987 will not be considered. Because the APEL for each year of the waiver is computed separately from the APEL for any other waiver year, a separate amendment must be submitted for each year in which the State chooses to raise its APEL. Documentation specific to the waiver year involved must be submitted to CMS.

§441.355 Duration, extension, and amendment of a waiver.

(a) *Effective dates and extension periods.* (1) The effective date for a waiver of Medicaid requirements to furnish home and community-based services to individuals age 65 or older under this subpart is established by CMS prospectively on the first day of the FFY following the date on which the waiver is approved.

(2) The initial waiver is approved for a 3-year period from the effective date. Subsequent renewals are approved for 5-year periods.

(3) If the agency requests it, the waiver may be extended for an additional 5-year period if CMS's review of the prior period shows that the assurances required by §441.352 were met.

(4) The agency may request that waiver modifications be made effective retroactive to the first day of the waiver year in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, addition of services under the waiver, a change in the qualifications of service providers, or a change in the eligible population.

(5) A request for an amendment that involves a substantive change is given a prospective effective date, but this date need not coincide with the start of the next FFY.

(b) *Extension or new waiver request.* CMS determines whether a request for extension of an existing waiver is actually an extension request, or a request for a new waiver. Generally, if a State's extension request proposes a substantive change in services furnished, eligible population, service area, statutory sections waived, or qualifications of service providers, CMS considers it a new waiver request.

(c) *Reconsideration of denial.* A determination of CMS to deny a request for a waiver (or for extension of a waiver) under this subpart may be reconsidered in accordance with § 441.357.

(d) *Existing waiver effectiveness after denial.* If CMS denies a request for an extension of an existing waiver under this subpart:

(1) The existing waiver remains in effect for a period of not less than 90 days after the date on which CMS denies the request, or, if the State seeks reconsideration in accordance with § 441.357, the date on which a final determination is made with respect to that review.

(2) CMS calculates an APEL for the period for which the waiver remains in effect, and this calculation is used to pro-rate the limit according to the number of days to which it applies.

§ 441.356 Waiver termination.

(a) *Termination by the State.* If a State chooses to terminate its waiver before an approved program is due to expire, the following conditions apply:

(1) The State must notify CMS in writing at least 30 days before terminating services to beneficiaries.

(2) The State must notify beneficiaries of services under the waiver at least 30 days before terminating services in accordance with § 431.210 of this chapter.

(3) CMS continues to apply the APEL described in § 441.354 through the end of the waiver year, but this limit is not applied in subsequent years.

(4) The State may not decrease the services available under the approved State plan to individuals age 65 or older by an amount that violates the comparability of service requirements set forth in § 440.240 of this chapter.

(b) *Termination by CMS.* (1) If CMS finds, during an approved waiver period, that an agency is not meeting one or more of the requirements for a waiver contained in this subpart, CMS notifies the agency in writing of its findings and grants an opportunity for a hearing in accordance with § 441.357. If CMS determines that the agency is not in compliance with this subpart after the notice and any hearing, CMS may terminate the waiver.

(2) If CMS terminates the waiver, the following conditions apply:

(i) The State must notify beneficiaries of services under the waiver at least 30 days before terminating services in accordance with § 431.210 of this chapter.

(ii) CMS continues to apply the APEL in § 441.354 of this subpart, but the limit is prorated according to the number of days in the fiscal year during which waiver services were offered. The limit expires concurrently with the termination of home and community-based services under the waiver.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.356 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.357 Hearing procedures for waiver denials.

The procedures specified in § 430.18 of this subchapter apply to State requests for hearings on denials, renewals, or amendments of waivers for home and community-based services for individuals age 65 or older.

§ 441.360 Limits on Federal financial participation (FFP).

FFP for home and community-based services listed in § 440.181 of this subchapter is not available in expenditures for the following:

(a) Services furnished in a facility subject to the health and welfare requirements described in § 441.352(a) during any period in which the facility is found not to be in compliance with the applicable State requirements described in that section.

(b) The cost of room and board except when furnished as part of respite care services in a facility, approved by the State, that is not a private residence. For purposes of this subpart, ''board'' means three meals a day or any other full nutritional regimen. ''Board'' does not include meals, which do not comprise a full nutritional regimen, furnished as part of adult day health services.

(c) The portion of the cost of room and board attributed to unrelated, live-in personal caregivers when the waiver beneficiary lives in the caregiver's

home or a residence owned or leased by the provider of the Medicaid services (the caregiver).

(d) Services that are not included in the approved State plan and not approved as waiver services by CMS.

(e) Services furnished to beneficiaries who are ineligible under the terms of the approved waiver.

(f) Services furnished by a provider when either the services or the provider do not meet the standards that are set by the State and included in the approved waiver.

(g) Services furnished to a beneficiary by his or her spouse.

§ 441.365 Periodic evaluation, assessment, and review.

(a) *Purpose*. This section prescribes requirements for periodic evaluation, assessment, and review of the care and services furnished to individuals receiving home and community-based waiver services under this subpart.

(b) *Evaluation and assessment review team*. (1) A review team, as described in paragraphs (b)(2) and (c) of this section, must periodically evaluate and assess the care and services furnished to beneficiaries under this subpart. The review team must be created by the State agency directly, or (through interagency agreement) by other departments of State government (such as the Department of Health or the Agency on Aging).

(2) Each review team must consist of at least one physician or registered nurse, and at least one other individual with health and social service credentials who the State believes is qualified to properly evaluate and assess the care and services provided under the waiver. If there is no physician on the review team, the Medicaid agency must ensure that a physician is available to provide consultation to the review team.

(3) For waiver services furnished to individuals who have been found to be likely to require the level of care furnished in a NF that is also an IMD, each review team must have a psychiatrist or physician and other appropriate mental health or social service personnel who are knowledgeable about geriatric mental illness.

(c) *Financial interests and employment of review team members*. (1) No member of a review team may have a financial interest in or be employed by any entity that furnishes care and services under the waiver to a beneficiary whose care is under review.

(2) No physician member of a review team may evaluate or assess the care of a beneficiary for whom he or she is the attending physician.

(3) No individual who serves as case manager, caseworker, benefit authorizer, or any similar position, may serve as member of a review team that evaluates and assesses care furnished to a beneficiary with whom he or she has had a professional relationship.

(d) *Number and location of review teams*. A sufficient number of teams must be located within the State so that onsite inspections can be made at appropriate intervals at sites where waiver beneficiaries receive care and services.

(e) *Frequency of periodic evaluations and assessments*. Periodic evaluations and assessments must be conducted at least annually for each beneficiary under the waiver. The review team and the agency have the option to determine the frequency of further periodic evaluations and assessments, based on the quality of services and access to care being furnished under the waiver and the condition of patients receiving care and services.

(f) *Notification before inspection*. No provider of care and services under the waiver may be notified in advance of a periodic evaluation, assessment, and review. However, when a beneficiary receives services in his own home or the home of a relative, notification must be provided to the residents of the household at least 48 hours in advance. The beneficiary must have an opportunity to decline access to the home. If the beneficiary declines access to his or her own home, or the home of a relative, the review is limited solely to the review of the provider's records. If the beneficiary is incompetent, the head of the household has the authority to decline access to the home.

(g) *Personal contact with and observation of beneficiaries and review of records*. (1) For beneficiaries of care and services under a waiver, the review team's

evaluation and assessment must include—

(i) A review of each beneficiary's medical record, the evaluation and reevaluation required by § 441.353(c), and the plan of care under which the waiver and other services are furnished; and

(ii) If the records described in paragraph (g)(1)(i) of this section are inadequate or incomplete, personal contact and observation of each beneficiary.

(2) The review team may personally contact and observe any beneficiary whose care the team evaluates and assesses.

(3) The review team may consult with both formal and informal caregivers when the beneficiary's records are inadequate or incomplete and when any apparent discrepancy exists between services required by the beneficiary and services furnished under the waiver.

(h) *Determinations by the review team.* The review team must determine in its evaluation and assessment whether—

(1) The services included in the plan of care are adequate to meet the health and welfare needs of each beneficiary;

(2) The services included in the plan of care have been furnished to the beneficiary as planned;

(3) It is necessary and in the interest of the beneficiary to continue receiving services through the waiver program; and

(4) It is feasible to meet the beneficiary's health and welfare needs through the waiver program.

(i) *Other information considered by review team.* When making determinations, under paragraph (h) of this section, for each beneficiary, the review team must consider the following information and may consider other information as it deems necessary:

(1) Whether the medical record, the determination of level of care, and the plan of care are consistent, and whether all ordered services have been furnished and properly recorded.

(2) Whether physician review of prescribed psychotropic medications (when required for behavior control) has occurred at least every 30 days.

(3) Whether tests or observations of each beneficiary indicated by his or her medical record are made at appropriate times and properly recorded.

(4) Whether progress notes entered in the record by formal and informal caregivers are made as required and appear to be consistent with the observed condition of the beneficiary.

(5) Whether reevaluations of the beneficiary's level of care have occurred at least as frequently as would be required if that individual were served in a NF.

(6) Whether the beneficiary receives adequate care and services, based, at a minimum, on the following when observations are necessary (the requirements for the necessity of observations are set forth in new § 441.365(g)(3)):

(i) Cleanliness.

(ii) Absence of bedsores.

(iii) Absence of signs of malnutrition or dehydration.

(7) Whether the beneficiary needs any service that is not included in the plan of care, or if included, is not being furnished by formal or informal caregivers under the waiver or through arrangements with another public or private source of assistance.

(8) Determination as to whether continued home and community-based services are required by the beneficiary to avoid the likelihood of placement in a NF.

(j) *Submission of review team's results.* The review team must submit to the Medicaid agency the results of its periodic evaluation, assessment and review of the care of the beneficiary:

(1) Within 1 month of the completion of the review.

(2) Immediately upon its determination that conditions exist that may constitute a threat to the life or health of a beneficiary.

(k) *Agency's action.* The Medicaid agency must establish and adhere to procedures for taking appropriate action in response to the findings reported by the review team. These procedures must provide for immediate response to any finding that the life or health of a beneficiary may be jeopardized.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.365 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

Subpart I—Community Supported Living Arrangements Services

SOURCE: 56 FR 48114, Sept. 24, 1991, unless otherwise noted.

§441.400 Basis and purpose.

This subpart implements section 1905(a)(24) of the Act, which adds community supported living arrangements services to the list of services that States may provide as medical assistance under title XIX (to the extent and as defined in section 1930 of the Act), and section 1930(h)(1)(B) of the Act, which specifies minimum protection requirements that a State which provides community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals must meet to ensure the health, safety and welfare of those individuals.

§441.402 State plan requirements.

If a State that is eligible to provide community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals provides such services, the State plan must specify that it complies with the minimum protection requirements in §441.404.

§441.404 Minimum protection requirements.

To be eligible to provide community supported living arrangements services to developmentally disabled individuals, a State must assure, through methods other than reliance on State licensure processes or the State quality assurance programs described under section 1930(d) of the Act, that:

(a) Individuals receiving community supported living arrangements services are protected from neglect, physical and sexual abuse, and financial exploitation;

(b) Providers of community supported living arrangements services—

(1) Do not use individuals who have been convicted of child or client abuse, neglect, or mistreatment, or of a felony involving physical harm to an individual; and

(2) Take all reasonable steps to determine whether applicants for employment by the provider have histories indicating involvement in child or client abuse, neglect, or mistreatment, or a criminal record involving physical harm to an individual;

(c) Providers of community supported living arrangements services are not unjustly enriched as a result of abusive financial arrangements (such as owner lease-backs) with developmentally disabled clients; and

(d) Providers of community supported living arrangements services, or the relatives of such providers, are not named beneficiaries of life insurance policies purchased by or on behalf of developmentally disabled clients.

Subpart J—Optional Self-Directed Personal Assistance Services Program

SOURCE: 73 FR 57881, Oct. 3, 2008, unless otherwise noted.

§441.450 Basis, scope, and definitions.

(a) *Basis*. This subpart implements section 1915(j) of the Act concerning the self-directed personal assistance services (PAS) option through a State Plan.

(b) *Scope*. A self-directed PAS option is designed to allow individuals, or their representatives, if applicable, to exercise decision-making authority in identifying, accessing, managing and purchasing their PAS. This authority includes, at a minimum, all of the following:

(1) The purchase of PAS and supports for PAS.

(2) Recruiting workers.

(3) Hiring and discharging workers.

(4) Training workers and accessing training provided by or through the State if additional worker training is required or desired by the participant, or participant's representative, if applicable.

(5) Specifying worker qualifications.

(6) Determining worker duties.

(7) Scheduling workers.

(8) Supervising workers.

(9) Evaluating worker performance.

(10) Determining the amount paid for a service, support or item.

(11) Scheduling when services are provided.

(12) Identifying service workers.

(13) Reviewing and approving invoices.

(c) *Definitions.* As used in this part—

Assessment of need means an evaluation of the needs, strengths, and preferences of participants for services. This includes one or more processes to obtain information about an individual, including health condition, personal goals and preferences, functional limitation, age, school, employment, household, and other factors that are relevant to the authorization and provision of services. Assessment information supports the development of the service plan and the subsequent service budget.

Individualized backup plan means a written plan that meets all of the following:

(1) Is sufficiently individualized to address each participant's critical contingencies or incidents that would pose a risk of harm to the participant's health or welfare;

(2) Must demonstrate an interface with the risk management provision at § 441.476 which requires States to assess and identify the potential risks to the participant (such as any critical health needs), and ensure that the risks and how they will be managed are the result of discussion and negotiation among the persons involved in the service plan development;

(3) Must not include the 911 emergency system or other emergency system as the sole backup feature of the plan; and

(4) Must be incorporated into the participant's service plan.

Legally liable relatives means persons who have a duty under the provisions of State law to care for another person. Legally liable relatives may include any of the following:

(1) The parent (biological or adoptive) of a minor child or the guardian of a minor child who must provide care to the child.

(2) Legally-assigned caretaker relatives.

(3) A spouse.

Self-directed personal assistance services (PAS) means personal care and related services, or home and community-based services otherwise available under the State plan or a 1915(c) waiver program that are provided to an individual who has been determined eligible for the PAS option. Self-directed PAS also includes, at the State's option, items that increase the individual's independence or substitutes (such as a microwave oven or an accessibility ramp) for human assistance, to the extent the expenditures would otherwise be made for the human assistance.

Self-direction means the opportunity for participants or their representatives to exercise choice and control over the budget, planning, and purchase of self-directed PAS, including the amount, duration, scope, provider, and location of service provision.

Service budget means an amount of funds that is under the control and direction of a participant, or the participant's representative, if any, when the State has selected the State plan option for provision of self-directed PAS. It is developed using a person-centered and directed process and is individually tailored in accordance with the participant's needs and personal preferences as established in the service plan.

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to remain in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan builds upon the participant's capacity to engage in activities that promote community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends and professionals, as desired or required by the participant, will be involved in the service-planning process.

Support system means information, counseling, training, and assistance that support the participant (or the participant's family or representative, as appropriate) in identifying, accessing, managing, and directing their PAS and supports and in purchasing their PAS identified in the service plan and budget.

Supports broker or consultant means an individual who supports participants in directing their PAS and service budgets. The supports broker or consultant is an agent of the participants and takes direction from the participants, or their representatives, if applicable, about what information, counseling, training or assistance is needed or desired. The supports broker or consultant is primarily responsible for facilitating participants' development of a service budget and effective management of the participants' PAS and budgets in a manner that comports with the participants' preferences. States must develop a protocol to ensure that supports brokers or consultants: are accessible to participants; have regularly scheduled phone and in-person contacts with participants; monitor whether participants' health status has changed and whether expenditure of funds are being made in accordance with service budgets. States must also develop the training requirements and qualifications for supports brokers or consultants that include, at a minimum, the following:

(1) An understanding of the philosophy of self-direction and person-centered and directed planning;

(2) The ability to facilitate participants' independence and participants' preferences in managing PAS and budgets, including any risks assumed by participants;

(3) The ability to develop service budgets and ensure appropriate documentation; and

(4) Knowledge of the PAS and resources available in the participant's community and how to access them.

The availability of a supports broker or consultant to each participant is a requirement of the support system.

§ 441.452 Self-direction: General.

(a) States must have in place, before electing the self-directed PAS option, personal care services through the State plan, or home and community-based services under a section 1915(c) waiver.

(b) The State must have both traditional service delivery and the self-directed PAS service delivery option available in the event that an individual voluntarily disenrolls or is involuntarily disenrolled, from the self-directed PAS service delivery option.

(c) The State's assessment of an individual's needs must form the basis of the level of services for which the individual is eligible.

(d) Nothing in this subpart will be construed as affecting an individual's Medicaid eligibility, including that of an individual whose Medicaid eligibility is attained through receipt of section 1915(c) waiver services.

§ 441.454 Use of cash.

(a) States have the option of disbursing cash prospectively to participants, or their representatives, as applicable, self-directing their PAS.

(b) States that choose to offer the cash option must ensure compliance with all applicable requirements of the Internal Revenue Service, including, but not limited to, retaining required forms and payment of FICA, FUTA and State unemployment taxes.

(c) States must permit participants, or their representatives, as applicable, using the cash option to choose to use the financial management entity for some or all of the functions described in § 441.484(c).

(d) States must make available a financial management entity to a participant, or the participant's representative, if applicable, who has demonstrated, after additional counseling, information, training, or assistance, that the participant cannot effectively manage the cash option described in paragraph (a) of this section.

§ 441.456 Voluntary disenrollment.

(a) States must permit a participant to voluntarily disenroll from the self-directed PAS option at any time and return to a traditional service delivery system.

(b) The State must specify in a section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§ 441.458 Involuntary disenrollment.

(a) States must specify the conditions under which a participant may be involuntarily disenrolled from the self-directed PAS option.

(b) CMS must approve the State's conditions under which a participant may be involuntarily disenrolled.

(c) The State must specify in the section 1915(j) State plan amendment the safeguards that are in place to ensure continuity of services during the transition from self-directed PAS.

§ 441.460 Participant living arrangements.

(a) Self-directed PAS are not available to an individual who resides in a home or property that is owned, operated, or controlled by a PAS provider who is not related to the individual by blood or marriage.

(b) States may specify additional restrictions on a participant's living arrangements if they have been approved by CMS.

§ 441.462 Statewideness, comparability and limitations on number served.

A State may do the following:

(a) Provide self-directed PAS without regard to the requirements of statewideness.

(b) Limit the population eligible to receive these services without regard to comparability of amount, duration, and scope of services.

(c) Limit the number of persons served without regard to comparability of amount, duration, and scope of services.

§ 441.464 State assurances.

A State must assure that the following requirements are met:

(a) *Necessary safeguards.* Necessary safeguards have been taken to protect the health and welfare of individuals furnished services under the program and to assure the financial accountability for funds expended for self-directed services.

(1) Safeguards must prevent the premature depletion of the participant directed budget as well as identify potential service delivery problems that might be associated with budget underutilization.

(2) These safeguards may include the following:

(i) Requiring a case manager, support broker or other person to monitor the participant's expenditures.

(ii) Requiring the financial management entity to flag significant budget variances (over and under expenditures) and bring them to the attention of the participant, the participant's representative, if applicable, case manager, or support broker.

(iii) Allocating the budget on a monthly or quarterly basis.

(iv) Other appropriate safeguards as determined by the State.

(3) Safeguards must be designed so that budget problems are identified on a timely basis so that corrective action may be taken, if necessary.

(b) *Evaluation of need.* The State must perform an evaluation of the need for personal care under the State Plan or services under a section 1915(c) waiver program for individuals who meet the following requirements:

(1) Are entitled to medical assistance for personal care services under the State plan or receiving home and community based services under a section 1915(c) waiver program.

(2) May require self-directed PAS.

(3) May be eligible for self-directed PAS.

(c) *Notification of feasible alternatives.* Individuals who are likely to require personal care under the State plan, or home and community-based services under a section 1915(c) waiver program are informed of the feasible alternatives, if available, under the State's self-directed PAS State plan option, at the choice of these individuals, to the provision of personal care services under the State plan, or PAS under a section 1915(c) home and community-based services waiver program. Information on feasible alternatives must be communicated to the individual in a manner and language understandable by the individual. Such information includes, but is not limited to, the following:

(1) Information about self-direction opportunities that is sufficient to inform decision-making about the election of self-direction and provided on a timely basis to an individual or the representative which minimally includes the following:

(i) Elements of self-direction compared to non-self-directed PAS.

(ii) Individual responsibilities and potential liabilities under the self-direction service delivery model.

(iii) The choice to receive PAS through a waiver program administered under section 1915(c) of the Act, regardless of delivery system, if applicable.

(iv) The option, if available, to receive and manage the cash amount of their individual budget allocation.

(2) When and how this information is provided.

(d) *Support system.* States must provide, or arrange for the provision of, a support system that meets the following conditions:

(1) Appropriately assesses and counsels an individual, or the individual's representative, if applicable, before enrollment, including information about disenrollment.

(2) Provides appropriate information, counseling, training, and assistance to ensure that a participant is able to manage the services and budgets. Such information must be communicated to the participant in a manner and language understandable by the participant. The support activities must include at least the following:

(i) Person-centered planning and how it is applied.

(ii) Information about the services available for self-direction.

(iii) Range and scope of individual choices and options.

(iv) Process for changing the service plan and service budget.

(v) Grievance process.

(vi) Risks and responsibilities of self-direction.

(vii) The ability to freely choose from available PAS providers.

(viii) Individual rights.

(ix) Reassessment and review schedules.

(x) Defining goals, needs, and preferences.

(xi) Identifying and accessing services, supports, and resources.

(xii) Development of risk management agreements.

(xiii) Development of an individualized backup plan.

(xiv) Recognizing and reporting critical events.

(xv) Information about an advocate or advocacy systems available in the State and how a participant, or a participant's representative, if applicable, can access the advocate or advocacy systems.

(3) Offers additional information, counseling, training, or assistance, including financial management services under either of the following conditions:

(i) At the request of the participant, or participant's representative, if applicable, for any reason.

(ii) When the State has determined the participant, or participant's representative, if applicable, is not effectively managing the services identified in the service plan or budget.

(4) The State may mandate the use of additional assistance, including the use of a financial management entity, or may initiate an involuntary disenrollment in accordance with §441.458, if, after additional information, counseling, training or assistance is provided to a participant (or participant's representative, if applicable), the participant (or participant's representative, if applicable) has continued to demonstrate an inability to effectively manage the services and budget.

(e) *Annual report.* The State must provide to CMS an annual report on the number of individuals served and the total expenditures on their behalf in the aggregate.

(f) *Three-year evaluation.* The State must provide to CMS an evaluation of the overall impact of the self-directed PAS option on the health and welfare of participating individuals compared to non-participants every 3 years.

§441.466 Assessment of need.

States must conduct an assessment of the participant's needs, strengths, and preferences in accordance with the following:

(a) States may use one or more processes and techniques to obtain information about an individual, including health condition, personal goals and preferences for the provision of services, functional limitations, age, school, employment, household, and other factors that are relevant to the need for and authorization and provision of services.

(b) Assessment information supports the determination that an individual requires PAS and also supports the development of the service plan and budget.

§ 441.468 Service plan elements.

(a) The service plan must include at least the following:

(1) The scope, amount, frequency, and duration of each service.

(2) The type of provider to furnish each service.

(3) Location of the service provision.

(4) The identification of risks that may pose harm to the participant along with a written individualized backup plan for mitigating those risks.

(b) A State must develop a service plan for each program participant using a person-centered and directed planning process to ensure the following:

(1) The identification of each program participant's preferences, choices, and abilities, and strategies to address those preferences, choices, and abilities.

(2) The option for the program participant, or participant's representative, if applicable, to exercise choice and control over services and supports discussed in the plan.

(3) Assessment of, and planning for avoiding, risks that may pose harm to a participant.

(c) All of the State's applicable policies and procedures associated with service plan development must be carried out and include, but are not limited to, the following:

(1) Allow the participant, or participant's representative, if applicable, the opportunity to engage in, and direct, the process to the extent desired.

(2) Allow the participant, or participant's representative, if applicable, the opportunity to involve family, friends, and professionals (as desired or required) in the development and implementation of the service plan.

(3) Ensure the planning process is timely.

(4) Ensure the participant's needs are assessed and that the services meet the participant's needs.

(5) Ensure the responsibilities for service plan development are identified.

(6) Ensure the qualifications of the individuals who are responsible for service plan development reflect the nature of the program's target population(s).

(7) Ensure the State reviews the service plan annually, or whenever necessary due to a change in the participant's needs or health status.

(8) Ensure that a participant may request revisions to a service plan, based on a change in needs or health status.

(d) When an entity that is permitted to provide other State plan services is responsible for service plan development, the State must describe the safeguards that are in place to ensure that the service provider's role in the planning process is fully disclosed to the participant, or participant's representative, if applicable, and controls are in place to avoid any possible conflict of interest.

(e) An approved self-directed service plan conveys authority to the participant, or participant's representative, if applicable, to perform, at a minimum, the following tasks:

(1) Recruit and hire workers to provide self-directed services, including specifying worker qualifications.

(2) Fire workers.

(3) Supervise workers in the provision of self-directed services.

(4) Manage workers in the provision of self-directed services, which includes the following functions:

(i) Determining worker duties.

(ii) Scheduling workers.

(iii) Training workers in assigned tasks.

(iv) Evaluating workers performance.

(5) Determine the amount paid for a service, support, or item.

(6) Review and approve provider invoices.

§ 441.470 Service budget elements.

A service budget must be developed and approved by the State based on the assessment of need and service plan and must include the following:

(a) The specific dollar amount a participant may utilize for services and supports.

(b) How the participant is informed of the amount of the service budget before the service plan is finalized.

(c) The procedures for how the participant, or participant's representative, if applicable, may adjust the budget, including the following:

(1) How the participant, or participant's representative, if applicable, may freely make changes to the budget.

(2) The circumstances, if any, that may require prior approval before a budget adjustment is made.

(3) The circumstances, if any, that may require a change in the service plan.

(d) The procedure(s) that governs how a person, at the election of the State, may reserve funds to purchase items that increase independence or substitute for human assistance, to the extent that expenditures would otherwise be made for the human assistance, including additional goods, supports, services or supplies.

(e) The procedure(s) that governs how a person may use a discretionary amount, if applicable, to purchase items not otherwise delineated in the budget or reserved for permissible purchases.

(f) How participants, or their representative, if applicable, are afforded the opportunity to request a fair hearing under §441.300 if a participant's, or participant's representative, if applicable, request for a budget adjustment is denied or the amount of the budget is reduced.

§441.472 Budget methodology.

(a) The State shall set forth a budget methodology that ensures service authorization resides with the State and meets the following criteria:

(1) The State's method of determining the budget allocation is objective and evidence based utilizing valid, reliable cost data.

(2) The State's method is applied consistently to participants.

(3) The State's method is open for public inspection.

(4) The State's method includes a calculation of the expected cost of the self-directed PAS and supports, if those services and supports were not self-directed.

(5) The State has a process in place that describes the following:

(i) Any limits it places on self-directed services and supports, and the basis for the limits.

(ii) Any adjustments that will be allowed and the basis for the adjustments.

(b) The State must have procedures to safeguard participants when the budgeted service amount is insufficient to meet a participant's needs.

(c) The State must have a method of notifying participants, or their representative, if applicable, of the amount of any limit that applies to a participant's self-directed PAS and supports.

(d) The budget may not restrict access to other medically necessary care and services furnished under the plan and approved by the State but not included in the budget.

(e) The State must have a procedure to adjust a budget when a reassessment indicates a change in a participant's medical condition, functional status or living situation.

§441.474 Quality assurance and improvement plan.

(a) The State must provide a quality assurance and improvement plan that describes the State's system of how it will perform activities of discovery, remediation and quality improvement in order to learn of critical incidents or events that affect participants, correct shortcomings, and pursue opportunities for system improvement.

(b) The quality assurance and improvement plan shall also describe the system performance measures, outcome measures, and satisfaction measures that the State must use to monitor and evaluate the self-directed State plan option. Quality of care measures must be made available to CMS upon request and include indicators approved or prescribed by the Secretary.

§441.476 Risk management.

(a) The State must specify the risk assessment methods it uses to identify potential risks to the participant.

(b) The State must specify any tools or instruments it uses to mitigate identified risks.

(c) The State must ensure that each service plan includes the risks that an

individual is willing and able to assume, and the plan for how identified risks will be mitigated.

(d) The State must ensure that the risk management plan is the result of discussion and negotiation among the persons designated by the State to develop the service plan, the participant, the participant's representative, if any, and others from whom the participant may seek guidance.

§ 441.478 Qualifications of providers of personal assistance.

(a) States have the option to permit participants, or their representatives, if applicable, to hire any individual capable of providing the assigned tasks, including legally liable relatives, as paid providers of the PAS identified in the service plan and budget.

(b) Participants, or their representatives, if applicable, retain the right to train their workers in the specific areas of personal assistance needed by the participant and to perform the needed assistance in a manner that comports with the participant's personal, cultural, and/or religious preferences. Participants, or their representatives, if applicable, also have the right to access other training provided by or through the State so that their PAS providers can meet any additional qualifications required or desired by participants, or participants' representatives, if applicable.

(c) Participants, or their representatives, if applicable, retain the right to establish additional staff qualifications based on participants' needs and preferences.

§ 441.480 Use of a representative.

(a) States may permit participants to appoint a representative to direct the provision of self-directed PAS on their behalf. The following types of representatives are permissible:

(1) A minor child's parent or guardian.

(2) An individual recognized under State law to act on behalf of an incapacitated adult.

(3) A State-mandated representative, after approval by CMS of the State criteria, if the participant has demonstrated, after additional counseling, information, training or assistance, the inability to self-direct PAS.

(b) A person acting as a representative for a participant receiving self-directed PAS is prohibited from acting as a provider of self-directed PAS to the participant.

§ 441.482 Permissible purchases.

(a) Participants, or their representatives, if applicable, may, at the State's option, use their service budgets to pay for items that increase a participant's independence or substitute (such as a microwave oven or an accessibility ramp) for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

(b) The services, supports and items that are purchased with a service budget must be linked to an assessed participant need or goal established in the service plan.

§ 441.484 Financial management services.

(a) States may choose to provide financial management services to participants, or their representatives, as applicable, self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions, utilizing a financial management entity, through the following arrangements:

(1) States may use a reporting or subagent through its fiscal intermediary in accordance with section 3504 of the IRS Code and Revenue Procedure 80–4 and Notice 2003–70; or

(2) States may use a vendor organization that has the capabilities to perform the required tasks in accordance with Section 3504 of the IRS Code and Revenue Procedure 70–6. When private entities furnish financial management services, the procurement method must meet the requirements set forth in 45 CFR 75.326 through 75.340.

(b) States must provide oversight of financial management services by performing the following functions:

(1) Monitoring and assessing the performance of financial management entity, including assuring the integrity of financial transactions they perform.

(2) Designating a State entity or entities responsible for this monitoring.

(3) Determining how frequently financial management entity performance will be assessed.

(c) A financial management entity must provide functions including, but not limited to, the following:

(1) Collect and process timesheets of the participant's workers.

(2) Process payroll, withholding, filing and payment of applicable Federal, State and local employment-related taxes and insurance.

(3) Maintain a separate account for each participant's budget.

(4) Track and report disbursements and balances of participant funds.

(5) Process and pay invoices for goods and services approved in the service plan.

(6) Provide to participants periodic reports of expenditures and the status of the approved service budget.

(d) States not utilizing a financial management entity must perform the functions listed in paragraph (c) of this section on behalf of participants self-directing PAS, with the exception of those participants utilizing the cash option who directly perform those functions.

(e) States will be reimbursed for the cost of financial management services, either provided directly or through a financial management entity, at the administrative rate of 50 percent.

[73 FR 57881, Oct. 3, 2008, as amended at 81 FR 3012, Jan. 20, 2016]

Subpart K—Home and Community-Based Attendant Services and Supports State Plan Option (Community First Choice)

SOURCE: 77 FR 26898, May 7, 2012, unless otherwise noted.

§ 441.500 Basis and scope.

(a) *Basis*. This subpart implements section 1915(k) of the Act, referred to as the Community First Choice option (hereafter Community First Choice), to provide home and community-based attendant services and supports through a State plan.

(b) *Scope*. Community First Choice is designed to make available home and community-based attendant services and supports to eligible individuals, as needed, to assist in accomplishing activities of daily living (ADLs), instrumental activities of daily living (IADLs), and health-related tasks through hands-on assistance, supervision, or cueing.

§ 441.505 Definitions.

As used in this subpart:

Activities of daily living (ADLs) means basic personal everyday activities including, but not limited to, tasks such as eating, toileting, grooming, dressing, bathing, and transferring.

Agency-provider model means a method of providing Community First Choice services and supports under which entities contract for or provide through their own employees, the provision of such services and supports, or act as the employer of record for attendant care providers selected by the individual enrolled in Community First Choice.

Backup systems and supports means electronic devices used to ensure continuity of services and supports. These items may include an array of available technology, personal emergency response systems, and other mobile communication devices. Persons identified by an individual can also be included as backup supports.

Health-related tasks means specific tasks related to the needs of an individual, which can be delegated or assigned by licensed health-care professionals under State law to be performed by an attendant.

Individual means the eligible individual and, if applicable, the individual's representative.

Individual's representative means a parent, family member, guardian, advocate, or other person authorized by the individual to serve as a representative in connection with the provision of CFC services and supports. This authorization should be in writing, when feasible, or by another method that clearly indicates the individual's free choice. An individual's representative may not also be a paid caregiver of an individual receiving services and supports under this subpart.

Instrumental activities of daily living (IADLs) means activities related to living independently in the community,

including but not limited to, meal planning and preparation, managing finances, shopping for food, clothing, and other essential items, performing essential household chores, communicating by phone or other media, and traveling around and participating in the community.

Other models means methods, other than an agency-provider model or the self-directed model with service budget, for the provision of self-directed services and supports, as approved by CMS.

Self-directed means a consumer controlled method of selecting and providing services and supports that allows the individual maximum control of the home and community–based attendant services and supports, with the individual acting as the employer of record with necessary supports to perform that function, or the individual having a significant and meaningful role in the management of a provider of service when the agency-provider model is utilized. Individuals exercise as much control as desired to select, train, supervise, schedule, determine duties, and dismiss the attendant care provider.

Self-directed model with service budget means methods of providing self-directed services and supports using an individualized service budget. These methods may include the provision of vouchers, direct cash payments, and/or use of a fiscal agent to assist in obtaining services.

§ 441.510 Eligibility.

To receive Community First Choice services and supports under this section, an individual must meet the following requirements:

(a) Be eligible for medical assistance under the State plan;

(b) As determined annually—

(1) Be in an eligibility group under the State plan that includes nursing facility services; or

(2) If in an eligibility group under the State plan that does not include such nursing facility services, have an income that is at or below 150 percent of the Federal poverty level (FPL). In determining whether the 150 percent of the FPL requirement is met, States must apply the same methodologies as would apply under their Medicaid State plan, including the same income disregards in accordance with section 1902(r)(2) of the Act; and,

(c) Receive a determination, at least annually, that in the absence of the home and community-based attendant services and supports provided under this subpart, the individual would otherwise require the level of care furnished in a hospital, a nursing facility, an intermediate care facility for individuals with intellectual disabilities, an institution providing psychiatric services for individuals under age 21, or an institution for mental diseases for individuals age 65 or over, if the cost could be reimbursed under the State plan. The State administering agency may permanently waive the annual recertification requirement for an individual if:

(1) It is determined that there is no reasonable expectation of improvement or significant change in the individual's condition because of the severity of a chronic condition or the degree of impairment of functional capacity; and

(2) The State administering agency, or designee, retains documentation of the reason for waiving the annual recertification requirement.

(d) For purposes of meeting the criterion under paragraph (b) of this section, individuals who qualify for medical assistance under the special home and community-based waiver eligibility group defined at section 1902(a)(10)(A)(ii)(VI) of the Act must meet all section 1915(c) requirements and receive at least one home and community-based waiver service per month.

(e) Individuals receiving services through Community First Choice will not be precluded from receiving other home and community-based long-term care services and supports through other Medicaid State plan, waiver, grant or demonstration authorities.

§ 441.515 Statewideness.

States must provide Community First Choice to individuals:

(a) On a statewide basis.

(b) In a manner that provides such services and supports in the most integrated setting appropriate to the individual's needs, and without regard to

the individual's age, type or nature of disability, severity of disability, or the form of home and community-based attendant services and supports that the individual requires to lead an independent life.

§ 441.520 Included services.

(a) If a State elects to provide Community First Choice, the State must provide all of the following services:

(1) Assistance with ADLs, IADLs, and health-related tasks through hands-on assistance, supervision, and/or cueing.

(2) Acquisition, maintenance, and enhancement of skills necessary for the individual to accomplish ADLs, IADLs, and health-related tasks.

(3) Backup systems or mechanisms to ensure continuity of services and supports, as defined in § 441.505 of this subpart.

(4) Voluntary training on how to select, manage and dismiss attendants.

(b) At the State's option, the State may provide permissible services and supports that are linked to an assessed need or goal in the individual's person-centered service plan. Permissible services and supports may include, but are not limited to, the following:

(1) Expenditures for transition costs such as rent and utility deposits, first month's rent and utilities, bedding, basic kitchen supplies, and other necessities linked to an assessed need for an individual to transition from a nursing facility, institution for mental diseases, or intermediate care facility for Individuals with Intellectual Disabilities to a home and community-based setting where the individual resides;

(2) Expenditures relating to a need identified in an individual's person-centered service plan that increases an individual's independence or substitutes for human assistance, to the extent that expenditures would otherwise be made for the human assistance.

§ 441.525 Excluded services.

Community First Choice may not include the following:

(a) Room and board costs for the individual, except for allowable transition services described in § 441.520(b)(1) of this subpart.

(b) Special education and related services provided under the Individuals with Disabilities Education Act that are related to education only, and vocational rehabilitation services provided under the Rehabilitation Act of 1973.

(c) Assistive devices and assistive technology services, other than those defined in § 441.520(a)(3) of this subpart, or those that meet the requirements at § 441.520(b)(2) of this subpart.

(d) Medical supplies and medical equipment, other than those that meet the requirements at § 441.520(b)(2) of this subpart.

(e) Home modifications, other than those that meet the requirements at § 441.520(b) of this subpart.

§ 441.530 Home and Community-Based Setting.

(a) States must make available attendant services and supports in a home and community-based setting consistent with both paragraphs (a)(1) and (a)(2) of this section.

(1) Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options, including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes but does not regiment individual initiative, autonomy, and

independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the above qualities at paragraphs (a)(1)(i) through (v) of this section, the following additional conditions must be met:

(A) The unit or dwelling is a specific physical place that can be owned, rented or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord tenant law of the State, county, city or other designated entity. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each participant and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors as needed.

(*2*) Individuals sharing units have a choice of roommates in that setting.

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time.

(D) Individuals are able to have visitors of their choosing at any time.

(E) The setting is physically accessible to the individual.

(F) Any modification of the additional conditions, under paragraphs (a)(1)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(*1*) Identify a specific and individualized assessed need.

(*2*) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(*3*) Document less intrusive methods of meeting the need that have been tried but did not work.

(*4*) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(*5*) Include regulation collection and review of data to measure the ongoing effectiveness of the modification.

(*6*) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(*7*) Include the informed consent of the individual.

(*8*) Include an assurance that interventions and supports will cause no harm to the individual.

(2) Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for individuals with intellectual disabilities;

(iv) A hospital providing long-term care services; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(b) [Reserved]

[79 FR 3032, Jan. 16, 2014]

§ 441.535 Assessment of functional need.

States must conduct a face-to-face assessment of the individual's needs, strengths, preferences, and goals for the services and supports provided under Community First Choice in accordance with the following:

(a) States may use one or more processes and techniques to obtain information, including telemedicine, or other information technology medium, in lieu of a face-to-face assessment if the following conditions apply:

(1) The health care professional(s) performing the assessment meet the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology;

(2) The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff; and

(3) The individual is provided the opportunity for an in-person assessment in lieu of one performed via telemedicine.

(b) Assessment information supports the determination that an individual requires Community First Choice and also supports the development of the person-centered service plan and, if applicable, service budget.

(c) The assessment of functional need must be conducted at least every 12 months, as needed when the individual's support needs or circumstances change significantly necessitating revisions to the person-centered service plan, and at the request of the individual.

(d) Other requirements as determined by the Secretary.

§ 441.540 Person-centered service plan.

(a) *Person-centered planning process.* The person-centered planning process is driven by the individual. The process—

(1) Includes people chosen by the individual.

(2) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(3) Is timely and occurs at times and locations of convenience to the individual.

(4) Reflects cultural considerations of the individual.

(5) Includes strategies for solving conflict or disagreement within the process, including clear conflict-of-interest guidelines for all planning participants.

(6) Offers choices to the individual regarding the services and supports they receive and from whom.

(7) Includes a method for the individual to request updates to the plan.

(8) Records the alternative home and community-based settings that were considered by the individual.

(b) *The person-centered service plan.* The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under Community First Choice, the plan must:

(1) Reflect that the setting in which the individual resides is chosen by the individual.

(2) Reflect the individual's strengths and preferences.

(3) Reflect clinical and support needs as identified through an assessment of functional need.

(4) Include individually identified goals and desired outcomes.

(5) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports cannot supplant needed paid services unless the natural supports are unpaid supports that are provided voluntarily to the individual in lieu of an attendant.

(6) Reflect risk factors and measures in place to minimize them, including individualized backup plans.

(7) Be understandable to the individual receiving services and supports,

and the individuals important in supporting him or her.

(8) Identify the individual and/or entity responsible for monitoring the plan.

(9) Be finalized and agreed to in writing by the individual and signed by all individuals and providers responsible for its implementation.

(10) Be distributed to the individual and other people involved in the plan.

(11) Incorporate the service plan requirements for the self-directed model with service budget at § 441.550, when applicable.

(12) Prevent the provision of unnecessary or inappropriate care.

(13) Other requirements as determined by the Secretary.

(c) *Reviewing the person-centered service plan.* The person-centered service plan must be reviewed, and revised upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual.

§ 441.545 Service models.

A State may choose one or more of the following as the service delivery model to provide self-directed home and community-based attendant services and supports:

(a) *Agency-provider model.* (1) The agency-provider model is a delivery method in which the services and supports are provided by entities, under a contract or provider agreement with the State Medicaid agency or delegated entity to provide services. Under this model, the entity either provides the services directly through their employees or arranges for the provision of services under the direction of the individual receiving services.

(2) Under the agency-provider model for Community First Choice, individuals maintain the ability to have a significant role in the selection and dismissal of the providers of their choice, for the delivery of their specific care, and for the services and supports identified in their person-centered service plan.

(b) *Self-directed model with service budget.* A self-directed model with a service budget is one in which the individual has both a person-centered service plan and a service budget based on the assessment of functional need.

(1) *Financial management entity.* States must make available financial management activities to all individuals with a service budget. The financial management entity performs functions including, but not limited to, the following activities:

(i) Collect and process timesheets of the individual's attendant care providers.

(ii) Process payroll, withholding, filing, and payment of applicable Federal, State, and local employment related taxes and insurance.

(iii) Separately track budget funds and expenditures for each individual.

(iv) Track and report disbursements and balances of each individual's funds.

(v) Process and pay invoices for services in the person-centered service plan.

(vi) Provide individual periodic reports of expenditures and the status of the approved service budget to the individual and to the State.

(vii) States may perform the functions of a financial management entity internally or use a vendor organization that has the capabilities to perform the required tasks in accordance with all applicable requirements of the Internal Revenue Service.

(2) *Direct cash.* States may disburse cash prospectively to individuals self-directing their Community First Choice services and supports, and must meet the following requirements:

(i) Ensure compliance with all applicable requirements of the Internal Revenue Service, and State employment and taxation authorities, including but not limited to, retaining required forms and payment of FICA, FUTA and State unemployment taxes.

(ii) Permit individuals using the cash option to choose to use the financial management entity for some or all of the functions described in paragraph (b)(1)(ii) of this section.

(iii) Make available a financial management entity to an individual who has demonstrated, after additional counseling, information, training, or assistance that the individual cannot effectively manage the cash option described in this section.

(iv) The State may require an individual to use a financial management entity, but must provide the individual with the conditions under which this option would be enforced.

(3) *Vouchers*. States have the option to issue vouchers to individuals who self-direct their Community First Choice services and supports as long as the requirements in paragraphs (b)(2)(i) through (iv) of this paragraph are met.

(c) *Other service delivery models*. States have the option of proposing other service delivery models. Such models are defined by the State and approved by CMS.

§ 441.550 Service plan requirements for self-directed model with service budget.

The person-centered service plan under the self-directed model with service budget conveys authority to the individual to perform, at a minimum, the following tasks:

(a) Recruit and hire or select attendant care providers to provide self-directed Community First Choice services and supports, including specifying attendant care provider qualifications.

(b) Dismiss specific attendant care providers of Community First Choice services and supports.

(c) Supervise attendant care providers in the provision of Community First Choice services and supports.

(d) Manage attendant care providers in the provision of Community First Choice services and supports, which includes the following functions:

(1) Determining attendant care provider duties.

(2) Scheduling attendant care providers.

(3) Training attendant care providers in assigned tasks.

(4) Evaluating attendant care providers' performance.

(e) Determining the amount paid for a service, support, or item, in accordance with State and Federal compensation requirements.

(f) Reviewing and approving provider payment requests.

§ 441.555 Support system.

For each service delivery model available, States must provide, or arrange for the provision of, a support system that meets all of the following conditions:

(a) Appropriately assesses and counsels an individual before enrollment.

(b) Provides appropriate information, counseling, training, and assistance to ensure that an individual is able to manage the services and budgets if applicable.

(1) This information must be communicated to the individual in a manner and language understandable by the individual. To ensure that the information is communicated in an accessible manner, information should be communicated in plain language and needed auxiliary aids and services should be provided.

(2) The support activities must include at least the following:

(i) Person-centered planning and how it is applied.

(ii) Range and scope of individual choices and options.

(iii) Process for changing the person-centered service plan and, if applicable, service budget.

(iv) Grievance process.

(v) Information on the risks and responsibilities of self-direction.

(vi) The ability to freely choose from available home and community-based attendant providers, available service delivery models and if applicable, financial management entities.

(vii) Individual rights, including appeal rights.

(viii) Reassessment and review schedules.

(ix) Defining goals, needs, and preferences of Community First Choice services and supports.

(x) Identifying and accessing services, supports, and resources.

(xi) Development of risk management agreements.

(A) The State must specify in the State Plan amendment any tools or instruments used to mitigate identified risks.

(B) States utilizing criminal or background checks as part of their risk management agreement will bear the costs of such activities.

(xii) Development of a personalized backup plan.

(xiii) Recognizing and reporting critical events.

(xiv) Information about an advocate or advocacy systems available in the State and how an individual can access the advocate or advocacy systems.

(c) Establishes conflict of interest standards for the assessments of functional need and the person-centered service plan development process that apply to all individuals and entities, public or private. At a minimum, these standards must ensure that the individuals or entities conducting the assessment of functional need and person-centered service plan development process are not:

(1) Related by blood or marriage to the individual, or to any paid caregiver of the individual.

(2) Financially responsible for the individual.

(3) Empowered to make financial or health-related decisions on behalf of the individual.

(4) Individuals who would benefit financially from the provision of assessed needs and services.

(5) Providers of State plan HCBS for the individual, or those who have an interest in or are employed by a provider of State plan HCBS for the individual, except when the State demonstrates that the only willing and qualified entity/entities to perform assessments of functional need and develop person-centered service plans in a geographic area also provides HCBS, and the State devises conflict of interest protections including separation of assessment/planning and HCBS provider functions within provider entities, which are described in the State plan, and individuals are provided with a clear and accessible alternative dispute resolution process.

(d) Ensures the responsibilities for assessment of functional need and person-centered service plan development are identified.

§ 441.560 Service budget requirements.

(a) For the self-directed model with a service budget, a service budget must be developed and approved by the State based on the assessment of functional need and person-centered service plan and must include all of the following requirements:

(1) The specific dollar amount an individual may use for Community First Choice services and supports.

(2) The procedures for informing an individual of the amount of the service budget before the person-centered service plan is finalized.

(3) The procedures for how an individual may adjust the budget including the following:

(i) The procedures for an individual to freely adjust amounts allocated to specific services and supports within the approved service budget.

(ii) The circumstances, if any, that may require prior approval by the State before a budget adjustment is made.

(4) The circumstances, if any, that may require a change in the person-centered service plan.

(5) The procedures that govern the determination of transition costs and other permissible services and supports as defined at § 441.520(b).

(6) The procedures for an individual to request a fair hearing under Subpart E of this title if an individual's request for a budget adjustment is denied or the amount of the budget is reduced.

(b) The budget methodology set forth by the State to determine an individual's service budget amount must:

(1) Be objective and evidence-based utilizing valid, reliable cost data.

(2) Be applied consistently to individuals.

(3) Be included in the State plan.

(4) Include a calculation of the expected cost of Community First Choice services and supports, if those services and supports are not self-directed.

(5) Have a process in place that describes the following:

(i) Any limits the State places on Community First Choice services and supports, and the basis for the limits.

(ii) Any adjustments that are allowed and the basis for the adjustments.

(c) The State must have procedures in place that will provide safeguards to individuals when the budgeted service amount is insufficient to meet the individual's needs.

(d) The State must have a method of notifying individuals of the amount of any limit that applies to an individual's Community First Choice services

and supports. Notice must be communicated in an accessible format, communicated in plain language, and needed auxiliary aids and services should be provided.

(e) The budget may not restrict access to other medically necessary care and services furnished under the State plan and approved by the State but which are not included in the budget.

(f) The State must have a procedure to adjust a budget when a reassessment indicates a change in an individual's medical condition, functional status, or living situation.

§ 441.565 Provider qualifications.

(a) For all service delivery models:

(1) An individual retains the right to train attendant care providers in the specific areas of attendant care needed by the individual, and to have the attendant care provider perform the needed assistance in a manner that comports with the individual's personal, cultural, and/or religious preferences.

(2) An individual retains the right to establish additional staff qualifications based on the individual's needs and preferences.

(3) Individuals also have the right to access other training provided by or through the State so that their attendant care provider(s) can meet any additional qualifications required or desired by individuals.

(b) For the agency-provider model, the State must define in writing adequate qualifications for providers in the agency model of Community First Choice services and supports.

(c) For the self-directed model with service budget, an individual has the option to permit family members, or any other individuals, to provide Community First Choice services and supports identified in the person-centered service plan, provided they meet the qualifications to provide the services and supports established by the individual, including additional training.

(d) For other models, the applicability of requirements at paragraphs (b) or (c) of this section will be determined based on the description and approval of the model.

§ 441.570 State assurances.

A State must assure the following requirements are met:

(a) Necessary safeguards have been taken to protect the health and welfare of enrollees in Community First Choice, including adherence to section 1903(i) of the Act that Medicaid payment shall not be made for items or services furnished by individuals or entities excluded from participating in the Medicaid Program.

(b) For the first full 12 month period in which the State plan amendment is implemented, the State must maintain or exceed the level of State expenditures for home and community-based attendant services and supports provided under sections 1115, 1905(a), 1915, or otherwise under the Act, to individuals with disabilities or elderly individuals attributable to the preceding 12 month period.

(c) All applicable provisions of the Fair Labor Standards Act of 1938.

(d) All applicable provisions of Federal and State laws regarding the following:

(1) Withholding and payment of Federal and State income and payroll taxes.

(2) The provision of unemployment and workers compensation insurance.

(3) Maintenance of general liability insurance.

(4) Occupational health and safety.

(5) Any other employment or tax related requirements.

§ 441.575 Development and Implementation Council.

(a) States must establish a Development and Implementation Council, the majority of which is comprised of individuals with disabilities, elderly individuals, and their representatives.

(b) States must consult and collaborate with the Council when developing and implementing a State plan amendment to provide Community First Choice services and supports.

§ 441.580 Data collection.

A State must provide the following information regarding the provision of home and community-based attendant

services and supports under Community First Choice for each Federal fiscal year for which the services and supports are provided:

(a) The number of individuals who are estimated to receive Community First Choice services and supports under this State plan option during the Federal fiscal year.

(b) The number of individuals who received the services and supports during the preceding Federal fiscal year.

(c) The number of individuals served broken down by type of disability, age, gender, education level, and employment status.

(d) The specific number of individuals who have been previously served under sections 1115, 1915(c) and (i) of the Act, or the personal care State plan option.

(e) Data regarding how the State provides Community First Choice and other home and community-based services.

(f) The cost of providing Community First Choice and other home and community-based services and supports.

(g) Data regarding how the State provides individuals with disabilities who otherwise qualify for institutional care under the State plan or under a waiver the choice to receive home and community-based services in lieu of institutional care.

(h) Data regarding the impact of Community First Choice services and supports on the physical and emotional health of individuals.

(i) Other data as determined by the Secretary.

§ 441.585 Quality assurance system.

(a) States must establish and maintain a comprehensive, continuous quality assurance system, described in the State plan amendment, which includes the following:

(1) A quality improvement strategy.

(2) Methods to continuously monitor the health and welfare of each individual who receives home and community-based attendant services and supports, including a process for the mandatory reporting, investigation, and resolution of allegations of neglect, abuse, or exploitation in connection with the provision of such services and supports.

(3) Measures individual outcomes associated with the receipt of home and community-based attendant services and supports as set forth in the person centered service plan, particularly for the health and welfare of individuals receiving such services and supports. These measures must be reported to CMS upon request.

(4) Standards for all service delivery models for training, appeals for denials and reconsideration procedures for an individual's person-centered service plan.

(5) Other requirements as determined by the Secretary.

(b) The State must ensure the quality assurance system will employ methods that maximizes individual independence and control, and provides information about the provisions of quality improvement and assurance to each individual receiving such services and supports.

(c) The State must elicit and incorporate feedback from individuals and their representatives, disability organizations, providers, families of disabled or elderly individuals, members of the community and others to improve the quality of the community-based attendant services and supports benefit.

§ 441.590 Increased Federal financial participation.

Beginning October 1, 2011, the FMAP applicable to the State will be increased by 6 percentage points, for the provision of Community First Choice services and supports, under an approved State plan amendment.

Subpart L—Vaccines for Children Program

SOURCE: 77 FR 66700, Nov. 6, 2012, unless otherwise noted.

§ 441.600 Basis and purpose.

This subpart implements sections 1902(a)(62) and 1928 of the Act by requiring states to provide for a program for the purchase and distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children.

§441.605 General requirements.

(a) Federally-purchased vaccines under the VFC Program are made available to children who are 18 years of age or younger and who are any of the following:

(1) Eligible for Medicaid.

(2) Not insured.

(3) Not insured with respect to the vaccine and who are administered pediatric vaccines by a federally qualified health center (FQHC) or rural health clinic.

(4) An Indian, as defined in section 4 of the Indian Health Care Improvement Act.

(b) Under the VFC program, vaccines must be administered by program-registered providers. Section 1928(c) of the Act defines a program-registered provider as any health care provider that meets the following requirements:

(1) Is licensed or authorized to administer pediatric vaccines under the law of the state in which the administration occurs without regard to whether or not the provider is a Medicaid-participating provider.

(2) Submits to the state an executed provider agreement in the form and manner specified by the Secretary.

(3) Has not been found, by the Secretary or the state to have violated the provider agreement or other applicable requirements established by the Secretary or the state.

§441.610 State plan requirements.

A state plan must provide that the Medicaid agency meets the requirements of this part.

§441.615 Administration fee requirements.

(a) Under the VFC Program, a provider who administers a qualified pediatric vaccine to a federally vaccine-eligible child, may not impose a charge for the cost of the vaccine.

(1) A provider can impose a fee for the administration of a qualified pediatric vaccine as long as the fee does not exceed the costs of the administration (as determined by the Secretary based on actual regional costs for the administration).

(2) A provider may not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents or legal guardian to pay the administration fee.

(b) The Secretary must publish each State's regional maximum charge for the VFC program, which represents the maximum amount that a provider in a state could charge for the administration of qualified pediatric vaccines to federally vaccine-eligible children under the VFC program.

(c) An interim formula has been established for the calculation of a state's regional maximum administration fee. That formula is as follows: National charge data × updated geographic adjustment factors (GAFs) = maximum VFC fee.

(d) The State Medicaid Agency must submit a state plan amendment that identifies the amount that the state will pay providers for the administration of a qualified pediatric vaccine to a Medicaid-eligible child under the VFC program. The amount identified by the state cannot exceed the state's regional maximum administration fee.

(e) Physicians participating in the VFC program can charge federally vaccine-eligible children who are not enrolled in Medicaid the maximum administration fee (if that fee reflects the provider's cost of administration) regardless of whether the state has established a lower administration fee under the Medicaid program. However, there would be no federal Medicaid matching funds available for the administration since these children are not eligible for Medicaid.

Subpart M—State Plan Home and Community-Based Services for the Elderly and Individuals with Disabilities

SOURCE: 79 FR 3033, Jan. 16, 2014, unless otherwise noted.

§441.700 Basis and purpose.

Section 1915(i) of the Act permits States to offer one or more home and community-based services (HCBS) under their State Medicaid plans to qualified individuals with disabilities or individuals who are elderly. Those services are listed in §440.182 of this chapter, and are described by the State, including any limitations of the

services. This optional benefit is known as the State plan HCBS benefit. This subpart describes what a State Medicaid plan must provide when the State elects to include the optional benefit, and defines State responsibilities.

§ 441.705 State plan requirements.

A State plan that provides section 1915(i) of the Act State plan home and community-based services must meet the requirements of this subpart.

§ 441.710 State plan home and community-based services under section 1915(i)(1) of the Act.

(a) Home and Community-Based Setting. States must make State plan HCBS available in a home and community-based setting consistent with both paragraphs (a)(1) and (a)(2) of this section.

(1) Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(ii) The setting is selected by the individual from among setting options, including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person–centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.

(iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact.

(v) Facilitates individual choice regarding services and supports, and who provides them.

(vi) In a provider-owned or controlled residential setting, in addition to the above qualities at paragraphs (a)(1)(i) through (v) of this section, the following additional conditions must be met:

(A) The unit or dwelling is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the state, county, city, or other designated entity. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS participant and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law;

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors;

(*2*) Individuals sharing units have a choice of roommates in that setting; and

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

(D) Individuals are able to have visitors of their choosing at any time;

(E) The setting is physically accessible to the individual; and

(F) Any modification of the additional conditions, under paragraphs (a)(1)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(*1*) Identify a specific and individualized assessed need.

(*2*) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(*3*) Document less intrusive methods of meeting the need that have been tried but did not work.

(*4*) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(*5*) Include regular collection and review of data to measure the ongoing effectiveness of the modification.

(*6*) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(*7*) Include the informed consent of the individual.

(*8*) Include an assurance that interventions and supports will cause no harm to the individual.

(2) Home and community-based settings do not include the following:

(i) A nursing facility.

(ii) An institution for mental diseases.

(iii) An intermediate care facility for individuals with intellectual disabilities.

(iv) A hospital.

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

(3) Compliance and transition:

(i) States submitting state plan amendments for new section 1915(i) of the Act benefits must provide assurances of compliance with the requirements of this section for home and community-based settings as of the effective date of the state plan amendment;

(ii) CMS will require transition plans for existing section 1915(c) waivers and approved state plans providing home and community-based services under section 1915(i) to achieve compliance with this section, as follows:

(A) For each approved section 1915(i) of the Act benefit subject to renewal or submitted for amendment within one year after the effective date of this regulation, the State must submit a transition plan at the time of the renewal or amendment request that sets forth the actions the State will take to bring the specific 1915(i) State plan benefit into compliance with this section. The approval will be contingent on the inclusion of the transition plan approved by CMS. The transition plan must include all elements required by the Secretary; and within one hundred and twenty days of the submission of the first renewal or amendment request the State must submit a transition plan detailing how the State will operate all section 1915(c) HCBS waivers and any section 1915(i) State plan benefit in accordance with this section. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(B) For States that do not have a section 1915(c) waiver or a section 1915(i) State plan benefit due for renewal or proposed for amendments within one year of the effective date of this regulation, the State must submit a transition plan detailing how the State will operate all section 1915(c) waivers and any section 1915(i) State plan benefit in accordance with this section. This plan must be submitted no later than one year after the effective date of this regulation. The transition plan must include all elements including timelines and deliverables as approved by the Secretary.

(iii) A State must provide at least a 30-day public notice and comment period regarding the transition plan(s) that the State intends to submit to

CMS for review and consideration, as follows:

(A) The State must at a minimum provide two (2) statements of public notice and public input procedures.

(B) The State must ensure the full transition plan(s) is available to the public for public comment.

(C) The State must consider and modify the transition plan, as the State deems appropriate, to account for public comment.

(iv) A State must submit to CMS, with the proposed transition plan:

(A) Evidence of the public notice required.

(B) A summary of the comments received during the public notice period, reasons why comments were not adopted, and any modifications to the transition plan based upon those comments.

(v) Upon approval by CMS, the State will begin implementation of the transition plans. The State's failure to submit an approvable transition plan as required by this section and/or to comply with the terms of the approved transition plan may result in compliance actions, including but not limited to deferral/disallowance of Federal Financial Participation.

(b) *Needs-Based Eligibility Requirement*. Meet needs-based criteria for eligibility for the State plan HCBS benefit, as required in § 441.715(a).

(c) *Minimum State plan HCBS Requirement*. Be assessed to require at least one section 1915(i) home and community-based service at a frequency determined by the State, as required in § 441.720(a)(5).

(d) *Target Population*. Meet any applicable targeting criteria defined by the State under the authority of paragraph (e)(2) of this section.

(e) *Nonapplication*. The State may elect in the State plan amendment approved under this subpart not to apply the following requirements when determining eligibility:

(1) Section 1902(a)(10)(C)(i)(III) of the Act, pertaining to income and resource eligibility rules for the medically needy living in the community, but only for the purposes of providing State plan HCBS.

(2) Section 1902(a)(10)(B) of the Act, pertaining to comparability of Medicaid services, but only for the purposes of providing section 1915(i) State plan HCBS. In the event that a State elects not to apply comparability requirements:

(i) The State must describe the group(s) receiving State plan HCBS, subject to the Secretary's approval. Targeting criteria cannot have the impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing. These groups must be defined on the basis of any combination of the following:

(A) Age.

(B) Diagnosis.

(C) Disability.

(D) Medicaid Eligibility Group.

(ii) The State may elect in the State plan amendment to limit the availability of specific services defined under the authority of § 440.182(c) of this chapter or to vary the amount, duration, or scope of those services, to one or more of the group(s) described in this paragraph.

§ 441.715 Needs-based criteria and evaluation.

(a) *Needs-based criteria*. The State must establish needs-based criteria for determining an individual's eligibility under the State plan for the HCBS benefit, and may establish needs-based criteria for each specific service. Needs-based criteria are factors used to determine an individual's requirements for support, and may include risk factors. The criteria are not characteristics that describe the individual or the individual's condition. A diagnosis is not a sufficient factor on which to base a determination of need. A criterion can be considered needs-based if it is a factor that can only be ascertained for a given person through an individualized evaluation of need.

(b) *More stringent institutional and waiver needs-based criteria*. The State plan HCBS benefit is available only if the State has in effect needs-based criteria (as defined in paragraph (a) of this section), for receipt of services in nursing facilities as defined in section

1919(a) of the Act, intermediate care facilities for individuals with intellectual disabilities as defined in §440.150 of this chapter, and hospitals as defined in §440.10 of this chapter for which the State has established long-term level of care (LOC) criteria, or waivers offering HCBS, and these needs-based criteria are more stringent than the needs-based criteria for the State plan HCBS benefit. If the State defines needs-based criteria for individual State plan home and community-based services, it may not have the effect of limiting who can benefit from the State plan HCBS in an unreasonable way, as determined by the Secretary.

(1) These more stringent criteria must meet the following requirements:

(i) Be included in the LOC determination process for each institutional service and waiver.

(ii) Be submitted for inspection by CMS with the State plan amendment that establishes the State Plan HCBS benefit.

(iii) Be in effect on or before the effective date of the State plan HCBS benefit.

(2) In the event that the State modifies institutional LOC criteria to meet the requirements under paragraph (b) or (c)(6) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, States may continue to receive FFP for individuals receiving institutional services or waiver HCBS under the LOC criteria previously in effect.

(c) *Adjustment authority*. The State may modify the needs-based criteria established under paragraph (a) of this section, without prior approval from the Secretary, if the number of individuals enrolled in the State plan HCBS benefit exceeds the projected number submitted annually to CMS. The Secretary may approve a retroactive effective date for the State plan amendment modifying the criteria, as early as the day following the notification period required under paragraph (c)(1) of this section, if all of the following conditions are met:

(1) The State provides at least 60 days notice of the proposed modification to the Secretary, the public, and each individual enrolled in the State plan HCBS benefit.

(2) The State notice to the Secretary is submitted as an amendment to the State plan.

(3) The adjusted needs-based eligibility criteria for the State plan HCBS benefit are less stringent than needs-based institutional and waiver LOC criteria in effect after the adjustment.

(4) Individuals who were found eligible for the State plan HCBS benefit before modification of the needs-based criteria under this adjustment authority must remain eligible for the HCBS benefit until such time as:

(i) The individual no longer meets the needs-based criteria used for the initial determination of eligibility; or

(ii) The individual is no longer eligible for or enrolled in Medicaid or the HCBS benefit.

(5) Any changes in service due to the modification of needs-based criteria under this adjustment authority are treated as actions as defined in §431.201 of this chapter and are subject to the requirements of part 431, subpart E of this chapter.

(6) In the event that the State also needs to modify institutional level of care criteria to meet the requirements under paragraph (b) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, the State may adjust the modified institutional LOC criteria under this adjustment authority. The adjusted institutional LOC criteria must be at least as stringent as those in effect before they were modified to meet the requirements in paragraph (b) of this section.

(d) *Independent evaluation and determination of eligibility*. Eligibility for the State plan HCBS benefit must be determined through an independent evaluation of each individual according to the requirements of this subpart. The independent evaluation complies with the following requirements:

(1) Is performed by an agent that is independent and qualified as defined in §441.730.

(2) Applies the needs-based eligibility criteria that the State has established under paragraph (a) of this section, and the general eligibility requirements under §§435.219 and 436.219 of this chapter.

(3) Includes consultation with the individual, and if applicable, the individual's representative as defined under § 441.735.

(4) Assesses the individual's support needs.

(5) Uses only current and accurate information from existing records, and obtains any additional information necessary to draw valid conclusions about the individual's support needs.

(6) Evaluations finding that an individual is not eligible for the State plan HCBS benefit are treated as actions defined in § 431.201 of this chapter and are subject to the requirements of part 431 subpart E of this chapter.

(e) *Periodic redetermination.* Independent reevaluations of each individual receiving the State plan HCBS benefit must be performed at least every 12 months, to determine whether the individual continues to meet eligibility requirements. Redeterminations must meet the requirements of paragraph (d) of this section.

§ 441.720 Independent assessment.

(a) *Requirements.* For each individual determined to be eligible for the State plan HCBS benefit, the State must provide for an independent assessment of needs, which may include the results of a standardized functional needs assessment, in order to establish a service plan. In applying the requirements of section 1915(i)(1)(F) of the Act, the State must:

(1) Perform a face-to-face assessment of the individual by an agent who is independent and qualified as defined in § 441.730, and with a person-centered process that meets the requirements of § 441.725(a) and is guided by best practice and research on effective strategies that result in improved health and quality of life outcomes.

(i) For the purposes of this section, a face-to-face assessment may include assessments performed by telemedicine, or other information technology medium, if the following conditions are met:

(A) The agent performing the assessment is independent and qualified as defined in § 441.730 and meets the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology.

(B) The individual receives appropriate support during the assessment, including the use of any necessary onsite support-staff.

(C) The individual provides informed consent for this type of assessment.

(ii) [Reserved]

(2) Conduct the assessment in consultation with the individual, and if applicable, the individual's authorized representative, and include the opportunity for the individual to identify other persons to be consulted, such as, but not limited to, the individual's spouse, family, guardian, and treating and consulting health and support professionals responsible for the individual's care.

(3) Examine the individual's relevant history including the findings from the independent evaluation of eligibility, medical records, an objective evaluation of functional ability, and any other records or information needed to develop the person-centered service plan as required in § 441.725.

(4) Include in the assessment the individual's physical, cognitive, and behavioral health care and support needs, strengths and preferences, available service and housing options, and if unpaid caregivers will be relied upon to implement any elements of the person-centered service plan, a caregiver assessment.

(5) For each service, apply the State's additional needs-based criteria (if any) that the individual may require. Individuals are considered enrolled in the State plan HCBS benefit only if they meet the eligibility and needs-based criteria for the benefit, and are also assessed to require and receive at least one home and community-based service offered under the State plan for medical assistance.

(6) Include in the assessment, if the State offers individuals the option to self-direct a State plan home and community-based service or services, any information needed for the self-directed portion of the service plan, as required in § 441.740(b), including the ability of the individual (with and without supports) to exercise budget or employer authority.

(7) Include in the assessment, for individuals receiving habilitation services, documentation that no Medicaid services are provided which would otherwise be available to the individual, specifically including but not limited to services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973, or the Individuals with Disabilities Education Improvement Act of 2004.

(8) Include in the assessment and subsequent service plan, for individuals receiving Secretary approved services under the authority of §440.182 of this chapter, documentation that no State plan HCBS are provided which would otherwise be available to the individual through other Medicaid services or other Federally funded programs.

(9) Include in the assessment and subsequent service plan, for individuals receiving HCBS through a waiver approved under §441.300, documentation that HCBS provided through the State plan and waiver are not duplicative.

(10) Coordinate the assessment and subsequent service plan with any other assessment or service plan required for services through a waiver authorized under section 1115 or section 1915 of the Social Security Act.

(b) *Reassessments*. The independent assessment of need must be conducted at least every 12 months and as needed when the individual's support needs or circumstances change significantly, in order to revise the service plan.

§441.725 Person-centered service plan.

(a) *Person-centered planning process*. Based on the independent assessment required in §441.720, the State must develop (or approve, if the plan is developed by others) a written service plan jointly with the individual (including, for purposes of this paragraph, the individual and the individual's authorized representative if applicable). The person-centered planning process is driven by the individual. The process:

(1) Includes people chosen by the individual.

(2) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(3) Is timely and occurs at times and locations of convenience to the individual.

(4) Reflects cultural considerations of the individual and is conducted by providing information in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with §435.905(b) of this chapter.

(5) Includes strategies for solving conflict or disagreement within the process, including clear conflict of interest guidelines for all planning participants.

(6) Offers choices to the individual regarding the services and supports the individual receives and from whom.

(7) Includes a method for the individual to request updates to the plan, as needed.

(8) Records the alternative home and community-based settings that were considered by the individual.

(b) The person-centered service plan. The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under the State plan HCBS benefit, the written plan must:

(1) Reflect that the setting in which the individual resides is chosen by the individual. The State must ensure that the setting chosen by the individual is integrated in, and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community to the same degree of access as individuals not receiving Medicaid HCBS.

(2) Reflect the individual's strengths and preferences.

(3) Reflect clinical and support needs as identified through an assessment of functional need.

(4) Include individually identified goals and desired outcomes.

(5) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports are unpaid supports that are provided voluntarily to the individual in lieu of State plan HCBS.

(6) Reflect risk factors and measures in place to minimize them, including individualized backup plans and strategies when needed.

(7) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her. At a minimum, for the written plan to be understandable, it must be written in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

(8) Identify the individual and/or entity responsible for monitoring the plan.

(9) Be finalized and agreed to, with the informed consent of the individual in writing, and signed by all individuals and providers responsible for its implementation.

(10) Be distributed to the individual and other people involved in the plan.

(11) Include those services, the purchase or control of which the individual elects to self-direct, meeting the requirements of § 441.740.

(12) Prevent the provision of unnecessary or inappropriate services and supports.

(13) Document that any modification of the additional conditions, under § 441.710(a)(1)(vi)(A) through (D) of this chapter, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

(i) Identify a specific and individualized assessed need.

(ii) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.

(iii) Document less intrusive methods of meeting the need that have been tried but did not work.

(iv) Include a clear description of the condition that is directly proportionate to the specific assessed need.

(v) Include a regular collection and review of data to measure the ongoing effectiveness of the modification.

(vi) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.

(vii) Include informed consent of the individual; and

(viii) Include an assurance that the interventions and supports will cause no harm to the individual.

(c) Reviewing the person-centered service plan. The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required in § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual.

§ 441.730 Provider qualifications.

(a) *Requirements.* The State must provide assurances that necessary safeguards have been taken to protect the health and welfare of enrollees in State plan HCBS, and must define in writing standards for providers (both agencies and individuals) of HCBS and for agents conducting individualized independent evaluation, independent assessment, and service plan development.

(b) *Conflict of interest standards.* The State must define conflict of interest standards that ensure the independence of individual and agency agents who conduct (whether as a service or an administrative activity) the independent evaluation of eligibility for State plan HCBS, who are responsible for the independent assessment of need for HCBS, or who are responsible for the development of the service plan. The conflict of interest standards apply to all individuals and entities, public or private. At a minimum, these agents must not be any of the following:

(1) Related by blood or marriage to the individual, or to any paid caregiver of the individual.

(2) Financially responsible for the individual.

(3) Empowered to make financial or health-related decisions on behalf of the individual.

(4) Holding financial interest, as defined in §411.354 of this chapter, in any entity that is paid to provide care for the individual.

(5) Providers of State plan HCBS for the individual, or those who have an interest in or are employed by a provider of State plan HCBS for the individual, except when the State demonstrates that the only willing and qualified agent to perform independent assessments and develop person-centered service plans in a geographic area also provides HCBS, and the State devises conflict of interest protections including separation of agent and provider functions within provider entities, which are described in the State plan for medical assistance and approved by the Secretary, and individuals are provided with a clear and accessible alternative dispute resolution process.

(c) *Training*. Qualifications for agents performing independent assessments and plans of care must include training in assessment of individuals whose physical, cognitive, or mental conditions trigger a potential need for home and community-based services and supports, and current knowledge of available resources, service options, providers, and best practices to improve health and quality of life outcomes.

§441.735 Definition of individual's representative.

In this subpart, the term *individual's representative* means, with respect to an individual being evaluated for, assessed regarding, or receiving State plan HCBS, the following:

(a) The individual's legal guardian or other person who is authorized under State law to represent the individual for the purpose of making decisions related to the person's care or well-being. In instances where state law confers decision-making authority to the individual representative, the individual will lead the service planning process to the extent possible.

(b) Any other person who is authorized under §435.923 of this chapter, or under the policy of the State Medicaid Agency to represent the individual, including but not limited to, a parent, a family member, or an advocate for the individual.

(c) When the State authorizes representatives in accordance with paragraph (b) of this section, the State must have policies describing the process for authorization; the extent of decision-making authorized; and safeguards to ensure that the representative uses substituted judgment on behalf of the individual. State policies must address exceptions to using substituted judgment when the individual's wishes cannot be ascertained or when the individual's wishes would result in substantial harm to the individual. States may not refuse the authorized representative that the individual chooses, unless in the process of applying the requirements for authorization, the State discovers and can document evidence that the representative is not acting in accordance with these policies or cannot perform the required functions. States must continue to meet the requirements regarding the person-centered planning process at §441.725 of this chapter.

§441.740 Self-directed services.

(a) *State option*. The State may choose to offer an election for self-directing HCBS. The term ''self-directed'' means, with respect to State plan HCBS listed in §440.182 of this chapter, services that are planned and purchased under the direction and control of the individual, including the amount, duration, scope, provider, and location of the HCBS. For purposes of this paragraph, individual means the individual and, if applicable, the individual's representative as defined in §441.735.

(b) *Service plan requirement*. Based on the independent assessment required in §441.720, the State develops a service plan jointly with the individual as required in §441.725. If the individual chooses to direct some or all HCBS, the service plan must meet the following additional requirements:

(1) Specify the State plan HCBS that the individual will be responsible for directing.

(2) Identify the methods by which the individual will plan, direct or control services, including whether the individual will exercise authority over the employment of service providers and/or authority over expenditures from the individualized budget.

(3) Include appropriate risk management techniques that explicitly recognize the roles and sharing of responsibilities in obtaining services in a self-directed manner and assure the appropriateness of this plan based upon the resources and support needs of the individual.

(4) Describe the process for facilitating voluntary and involuntary transition from self-direction including any circumstances under which transition out of self-direction is involuntary. There must be state procedures to ensure the continuity of services during the transition from self-direction to other service delivery methods.

(5) Specify the financial management supports, as required in paragraph (e) of this section, to be provided.

(c) *Employer authority*. If the person-centered service plan includes authority to select, manage, or dismiss providers of the State plan HCBS, the person-centered service plan must specify the authority to be exercised by the individual, any limits to the authority, and specify parties responsible for functions outside the authority the individual exercises.

(d) *Budget authority*. If the person-centered service plan includes an individualized budget (which identifies the dollar value of the services and supports under the control and direction of the individual), the person-centered service plan must meet the following requirements:

(1) Describe the method for calculating the dollar values in the budget, based on reliable costs and service utilization.

(2) Define a process for making adjustments in dollar values to reflect changes in an individual's assessment and service plan.

(3) Provide a procedure to evaluate expenditures under the budget.

(4) Not result in payment for medical assistance to the individual.

(e) *Functions in support of self-direction*. When the State elects to offer self-directed State plan HCBS, it must offer the following individualized supports to individuals receiving the services and their representatives:

(1) Information and assistance consistent with sound principles and practice of self-direction.

(2) Financial management supports to meet the following requirements:

(i) Manage Federal, State, and local employment tax, labor, worker's compensation, insurance, and other requirements that apply when the individual functions as the employer of service providers.

(ii) Make financial transactions on behalf of the individual when the individual has personal budget authority.

(iii) Maintain separate accounts for each individual's budget and provide periodic reports of expenditures against budget in a manner understandable to the individual.

(3) Voluntary training on how to select, manage, and dismiss providers of State plan HCBS.

§ 441.745 State plan HCBS administration: State responsibilities and quality improvement.

(a) *State plan HCBS administration*—(1) *State responsibilities*. The State must carry out the following responsibilities in administration of its State plan HCBS:

(i) *Number served*. The State will annually provide CMS with the projected number of individuals to be enrolled in the benefit and the actual number of unduplicated individuals enrolled in State plan HCBS in the previous year.

(ii) *Access to services*. The State must grant access to all State plan HCBS assessed to be needed in accordance with a service plan consistent with § 441.725, to individuals who have been determined to be eligible for the State plan HCBS benefit, subject to the following requirements:

(A) A State must determine that provided services meet medical necessity criteria.

(B) A State may limit access to services through targeting criteria established by § 441.710(e)(2).

(C) A State may not limit access to services based upon the income of eligible individuals, the cost of services, or the individual's location in the State.

(iii) *Appeals*. A State must provide individuals with advance notice of and the right to appeal terminations, suspensions, or reductions of Medicaid eligibility or covered services as described in part 431, subpart E.

(2) *Administration*—(i) *Option for presumptive payment*. (A) The State may provide for a period of presumptive payment, not to exceed 60 days, for Medicaid eligible individuals the State has reason to believe may be eligible for the State plan HCBS benefit. FFP is available for both services that meet the definition of medical assistance and necessary administrative expenditures for evaluation of eligibility for the State plan HCBS benefit under §441.715(d) and assessment of need for specific HCBS under §441.720(a), prior to an individual's receipt of State plan HCBS or determination of ineligibility for the benefit.

(B) If an individual the State has reason to believe may be eligible for the State plan HCBS benefit is evaluated and assessed under the presumptive payment option and found not to be eligible for the benefit, FFP is available for services that meet the definition of medical assistance and necessary administrative expenditures. The individual so determined will not be considered to have enrolled in the State plan HCBS benefit for purposes of determining the annual number of participants in the benefit.

(ii) *Option for phase-in of services and eligibility*. (A) In the event that a State elects to establish targeting criteria through §441.710(e)(2), the State may limit the enrollment of individuals or the provision services to enrolled individuals based upon criteria described in a phase-in plan, subject to CMS approval. A State which elects to target the State plan HCBS benefit and to phase-in enrollment and/or services must submit a phase-in plan for approval by CMS that describes, at a minimum:

(*1*) The criteria used to limit enrollment or service delivery.

(*2*) The rationale for phasing-in services and/or eligibility.

(*3*) Timelines and benchmarks to ensure that the benefit is available statewide to all eligible individuals within the initial 5-year approval.

(B) If a State elects to phase-in the enrollment of individuals based on highest need, the phase-in plan must use the needs-based criteria described in §441.715(a) to establish priority for enrollment. Such criteria must be based upon the assessed need of individuals, with higher-need individuals receiving services prior to individuals with lower assessed need.

(C) If a State elects to phase-in the provision of any services, the phase-in plan must include a description of the services that will not be available to all eligible individuals, the rationale for limiting the provision of services, and assurance that all individuals with access to a willing and qualified provider may receive services.

(D) The plan may not include a cap on the number of enrollees.

(E) The plan must include a timeline to assure that all eligible individuals receive all included services prior to the end of the first 5-year approval period, described in paragraph (a)(2)(vi) of this section.

(iii) *Reimbursement methodology*. The State plan amendment to provide State plan HCBS must contain a description of the reimbursement methodology for each covered service, in accordance with CMS sub-regulatory guidance. To the extent that the reimbursement methodologies for any self-directed services differ from those descriptions, the method for setting reimbursement methodology for the self-directed services must also be described.

(iv) *Operation*. The State plan amendment to provide State plan HCBS must contain a description of the State Medicaid agency line of authority for operating the State plan HCBS benefit, including distribution of functions to other entities.

(v) *Modifications*. The agency may request that modifications to the benefit be made effective retroactive to the first day of a fiscal year quarter, or another date after the first day of a fiscal year quarter, in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, the following:

(A) Revisions to services available under the benefit including elimination or reduction in services, and changes in

the scope, amount and duration of the services.

(B) Changes in the qualifications of service providers, rate methodology, or the eligible population.

(*1*) *Request for Amendments*. A request for an amendment that involves a substantive change as determined by CMS—

(*i*) May only take effect on or after the date when the amendment is approved by CMS; and

(*ii*) Must be accompanied by information on how the State will ensure for transitions with minimal adverse impact on individuals impacted by the change.

(*2*) [Reserved]

(vi) *Periods of approval*. (A) If a State elects to establish targeting criteria through §441.710(e)(2)(i), the approval of the State Plan Amendment will be in effect for a period of 5 years from the effective date of the amendment. To renew State plan HCBS for an additional 5-year period, the State must provide a written request for renewal to CMS at least 180 days prior to the end of the approval period. CMS approval of a renewal request is contingent upon State adherence to Federal requirements and the state meeting its objectives with respect to quality improvement and beneficiary outcomes.

(B) If a State does not elect to establish targeting criteria through §441.710(e)(2)(i), the limitations on length of approval does not apply.

(b) *Quality improvement strategy: Program performance and quality of care*. States must develop and implement an HCBS quality improvement strategy that includes a continuous improvement process and measures of program performance and experience of care. The strategy must be proportionate to the scope of services in the State plan HCBS benefit and the number of individuals to be served. The State will make this information available to CMS at a frequency determined by the Secretary or upon request.

(1) *Quality Improvement Strategy*. The quality improvement strategy must include all of the following:

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement.

(ii) Be evidence-based, and include outcome measures for program performance, quality of care, and individual experience as determined by the Secretary.

(iii) Provide evidence of the establishment of sufficient infrastructure to implement the program effectively.

(iv) Measure individual outcomes associated with the receipt of HCBS, related to the implementation of goals included in the individual service plan.

(2) [Reserved]

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

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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 individuals with intellectual disabilities. 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 individuals with intellectual disabilities;
Section 1905 (f), definition of nursing facility services;
Section 1910, certification and approval of ICFs/IID 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 individuals with intellectual disabilities.

(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 Individuals with Intellectual Disabilities or persons with related conditions (ICF/IID).

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 beneficiary 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/IID 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/IID 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/IID.

(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 ICF/IIDs.

(a) The agreement for an ICF/IID remains in effect until the Secretary determines that the facility no longer meets the applicable requirements. The State Survey Agency must conduct a survey of the facility to determine compliance with the requirements at a survey interval of no greater than 15 months.

(b) FFP is available for services furnished by a facility for up to 30 days after its agreement expires or terminates under the conditions specified in § 441.11 of this subchapter.

[77 FR 29031, May 16, 2012]

§ 442.16 [Reserved]

§ 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/IID 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/IID.

(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/IID.

(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/IID 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 beneficiary health and safety. When the survey agency certifies that there is jeopardy to beneficiary 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/IID 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/IID 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 beneficiaries' 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/IID prevails on appeal from termination or, in the case of an ICF/IID, 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/IID

§ 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/IID'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/IID located on an Indian reservation.

(c) The agency must obtain notice of certification from the survey agency for all other ICFs/IID.

(d) The notice must indicate that one of the following provisions pertains to the ICF/IID:

(1) An ICF/IID meets the conditions of participation set forth in subpart I of part 483 of this chapter.

(2) The ICF/IID 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/IID 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.

(e) The failure to meet one or more of the applicable conditions of participation is cause for termination or non-renewal of the ICF/IID provider agreement.

[56 FR 48866, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 59 FR 56236, Nov. 10, 1994; 79 FR 27153, May 12, 2014]

§ 442.105 [Reserved]

§ 442.109 Certification period for ICF/IIDs: General provisions.

(a) A survey agency may certify a facility that fully meets applicable requirements. The State Survey Agency must conduct a survey of each ICF/IID not later than 15 months after the last day of the previous survey.

(b) The statewide average interval between surveys must be 12 months or less, computed in accordance with paragraph (c) of this section.

(c) The statewide average interval is computed at the end of each Federal fiscal year by comparing the last day of the most recent survey for each participating facility to the last day of each facility's previous survey.

[77 FR 29031, May 16, 2012]

§ 442.110 Certification period for ICF/IID with standard-level deficiencies.

Facilities with standard-level deficiencies may be certified under § 442.101 with a condition that the certification will continue if either of the following applies:

(a) The survey agency finds that all deficiencies have been satisfactorily corrected.

(b) The survey agency finds that the facility has made substantial progress in correcting the deficiencies and has a new plan of correction that is acceptable.

[79 FR 27153, May 12, 2014]

§ 442.117 Termination of certification for ICFs/IID 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/IID 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/IID.

(a) *Basis for denial of payments.* The Medicaid agency may deny payment for new admissions to an ICF/IID 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/IID.

(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/IID.

(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/IID.

(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/IID; 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/IID 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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AUTHORITY: 42 U.S.C. 1302 and 1396r–8.

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 beneficiary, under an assignment, power of attorney, or similar arrangement, 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 beneficiary if he is a noncash beneficiary 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 beneficiary by a provider may not be made to or through a factor, either directly or by power of attorney.

(i) The payment prohibition in section 1902(a)(32) of the Act and paragraph (d) of this section does not apply to payments to a third party on behalf of an individual practitioner for benefits such as health insurance, skills training, and other benefits customary for employees, in the case of a class of practitioners for which the Medicaid program is the primary source of revenue, if the practitioner voluntarily consents to such payments to third parties on the practitioner's behalf.

[43 FR 45253, Sept. 29, 1978, as amended at 46 FR 42672, Aug. 24, 1981; 61 FR 38398, July 24, 1996; 79 FR 3039, Jan. 16, 2014; 84 FR 19728, May 6, 2019; 87 FR 29690, May 16, 2022]

§ 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. The provider may only 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 § 447.52(e). 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.

[78 FR 42307, July 15, 2013]

§ 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 §§ 447.52 through 447.54), 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 §§ 447.52 through 447.54), 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 §§ 447.52 through 447.54; 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 §§ 447.52 through 447.54) 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, as amended at 78 FR 42307, July 15, 2013]

§ 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 beneficiaries 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 beneficiaries 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 beneficiaries 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 beneficiary—

(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 beneficiary.

(d) *Federal requirements.* (1) Direct payments to beneficiaries 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.

§ 447.26 Prohibition on payment for provider-preventable conditions.

(a) *Basis and purpose.* The purpose of this section is to protect Medicaid beneficiaries and the Medicaid program by prohibiting payments by States for services related to provider-preventable conditions.

(1) Section 2702 of the Affordable Care Act requires that the Secretary exercise authority to prohibit Federal payment for certain provider preventable conditions (PPCs) and health care-acquired conditions (HCACs).

(2) Section 1902(a)(19) of the Act requires that States provide care and services consistent with the best interests of the beneficiaries.

(3) Section 1902(a)(30) of the Act requires that State payment methods must be consistent with efficiency, economy, and quality of care.

(b) *Definitions.* As used in this section—

Health care-acquired condition means a condition occurring in any inpatient hospital setting, identified as a HAC by the Secretary under section 1886(d)(4)(D)(iv) of the Act for purposes of the Medicare program identified in the State plan as described in section 1886(d)(4)(D)(ii) and (iv) of the Act; other than Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) as related to total knee replacement or hip replacement surgery in pediatric and obstetric patients.

Other provider-preventable condition means a condition occurring in any health care setting that meets the following criteria:

(i) Is identified in the State plan.

(ii) Has been found by the State, based upon a review of medical literature by qualified professionals, to be reasonably preventable through the application of procedures supported by evidence-based guidelines.

(iii) Has a negative consequence for the beneficiary.

(iv) Is auditable.

(v) Includes, at a minimum, wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part; surgical or other invasive procedure performed on the wrong patient.

Provider-preventable condition means a condition that meets the definition of a ''health care-acquired condition'' or an ''other provider-preventable condition'' as defined in this section.

(c) *General rules.* (1) A State plan must provide that no medical assistance will be paid for ''provider-preventable conditions'' as defined in this section; and as applicable for individuals dually eligible for both the Medicare and Medicaid programs.

(2) No reduction in payment for a provider preventable condition will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider.

(3) Reductions in provider payment may be limited to the extent that the following apply:

(i) The identified provider-preventable conditions would otherwise result in an increase in payment.

(ii) The State can reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the provider-preventable conditions.

(4) FFP will not be available for any State expenditure for provider-preventable conditions.

(5) A State plan must ensure that non-payment for provider-preventable conditions does not prevent access to services for Medicaid beneficiaries.

(d) *Reporting.* State plans must require that providers identify provider-

preventable conditions that are associated with claims for Medicaid payment or with courses of treatment furnished to Medicaid patients for which Medicaid payment would otherwise be available.

[76 FR 32837, June 6, 2011]

§ 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 beneficiary'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 beneficiary 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 beneficiary 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 beneficiary'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 post-payment 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]

MEDICAID PREMIUMS AND COST SHARING

SOURCE: 78 FR 42307, July 15, 2013, unless otherwise noted.

§ 447.50 Premiums and cost sharing: Basis and purpose.

Sections 1902(a)(14), 1916 and 1916A of the Act permit states to require certain beneficiaries to share in the costs of providing medical assistance through premiums and cost sharing. Sections 447.52 through 447.56 specify the standards and conditions under which states may impose such premiums and or cost sharing.

§ 447.51 Definitions.

As used in this part—

Alternative non-emergency services provider means a Medicaid provider, such as a physician's office, health care clinic, community health center, hospital outpatient department, or similar provider that can provide clinically appropriate services in a timely manner.

Contract health service means any health service that is:

(1) Delivered based on a referral by, or at the expense of, an Indian health program; and

(2) Provided by a public or private medical provider or hospital that is not a provider or hospital of the IHS or any other Indian health program

Cost sharing means any copayment, coinsurance, deductible, or other similar charge.

Emergency services has the same meaning as in § 438.114 of this chapter.

Federal poverty level (FPL) means the Federal poverty level updated periodically in the FEDERAL REGISTER by the Secretary of Health and Human Services under the authority of 42 U.S.C. 9902(2).

Indian means any individual defined at 25 U.S.C. 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(1) Is a member of a Federally-recognized Indian tribe;

(2) Resides in an urban center and meets one or more of the following four criteria:

(i) 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;

(ii) Is an Eskimo or Aleut or other Alaska Native;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(iv) Is determined to be an Indian under regulations promulgated by the Secretary;

(3) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(4) 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.

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).

Inpatient stay means the services received during a continuous period of inpatient days in either a single medical institution or multiple medical institutions, and also includes a return to an inpatient medical institution after a brief period when the return is for treatment of a condition that was present in the initial period. Inpatient has the same meaning as in § 440.2 of this chapter.

Non-emergency services means any care or services that are not considered emergency services as defined in this section. This does not include any services furnished in a hospital emergency department that are required to be provided as an appropriate medical screening examination or stabilizing examination and treatment under section 1867 of the Act.

Outpatient services for purposes of imposing cost sharing means any service or supply not meeting the definition of an inpatient stay.

Preferred drugs means drugs that the state has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost effective drugs within each therapeutically equivalent or therapeutically similar class of drugs, or all drugs within such a class if the agency does not differentiate between preferred and non-preferred drugs.

Premium means any enrollment fee, premium, or other similar charge.

§ 447.52 Cost sharing.

(a) *Applicability*. Except as provided in § 447.56(a) (exemptions), the agency may impose cost sharing for any service under the state plan.

(b) *Maximum Allowable Cost Sharing*. (1) At State option, cost sharing imposed for any service (other than for drugs and non-emergency services furnished in an emergency department, as described in §§ 447.53 and 447.54 respectively) may be established at or below the amounts shown in the following table (except that the maximum allowable cost sharing for individuals with family income at or below 100 percent of the FPL shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI–U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment):

Services	Maximum allowable cost sharing		
	Individuals with family income ≤100% of the FPL	Individuals with family income 101–150% of the FPL	Individuals with family income >150% of the FPL
Outpatient Services (*physician visit, physical therapy, etc.*).	$4	10% of cost the agency pays	20% of cost the agency pays.
Inpatient Stay	75	10% of total cost the agency pays for the entire stay.	20% of total cost the agency pays for the entire stay.

(2) States with cost sharing for an inpatient stay that exceeds $75, as of July 15, 2013, must submit a plan to CMS that provides for reducing inpatient cost sharing to $75 on or before July 1, 2017.

(3) In states that do not have fee-for-service payment rates, any cost sharing imposed on individuals at any income level may not exceed the maximum amount established, for individuals with income at or below 100 percent of the FPL described in paragraph (b)(1) of this section.

(c) *Maximum cost sharing.* In no case shall the maximum cost sharing established by the agency be equal to or exceed the amount the agency pays for the service.

(d) *Targeted cost sharing.* (1) Except as provided in paragraph (d)(2) of this section, the agency may target cost sharing to specified groups of individuals with family income above 100 percent of the FPL.

(2) For cost sharing imposed for non-preferred drugs under § 447.53 and for non-emergency services provided in a hospital emergency department under § 447.54, the agency may target cost sharing to specified groups of individuals regardless of income.

(e) *Denial of service for nonpayment.* (1) The agency may permit a provider, including a pharmacy or hospital, to require an individual to pay cost sharing as a condition for receiving the item or service if—

(i) The individual has family income above 100 percent of the FPL,

(ii) The individual is not part of an exempted group under § 447.56(a), and

(iii) For cost sharing imposed for non-emergency services furnished in an emergency department, the conditions under § 447.54(d) of this part have been satisfied.

(2) Except as provided under paragraph (e)(1) of this section, the state plan must specify that no provider may deny services to an eligible individual on account of the individual's inability to pay the cost sharing.

(3) Nothing in this section shall be construed as prohibiting a provider from choosing to reduce or waive such cost sharing on a case-by-case basis.

(f) *Prohibition against multiple charges.* For any service, the agency may not impose more than one type of cost sharing.

(g) *Income-related charges.* Subject to the maximum allowable charges specified in §§ 447.52(b), 447.53(b) and 447.54(b), the plan may establish different cost sharing charges for individuals at different income levels. If the agency imposes such income-related charges, it must ensure that lower income individuals are charged less than individuals with higher income.

(h) *Services furnished by a managed care organization (MCO).* Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the cost sharing specified in the state plan and the requirements set forth in §§ 447.50 through 447.57.

(i) *State Plan Specifications.* For each cost sharing charge imposed under this part, the state plan must specify—

(1) The service for which the charge is made;

(2) The group or groups of individuals that may be subject to the charge;

(3) The amount of the charge;

(4) The process used by the state to—

(i) Ensure individuals exempt from cost sharing are not charged,

(ii) Identify for providers whether cost sharing for a specific item or service may be imposed on an individual and whether the provider may require the individual, as a condition for receiving the item or service, to pay the cost sharing charge; and

(5) If the agency imposes cost sharing under § 447.54, the process by which hospital emergency room services are identified as non-emergency service.

§ 447.53 Cost sharing for drugs.

(a) The agency may establish differential cost sharing for preferred and non-preferred drugs. The provisions in § 447.56(a) shall apply except as the agency exercises the option under paragraph (d) of this section. All drugs will be considered preferred drugs if so identified or if the agency does not differentiate between preferred and non-preferred drugs.

(b) At state option, cost sharing for drugs may be established at or below the amounts shown in the following table (except that the maximum allowable cost sharing shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI–U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment.

Such increase shall not be applied to any cost sharing that is based on the amount the agency pays for the service):

Services	Maximum allowable cost sharing	
	Individuals with family income ≤150% of the FPL	Individuals with family income >150% of the FPL
Preferred Drugs	$4	$4.
Non-Preferred Drugs	8	20% of the cost the agency pays.

(c) In states that do not have fee-for-service payment rates, cost sharing for prescription drugs imposed on individuals at any income level may not exceed the maximum amount established for individuals with income at or below 150 percent of the FPL in paragraph (b) of this section.

(d) For individuals otherwise exempt from cost sharing under § 447.56(a), the agency may impose cost sharing for non-preferred drugs, not to exceed the maximum amount established in paragraph (b) of this section.

(e) In the case of a drug that is identified by the agency as a non-preferred drug within a therapeutically equivalent or therapeutically similar class of drugs, the agency must have a timely process in place so that cost sharing is limited to the amount imposed for a preferred drug if the individual's prescribing provider determines that a preferred drug for treatment of the same condition either will be less effective for the individual, will have adverse effects for the individual, or both. In such cases the agency must ensure that reimbursement to the pharmacy is based on the appropriate cost sharing amount.

§ 447.54 Cost sharing for services furnished in a hospital emergency department.

(a) The agency may impose cost sharing for non-emergency services provided in a hospital emergency department. The provisions in § 447.56(a) shall apply except as the agency exercises the option under paragraph (c) of this section.

(b) At state option, cost sharing for non-emergency services provided in an emergency department may be established at or below the amounts shown in the following table (except that the maximum allowable cost sharing identified for individuals with family income at or below 150 percent of the FPL shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI–U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment):

Services	Maximum allowable cost sharing	
	Individuals with family income ≤150% of the FPL	Individuals with family income >150% of the FPL
Non-emergency Use of the Emergency Department	$8	No Limit.

(c) For individuals otherwise exempt from cost sharing under § 447.56(a), the agency may impose cost sharing for non-emergency use of the emergency department, not to exceed the maximum amount established in paragraph (b) of this section for individuals with income at or below 150 percent of the FPL.

(d) For the agency to impose cost sharing under paragraph (a) or (c) of this section for non-emergency use of the emergency department, the hospital providing the care must—

(1) Conduct an appropriate medical screening under § 489.24 subpart G to determine that the individual does not need emergency services.

(2) Before providing non-emergency services and imposing cost sharing for such services:

(i) Inform the individual of the amount of his or her cost sharing obligation for non-emergency services provided in the emergency department;

(ii) Provide the individual with the name and location of an available and accessible alternative non-emergency services provider;

(iii) Determine that the alternative provider can provide services to the individual in a timely manner with the imposition of a lesser cost sharing amount or no cost sharing if the individual is otherwise exempt from cost sharing; and

(iv) Provide a referral to coordinate scheduling for treatment by the alternative provider.

(e) Nothing in this section shall be construed to:

(1) Limit a hospital's obligations for 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 for payment or coverage of emergency medical services by any managed care organization.

§ 447.55 Premiums.

(a) The agency may impose premiums upon individuals whose income exceeds 150 percent of the FPL, subject to the exemptions set forth in § 447.56(a) and the aggregate limitations set forth in § 447.56(f) of this part, except that:

(1) Pregnant women described in described in paragraph (a)(1)(ii) of this section may be charged premiums that do not exceed 10 percent of the amount by which their family income exceeds 150 percent of the FPL after deducting expenses for care of a dependent child.

(i) The agency may use state or local funds available under other programs for payment of a premium for such pregnant women. Such funds shall not be counted as income to the individual for whom such payment is made.

(ii) Pregnant women described in this clause include pregnant women eligible for Medicaid under § 435.116 of this chapter whose income exceeds the higher of –

(A) 150 percent FPL; and

(B) If applicable, the percent FPL described in section 1902(l)(2)(A)(iv) of the Act up to 185 percent FPL.

(2) Individuals provided medical assistance only under sections 1902(a)(10)(A)(ii)(XV) or 1902(a)(10)(A)(ii)(XVI) of the Act and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA), may be charged premiums on a sliding scale based on income.

(3) Disabled children provided medical assistance under section 1902(a)(10)(A)(ii)(XIX) of the Act in accordance with the Family Opportunity Act, may be charged premiums on a sliding scale based on income. The aggregate amount of the child's premium imposed under this paragraph and any premium that the parent is required to pay for family coverage under section 1902(cc)(2)(A)(i) of the Act, and other cost sharing charges may not exceed:

(i) 5 percent of the family's income if the family's income is no more than 200 percent of the FPL.

(ii) 7.5 percent of the family's income if the family's income exceeds 200 percent of the FPL but does not exceed 300 percent of the FPL.

(4) Qualified disabled and working individuals described in section 1905(s) of the Act, whose income exceeds 150 percent of the FPL, may be charged premiums on a sliding scale based on income, expressed as a percentage of Medicare cost sharing described at section 1905(p)(3)(A)(i) of the Act.

(5) Medically needy individuals, as defined in §§ 435.4 and 436.3 of this chapter, may be charged on a sliding scale. The agency must impose an appropriately higher charge for each higher level of family income, not to exceed $20 per month for the highest level of family income.

(b) *Consequences for non-payment.* (1) For premiums imposed under paragraphs (a)(1), (a)(2), (a)(3) and (a)(4) of this section, the agency may not require a group or groups of individuals to prepay.

(2) Except for premiums imposed under paragraph (a)(5) of this section, the agency may terminate an individual from medical assistance on the basis of failure to pay for 60 days or more.

(3) For premiums imposed under paragraph (a)(2) of this section—

(i) For individuals with annual income exceeding 250 percent of the FPL, the agency may require payment of 100 percent of the premiums imposed under this paragraph for a year, such that payment is only required up to 7.5 percent of annual income for individuals whose annual income does not exceed 450 percent of the FPL.

(ii) For individuals whose annual adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986) exceeds $75,000, increased by inflation each calendar year after 2000, the agency must require payment of 100 percent of the premiums for a year, except that the agency may choose to subsidize the premiums using state funds which may not be federally matched by Medicaid.

(4) For any premiums imposed under this section, the agency may waive payment of a premium in any case where the agency determines that requiring the payment will create an undue hardship for the individual or family.

(5) The agency may not apply further consequences or penalties for non-payment other than those listed in this section.

(c) *State plan specifications.* For each premium, enrollment fee, or similar charge imposed under paragraph (a) of this section, subject to the requirements of paragraph (b) of this section, the plan must specify—

(1) The group or groups of individuals that may be subject to the charge;

(2) The amount and frequency of the charge;

(3) The process used by the state to identify which beneficiaries are subject to premiums and to ensure individuals exempt from premiums are not charged; and

(4) The consequences for an individual or family who does not pay.

§ 447.56 Limitations on premiums and cost sharing.

(a) *Exemptions.* (1) The agency may not impose premiums or cost sharing upon the following groups of individuals:

(i) Individuals ages 1 and older and under age 18 eligible under § 435.118 of this chapter.

(ii) Infants under age 1 eligible under § 435.118 of this chapter whose income does not exceed the higher of—

(A) 150 percent FPL (for premiums) or 133 percent FPL (for cost sharing); and

(B) If applicable, the percent FPL described in section 1902(l)(2)(A)(iv) of the Act up to 185 percent FPL.

(iii) Individuals under age 18 eligible under §§ 435.120–435.122 or § 435.130 of this chapter.

(iv) Children for 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 receiving benefits under Part E of that title, without regard to age.

(v) At state option, individuals under age 19, 20 or age 21, eligible under § 435.222 of this chapter.

(vi) Disabled children, except as provided at § 447.55(a)(4) (premiums), who are receiving medical assistance by virtue of the application of the Family Opportunity Act in accordance with sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(vii) Pregnant women, except for premiums allowed under § 447.55(a)(1) and cost sharing for services specified in the state plan as not pregnancy-related, during the pregnancy and through the 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.

(viii) Any individual whose medical assistance for services furnished in an institution, or at state option in a home and community-based setting, is reduced by amounts reflecting available income other than required for personal needs.

(ix) An individual receiving hospice care, as defined in section 1905(o) of the Act.

(x) 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 is exempt from premiums. Indians who are currently receiving or have ever received an item or service furnished by an Indian

health care provider or through referral under contract health services are exempt from all cost sharing.

(xi) Individuals who are receiving Medicaid because of the state's election to extend coverage as authorized by § 435.213 of this chapter (Breast and Cervical Cancer).

(2) The agency may not impose cost sharing for the following services:

(i) Emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a) of this chapter;

(ii) Family planning services and supplies described in section 1905(a)(4)(C) of the Act, including contraceptives and 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;

(iii) Preventive services, at a minimum the services specified at § 457.520 of chapter D, 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; and

(iv) Pregnancy-related services, including those defined at §§ 440.210(a)(2) and 440.250(p) of this chapter, and counseling and drugs for cessation of tobacco use All services provided to pregnant women will be considered as pregnancy-related, except those services specifically identified in the state plan as not being related to the pregnancy.

(v) Provider-preventable services as defined in § 447.26(b).

(b) *Applicability*. Except as permitted under § 447.52(d) (targeted cost sharing), the agency may not exempt additional individuals from cost sharing obligations that apply generally to the population at issue.

(c) *Payments to providers*. (1) Except as provided under paragraphs (c)(2) and (c)(3) of this section, the agency must reduce the payment it makes to a provider by the amount of a beneficiary's cost sharing obligation, regardless of whether the provider has collected the payment or waived the cost sharing.

(2) For items and services provided to Indians who are exempt from cost sharing under paragraph (a)(1)(x) of this section, the agency may not reduce the payment it makes to a provider, including an Indian health care provider, by the amount of cost sharing that will otherwise be due from the Indian.

(3) 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 cost sharing charges that are bad debts of providers.

(d) *Payments to managed care organizations*. If the agency contracts with a managed care organization, the agency must calculate its payments to the organization to include cost sharing established under the state plan, for beneficiaries not exempt from cost sharing under paragraph (a) of this section, regardless of whether the organization imposes the cost sharing on its recipient members or the cost sharing is collected.

(e) *Payments to states*. No FFP in the state's expenditures for services is available for—

(1) Any premiums or cost sharing amounts that recipients should have paid under §§ 447.52 through 447.55 (except for amounts that the agency pays as bad debts of providers under paragraph (c)(3) of this section; and

(2) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium, except for amounts for premium assistance to obtain coverage for eligible individuals through family coverage that may include ineligible individuals when authorized in the approved state plan.

(f) *Aggregate limits*. (1) Medicaid premiums and cost sharing incurred by all individuals in the Medicaid household may not exceed an aggregate limit of 5 percent of the family's income applied on either a quarterly or monthly basis, as specified by the agency.

(2) If the state adopts premiums or cost sharing rules that could place beneficiaries at risk of reaching the aggregate family limit, the state plan must indicate a process to track each family's incurred premiums and cost sharing through an effective mechanism that does not rely on beneficiary documentation.

(3) The agency must inform beneficiaries and providers of the beneficiaries aggregate limit and notify beneficiaries and providers when a beneficiary has incurred out-of-pocket expenses up to the aggregate family limit and individual family members are no longer subject to cost sharing for the remainder of the family's current monthly or quarterly cap period.

(4) The agency must have a process in place for beneficiaries to request a reassessment of their family aggregate limit if they have a change in circumstances or if they are being terminated for failure to pay a premium.

(5) Nothing in paragraph (f) shall preclude the agency from establishing additional aggregate limits, including but not limited to a monthly limit on cost sharing charges for a particular service.

§ 447.57 Beneficiary and public notice requirements.

(a) The agency must make available a public schedule describing current premiums and cost sharing requirements containing the following information:

(1) The group or groups of individuals who are subject to premiums and/or cost sharing and the current amounts;

(2) Mechanisms for making payments for required premiums and cost sharing charges;

(3) The consequences for an applicant or recipient who does not pay a premium or cost sharing charge;

(4) A list of hospitals charging cost sharing for non-emergency use of the emergency department; and

(5) A list of preferred drugs or a mechanism to access such a list, including the agency Web site.

(b) The agency must make the public schedule available to the following in a manner that ensures that affected applicants, beneficiaries, and providers are likely to have access to the notice:

(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, notice to beneficiaries must be in accordance with § 435.905(b) of this chapter;

(2) Applicants, at the time of application;

(3) All participating providers; and

(4) The general public.

(c) Prior to submitting to the Centers for Medicare & Medicaid Services for approval a state plan amendment (SPA) to establish or substantially modify existing premiums or cost sharing, or change the consequences for non-payment, the agency must provide the public with advance notice of the SPA, specifying the amount of premiums or cost sharing and who is subject to the charges. The agency must provide a reasonable opportunity to comment on such SPAs. The agency must submit documentation with the SPA to demonstrate that these requirements were met. If premiums or cost sharing is substantially modified during the SPA approval process, the agency must provide additional public notice.

§ 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]

§ 447.90 FFP: Conditions related to pending investigations of credible allegations of fraud against the Medicaid program.

(a) *Basis and purpose*. This section implements section 1903(i)(2)(C) of the Act which prohibits payment of FFP with respect to items or services furnished by an individual or entity with respect to which there is pending an investigation of a credible allegation of fraud except under specified circumstances.

(b) *Denial of FFP*. No FFP is available with respect to any amount expended for an item or service furnished by any individual or entity to whom a State has failed to suspend payments in whole or part as required by § 455.23 of this chapter unless—

(1) The item or service is furnished as an emergency item or service, but not including items or services furnished in an emergency room of a hospital; or

(2) The State determines and documents that good cause as specified at § 455.23(e) or (f) of this chapter exists not to suspend such payments, to suspend payments only in part, or to discontinue a previously imposed payment suspension.

[76 FR 5965, Feb. 2, 2011]

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 access to care and service payment rates.

(a) The agency must maintain documentation of payment rates and make it available to HHS upon request.

(b) In consultation with the medical care advisory committee under § 431.12 of this chapter, the agency must develop a medical assistance access monitoring review plan and update it, in accordance with the timeline established in paragraph (b)(5) of this section. The plan must be published and made available to the public for review and comment for a period of no less than 30 days, prior to being finalized and submitted to CMS for review.

(1) *Access monitoring review plan data requirements*. The access monitoring review plan must include an access monitoring analysis that includes: Data sources, methodologies, baselines, assumptions, trends and factors, and thresholds that analyze and inform determinations of the sufficiency of access to care which may vary by geographic location within the state and will be used to inform state policies affecting access to Medicaid services such as provider payment rates, as well as the items specified in this section. The access monitoring review plan must specify data elements that will support the state's analysis of whether beneficiaries have sufficient access to care. The plan and monitoring analysis will consider:

(i) The extent to which beneficiary needs are fully met;

(ii) The availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service;

(iii) Changes in beneficiary utilization of covered services in each geographic area.

(iv) The characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and

(v) Actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service.

(2) *Access monitoring review plan beneficiary and provider input.* The access monitoring review plan must include an analysis of data and the state's conclusion of the sufficiency of access to care that will consider relevant provider and beneficiary information, including information obtained through public rate-setting processes, the medical care advisory committees established under § 431.12 of this chapter, the processes described in paragraph (b)(7) of this section, and other mechanisms (such as letters from providers and beneficiaries to State or Federal officials), which describe access to care concerns or suggestions for improvement in access to care.

(3) *Access monitoring review plan comparative payment rate review.* For each of the services reviewed, by the provider types and sites of service (e.g., primary care physicians in office settings) described within the access monitoring analysis, the access monitoring review plan must include an analysis of the percentage comparison of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates) and private health insurer payment rates within geographic areas of the state.

(4) *Access monitoring review plan standards and methodologies.* The access monitoring review plan and analysis must, at a minimum, include: The specific measures that the state uses to analyze access to care (such as, but not limited to: Time and distance standards, providers participating in the Medicaid program, providers with open panels, providers accepting new Medicaid beneficiaries, service utilization patterns, identified beneficiary needs, data on beneficiary and provider feedback and suggestions for improvement, the availability of telemedicine and telehealth, and other similar measures), how the measures relate to the access monitoring review plan described in paragraph (b)(1) of this section, baseline and updated data associated with the measures, any issues with access that are discovered as a result of the review, and the state agency's recommendations on the sufficiency of access to care based on the review. In addition, the access monitoring review plan must include procedures to periodically monitor access for at least 3 years after the implementation of a provider rate reduction or restructuring, as discussed in paragraph (b)(6)(ii) of this section.

(5) *Access monitoring review plan timeframe.* Beginning October 1, 2016 the State agency must:

(i) Develop its access monitoring review plan by October 1 of the first review year, and update this plan by October 1 of each subsequent review period;

(ii) For all of the following, complete an analysis of the data collected using the methodology specified in the access monitoring review plan in paragraphs (b)(1) through (4) of this section, with a separate analysis for each provider type and site of service furnishing the type of service at least once every 3 years:

(A) Primary care services (including those provided by a physician, FQHC, clinic, or dental care).

(B) Physician specialist services (for example, cardiology, urology, radiology).

(C) Behavioral health services (including mental health and substance use disorder).

(D) Pre- and post-natal obstetric services including labor and delivery.

(E) Home health services.

(F) Any additional types of services for which a review is required under paragraph (b)(6) of this section;

(G) Additional types of services for which the state or CMS has received a

significantly higher than usual volume of beneficiary, provider or other stakeholder access complaints for a geographic area, including complaints received through the mechanisms for beneficiary input consistent with paragraph (b)(7) of this section; and

(H) Additional types of services selected by the state.

(6) *Special provisions for proposed provider rate reductions or restructuring*—(i) *Compliance with access requirements.* The State shall submit with any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, an access review, in accordance with the access monitoring review plan, for each service affected by the State plan amendments as described under paragraph (b)(1) of this section completed within the prior 12 months. That access review must demonstrate sufficient access for any service for which the state agency proposes to reduce payment rates or restructure provider payments to demonstrate compliance with the access requirements at section 1902(a)(30)(A) of the Act.

(ii) *Monitoring procedures.* In addition to the analysis conducted through paragraphs (b)(1) through (4) of this section that demonstrates access to care is sufficient as of the effective date of the State plan amendment, a state must establish procedures in its access monitoring review plan to monitor continued access to care after implementation of state plan service rate reduction or payment restructuring. The frequency of monitoring should be informed by the public review described in paragraph (b) of this section and should be conducted no less frequently than annually.

(A) The procedures must provide for a periodic review of state determined and clearly defined measures, baseline data, and thresholds that will serve to demonstrate continued sustained service access, consistent with efficiency, economy, and quality of care.

(B) The monitoring procedures must be in place for a period of at least 3 years after the effective date of the state plan amendment that authorizes the payment reductions or restructuring.

(7) *Mechanisms for ongoing beneficiary and provider input.* (i) States must have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanisms), consistent with the access requirements and public process described in § 447.204.

(ii) States should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and response.

(iii) States must maintain a record of data on public input and how the state responded to this input. This record will be made available to CMS upon request.

(8) *Addressing access questions and remediation of inadequate access to care.* When access deficiencies are identified, the state must, within 90 days after discovery, submit a corrective action plan with specific steps and timelines to address those issues. While the corrective action plan may include longer-term objectives, remediation of the access deficiency should take place within 12 months.

(i) The state's corrective actions may address the access deficiencies through a variety of approaches, including, but not limited to: Increasing payment rates, improving outreach to providers, reducing barriers to provider enrollment, proving additional transportation to services, providing for telemedicine delivery and telehealth, or improving care coordination.

(ii) The resulting improvements in access must be measured and sustainable.

[43 FR 45253, Sept. 29, 1978, as amended at 80 FR 67611, Nov. 2, 2015; 81 FR 21480, Apr. 12, 2016]

§ 447.204 Medicaid provider participation and public process to inform access to care.

(a) The agency's payments must be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that services under the plan are available to beneficiaries at least to the extent that

those services are available to the general population. In reviewing payment sufficiency, states are required to consider, prior to the submission of any state plan amendment that proposes to reduce or restructure Medicaid service payment rates:

(1) The data collected, and the analysis performed, under § 447.203.

(2) Input from beneficiaries, providers and other affected stakeholders on beneficiary access to the affected services and the impact that the proposed rate change will have, if any, on continued service access. The state should maintain a record of the public input and how it responded to such input.

(b) The state must submit to CMS with any such proposed state plan amendment affecting payment rates:

(1) Its most recent access monitoring review plan performed under § 447.203(b)(6) for the services at issue;

(2) An analysis of the effect of the change in payment rates on access; and

(3) A specific analysis of the information and concerns expressed in input from affected stakeholders.

(c) CMS may disapprove a proposed state plan amendment affecting payment rates if the state does not include in its submission the supporting documentation described in paragraph (b) of this section, for failure to document compliance with statutory access requirements. Any such disapproval would follow the procedures described at part 430 Subpart B of this title.

(d) To remedy an access deficiency, CMS may take a compliance action using the procedures described at § 430.35 of this chapter.

[80 FR 67612, Nov. 2, 2015]

§ 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.

(iv) A Web site developed and maintained by the single State agency or other responsible State agency that is accessible to the general public, provided that the Web site:

(A) Is clearly titled and can be easily reached from a hyperlink included on Web sites that provide general information to beneficiaries and providers, and included on the State-specific page on the Federal Medicaid Web site.

(B) Is updated for bulletins on a regular and known basis (for example, the first day of each month), and the public notice is issued as part of the regular update;

(C) Includes the actual date it was released to the public on the Web site; or

(D) Complies with national standards to ensure access to individuals with disabilities; and

(E) Includes protections to ensure that the content of the issued notice is not modified after the initial publication and is maintained on the Web site for no less than a 3-year period.

[46 FR 58680, Dec. 3, 1981; 47 FR 8567, Mar. 1, 1982, as amended at 48 FR 56057, Dec. 19, 1983; 80 FR 67612, Nov. 2, 2015]

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/IID.

(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 Individuals with Intellectual Disabilities (ICF/IID) 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 beneficiaries 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 Intellectual Disability 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 § 483.35(e) 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/IID.* In determining payment when there has been a sale or transfer of assets of an NF or ICF/IID, 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/IID 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; 81 FR 68847, Oct. 4, 2016]

§ 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/IID, 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) Except as provided in paragraph (b) of this section, 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) The agency may pay a public provider that provides services free or at a nominal charge at the same rate that would be used if the provider charges were equal to or greater than its costs.

[75 FR 73975, Nov. 30, 2010]

§ 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, NFs, and ICFs/IID within one of the following categories:

(1) State government-owned or operated facilities (that is, all facilities that are either owned or operated by the State).

(2) Non-State government-owned or operated facilities (that is, all government facilities that are neither owned nor operated by the State).

(3) Privately-owned and operated facilities.

(b) *General rules.* (1) 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) Except as provided for in paragraph (c) of this section, aggregate Medicaid payments to a group of 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.

(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.

(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 non-State government owned or operated hospitals,—March 19, 2002.

(2) For all other facilities—March 13, 2001.

[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; 75 FR 73975, Nov. 30, 2010; 77 FR 31512, May 29, 2012]

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.

§ 447.294 Medicaid disproportionate share hospital (DSH) allotment reductions.

(a) *Basis and purpose.* This section sets forth the DSH health reform methodology (DHRM) for calculating State-specific annual DSH allotment reductions as required under section 1923(f) of the Act.

(b) *Definitions.* For purposes of this section—

Aggregate DSH allotment reductions mean the amounts identified in section 1923(f)(7)(A)(ii) of the Act.

Budget neutrality factor (BNF) is a factor incorporated in the DHRM that takes into account the extent to which the DSH allotment for a State was included in the budget neutrality calculation for a coverage expansion approved under section 1115 as of July 31, 2009.

DSH payment means the amount reported in accordance with § 447.299(c)(17).

Effective DSH allotment means the amount of DSH allotment determined by subtracting the State-specific DSH allotment reduction from a State's unreduced DSH allotment.

High level of uncompensated care factor (HUF) is a factor incorporated in the DHRM that results in larger percentage DSH allotment reduction for States that do not target DSH payments on hospitals with high levels of uncompensated care.

High Medicaid volume hospital means a disproportionate share hospital that has an MIUR at least one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the State.

High uncompensated care hospital means a hospital that exceeds the mean ratio of uncompensated care costs to total Medicaid and uninsured inpatient and outpatient hospital service costs for all disproportionate share hospitals within a state.

High volume of Medicaid inpatients factor (HMF) is a factor incorporated in the DHRM that results in larger percentage DSH allotment reduction for States that do not target DSH payments on hospitals with high volumes of Medicaid inpatients.

Hospital with high volumes of Medicaid inpatients means a disproportionate share hospital that meets the requirements of section 1923(b)(1)(A) of the Act.

Low DSH adjustment factor (LDF) is a factor incorporated in the DHRM that results in a smaller percentage DSH allotment reduction on low DSH States.

Low DSH State means a State that meets the criterion described in section 1923(f)(5)(B) of the Act.

Mean HUF reduction percentage is determined by calculating the quotient of each state's HUF reduction amount divided by its unreduced DSH allotment, then calculating the mean for each state group, then converting the result to a percentage.

Medicaid inpatient utilization rate (MIUR) means the rate defined in section 1923(b)(2) of the Act.

Non-high Medicaid volume hospital means a disproportionate share hospitals that does not meet the requirements of section 1923(b)(1)(A) of the Act.

State group means similarly situated States that are collectively identified by DHRM as defined in § 447.294(e)(1).

State-specific DSH allotment reduction means the amount of annual DSH allotment reduction for a particular State as determined by the DHRM.

Total hospital cost has the meaning given the term in § 447.299(c)(20).

Total Medicaid cost means the amount for each hospital reported in accordance with § 447.299(c)(10).

Total population means the 1-year estimates data of the total non-institutionalized population identified by United States Census Bureau's American Community Survey.

Total uninsured cost means the amount reported for each DSH in accordance with § 447.299(c)(14).

Uncompensated care cost means the amount reported for each hospital in accordance with § 447.299(c)(16).

Uncompensated care level means a hospital's uncompensated care cost divided by the sum of its total Medicaid cost and its total uninsured cost.

Unreduced DSH allotment means the DSH allotment calculated under section 1923(f) of the Act prior to annual reductions under this section.

Uninsured percentage factor (UPF) is a factor incorporated in the DHRM that results in larger percentage DSH allotment reductions for States that have the lowest percentages of uninsured individuals.

Uninsured population means 1-year estimates data of the number of uninsured identified by United States Census Bureau's American Community Survey.

(c) *Aggregate DSH allotment reduction amounts*. The aggregate DSH allotment reduction amounts are as provided in section 1923(f)(7)(A)(ii) of the Act.

(d) *State data submission requirements*. States are required to submit the mean MIUR, determined in accordance with section 1923(b)(1)(A) of the Act, for all hospitals receiving Medicaid payments in the State and the value of one standard deviation above such mean. The State must provide this data to CMS by June 30 of each year. To determine which state plan rate year's data the state must submit, subtract 3 years from the calendar year in which the data is due.

(e) *DHRM methodology*. Section 1923(f)(7) of the Act requires aggregate annual reduction amounts as specified in paragraph (f) of this section to be reduced through the DHRM. The DHRM is calculated on an annual basis based on the most recent data available to CMS at the time of the calculation. The DHRM is determined as follows:

(1) *Establishing State groups*. For each FY, CMS will separate low-DSH States and non-low DSH states into distinct State groups.

(2) *Aggregate DSH allotment reduction allocation*. CMS will allocate a portion of the aggregate DSH allotment reductions to each State group by the following:

(i) Dividing the sum of each State group's preliminary unreduced DSH allotments by the sum of both State groups' preliminary unreduced DSH allotment amounts to determine a percentage.

(ii) Multiplying the value of paragraph (e)(2)(i) of this section by the aggregate DSH allotment reduction amount under paragraph (c) of this section for the applicable fiscal year.

(iii) Applying the low DSH adjustment factor under paragraph (e)(3) of this section.

(3) *Low DSH adjustment factor (LDF) calculation*. CMS will calculate the LDF by the following:

(i) Dividing each State's preliminary unreduced DSH allotment by their respective total estimated Medicaid service expenditures for the applicable fiscal year.

(ii) Calculating for each State group the mean of all values determined in paragraph (e)(3)(i) of this section.

(iii) Dividing the value of paragraph (e)(3)(ii) of this section for the low-DSH State group by the value of paragraph (e)(3)(ii) for the non-low DSH state group.

(4) *LDF application*. CMS will determine the final aggregate DSH allotment reduction allocation for each State group through application of the LDF by the following:

(i) Multiplying the LDF by the aggregate DSH allotment reduction for the low DSH State group.

(ii) Utilizing the value of paragraph (e)(4)(i) of this section as the aggregate DSH allotment reduction allocated to the low DSH State group.

(iii) Subtracting the value of paragraph (e)(4)(ii) of this section from the value of paragraph (e)(2)(ii) of this section for the low DSH State group; and

(iv) Adding the value of paragraph (e)(4)(iii) of this section to the value of paragraph (e)(2)(ii) of this section for the non-low DSH State group.

(5) *Reduction factor allocation.* CMS will allocate the aggregate DSH allotment reduction amount to three core factors by multiply the aggregate DSH allotment reduction amount for each State group by the following:

(i) UPF—50 percent.

(ii) HMF—25 percent.

(iii) HUF—25 percent.

(6) *Uninsured percentage factor (UPF) calculation.* CMS will calculate the UPF by the following:

(i) Dividing the total State population by the uninsured in State for each State.

(ii) Determining the uninsured reduction allocation component for each State as a percentage by dividing each State's value of paragraph (e)(6)(i) of this section by the sum of the values of paragraph (e)(6)(i) of this section for the respective State group (the sum of the values of all States in the State group should total 100 percent).

(iii) Determine a weighting factor by dividing each State's unreduced DSH allotment by the sum of all preliminary unreduced DSH allotments for the respective State group.

(iv) Multiply the weighting factor calculated in (e)(6)(iii) of this section by the value of each State's uninsured reduction allocation component from paragraph (e)(6)(ii) of this section.

(v) Determine the UPF as a percentage by dividing the product of paragraph (e)(6)(iv) of this section for each State by the sum of the values of paragraph (e)(6)(iv) of this section for the respective State group (the sum of the values of all States in the State group should total 100 percent).

(7) *UPF application and reduction amount.* CMS will determine the UPF portion of the final aggregate DSH allotment reduction allocation for each State by multiplying the State's UPF by the aggregate DSH allotment reduction allocated to the UPF factor under paragraph (e)(5) of this section for the respective State group.

(8) *High volume of Medicaid inpatients factor (HMF) calculation.* CMS will calculate the HMF by determining a percentage for each State by dividing the State's total DSH payments made to non-high Medicaid volume hospitals by the total of such payments for the entire State group.

(9) *HMF application and reduction amount.* CMS will determine the HMF portion of the final aggregate DSH allotment reduction allocation for each State by multiplying the State's HMF by the aggregate DSH allotment reduction allocated to the HMF factor under paragraph (e)(5) of this section for the respective State group.

(10) *High level of uncompensated care factor (HUF) calculation.* CMS will calculate the HUF by determining a percentage for each State by dividing the State's total DSH payments made to non-High Uncompensated Care Level hospitals by the total of such payments for the entire State group.

(11) *HUF application and reduction amount.* CMS will determine the HUF portion of the final aggregate DSH allotment reduction allocation by multiplying each State's HUF by the aggregate DSH allotment reduction allocated to the HUF factor under paragraph (e)(5) of this section for the respective State group.

(12) *Section 1115 budget neutrality factor (BNF) calculation.* This factor is only calculated for States for which all or a portion of the DSH allotment was included in the calculation of budget neutrality under a section 1115 demonstration for the specific fiscal year subject to reduction pursuant to an approval on or before July 31, 2009. CMS will calculate the BNF for qualifying states by the following:

(i) For States whose DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 as of July 31, 2009, (without regard to approved amendments since that date) determining the amount of the State's

DSH allotment included in the budget neutrality calculation for coverage expansion for the specific fiscal year subject to reduction. This amount is not subject to reductions under the HMF and HUF calculations.

(ii) Determining the amount of the State's DSH allotment included in the budget neutrality calculation for non-coverage expansion purposes for the specific fiscal year subject to reduction.

(iii) Multiplying each qualifying State's value of paragraph (e)(12)(ii) of this section by the mean HMF reduction percentage for the respective State group.

(iv) Multiplying each qualifying State's value of paragraph (e)(12)(ii) of this section by the mean HUF reduction percentage for the respective State group.

(v) For each State, calculating the sum of the value of paragraphs (e)(12)(iii) and of (e)(12)(iv) of this section.

(13) *Section 1115 budget neutrality factor (BNF) application*. This factor will be applied in the State-specific DSH allotment reduction calculation.

(14) *State-specific DSH allotment reduction calculation*. CMS will calculate the state-specific DSH reduction by the following:

(i) Taking the sum of the value of paragraphs (e)(7), (e)(9), and (e)(11) of this section for each State.

(ii) For States qualifying under paragraph (e)(12) of this section, adding the value of paragraph (e)(12)(v) of this section.

(iii) Reducing the amount of paragraph (e)(14)(i) of this section for each State that does not qualify under paragraph (e)(12)(v) of this section based on the proportion of each State's preliminary unreduced DSH allotment compared to the national total of preliminary unreduced DSH allotments so that the sum of paragraph (e)(14)(iii) of this section equals the sum of paragraph (e)(12)(v) of this section.

(iv) No state will receive a reduction as calculated in paragraph (e)(14) of this section in excess of 90 percent of its preliminary unreduced DSH allotment for the respective fiscal year. For any state assigned a reduction amount determined under paragraph (e)(14) of this section in excess of 90 percent of its unreduced DSH allotment, the reduction amount that exceeds 90 percent of that state's unreduced DSH allotment will be distributed among the remaining states in the state group that do not exceed the 90 percent reduction cap, based on the proportion of each of these remaining states' allotment reduction amount before any distribution is performed pursuant to this paragraph (e)(14)(iv) to the aggregate allotment reduction amount for the state group. This operation will be performed until all reduction amounts in excess of the 90 percent reduction cap for all states are allocated within each respective state group.

(f) *Annual DSH allotment reduction application*. For each fiscal year identified in section 1923(f)(7)(A)(ii) of the Act, CMS will subtract the State-specific DSH allotment amount determined in paragraph (e)(14) of this section from that State's final unreduced DSH allotment. This amount is the State's final DSH allotment for the fiscal year.

[78 FR 57311, Sept. 18, 2013, as amended at 84 FR 50332, Sept. 25, 2019]

§ 447.295 Hospital-specific disproportionate share hospital payment limit: Determination of individuals without health insurance or other third party coverage.

(a) *Basis and purpose*. This section sets forth the methodology for determining the costs for individuals who have no health insurance or other source of third party coverage for services furnished during the year for purposes of calculating the hospital-specific disproportionate share hospital payment limit under section 1923(g) of the Act.

(b) *Definitions*.

Health insurance coverage limit means a limit imposed by a third party payer that establishes a maximum dollar value or maximum number of specific services, for benefits received by an individual.

Individuals who have no health insurance (or other source of third party coverage) for the services furnished during the year means individuals who have no source of third party coverage for the

specific inpatient hospital or outpatient hospital service furnished by the hospital.

No source of third party coverage for a specific inpatient hospital or outpatient hospital service means that the service is not included in an individual's health benefits coverage through a group health plan or health insurer, and for which there is no other legally liable third party. When a health insurance coverage limit is imposed by a third party payer, specific services beyond the limit would not be within the individual's health benefit package from that third party payer. For American Indians/Alaska Natives, IHS and tribal coverage is only considered third party coverage when services are received directly from IHS or tribal health programs (direct health care services) or when IHS or a tribal health program has authorized coverage through the contract health service program (through a purchase order or equivalent document). Administrative denials of payment, or requirements for satisfaction of deductible, copayment or coinsurance liability, do not affect the determination that a specific service is included in the health benefits coverage.

(c) *Determination of an individual's third party coverage status.* Individuals who have no source of third party coverage for a specific inpatient hospital or outpatient hospital service must be considered, for purposes of that service, to be uninsured. This determination is not dependent on the receipt of payment by the hospital from the third party.

(1) The determination of an individual's status as having a source of third party coverage must be a service-specific coverage determination. The service-specific coverage determination can occur only once per individual per service provided and applies to the entire service, including all elements as that service, or similar services, would be defined in Medicaid.

(2) Individuals who are inmates in a public institution or are otherwise involuntarily in secure custody as a result of criminal charges are considered to have a source of third party coverage.

(d) *Hospital-specific DSH limit calculation.* Only costs incurred in providing inpatient hospital and outpatient hospital services to Medicaid individuals, and revenues received with respect to those services, and costs incurred in providing inpatient hospital and outpatient hospital services, and revenues received with respect to those services, for which a determination has been made in accordance with paragraph (c) of this section that the services were furnished to individuals who have no source of third party coverage for the specific inpatient hospital or outpatient hospital service are included when calculating the costs and revenues for Medicaid individuals and individuals who have no health insurance or other source of third party coverage for purposes of section 1923(g)(1) of the Act.

[79 FR 71694, Dec. 3, 2014]

§ 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)(1) 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 § 455.304 of this chapter, 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. The total annual costs are determined on a hospital-specific basis, not a service-specific basis. For purposes of this section, costs—

(i) Are defined as costs net of third-party payments, including, but not limited to, payments by Medicare and private insurance.

(ii) Must capture the total burden on the hospital of treating Medicaid eligible patients prior to payment by Medicaid. Thus, costs must be determined in the aggregate and not by estimating the cost of individual patients. For example, if a hospital treats two Medicaid eligible patients at a cost of $2,000 and receives a $500 payment from a third party for each individual, the total cost to the hospital for purposes of this section is $1,000, regardless of whether the third party payment received for one patient exceeds the cost of providing the service to that individual.

(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 individuals with no source of third party coverage for the hospital services they receive.

(i) The amount should be the result of subtracting paragraphs (c)(12) and (c)(13), from paragraph (c)(14) of this section.

(ii) The uncompensated care costs of providing physician services to the uninsured cannot be included in this amount.

(iii) 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.

(iv) The uncompensated care costs do not 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) *Medicaid provider number*. The provider identification number assigned by the Medicaid program.

(19) *Medicare provider number*. The provider identification number assigned by the Medicare program.

(20) *Total hospital cost*. The total annual costs incurred by each hospital for furnishing inpatient hospital and outpatient hospital services.

(21) *Reporting*. 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), (c)(17), (c)(18), and (c)(19).

(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; 77 FR 31512, May 29, 2012; 78 FR 57313, Sept. 18, 2013; 82 FR 16122, Apr. 3, 2017; 85 FR 72909, Nov. 16, 2020]

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-owned or operated facilities (that is, all facilities that are owned or operated by the State.)

(2) Non-State government owned or operated facilities (that is, all government operated facilities that are neither owned nor operated by the State).

(3) Privately-owned and operated facilities.

(b) *General rules.* (1) 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) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to a group of 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.

(c) *Exceptions.* 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).

(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)(1) of this section by one of the following dates:

(1) For non-State government-owned or operated hospitals—March 19, 2002.

(2) For all other facilities—March 13, 2001.

[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; 75 FR 73975, Nov. 30, 2010; 77 FR 31513, May 29, 2012]

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 beneficiaries: 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]

Subpart G—Payments for Primary Care Services Furnished by Physicians

SOURCE: 77 FR 66700, Nov. 6, 2012, unless otherwise noted.

§447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.

(a) States pay for services furnished by a physician as defined in §440.50 of this chapter, or under the personal supervision of a physician who self-attests to a specialty designation of family medicine, general internal medicine or pediatric medicine or a subspecialty recognized by the American Board of Medical Specialties (ABMS), the American Board of Physician Specialties (ABPS) or the American Osteopathic Association (AOA). Such physician then attests that he/she:

(1) Is Board certified with such a specialty or subspecialty and/or

(2) Has furnished evaluation and management services and vaccine administration services under codes described in paragraph (b) of this section that equal at least 60 percent of the Medicaid codes he or she has billed during the most recently completed CY or, for newly eligible physicians, the prior month.

(b) At the end of CY 2013 and 2014 the Medicaid agency must review a statistically valid sample of physicians who received higher payments to verify that they meet the requirements of paragraph (a)(1) or (2) of this section.

(c) Primary care services designated in the Healthcare Common Procedure Coding System (HCPCS) are as follows:

(1) Evaluation and Management (E&M) codes 99201 through 99499.

(2) Current Procedural Terminology (CPT) vaccine administration codes 90460, 90461, 90471, 90472, 90473 and 90474, or their successor codes.

(d)(1) The state must submit to CMS, in such form and at such time as CMS specifies, information relating to participation by physicians described in paragraph (a) of this section and the utilization of E&M codes described in paragraph (c) of this section (whether furnished by or under the supervision of a physician described in paragraph (a)) of this section for the following peri—s—

(i) As of July 1, 2009, and

(ii) CY 2013

(2) As soon as practicable after receipt, CMS will post this information on *www.Medicaid.gov*.

[77 FR 66700, Nov. 6, 2012, as amended at 77 FR 74382, Dec. 14, 2012]

§447.405 Amount of required minimum payments.

(a) For CYs 2013 and 2014, a state must pay for physician services described in §447.400 based on the lower of:

(1) The Medicare Part B fee schedule rate that is applicable to the specific site of service or, at the state's option, the office setting and is also adjusted for either the specific geographic location of the service or reflects the mean over all counties of the rate for each E&M code. If there is no applicable rate, the rate specified in a fee schedule established and announced by CMS (that is, the product of multiplying the Medicare CF in effect at the beginning of CYs 2013 or 2014 (or the CY 2009 CF, if higher) and the CY 2013 and 2014 relative value units (RVUs).

(2) The provider's actual billed charge for the service.

(b) For vaccines provided under the Vaccines for Children Program in CYs 2013 and 2014, a State must pay the lesser of:

(1) The Regional Maximum Administration Fee; or,

(2) The Medicare fee schedule rate in CY 2013 or 2014 (or, if higher, the rate using the 2009 conversion factor and the 2013 and 2014 RVUs) for code 90460.

[77 FR 66700, Nov. 6, 2012, as amended at 77 FR 74382, Dec. 14, 2012]

§447.410 State plan requirements.

The state must amend its state plan to reflect the increase in fee schedule payments in CYs 2013 and 2014 unless, for each of the billing codes eligible for payment, the state currently reimburses at least as much as the higher of the CY 2013 and CY 2014 Medicare rate or the rate that would be derived using the CY 2009 conversion factor and the CY 2013 and 2014 Medicare relative value units (RVUs). The amendment must:

(a) Identify all eligible codes that the state will reimburse at the Medicare rate in CYs 2013 and 2014.

(b) Identify all codes that were not reimbursed under the Medicaid program as of July 1, 2009.

(c) Specify either that the state will make all adjustments applicable to the specific site of service or, at the state's option, the office setting and will also either adjust for the specific geographic location of the service or pay rates that reflect the mean over all counties of the rate for each E&M code. The state must specify the formula that the state will use to determine the mean rate for each E&M code.

§ 447.415 Availability of Federal financial participation (FFP).

(a) For primary care services furnished by physicians specified in § 447.400, FFP will be available at the rate of 100 percent for the amount by which the payment required to comply with § 447.405 exceeds the Medicaid payment that would have been made under the approved state plan in effect on July 1, 2009.

(b) For purposes of calculating the payment that would have been made under the approved State plan in effect on July 1, 2009, the state must exclude incentive, bonus, and performance-based payments but must include supplemental payments for which the approved methodology is linked to volume and payment for specific codes.

(c) For vaccine administration, the state must impute the payment that would have been made for code 90460 under the approved Medicaid state plan. The imputed rate for July 1, 2009, for code 90460 equals the payment rates for codes 90465 and 90471 weighted by service volume.

(d) For any payment made under a bundled rate methodology, including bundled rates for vaccines and vaccine administration, the amount directly attributable to the applicable primary care service must be isolated for purposes of determining the availability of the 100 percent FFP rate. Bundled rates, for purposes of this provision, do not include encounter and per diem rates.

Subpart H [Reserved]

Subpart I—Payment for Drugs

SOURCE: 81 FR 5347, Feb. 1, 2016, 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 best prices 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.

(4) Implements section 1903(m)(2)(A)(xiii) of the Act, in part, and section 1927(b) of the Act with regard to rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid managed care organizations (MCOs).

(5) Implements section 1902(a)(30)(A) of the Act with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs.

(b) *Purpose*. This subpart specifies certain requirements in the Social Security Act, including changes from the Affordable Care Act and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is 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 name drug.

Bona fide service fee means a fee paid by a manufacturer to an entity that represents 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 is 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. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means any 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.

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

(3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale.

Clotting factor means a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by CMS and posted on the CMS Web site.

CMS-authorized supplemental rebate agreement means an agreement that is approved through a state plan amendment (SPA) by CMS, which allows a state to enter into single and/or multistate supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal Government.

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.

Covered outpatient drug means, of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;

(ii) Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a ''new drug'' (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

(iv) Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug):

(i) Inpatient Services;

(ii) Hospice Services;

(iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;

(iv) Physician services;

(v) Outpatient hospital services;

(vi) Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;

(vii) Other laboratory and x-ray services; or

(viii) Renal dialysis.

(3) A covered outpatient drug does not include:

(i) Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;

(ii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;

(iii) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(iv) Over-the-counter products that are not drugs.

Customary prompt pay discount means any discount off of 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.

Innovator multiple source drug means a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section). It also 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 biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (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.

Line extension means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

(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) For authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity under whose own label or trade name the product will be distributed.

Multiple source drug means, for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all of the following criteria:

(1) Is rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/*).

(2) Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by FDA.

(3) Is sold or marketed in the United States during the period.

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard 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 or her designee and a manufacturer to implement section 1927 of the Act.

New formulation means, for a drug, a change to the drug, including, but not limited to: an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.

Nominal price means a price that is less than 10 percent of the average manufacturer price (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 ANDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug; or

(5) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product's drug category changes to correlate with the new product application type.

Oral solid dosage form means, an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.

Over-the-counter (OTC) drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group meaning from birth through 16 years of age, or a subset of this group as specified in the ''Indication and Usage'' section of the FDA approved labeling, or in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in a pediatric age group, or a subset of this group.

Professional dispensing fee means the professional 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 beneficiary. 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.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug, including a drug product approved for marketing as a nonprescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in this section), and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

United States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:

(1) Evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or

(2) Outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

[81 FR 5347, Feb. 1, 2016, as amended at 81 FR 80005, Nov. 15, 2016; 84 FR 64786, Nov. 25, 2019; 85 FR 87101, Dec. 31, 2020; 86 FR 64825, Nov. 19, 2021]

§ 447.504 Determination of average manufacturer price.

(a) *Definitions*. For the purpose of this section, the following definitions apply:

Average manufacturer price (AMP) means, for 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), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Average unit price means a manufacturer's sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Charitable and not-for profit pharmacies means organizations exempt from taxation as defined by section

501(c)(3) of the Internal Revenue Code of 1986.

Insurers means entities that are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies.

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.

Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(b) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP*. Except for those sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions identified in paragraph (c) of this section, AMP for covered outpatient drugs includes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to wholesalers for drugs distributed to retail community pharmacies.

(2) Sales to retail community pharmacies (including those sales, nominal price sales, and associated discounts, rebates (other than rebates under section 1927 of the Act or as specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies).

(c) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions excluded from AMP*. AMP excludes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(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) Sales outside the United States.

(5) Sales to hospitals.

(6) Sales to health maintenance organizations (HMOs) (including managed care organizations (MCOs)), including HMO or MCO operated pharmacies.

(7) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, 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.

(8) Sales to mail order pharmacies.

(9) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, and mental health centers).

(10) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(11) Sales to charitable pharmacies.

(12) Sales to not-for-profit pharmacies.

(13) Sales, associated rebates, discounts, or other price concessions paid directly to insurers.

(14) Bona fide service fees, as defined in § 447.502, paid by manufacturers to wholesalers or retail community pharmacies.

(15) Customary prompt pay discounts extended to wholesalers.

(16) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only those costs.

(17) Associated discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program under section 1860D–14A of the Act.

(18) Payments received from and rebates and discounts provided to pharmacy benefit manufacturers (PBMs).

(19) 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.

(20) Sales to hospices (inpatient and outpatient).

(21) Sales to prisons.

(22) Sales to physicians.

(23) Direct sales to patients.

(24) Free goods, not contingent upon any purchase requirement.

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, 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 AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that: The voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(29) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(30) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(d) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* Except for those sales, nominal price sales, and associated discounts, rebates, payments, and other financial transactions identified in paragraph (e) of this section, AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i) covered outpatient drugs identified in accordance with § 447.507 shall include sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions to all entities specified in paragraph (b) of this section, as well as the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales to insurers (except for rebates under section 1927 of the Act and this subpart).

(5) Sales to hospitals.

(6) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, mental health centers).

(7) Sales to mail order pharmacies.

(8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, 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.

(9) Sales to hospices (inpatient and outpatient).

(10) Sales to manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy.

(e) *Sales, nominal price sales, and associated discounts, rebates, payments, or other transactions excluded from AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* AMP for 5i covered outpatient drugs identified in accordance with § 447.507 excludes the following sales, nominal price sales, and associated discounts, rebates, or other financial transactions:

(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) Sales outside the United States.

(5) Bona fide service fees as defined in § 447.502 paid by manufacturers to wholesalers or retail community pharmacies.

(6) Customary prompt pay discounts extended to wholesalers.

(7) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only these costs.

(8) 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 for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

(9) 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.

(10) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(11) Sales to patients.

(12) Free goods, not contingent upon any purchase requirement.

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, 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 AMP eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the

pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(17) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(18) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(19) Sales to charitable pharmacies.

(20) Sales to not-for-profit pharmacies.

(f) *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 that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees (other than bona fide service fees), and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in that 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, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation.

[81 FR 5347, Feb. 1, 2016, as amended at 85 FR 87102, Dec. 31, 2020]

EFFECTIVE DATE NOTE: At 85 FR 87102, Dec. 31, 2020, § 557.504 was amended, effective January 1, 2023, by revising paragraphs (c)(25) through (29) and paragraphs (e)(13) through (17) to read as follows:

§ 447.504 Determination of average manufacturer price.

* * * * *

(c) * * *

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP-eligible entity does not receive any price concession.

(28) Manufacturer–sponsored patient refund/rebate programs, to the extent that the manufacturer ensures that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(29) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession

* * * * *

(e) * * *

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP-

eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer ensures the manufacturer provided a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy agent, or other AMP-eligible entity does not receive any price concession.

(17) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy agent, or other AMP-eligible entity does not receive any price concession.

* * * * *

§ 447.505 Determination of best price.

(a) *Definitions*. For the purpose of this section, the following definitions apply:

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement.

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.

(b) *Prices included in best price*. Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in paragraph (a) of this section.

(c) *Prices excluded from best price*. Best price excludes the following:

(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, or the PHS.

(2) Any prices charged to 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).

(3) Any prices charged under the FSS of the GSA.

(4) Any prices, rebates, or discounts provided to a designated State Pharmacy Assistance Program (SPAP).

(5) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(6) 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 for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

(7) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(8) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer 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.

(10) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

(13) Free goods, not contingent upon any purchase requirement.

(14) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including, but not limited to, reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only these costs.

(15) Nominal prices to certain entities as set forth in § 447.508.

(16) Bona fide service fees as defined in § 447.502.

(17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.

(18) Sales outside the United States.

(19) Direct sales to patients.

(d) *Further clarification of best price.* (1) Best price is net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, 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.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of best price by statute or regulation.

[81 FR 5347, Feb. 1, 2016, as amended at 85 FR 87102, Dec. 31, 2020]

EFFECTIVE DATE NOTE: At 85 FR 87102, Dec. 31, 2020, § 447.505 was amended by revising paragraphs (c)(8) through (12), effective Jan. 1, 2023. For the convenience of the user, the revised text is set forth as follows:

§ 447.505 Determination of best price.

* * * * *

(c) * * *

(8) Manufacturer-sponsored drug discount card programs, but only to the extent the manufacturer ensures that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent the manufacturer ensures 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.

(10) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer ensures the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is

passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

* * * * *

§ 447.506 Authorized generic drugs.

(a) *Definitions*. For the purpose of this section, the following definitions apply:

Primary manufacturer means a manufacturer that holds the NDA of the authorized generic drug.

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug.

(b) *Exclusion of authorized generic drugs from AMP by a primary manufacturer*. The primary manufacturer must exclude from its calculation of AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies when reporting the AMP of the brand name drug of that authorized generic drug.

(c) *Inclusion of authorized generic drugs in best price by a primary manufacturer*. A primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or an innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding the NDA.

(d) *Inclusion of authorized generic in AMP and best price by a secondary manufacturer*. The secondary manufacturer of an authorized generic drug must provide a rebate based on its sales of authorized generics, and must calculate AMP and best price, consistent with the requirements specified in §§ 447.504 and 447.505.

[81 FR 5347, Feb. 1, 2016, as amended at 85 FR 87102, Dec. 31, 2020]

§ 447.507 Identification of inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs).

(a) *Identification of a 5i drug*. A manufacturer must identify to CMS each covered outpatient drug that qualifies as a 5i drug.

(b) *Not generally dispensed through a retail community pharmacy*. A manufacturer must determine if the 5i drug is not generally dispensed through a retail community pharmacy based on the percentage of sales to entities other than retail community pharmacies.

(1) A 5i drug is not generally dispensed through a retail community pharmacy if 70 percent or more of the sales (based on units at the NDC–9 level) of the 5i drug, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining and reporting to CMS whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly basis.

§ 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 as described in section 340B(a)(4) of the PHSA.

(2) An ICF/IID providing services as set forth in § 440.150 of this chapter.

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(4) A public or non-profit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides family planning services described under section of 1001(a) of PHSA, 42 U.S.C. 300.

(5) An entity that:

(i) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and

(ii) Is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but does not receive funding under a provision of law referred to in such section.

(b) *Nonapplication*. This restriction does not apply to sales by a manufacturer of covered outpatient drugs that

are sold under a master agreement under 38 U.S.C. 8126.

(c) *Rule of construction.* Nothing in this section is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a)(5) of this section, including the prohibition set forth in section 1008 of the PHSA.

§ 447.509 Medicaid drug rebates (MDR).

(a) *Determination of rebate amount*—(1) *Basic rebate for single source drugs and innovator multiple source drugs.* The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug is equal to the product of:

(i) The total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) The greater of:

(A) The difference between the AMP and the best price for the dosage form and strength of the drug; or

(B) The AMP for the dosage form and strength of the drug multiplied by one of the following percentages:

(*1*) For a clotting factor, 17.1 percent;

(*2*) For a drug approved by FDA exclusively for pediatric indications, 17.1 percent; or

(*3*) For all other single source drugs and innovator multiple source drugs, 23.1 percent.

(2) *Additional rebate for single source and innovator multiple source drugs.* In addition to the basic rebate described in paragraph (a)(1) of this section, for each dosage form and strength of a single source drug or an innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds:

(B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(3) *Total rebate.* The total rebate amount for single source drugs and innovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(4) *Treatment of new formulations.* (i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for the rebate periods beginning January 1, 2010 through September 30, 2018 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(ii) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for the rebate periods beginning on October 1, 2018 through December 31, 2021 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the

State plan in the rebate period (as reported by the State).

(iii) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug, provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form, the rebate obligation for the rebate periods beginning on and after January 1, 2022 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(iv) The alternative rebate is required to be calculated if the manufacturer of the line extension drug also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

(5) *Limit on rebate*. In no case will the total rebate amount exceed 100 percent of the AMP of the single source or multiple source innovator drug.

(6) *Rebate for noninnovator multiple source drugs*. The amount of the basic rebate for each dosage form and strength of a noninnovator multiple source drug will be equal to the product of:

(i) The total number of units of such dosage form and strength for which payment was made under the State plan for the rebate period; and

(ii) The AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

(7) *Additional rebate for noninnovator multiple source drugs*. In addition to the basic rebate described in paragraph (a)(6) of this section, for each dosage form and strength of a noninnovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(B) The base date AMP has the meaning of AMP set forth in sections 1927(c)(2)(A)(ii)(II), 1927(c)(2)(B) and 1927(c)(3)(C) of the Act.

(8) *Total rebate*. The total rebate amount for noninnovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(9) *Limit on rebate*. In no case will the total rebate amount exceed 100 percent of the AMP for the noninnovator multiple source drug.

(b) *Rebates for drugs dispensed through Medicaid managed care organizations (MCOs)*. (1) Manufacturers participating in the Medicaid drug rebate program will provide a rebate for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs.

(2) Manufacturers are exempt from the requirement in paragraph (b)(1) of this section if such drugs are the following:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act; and

(ii) Discounted under section 340B of the PHSA.

(c) *Federal offset of rebates*. States must remit to the Federal government the amount of the savings resulting from the following increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by

FDA exclusively for pediatric indications:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 8.0 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 23.1 percent, then the offset amount is the difference between AMP times 23.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 23.1 percent, then there is no offset amount.

(2) For single source or innovator multiple source drugs that are clotting factors and drugs approved by FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 2.0 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 17.1 percent, then the offset amount is the difference between AMP times 17.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 17.1 percent, then there is no offset amount.

(3) For a drug that is a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, the offset amount is the difference between the unit rebate amount (URA) calculation for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act.

(4) For noninnovator multiple source drugs, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

[81 FR 5347, Feb. 1, 2016, as amended at 84 FR 12136, Apr. 1, 2019; 85 FR 87103, Dec. 31, 2020]

§ 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 the following:

(1) AMP, calculated in accordance with § 447.504.

(2) Best price, calculated in accordance with § 447.505.

(3) Customary prompt pay discounts, which are 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.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) 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 any revision 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. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction; that is, not based on any changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation.

(vi) The change is a result of a VBP arrangement, as defined in §447.502, requiring the manufacturer to make changes outside of the 12-quarter rule in this paragraph (b), when the outcome must be evaluated outside of the 12-quarter period.

(2) A manufacturer must report revised AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report*—(1) *Reporting period*. A manufacturer may report a revised Deficit Reduction Act (DRA) base date AMP to CMS within the first 4 full calendar quarters following July 17, 2007.

(2) *Recalculation of the DRA base date AMP*. (i) A manufacturer's recalculation of the DRA base date AMP must only reflect the revisions to AMP as provided for in §447.504 in effect from October 1, 2007 to December 14, 2010.

(ii) A manufacturer may choose to recalculate the DRA base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the DRA base date AMP.

(3) *Reporting a revised Affordable Care Act base date AMP*. A manufacturer may report a revised Affordable Care Act base date AMP to CMS within the first 4 full calendar quarters following April 1, 2016.

(4) *Recalculation of the Affordable Care Act base date AMP*. (i) A manufacturer's recalculation of the Affordable Care Act base date AMP must only reflect the revisions to AMP as provided for in §447.504.

(ii) A manufacturer may choose to recalculate the Affordable Care Act base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the Affordable Care Act base date AMP.

(d) *Monthly AMP*—(1) *Definition*. 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 is calculated based on §447.504, except the period covered is based on monthly, as opposed to quarterly, sales.

(i) The monthly AMP is 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.

(ii) It is calculated as net sales divided by number of units sold, excluding goods or any other items specifically excluded in the statute or regulations. Monthly AMP is calculated based on the best data available to the manufacturer at the time of submission.

(iii) In calculating monthly AMP, a manufacturer must estimate the impact of its lagged AMP-eligible price concessions using a 12-month rolling percentage in accordance with the methodology described in this paragraph (d)(2).

(A) For each NDC–9 with at least 12 months of AMP-eligible sales, after adjusting for sales excluded from AMP, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period (inclusive of the current reporting period) available associated with sales subject to the AMP reporting requirement divided by the total in dollars for the sales subject to the AMP reporting requirement for the same 12-month period.

(B) For each NDC–9 with less than 12 months of AMP-eligible sales, the calculation described in paragraph (d)(2)(iii)(A) of this section is performed for the time period equaling the total number of months of AMP-eligible sales.

(iv) The manufacturer multiplies the applicable percentage described in paragraph (d)(2)(iii)(A) or (B) of this section by the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted. The result of this multiplication is then subtracted from the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted.

(v) The manufacturer uses the result of the calculation described in paragraph (d)(2)(iv) of this section as the

numerator and the number of units sold in the month (after adjusting for sales excluded from AMP) as the denominator to calculate the manufacturer's AMP for the NDC for the month being submitted.

(vi) *Example.* After adjusting for sales excluded from AMP, the total lagged price concessions over the most recent 12-month period available associated with sales for NDC 12345–6789 subject to the AMP reporting requirement equal $200,000, and the total in dollars for the sales subject to the AMP reporting requirement for the same period equals $600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the AMP reporting requirement for the month being reported equals $50,000 for 10,000 units sold. The manufacturer's AMP calculation for this NDC for this month is: $50,000 − (0.33333 × $50,000) = $33,334 (net total sales amount); $33,334/10,000 = $3.33340 (AMP).

(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, except as allowed in paragraph (b)(1) of this section.

(4) *Exception.* A manufacturer must report revisions to monthly AMP within the 36-month time period, 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.

(6) *Monthly AMP units.* A manufacturer must report the total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP to CMS not later than 30 days after the last day of each month.

(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 paragraphs (e)(1) through (3) of this section.

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period.

(i) 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.

(ii) The 10-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 10-year period if all 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 designated by CMS.

[81 FR 5347, Feb. 1, 2016, as amended at 85 FR 87103, Dec. 31, 2020]

§ 447.511 Requirements for States.

(a) *Invoices submitted to participating drug manufacturers.* Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data and any subsequent changes to the data fields on the CMS–R–144 Medicaid Drug Rebate Invoice form:

(1) The State code.

(2) National Drug Code.
(3) Period covered.
(4) Product FDA list name.
(5) Unit rebate amount.
(6) Units reimbursed.
(7) Rebate amount claimed.
(8) Number of prescriptions.
(9) Medicaid amount reimbursed.
(10) Non-Medicaid amount reimbursed.
(11) Total amount reimbursed.

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers on the CMS–R–144, as specified in paragraph (a) of this section. The state data submission will be due no later than 60 days after the end of each rebate period. In the event that a due date falls on a weekend or Federal holiday, the submission will be due on the first business day following that weekend or Federal holiday. Any adjustments to previously submitted data will be transmitted to the manufacturer and CMS in the same reporting period.

(c) *State that has participating Medicaid Managed care organizations (MCO).* A State that has participating Medicaid managed care organizations (MCO) which includes covered outpatient drugs in its contracts with the MCOs, must report data described in paragraph (a) of this section for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is required under contract for coverage of such drugs under section 1903 of the Act. These data must be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

(d) *State data certification.* Each data submission in this section must be certified by one of the following:

(1) The State Medicaid Director (SMD);

(2) The Deputy State Medicaid Director (DSMD);

(3) An individual other than the SMD or DSMD, who has authority equivalent to an SMD or DSMD; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (d)(1) through (3) of this section.

(e) *State data certification language.* Each data submission by a state must include the following certification language: ''I hereby certify, to the best of my knowledge, that the state's data submission is complete and accurate at the time of this submission, and was prepared in accordance with the state's good faith, reasonable efforts based on existing guidance from CMS, section 1927 of the Act and applicable Federal regulations. I further certify that the state has transmitted data to CMS, including any adjustments to previous rebate periods, in the same reporting period as provided to the manufacturer. Further, the state certifies that it has applied any necessary edits to the data for both CMS and the manufacturer to avoid inaccuracies at both the NDC/line item and file/aggregate level. Such edits are to be applied in the same manner and in the same reporting period to both CMS and the manufacturer.''

[43 FR 45253, Sept. 29, 1978, as amended at 85 FR 87103, Dec. 31, 2020]

§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. If a specific limit has not been established under §447.514, 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 must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the following:

(1) AAC plus a professional dispensing fee 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 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 beneficiary.

(2) The agency must decide what certification form and procedure are used.

(3) A check off 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 available for purchase by retail community pharmacies on a nationwide basis that FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in the ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/.* Only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and such limit will only be applied to those equivalent drug products.

(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.* (1) The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, prior to the application of any federal or state drug rebate considerations, payment levels determined by applying for each pharmaceutically and therapeutically equivalent multiple source drug product, a professional dispensing fee established by the state agency plus an amount established by CMS that is equal to 175 percent of the weighted average of the most recently reported monthly AMPs for such multiple source drugs, using manufacturer submitted utilization data for each multiple source drug for which a Federal upper limit (FUL) is established.

(2) *Exception.* If the amount established by CMS in paragraph (b)(1) of this section for a pharmaceutically and therapeutically equivalent multiple source drug product is lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs, CMS will use a percent of the weighted average of the most recently reported monthly AMPs that equals the most current average acquisition costs paid by retail community pharmacies as determined by such survey.

(c) *Ensuring a drug is for sale nationally.* To assure that a multiple source 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 termination date reported by the manufacturer to CMS.

(2) The monthly AMP units data will be used to calculate the weighted average of monthly AMPs for all multiple source drugs to establish the FUL.

(d) The FUL will be applied as an aggregate upper limit.

§ 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.* (1) The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:

(i) A covered entity described in section 1927(a)(5)(B) of the Act.

(ii) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(iii) An Indian Health Service, tribal and urban Indian pharmacy.

(2) The agency's payment methodology in paragraph (a)(1) of this section must be in accordance with the definition of AAC in § 447.502.

(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), are in accordance with the upper limits specified in § 447.514(b).

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512.

(2) *Assurances*. The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 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.

(d)(1) *Data requirements*. When proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to evaluate their proposed changes in accordance with the requirements of this subpart, and States must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide adequate data such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process.

(2) A State participating in VBP arrangements approved under a CMS-authorized supplemental rebate agreement (SRA) must report data described in paragraph (d)(3) of this section on an annual basis.

(3) Within 60 days of the end of each year, the State must submit all of the following data, including cumulative data to date:

(i) State.

(ii) National drug code(s) (for drugs covered under the CMS-authorized VBP SRA).

(iii) Product's FDA list name.

(iv) Number of prescriptions.

(v) Cost to the State to administer the CMS-authorized VBP SRA (for example, systems changes, tracking outcomes, etc.).

(vi) Total savings generated by the supplemental rebate due to the CMS-authorized VBP SRA.

[81 FR 5347, Feb. 16, 2016, as amended at 86 FR 87104, Dec. 31, 2020]

§ 447.520 Federal Financial Participation (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 to secure rebates.

(2) 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.

(b) 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 to secure rebates.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

§ 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

(a) Medicaid coverage of investigational drugs may be provided at State option under section 1905(a)(12) of the Act when such drug is the subject of an investigational new drug application (IND) that has been allowed by FDA to proceed.

(b) A State agency electing to provide coverage of an investigational drug must include in its State plan a description of the coverage and payment for such drug.

(c) The State plan must indicate that any reimbursement for investigational drugs by the State are consistent with FDA regulations at 21 CFR part 312 if they are to be eligible to receive FFP for these drugs.

(d) Medicaid coverage of other drugs may be provided at State option under section 1905(a)(12) of the Act provided that they are not eligible to be covered as covered outpatient drugs in the Medicaid Drug Rebate program.

(e) Investigational drugs and other drugs are not subject to the rebate requirements of section 1927 of the Act provided they do not meet the definition of a covered outpatient drug as set forth in section 1927(k) of the Act.

PART 455—PROGRAM INTEGRITY: MEDICAID

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AUTHORITY: 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 beneficiaries.

(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 beneficiary 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.

Credible allegation of fraud. A credible allegation of fraud may be an allegation, which has been verified by the State, from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

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.

Fraud hotline tip. A fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

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; 76 FR 5965, Feb. 2, 2011; 86 FR 6131, Jan. 19, 2021]

§ 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 beneficiary 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 beneficiary 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 beneficiary. This resolution may include but is not limited to—

(1) Sending a warning letter to the provider or beneficiary, 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 Beneficiary verification procedure.

(a) The agency must have a method for verifying with beneficiaries 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 beneficiaries; 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.

(c) The agency must enter into a written agreement with the unit under which:

(1) The agency will agree to comply with all requirements of § 455.21(a);

(2) The unit will agree to comply with the requirements of § 1007.11(c) of this title; and

(3) The agency and the unit will agree to—

(i) Establish a practice of regular meetings or communication between the two entities;

(ii) Establish procedures for how they will coordinate their efforts;

(iii) Establish procedures for §§ 1007.9(e) through 1007.9(h) of this title;

(iv) Establish procedures by which the unit will receive referrals of potential fraud from managed care organizations, if applicable, either directly or through the agency, as required at § 438.608(a)(7) of this title; and

(v) Review and, as necessary, update the agreement no less frequently than every five (5) years to ensure that the agreement reflects current law and practice.

[43 FR 45262, Sept. 29, 1978, as amended at 84 FR 10713, Mar. 22, 2019]

§ 455.23 Suspension of payments in cases of fraud.

(a) *Basis for suspension.* (1) The State Medicaid agency must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program against an individual or entity unless the agency has good cause to not suspend payments or to suspend payment only in part.

(2) The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments.

(3) A provider may request, and must be granted, administrative review where State law so requires.

(b) *Notice of suspension.* (1) The State agency must send notice of its suspension of program payments within the following timeframes:

(i) Five days of taking such action unless requested in writing by a law enforcement agency to temporarily withhold such notice.

(ii) Thirty days if requested by law enforcement in writing to delay sending such notice, which request for delay may be renewed in writing up to twice and in no event may exceed 90 days.

(2) The notice must include or address all of the following:

(i) State that payments are being suspended in accordance with this provision.

(ii) Set forth the general allegations as to the nature of the suspension action, but need not disclose any specific information concerning an ongoing investigation.

(iii) State that the suspension is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which the suspension will be terminated.

(iv) Specify, when applicable, to which type or types of Medicaid claims or business units of a provider suspension is effective.

(v) Inform the provider of the right to submit written evidence for consideration by State Medicaid Agency.

(vi) Set forth the applicable State administrative appeals process and corresponding citations to State law.

(c) *Duration of suspension.* (1) All suspension of payment actions under this section will be temporary and will not continue after either of the following:

(i) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider.

(ii) Legal proceedings related to the provider's alleged fraud are completed.

(2) A State must document in writing the termination of a suspension including, where applicable and appropriate, any appeal rights available to a provider.

(d) *Referrals to the Medicaid fraud control unit.* (1) Whenever a State Medicaid agency investigation leads to the initiation of a payment suspension in whole or part, the State Medicaid Agency must make a fraud referral to either of the following:

(i) To a Medicaid fraud control unit established and certified under part 1007 of this title; or

(ii) In States with no certified Medicaid fraud control unit, to an appropriate law enforcement agency.

(2) The fraud referral made under paragraph (d)(1) of this section must meet all of the following requirements:

(i) Be made in writing and provided to the Medicaid fraud control unit not later than the next business day after the suspension is enacted.

(ii) Conform to fraud referral performance standards issued by the Secretary.

(3)(i) If the Medicaid fraud control unit or other law enforcement agency accepts the fraud referral for investigation, the payment suspension may be continued until such time as the investigation and any associated enforcement proceedings are completed.

(ii) On a quarterly basis, the State must request a certification from the Medicaid fraud control unit or other law enforcement agency that any matter accepted on the basis of a referral continues to be under investigation thus warranting continuation of the suspension.

(4) If the Medicaid fraud control unit or other law enforcement agency declines to accept the fraud referral for investigation the payment suspension must be discontinued unless the State Medicaid agency has alternative Federal or State authority by which it may impose a suspension or makes a fraud referral to another law enforcement agency. In that situation, the provisions of paragraph (d)(3) of this section apply equally to that referral as well.

(5) A State's decision to exercise the good cause exceptions in paragraphs (e) or (f) of this section not to suspend payments or to suspend payments only in part does not relieve the State of the obligation to refer any credible allegation of fraud as provided in paragraph (d)(1) of this section.

(e) *Good cause not to suspend payments.* A State may find that good cause exists not to suspend payments, or not to continue a payment suspension previously imposed, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) Law enforcement officials have specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation.

(2) Other available remedies implemented by the State more effectively or quickly protect Medicaid funds.

(3) The State determines, based upon the submission of written evidence by the individual or entity that is the subject of the payment suspension, that the suspension should be removed.

(4) beneficiary access to items or services would be jeopardized by a payment suspension because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of beneficiaries within a HRSA-designated medically underserved area.

(5) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(6) The State determines that payment suspension is not in the best interests of the Medicaid program.

(f) *Good cause to suspend payment only in part.* A State may find that good cause exists to suspend payments in part, or to convert a payment suspension previously imposed in whole to

one only in part, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) beneficiary access to items or services would be jeopardized by a payment suspension in whole or part because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of beneficiaries within a HRSA-designated medically underserved area.

(2) The State determines, based upon the submission of written evidence by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part.

(3)(i) The credible allegation focuses solely and definitively on only a specific type of claim or arises from only a specific business unit of a provider; and

(ii) The State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.

(4) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(5) The State determines that payment suspension only in part is in the best interests of the Medicaid program.

(g) *Documentation and record retention.* State Medicaid agencies must meet the following requirements:

(1) Maintain for a minimum of 5 years from the date of issuance all materials documenting the life cycle of a payment suspension that was imposed in whole or part, including the following:

(i) All notices of suspension of payment in whole or part.

(ii) All fraud referrals to the Medicaid fraud control unit or other law enforcement agency.

(iii) All quarterly certifications of continuing investigation status by law enforcement.

(iv) All notices documenting the termination of a suspension.

(2)(i) Maintain for a minimum of 5 years from the date of issuance all materials documenting each instance where a payment suspension was not imposed, imposed only in part, or discontinued for good cause.

(ii) This type of documentation must include, at a minimum, detailed information on the basis for the existence of the good cause not to suspend payments, to suspend payments only in part, or to discontinue a payment suspension and, where applicable, must specify how long the State anticipates such good cause will exist.

(3) Annually report to the Secretary summary information on each of following:

(i) Suspension of payment, including the nature of the suspected fraud, the basis for suspension, and the outcome of the suspension.

(ii) Situation in which the State determined good cause existed to not suspend payments, to suspend payments only in part, or to discontinue a payment suspension as described in this section, including describing the nature of the suspected fraud and the nature of the good cause.

[76 FR 5966, Feb. 2, 2011]

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.

Affiliation means, for purposes of applying § 455.107, any of the following:

(1) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.

(2) A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.

(3) An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of this paragraph (3), sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.

(4) An interest in which an individual is acting as an officer or director of a corporation.

(5) Any payment assignment relationship under § 447.10(g) of this chapter.

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosable event means, for purposes of § 455.107, any of the following:

(1) Currently has an uncollected debt to Medicare, Medicaid, or CHIP, regardless of—

(i) The amount of the debt;

(ii) Whether the debt is currently being repaid (for example, as part of a repayment plan); or

(iii) Whether the debt is currently being appealed;

(2) Has been or is subject to a payment suspension under a federal health care program (as that latter term is defined in section 1128B(f) of the Act), regardless of when the payment suspension occurred or was imposed;

(3) Has been or is excluded by the OIG from participation in Medicare, Medicaid, or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed; or

(4) Has had its Medicare, Medicaid, or CHIP enrollment denied, revoked or terminated, regardless of—

(i) The reason for the denial, revocation, or termination;

(ii) Whether the denial, revocation, or termination is currently being appealed; or

(iii) When the denial, revocation, or termination occurred or was imposed.

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).

Health insuring organization (HIO) has the meaning specified in § 438.2.

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.

Managed care entity (MCE) means managed care organizations (MCOs), PIHPs, PAHPs, PCCMs, and HIOs.

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.

Prepaid ambulatory health plan (PAHP) has the meaning specified in § 438.2.

Prepaid inpatient health plan (PIHP) has the meaning specified in § 438.2.

Primary care case manager (PCCM) has the meaning specified in § 438.2.

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 agreement.

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).

Termination means—

(1) For a—

(i) Medicaid or CHIP provider, a State Medicaid program or CHIP has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired; and

(ii) Medicare provider, supplier or eligible professional, the Medicare program has revoked the provider or supplier's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired.

(2)(i) In all three programs, there is no expectation on the part of the provider or supplier or the State or Medicare program that the revocation is temporary.

(ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

(3) The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to—

(i) Fraud;

(ii) Integrity; or

(iii) Quality.

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; 76 FR 5967, Feb. 2, 2011; 84 FR 47856, Sept. 10, 2019]

§ 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 455.107 are met.

[84 FR 47856, Sept. 10, 2019]

§ 455.104 Disclosure by Medicaid providers and fiscal agents: Information on ownership and control.

(a) *Who must provide disclosures.* The Medicaid agency must obtain disclosures from disclosing entities, fiscal agents, and managed care entities.

(b) *What disclosures must be provided.* The Medicaid agency must require that disclosing entities, fiscal agents, and managed care entities provide the following disclosures:

(1)(i) The name and address of any person (individual or corporation) with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity. The address for corporate entities must include as applicable primary business address, every business location, and P.O. Box address.

(ii) Date of birth and Social Security Number (in the case of an individual).

(iii) Other tax identification number (in the case of a corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest.

(2) Whether the person (individual or corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling; or whether the person (individual or corporation) with an ownership or control interest in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling.

(3) The name of any other disclosing entity (or fiscal agent or managed care entity) in which an owner of the disclosing entity (or fiscal agent or managed care entity) has an ownership or control interest.

(4) The name, address, date of birth, and Social Security Number of any managing employee of the disclosing entity (or fiscal agent or managed care entity).

(c) *When the disclosures must be provided*—(1) *Disclosures from providers or disclosing entities.* Disclosure from any provider or disclosing entity is due at any of the following times:

(i) Upon the provider or disclosing entity submitting the provider application.

(ii) Upon the provider or disclosing entity executing the provider agreement.

(iii) Upon request of the Medicaid agency during the re-validation of enrollment process under § 455.414.

(iv) Within 35 days after any change in ownership of the disclosing entity.

(2) *Disclosures from fiscal agents.* Disclosures from fiscal agents are due at any of the following times:

(i) Upon the fiscal agent submitting the proposal in accordance with the State's procurement process.

(ii) Upon the fiscal agent executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the fiscal agent.

(3) *Disclosures from managed care entities.* Disclosures from managed care entities (MCOs, PIHPs, PAHPs, and HIOs), except PCCMs are due at any of the following times:

(i) Upon the managed care entity submitting the proposal in accordance with the State's procurement process.

(ii) Upon the managed care entity executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the managed care entity.

(4) *Disclosures from PCCMs.* PCCMs will comply with disclosure requirements under paragraph (c)(1) of this section.

(d) *To whom must the disclosures be provided.* All disclosures must be provided to the Medicaid agency.

(e) *Consequences for failure to provide required disclosures.* Federal financial participation (FFP) is not available in payments made to a disclosing entity that fails to disclose ownership or control information as required by this section.

[76 FR 5967, Feb. 2, 2011]

§ 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.

§ 455.107 Disclosure of affiliations.

(a) *Definitions.* For purposes of this section only, the following terms apply to the definition of disclosable event in § 455.101:

(1) ''Uncollected debt'' only applies to the following:

(i) Medicare, Medicaid, or CHIP overpayments for which CMS or the State has sent notice of the debt to the affiliated provider or supplier.

(ii) Civil money penalties imposed under this title.

(iii) Assessments imposed under this title.

(2) ''Revoked,'' ''Revocation,'' ''Terminated,'' and ''Termination'' include situations where the affiliated provider or supplier voluntarily terminated its Medicare, Medicaid, or CHIP enrollment to avoid a potential revocation or termination.

(b) *General.* (1)(i) *Selection of option.* A State, in consultation with CMS, must select one of the two options identified in paragraph (b)(2) of this section for requiring the disclosure of affiliation information.

(ii) *Change of selection.* A State may not change its selection under paragraph (b) of this section after it has been made.

(2)(i) *First option.* In a State that has selected the option in this paragraph (b)(2)(i), a provider that is not enrolled in Medicare but is initially enrolling in Medicaid or CHIP (or is revalidating its Medicaid or CHIP enrollment information) must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms ''person with an ownership or control interest'' and ''managing employee'' as defined in § 455.101) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event (as defined in § 455.101).

(ii) *Second option.* In a State that has selected the option in this paragraph (b)(2)(ii), and upon request by the State, a provider that is not enrolled in Medicare but is initially enrolling in Medicaid or CHIP (or is revalidating its Medicaid or CHIP enrollment information) must disclose any and all affiliations that it or any of its owning or managing employees or organizations (consistent with the terms ''person with an ownership or control interest'' and ''managing employee'' as defined in § 455.101) has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider or supplier that has a disclosable event (as defined in § 455.101). The State will request such disclosures when it, in consultation with CMS, has determined that the initially enrolling or revalidating provider may have at least one such affiliation.

(c) *Information.* The initially enrolling or revalidating provider must disclose the following information about each affiliation:

(1) General identifying information about the affiliated provider or supplier, which includes the following:

(i) Legal name as reported to the Internal Revenue Service or the Social Security Administration (if the affiliated provider or supplier is an individual).

(ii) ''Doing business as'' name (if applicable).

(iii) Tax identification number.

(iv) National Provider Identifier (NPI).

(2) Reason for disclosing the affiliated provider or supplier.

(3) Specific data regarding the affiliation relationship, including the following:

(i) Length of the relationship.

(ii) Type of relationship.

(iii) Degree of affiliation.

(4) If the affiliation has ended, the reason for the termination.

(d) *Mechanism.* The information described in paragraphs (b) and (c) of this section must be furnished to the State in a manner prescribed by the State in consultation with the Secretary.

(e) *Denial or termination.* The failure of the provider to fully and completely report the information required in this section when the provider knew or should reasonably have known of this information may result in, as applicable, the denial of the provider's initial enrollment application or the termination of the provider's enrollment in Medicaid or CHIP.

(f) *Undue risk.* Upon receipt of the information described in paragraphs (b) and (c) of this section, the State, in consultation with CMS, determines whether any of the disclosed affiliations poses an undue risk of fraud, waste, or abuse by considering the following factors:

(1) The duration of the affiliation.

(2) Whether the affiliation still exists and, if not, how long ago the affiliation ended.

(3) The degree and extent of the affiliation.

(4) If applicable, the reason for the termination of the affiliation.

(5) Regarding the affiliated provider's or supplier's disclosable event under paragraph (b) of this section, all of the following:

(i) The type of disclosable event.

(ii) When the disclosable event occurred or was imposed.

(iii) Whether the affiliation existed when the disclosable event occurred or was imposed.

(iv) If the disclosable event is an uncollected debt—

(A) The amount of the debt;

(B) Whether the affiliated provider or supplier is repaying the debt; and

(C) To whom the debt is owed.

(v) If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event.

(6) Any other evidence that the State, in consultation with CMS, deems relevant to its determination.

(g) *Determination of undue risk.* A determination by the State, in consultation with CMS, that a particular affiliation poses an undue risk of fraud, waste, or abuse will result in, as applicable, the denial of the provider's initial enrollment in Medicaid or CHIP or the termination of the provider's enrollment in Medicaid or CHIP.

(h) *Undisclosed affiliations.* The State, in consultation with CMS, may apply paragraph (g) of this section to situations where a reportable affiliation (as described in paragraphs (b) and (c) of this section) poses an undue risk of fraud, waste, or abuse, but the provider has not yet disclosed or is not required at that time to disclose the affiliation to the State.

[84 FR 47856, Sept. 10, 2019]

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 uncompensated care cost estimates used for calculations of prospective DSH payments for Medicaid State plan year 2011 and thereafter.

Subpart E—Provider Screening and Enrollment

SOURCE: 76 FR 5968, Feb. 2, 2011, unless otherwise noted.

§ 455.400 Purpose.

This subpart implements sections 1866(j), 1902(a)(39), 1902(a)(77), and 1902(a)(78) of the Act. It sets forth State plan requirements regarding the following:

(a) Provider screening and enrollment requirements.

(b) Fees associated with provider screening.

(c) Temporary moratoria on enrollment of providers.

§ 455.405 State plan requirements.

A State plan must provide that the requirements of § 455.410 through § 455.450 and § 455.470 are met.

§ 455.410 Enrollment and screening of providers.

(a) The State Medicaid agency must require all enrolled providers to be screened under to this subpart.

(b) The State Medicaid agency must require all ordering or referring physicians or other professionals providing services under the State plan or under a waiver of the plan to be enrolled as participating providers.

(c) The State Medicaid agency may rely on the results of the provider screening performed by any of the following:

(1) Medicare contractors.

(2) Medicaid agencies or Children's Health Insurance Programs of other States.

(d) The State Medicaid agency must allow enrollment of all Medicare-enrolled providers and suppliers for purposes of processing claims to determine Medicare cost-sharing (as defined in section 1905(p)(3) of the Act) if the providers or suppliers meet all Federal Medicaid enrollment requirements, including, but not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. This paragraph (d) applies even if the Medicare-enrolled provider or supplier is of a type not recognized by the State Medicaid Agency.

[76 FR 5968, Feb. 2, 2011, as amended at 86 FR 45521, Aug. 13, 2021]

§ 455.412 Verification of provider licenses.

The State Medicaid agency must—

(a) Have a method for verifying that any provider purporting to be licensed in accordance with the laws of any State is licensed by such State.

(b) Confirm that the provider's license has not expired and that there are no current limitations on the provider's license.

§ 455.414 Revalidation of enrollment.

The State Medicaid agency must revalidate the enrollment of all providers regardless of provider type at least every 5 years.

§ 455.416 Termination or denial of enrollment.

The State Medicaid agency—

(a) Must terminate the enrollment of any provider where any person with a 5 percent or greater direct or indirect ownership interest in the provider did not submit timely and accurate information and cooperate with any screening methods required under this subpart.

(b) Must deny enrollment or terminate the enrollment of any provider where any person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with the Medicare, Medicaid, or title XXI program in the last 10 years, unless the State Medicaid agency determines that denial or termination of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(c) Must deny enrollment or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act or under the Medicaid program or CHIP of any other State.

(d) Must terminate the provider's enrollment or deny enrollment of the provider if the provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to submit timely or accurate information, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(e) Must terminate or deny enrollment if the provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the Medicaid agency within 30 days of a CMS or a State Medicaid agency request, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(f) Must terminate or deny enrollment if the provider fails to permit access to provider locations for any site visits under § 455.432, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid

program and the State Medicaid agency documents that determination in writing.

(g) May terminate or deny the provider's enrollment if CMS or the State Medicaid agency—

(1) Determines that the provider has falsified any information provided on the application; or

(2) Cannot verify the identity of any provider applicant.

§ 455.420 Reactivation of provider enrollment.

After deactivation of a provider enrollment number for any reason, before the provider's enrollment may be reactivated, the State Medicaid agency must re-screen the provider and require payment of associated provider application fees under § 455.460.

§ 455.422 Appeal rights.

The State Medicaid agency must give providers terminated or denied under § 455.416 any appeal rights available under procedures established by State law or regulations.

§ 455.432 Site visits.

The State Medicaid agency—

(a) Must conduct pre-enrollment and post-enrollment site visits of providers who are designated as ''moderate'' or ''high'' categorical risks to the Medicaid program. The purpose of the site visit will be to verify that the information submitted to the State Medicaid agency is accurate and to determine compliance with Federal and State enrollment requirements.

(b) Must require any enrolled provider to permit CMS, its agents, its designated contractors, or the State Medicaid agency to conduct unannounced on-site inspections of any and all provider locations.

§ 455.434 Criminal background checks.

The State Medicaid agency—

(a) As a condition of enrollment, must require providers to consent to criminal background checks including fingerprinting when required to do so under State law or by the level of screening based on risk of fraud, waste or abuse as determined for that category of provider.

(b) Must establish categorical risk levels for providers and provider categories who pose an increased financial risk of fraud, waste or abuse to the Medicaid program.

(1) Upon the State Medicaid agency determining that a provider, or a person with a 5 percent or more direct or indirect ownership interest in the provider, meets the State Medicaid agency's criteria hereunder for criminal background checks as a ''high'' risk to the Medicaid program, the State Medicaid agency will require that each such provider or person submit fingerprints.

(2) The State Medicaid agency must require a provider, or any person with a 5 percent or more direct or indirect ownership interest in the provider, to submit a set of fingerprints, in a form and manner to be determined by the State Medicaid agency, within 30 days upon request from CMS or the State Medicaid agency.

§ 455.436 Federal database checks.

The State Medicaid agency must do all of the following:

(a) Confirm the identity and determine the exclusion status of providers and any person with an ownership or control interest or who is an agent or managing employee of the provider through routine checks of Federal databases.

(b) Check the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the Excluded Parties List System (EPLS), and any such other databases as the Secretary may prescribe.

(c)(1) Consult appropriate databases to confirm identity upon enrollment and reenrollment; and

(2) Check the LEIE and EPLS no less frequently than monthly.

§ 455.440 National Provider Identifier.

The State Medicaid agency must require all claims for payment for items and services that were ordered or referred to contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred such items or services.

§ 455.450 Screening levels for Medicaid providers.

A State Medicaid agency must screen all initial applications, including applications for a new practice location, and any applications received in response to a re-enrollment or revalidation of enrollment request based on a categorical risk level of ''limited,'' ''moderate,'' or ''high.'' If a provider could fit within more than one risk level described in this section, the highest level of screening is applicable.

(a) *Screening for providers designated as limited categorical risk.* When the State Medicaid agency designates a provider as a limited categorical risk, the State Medicaid agency must do all of the following:

(1) Verify that a provider meets any applicable Federal regulations, or State requirements for the provider type prior to making an enrollment determination.

(2) Conduct license verifications, including State licensure verifications in States other than where the provider is enrolling, in accordance with § 455.412.

(3) Conduct database checks on a pre- and post-enrollment basis to ensure that providers continue to meet the enrollment criteria for their provider type, in accordance with § 455.436.

(b) *Screening for providers designated as moderate categorical risk.* When the State Medicaid agency designates a provider as a ''moderate'' categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the ''limited'' screening requirements described in paragraph (a) of this section.

(2) Conduct on-site visits in accordance with § 455.432.

(c) *Screening for providers designated as high categorical risk.* When the State Medicaid agency designates a provider as a ''high'' categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the ''limited'' and ''moderate'' screening requirements described in paragraphs (a) and (b) of this section.

(2)(i) Conduct a criminal background check; and

(ii) Require the submission of a set of fingerprints in accordance with § 455.434.

(d) *Denial or termination of enrollment.* A provider, or any person with 5 percent or greater direct or indirect ownership in the provider, who is required by the State Medicaid agency or CMS to submit a set of fingerprints and fails to do so may have its—

(1) Application denied under § 455.434; or

(2) Enrollment terminated under § 455.416.

(e) *Adjustment of risk level.* The State agency must adjust the categorical risk level from ''limited'' or ''moderate'' to ''high'' when any of the following occurs:

(1) The State Medicaid agency imposes a payment suspension on a provider based on credible allegation of fraud, waste or abuse, the provider has an existing Medicaid overpayment, or the provider has been excluded by the OIG or another State's Medicaid program within the previous 10 years.

(2) The State Medicaid agency or CMS in the previous 6 months lifted a temporary moratorium for the particular provider type and a provider that was prevented from enrolling based on the moratorium applies for enrollment as a provider at any time within 6 months from the date the moratorium was lifted.

§ 455.452 Other State screening methods.

Nothing in this subpart must restrict the State Medicaid agency from establishing provider screening methods in addition to or more stringent than those required by this subpart.

§ 455.460 Application fee.

(a) Beginning on or after March 25, 2011, States must collect the applicable application fee prior to executing a provider agreement from a prospective or re-enrolling provider other than either of the following:

(1) Individual physicians or nonphysician practitioners.

(2)(i) Providers who are enrolled in either of the following:

(A) Title XVIII of the Act.

(B) Another State's title XIX or XXI plan.

(ii) Providers that have paid the applicable application fee to—

(A) A Medicare contractor; or

(B) Another State.

(b) If the fees collected by a State agency in accordance with paragraph (a) of this section exceed the cost of the screening program, the State agency must return that portion of the fees to the Federal government.

§ 455.470 Temporary moratoria.

(a)(1) The Secretary consults with any affected State Medicaid agency regarding imposition of temporary moratoria on enrollment of new providers or provider types prior to imposition of the moratoria, in accordance with § 424.570 of this chapter.

(2) The State Medicaid agency will impose temporary moratoria on enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program.

(3)(i) The State Medicaid agency is not required to impose such a moratorium if the State Medicaid agency determines that imposition of a temporary moratorium would adversely affect beneficiaries' access to medical assistance.

(ii) If a State Medicaid agency makes such a determination, the State Medicaid agency must notify the Secretary in writing.

(b)(1) A State Medicaid agency may impose temporary moratoria on enrollment of new providers, or impose numerical caps or other limits that the State Medicaid agency identifies as having a significant potential for fraud, waste, or abuse and that the Secretary has identified as being at high risk for fraud, waste, or abuse.

(2) Before implementing the moratoria, caps, or other limits, the State Medicaid agency must determine that its action would not adversely impact beneficiaries' access to medical assistance.

(3) The State Medicaid agency must notify the Secretary in writing in the event the State Medicaid agency seeks to impose such moratoria, including all details of the moratoria; and obtain the Secretary's concurrence with imposition of the moratoria.

(c)(1) The State Medicaid agency must impose the moratorium for an initial period of 6 months.

(2) If the State Medicaid agency determines that it is necessary, the State Medicaid agency may extend the moratorium in 6-month increments.

(3) Each time, the State Medicaid agency must document in writing the necessity for extending the moratorium.

Subpart F—Medicaid Recovery Audit Contractors Program

SOURCE: 76 FR 57843, Sept. 16, 2011, unless otherwise noted.

§ 455.500 Purpose.

This subpart implements section 1902(a)(42)(B) of the Act that establishes the Medicaid Recovery Audit Contractor (RAC) program.

§ 455.502 Establishment of program.

(a) The Medicaid Recovery Audit Contractor program (Medicaid RAC program) is established as a measure for States to promote the integrity of the Medicaid program.

(b) States must enter into contracts, consistent with State law and in accordance with this section, with one or more eligible Medicaid RACs to carry out the activities described in § 455.506 of this subpart.

(c) States must comply with reporting requirements describing the effectiveness of their Medicaid RAC programs as specified by CMS.

§ 455.504 Definitions.

As used in this subpart—

Medicaid RAC program means a recovery audit contractor program administered by a State to identify overpayments and underpayments and recoup overpayments.

Medicare RAC program means a recovery audit contractor program administered by CMS to identify underpayments and overpayments and recoup overpayments, established under the authority of section 1893(h) of the Act.

§ 455.506 Activities to be conducted by Medicaid RACs and States.

(a) Medicaid RACs will review claims submitted by providers of items and services or other individuals furnishing items and services for which payment

has been made under section 1902(a) of the Act or under any waiver of the State Plan to identify underpayments and overpayments and recoup overpayments for the States.

(1) States may exclude Medicaid managed care claims from review by Medicaid RACs.

(b) States may coordinate with Medicaid RACs regarding the recoupment of overpayments.

(c) States must coordinate the recovery audit efforts of their RACs with other auditing entities.

(d) States must make referrals of suspected fraud and/or abuse, as defined in 42 CFR 455.2, to the MFCU or other appropriate law enforcement agency.

(e) States must set limits on the number and frequency of medical records to be reviewed by the RACs, subject to requests for exception from RACs to States.

§455.508 Eligibility requirements for Medicaid RACs.

An entity that wishes to perform the functions of a Medicaid RAC must enter into a contract with a State to carry out any of the activities described in §455.506 under the following conditions:

(a) The entity must demonstrate to a State that it has the technical capability to carry out the activities described in §455.506 of this subpart. Evaluation of technical capability must include the employment of trained medical professionals, as defined by the State, who are in good standing with the relevant State licensing authorities, where applicable, to review Medicaid claims.

(b) The entity must hire a minimum of 1.0 FTE Contractor Medical Director who is a Doctor of Medicine or Doctor of Osteopathy in good standing with the relevant State licensing authorities and has relevant work and educational experience. A State may seek to be excepted, in accordance with §455.516, from requiring its RAC to hire a minimum of 1.0 FTE Contractor Medical Director by submitting to CMS a written request for CMS review and approval.

(c) The entity must hire certified coders unless the State determines that certified coders are not required for the effective review of Medicaid claims.

(d) The entity must work with the State to develop an education and outreach program, which includes notification to providers of audit policies and protocols.

(e) The entity must provide minimum customer service measures including:

(1) Providing a toll-free customer service telephone number in all correspondence sent to providers and staffing the toll-free number during normal business hours from 8:00 a.m. to 4:30 p.m. in the applicable time zone.

(2) Compiling and maintaining provider approved addresses and points of contact.

(3) Mandatory acceptance of provider submissions of electronic medical records on CD/DVD or via facsimile at the providers' request.

(4) Notifying providers of overpayment findings within 60 calendar days.

(f) The entity must not review claims that are older than 3 years from the date of the claim, unless it receives approval from the State.

(g) The entity should not audit claims that have already been audited or that are currently being audited by another entity.

(h) The entity must refer suspected cases of fraud and/or abuse to the State in a timely manner, as defined by the State.

(i) The entity meets other requirements as the State may require.

§455.510 Payments to RACs.

(a) *General.* Fees paid to RACs must be made only from amounts recovered.

(b) *Overpayments.* States must determine the contingency fee rate to be paid to Medicaid RACs for the identification and recovery of Medicaid provider overpayments.

(1) The contingency fees paid to Medicaid RACs must be based on a percentage of the overpayment recovered.

(2) States must determine at what stage in the Medicaid RAC audit process, after an overpayment has been recovered, Medicaid RACs will receive contingency fee payments.

(3) If a provider appeals a Medicaid RAC overpayment determination and the determination is reversed, at any

level, then the Medicaid RAC must return the contingency fees associated with that payment within a reasonable timeframe, as prescribed by the State.

(4) Except as provided in paragraph (5) of this section, the contingency fee may not exceed that of the highest Medicare RAC, as specified by CMS in the FEDERAL REGISTER, unless the State submits, and CMS approves, a waiver of the specified maximum rate. If a State does not obtain a waiver of the specified maximum rate, any amount exceeding the specified maximum rate is not eligible for FFP, either from the collected overpayment amounts, or in the form of any other administrative or medical assistance claimed expenditure.

(5) CMS will review and consider, on a case-by-case basis, a State's well-justified request that CMS provide FFP in paying a Medicaid RAC(s) a contingency fee in excess of the then-highest contingency fee paid to a Medicare RAC.

(c) *Underpayments.* (1) States must determine the fee paid to a Medicaid RAC to identify underpayments.

(2) States must adequately incentivize the detection of underpayments.

(3) States must notify providers of underpayments that are identified by the RACs.

§ 455.512 Medicaid RAC provider appeals.

States must provide appeal rights under State law or administrative procedures to Medicaid providers that seek review of an adverse Medicaid RAC determination.

§ 455.514 Federal share of State expense of the Medicaid RAC program.

(a) Funds expended by States for the operation and maintenance of a Medicaid RAC program, not including fees paid to RACs, are considered necessary for the proper and efficient administration of the States' plan or waivers of the plan.

(b) FFP is available to States for administrative costs of operation and maintenance of Medicaid RACs subject to CMS' reporting requirements.

§ 455.516 Exceptions from Medicaid RAC programs.

A State may seek to be excepted from some or all Medicaid RAC contracting requirements by submitting to CMS a written justification for the request for CMS review and approval through the State Plan amendment process.

§ 455.518 Applicability to the territories.

The aforementioned provisions in § 455.500 through § 455.516 of this subpart are applicable to Guam, Puerto Rico, U.S. Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(Authority: Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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AUTHORITY: 42 U.S.C. 1302.

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 beneficiary 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) Beneficiary utilization profiles;

(2) Provider service profiles; and

(3) Exceptions criteria; and

(b) Identifies exceptions so that the agency can correct misutilization practices of beneficiaries 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 beneficiary 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 beneficiary 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 beneficiary.

(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 beneficiary'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 beneficiary'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 Beneficiary information required for UR.

The UR plan must provide that each beneficiary'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 beneficiary.

(b) The name of the beneficiary'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 beneficiaries 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 beneficiary'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;

[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.

(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 beneficiary'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 beneficiary; 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 beneficiary'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 beneficiary's need for admission and gives notice of an adverse final decision—

(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 beneficiary 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 beneficiary'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 beneficiary'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 beneficiary'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 beneficiary'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 beneficiary's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a beneficiary 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 beneficiary'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 beneficiary'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 beneficiary 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 beneficiary; 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 beneficiary'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 beneficiary'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 beneficiary 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 beneficiary 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 beneficiary'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 [Reserved]

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 beneficiary.

(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 beneficiary'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 beneficiary'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 beneficiary'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 Beneficiary information required for UR.

The UR plan must provide that each beneficiary's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the beneficiary.

(b) The name of the beneficiary'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 beneficiaries 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 beneficiary'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 beneficiary 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 beneficiary'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 beneficiary'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 beneficiary's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a beneficiary 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 beneficiary'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 beneficiary'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 beneficiary 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 beneficiary; 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 beneficiary'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 beneficiary'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 beneficiary 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 beneficiary that ICF services are needed.

(2) Recertification must be made at least—

(i) Every 12 months after certification in an institution for Individuals with Intellectual Disabilities or persons with related conditions; and

(ii) Every 60 days after certification in an ICF other than an institution for Individuals with Intellectual Disabilities 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 beneficiary's need for care in the ICF.

(b) In an institution for Individuals with Intellectual Disabilities 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 beneficiary whose needs could be met by alternative services that are currently unavailable, the facility must enter this fact in the beneficiary'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 beneficiary'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 beneficiary.
(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 beneficiary'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 beneficiary'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 individuals with intellectual disabilities, a least one individual knowledgeable in the treatment of intellectual disability.

(c) The group performing UR may not include any individual who—

(1) Is directly responsible for the care of the beneficiary 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 Beneficiary information required for UR.

The UR plan must provide that each beneficiary's record include information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the beneficiary.

(b) The name of the beneficiary's physician.

(c) The name of the qualified Intellectual Disability 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 Intellectual Disability 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 beneficiaries 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 beneficiaries 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 beneficiary 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 beneficiary'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 beneficiary'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 beneficiary's continued stay on or before the expiration of each assigned continued stay review date.

(c) For each continued stay of a beneficiary 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 beneficiary'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 beneficiary's attending physician or, in institutions for individuals with intellectual disabilities, the beneficiary's qualified Intellectual Disability 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 Intellectual Disability 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 Intellectual Disability 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 beneficiary 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 Intellectual Disability professional, if applicable;

(d) The Medicaid agency;

(e) The beneficiary; 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 beneficiary 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 beneficiary 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 Individuals with Intellectual Disabilities 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 beneficiaries 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 Individuals with Intellectual Disabilities 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 Individuals with Intellectual Disabilities 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 beneficiaries.

No physician member of a team may inspect the care of a beneficiary 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 beneficiaries.

§ 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 beneficiaries in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each beneficiary 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 beneficiaries and review of records.

(a) For beneficiaries under age 21 in psychiatric facilities and beneficiaries 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 beneficiary; and

(2) Review of each beneficiary's medical record.

(b) For beneficiaries age 65 or older in IMDs, the team's inspection must include—

(1) Review of each beneficiary'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 beneficiary

[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 beneficiary, and the rehabilitative and social needs of each beneficiary in an ICF; and

(2) Promote his maximum physical, mental, and psychosocial functioning.

(b) It is necessary and desirable for the beneficiary to remain in the facility;

(c) It is feasible to meet the beneficiary's health needs and, in an ICF, the beneficiary's rehabilitative needs, through alternative institutional or noninstitutional services; and

(d) Each beneficiary under age 21 in a psychiatric facility and each beneficiary in an institution for Individuals with Intellectual Disabilities 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 beneficiary, 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 beneficiary 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 beneficiary;

(e) The beneficiary 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 beneficiary 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 beneficiary needs any service that is not furnished by the facility or through arrangements with others; and

(h) The beneficiary needs continued placement in the facility or there is an appropriate plan to transfer the beneficiary 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 beneficiaries; and

(2) Specific findings about individual beneficiaries 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 beneficiary 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 beneficiary:

(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 beneficiary 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 beneficiary, 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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiaries for whose care the agency intends to claim FFP even if the beneficiaries 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 beneficiaries who received services in facilities that did not meet the requirements of this subpart is divided by the total number of beneficiaries 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 beneficiary in a facility, the reduction will be computed on the total number of beneficiaries 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 beneficiaries 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 beneficiary 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 beneficiary in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the beneficiary 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) *Minimum standards for DUR programs*—(1) *Minimum standards.* In operating their DUR programs, States must include the following minimum standards:

(i) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on:

(A) Days' supply for patients not currently receiving opioid therapy for initial prescription fills;

(B) Quantity of prescription dispensed for initial and subsequent prescription fills;

(C) Therapeutically-duplicative initial and subsequent opioid prescription fills; and

(D) Early refills, for subsequent prescription fills.

(ii) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on the maximum daily morphine milligram equivalent for treatment of pain, for initial and subsequent prescription fills.

(iii) A retrospective claims review automated process that indicates prescription fills of opioids in excess of the prospective safety edit limitations specified by the state under paragraph (h)(1)(i) or (ii) of this section to provide for the ongoing review of opioid claims data to identify patterns of fraud, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits.

(iv) A retrospective claims review automated process and, at the option of the State, prospective safety edits that monitor when an individual is concurrently prescribed opioids and:

(A) Benzodiazepines; or

(B) Antipsychotics.

(v) A program to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP).

(vi) A process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

(vii) Prospective safety edits, retrospective claims review automated processes, or a combination of these approaches as determined by the State, to identify when:

(A) A beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for Medication Assisted Treatment (MAT) of an opioid use disorder or has been diagnosed with an opioid use disorder, within a timeframe specified by the State, in the absence of a new indication to support utilization of opioids (such as new cancer diagnosis or entry into hospice care); and

(B) A beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of any FDA-approved opioid antagonist/reversal agent.

(2) *Exclusion*. The requirements in paragraphs (h)(1)(i) through (vii) of this section do not apply with respect to individuals receiving hospice or palliative care or treatment for cancer; individuals who are residents of long-term care facilities, intermediate care facilities for the intellectually disabled, or facilities that dispense frequently abused drugs through a contract with a single pharmacy; or other individuals the State elects to exempt. While States are not required to apply the requirements in paragraphs (h)(1)(i) through (vii) with respect to these individuals, States may elect to do so.

(i) *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; 85 FR 87104, Dec. 31, 2020]

§ 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 beneficiary, and applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the beneficiary or the beneficiary'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 beneficiary or the beneficiary'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 beneficiary 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 beneficiary 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 beneficiaries or the beneficiaries' 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 beneficiary or beneficiary'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 beneficiary or the beneficiary'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 beneficiaries, 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 beneficiaries, 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.

(c) *Public availability.* All fee-for-service (FFS) and managed care DUR reports received by CMS under paragraph (b) of this section and, as applicable, pursuant to § 438.3(s) of this chapter, will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs.

[57 FR 49408, Nov. 2, 1992, as amended at 85 FR 87104, Dec. 31, 2020]

§ 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) beneficiaries in managed care programs.

(iii) beneficiaries 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 75.326 through 75.340. 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 beneficiary. 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.

[57 FR 49408, Nov. 2, 1992, as amended at 81 FR 3012, Jan. 20, 2016]

§ 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.

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Subpart A—Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

SOURCE: 66 FR 2670, Jan. 11, 2001, unless otherwise noted.

§ 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:

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.

Advanced payments of the premium tax credit (APTC) has the meaning given the term in 45 CFR 155.20.

Affordable Insurance Exchange (Exchange) has the meaning given the term ''Exchange'' in 45 CFR 155.20.

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.

Application means the single, streamlined application form that is used by the State in accordance with § 435.907(b) of this chapter and 45 CFR 155.405 for individuals to apply for coverage for all insurance affordability programs.

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.

Combined eligibility notice means an eligibility notice that informs an individual, or multiple family members of a household of eligibility for each of the insurance affordability programs and enrollment in a qualified health plan through the Exchange, for which a determination or denial of eligibility was made, as well as any right to request a review, fair hearing or appeal related to the determination made for each program. A combined notice must meet the requirements of § 457.340(e) and contain the content described in § 457.340(e)(1), except that information described in § 457.340(e)(1)(i)(C) may be provided in a combined notice issued by another insurance affordability program or in a supplemental notice provided by the State. A combined eligibility notice must be issued in accordance with the agreement(s) consummated by the State in accordance with § 457.348(a).

Comprehensive risk contract means a risk contract between the State and an MCO 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) Federally Qualified Health Center (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.

Coordinated content means information included in an eligibility notice regarding, if applicable—

(1) The transfer of an individual's or household's electronic account to another insurance affordability program;

(2) Any notice sent by the State to another insurance affordability program regarding an individual's eligibility for CHIP;

(3) The potential impact, if any, of—

(i) The State's determination of eligibility or ineligibility for CHIP on eligibility for another insurance affordability program; or

(ii) A determination of eligibility for, or enrollment in, another insurance affordability program on an individual's eligibility for CHIP; and

(iii) [Reserved]

(4) The status of household members on the same application or renewal

form whose eligibility is not yet determined.

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.

Electronic account means an electronic file that includes all information collected and generated by the State regarding each individual's CHIP eligibility and enrollment, including all documentation required under § 457.380 and including any information collected or generated as part of a review process conducted in accordance with subpart K of this part, the Exchange appeals process conducted under 45 CFR part 155, subpart F or other insurance affordability program appeals process.

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.

Exchange appeals entity has the meaning given to the term ''appeals entity,'' as defined in 45 CFR 155.500.

External quality review (EQR) means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO, PIHP, or PAHP, or their contractors furnish to CHIP beneficiaries.

External quality review organization (EQRO) means an organization that meets the competence and independence requirements set forth in § 438.354 of this chapter, and holds a contract with a State to perform external quality review, other EQR-related activities as set forth in § 438.358 of this chapter, or both.

Federal fiscal year starts on the first day of October each year and ends on the last day of the following September.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 2791(b)(3) of the Public Health Service Act.

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.

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).

Household income is defined as provided in § 435.603(d) of this chapter.

Insurance affordability program is defined as provided in § 435.4 of this chapter.

Joint application has the meaning assigned at § 457.301.

Joint review request means a request for a review under subpart K of this part which is included in an appeal request submitted to an Exchange or Exchange appeals entity or other insurance affordability program or appeals entity, in accordance with the signed agreement between the State and an Exchange or Exchange appeals entity or other program or appeals entity in accordance with § 457.348(b).

Low-income child means a child whose household 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.

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 requirements of subpart I of part 489 of this chapter; or

(2) Makes the services it provides to its CHIP enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other CHIP beneficiaries within the area served by the entity and

(3) Meets the solvency standards of § 438.116 of this chapter.

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.

Premium Lock-Out is defined as a State-specified period of time not to exceed 90 days that a CHIP eligible child who has an unpaid premium or enrollment fee (as applicable) will not be permitted to reenroll for coverage in CHIP. Premium lock-out periods are not applicable to children who have paid outstanding premiums or enrollment fees.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides services to enrollees under contract with the State, 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.

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides services to enrollees under contract with the State, 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.

(3) Does not have a comprehensive risk contract.

Presumptive income standard has the meaning assigned at § 457.301.

Primary care case management means a system under which:

(1) A PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to CHIP beneficiaries; or

(2) A PCCM entity contracts with the State to provide a defined set of functions to CHIP beneficiaries.

Primary care case management entity (PCCM entity) means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

(1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

(2) Development of enrollee care plans.

(3) Execution of contracts with and/or oversight responsibilities for the activities of fee-for-service providers in the fee-for-service program.

(4) Provision of payments to fee-for-service providers on behalf of the State.

(5) Provision of enrollee outreach and education activities.

(6) Operation of a customer service call center.

(7) Review of provider claims, utilization and practice patterns to conduct provider profiling and/or practice improvement.

(8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

(9) Coordination with behavioral health systems/providers.

(10) Coordination with long-term services and supports systems/providers.

Primary care case manager (PCCM) means a physician, a physician group practice or, at State option, any of the following in addition to primary care case management services:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.

Public agency has the meaning assigned in § 457.301.

Qualified entity has the meaning assigned at § 457.301.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract.

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

Secure electronic interface is defined as provided in § 435.4 of this chapter.

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.

Shared eligibility service is defined as provided in § 435.4 of this chapter.

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; 77 FR 17213, Mar. 23, 2012; 78 FR 42312, July 15, 2013; 81 FR 27896, May 6, 2016; 81 FR 47046, July 20, 2016; 81 FR 86463, Nov. 30, 2016]

§ 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. The Secretary will periodically specify updated requirements on the format of State plan through a process consistent with the requirements of the Paperwork Reduction Act.

[81 FR 86463, Nov. 30, 2016]

§ 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. The Secretary will periodically specify updated requirements on the format of State plan amendments through a process consistent with the requirements of the Paperwork Reduction Act. 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; 81 FR 86463, Nov. 30, 2016]

§ 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 coordination with other insurance affordability programs in the determination of eligibility and enrollment in coverage to ensure that all eligible individuals are enrolled in the appropriate program, including through use of the procedures described in §§ 457.305, 457.348 and 457.350 of this part.

[65 FR 33622, May 24, 2000, as amended at 77 FR 17214, Mar. 23, 2012]

§ 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, 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. This information must be provided in plain language and is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter.

(1) The State must provide individuals with a choice to receive notices and information required under this subpart and subpart K of this part, in electronic format or by regular mail, provided that the State establish safeguards in accordance with § 435.918 of this chapter.

(2) [Reserved]

(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.

[65 FR 33622, May 24, 2000, as amended at 78 FR 42312, July 15, 2013; 81 FR 86463, Nov. 30, 2016]

§ 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 State plan is in substantial noncompliance with the requirements of Title XXI of the Act or the regulations in this part; 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 or the regulations in this part. (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.)

(3) For purposes of this paragraph (a), substantial non-compliance includes, but is not limited to, failure to comply with requirements that significantly affect federal or state oversight or state reporting.

(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; 81 FR 27897, May 6, 2016]

§ 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]

§ 457.216 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.

§ 457.220 Funds from units of government as the State share of financial participation.

(a) Public funds 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 public funds are appropriated directly to the State or local CHIP agency, or are transferred from other public agencies (including Indian tribes) to the State or local agency and are under its administrative control, or are certified by the contributing public agency as representing expenditures eligible for FFP under this section.

(c) The public funds are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

[75 FR 73976, Nov. 30, 2010]

§ 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 75, 45 CFR part 95, subpart F, and part 11, State Medicaid Manual.

[65 FR 33622, May 24, 2000, as amended at 81 FR 3012, Jan. 20, 2016]

§ 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.

(4) Section 2107(e)(1)(O) of the Affordable Care Act, which relates to coordination of CHIP with the Exchanges and the State Medicaid agency.

(5) Section 2107(e)(1)(F) of the Affordable Care Act, which relates to income determined based on modified adjusted gross income.

(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 §§ 435.4, 435.229, 435.905 through 435.908, 435.1102, 435.940 through 435.958, 435.1200, 436.3, 436.229, and 436.1102 of this chapter.

[65 FR 33622, May 24, 2000, as amended at 77 FR 17214, Mar. 23, 2012]

§ 457.301 Definitions and use of terms.

As used in this subpart—

Eligibility determination means an approval or denial of eligibility in accordance with § 457.340 as well as a renewal or termination of eligibility under § 457.343 of this subpart.

Family size is defined as provided in § 435.603(b) of this chapter.

Medicaid applicable income level means, for a child, the effective income level (expressed as a percentage of the Federal poverty level and converted to a modified adjusted gross income equivalent level in accordance with guidance issued by the Secretary under section 1902(e)(14)(A) and (E) of the Act) specified under the policies of the State plan under title XIX of the Act as of March 31, 1997 for the child to be eligible for Medicaid under either section 1902(l)(2) or 1905(n)(2) of the Act, or under a section 1115 waiver authorized by the Secretary (taking into consideration any applicable income methodologies adopted under the authority of section 1902(r)(2) of the Act).

Non-applicant means an individual who is not seeking an eligibility determination for him or herself and is included in an applicant's or enrollee's household to determine eligibility for such applicant or enrollee.

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; 77 FR 17214, Mar. 23, 2012]

§ 457.305 State plan provisions.

The State plan must include a description of—

(a) The standards, consistent with § 457.310 and § 457.320 of this subpart, and financial methodologies consistent with § 457.315 of this subpart 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 applicants for and, if eligible, facilitating their enrollment in other insurance affordability programs; and processes for implementing waiting lists and enrollment caps (if any).

[77 FR 17214, Mar. 23, 2012]

§ 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 household income, as determined in accordance with § 457.315 of this subpart, at or below 200 percent of the Federal poverty level for a family of the size involved;

(ii) Resides in a State with no Medicaid applicable income level;

(iii) Resides in a State that has a Medicaid applicable income level and has a household 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), except for eligibility under § 435.214 of this chapter (related to coverage for family planning services);

(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.

(d) A targeted low-income child must also include any child enrolled in Medicaid on December 31, 2013 who is determined to be ineligible for Medicaid as a result of the elimination of income disregards as specified under § 435.603(g) of this chapter, regardless of any other standards set forth in this section except those in paragraph (c) of this section. Such a child shall continue to be a targeted low-income child under this paragraph until the date of the child's next renewal under § 457.343 of this subpart.

[66 FR 2675, Jan. 11, 2001, as amended at 71 FR 39229, July 12, 2006; 77 FR 17214, Mar. 23, 2012; 81 FR 86463, Nov. 30, 2016]

§ 457.315 Application of modified adjusted gross income and household definition.

(a) Effective January 1, 2014, the State must apply the financial methodologies set forth in paragraphs (b) through (i) of § 435.603 of this chapter in determining the financial eligibility of all individuals for CHIP. The exception to application of such methods for individuals for whom the State relies on a finding of income made by an Express Lane agency at § 435.603(j)(1) of this subpart also applies.

(b) In the case of determining ongoing eligibility for enrollees determined eligible for CHIP on or before December 31, 2013, application of the financial methodologies set forth in this section will not be applied until March 31, 2014 or the next regularly-scheduled renewal of eligibility for such individual under § 457.343, whichever is later.

[77 FR 17214, Mar. 23, 2012]

§ 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) Spenddowns;

(5) Residency, in accordance with paragraph (d) of this section;

(6) Disability status, provided that such standards do not restrict eligibility;

(7) Access to, or coverage under, other health coverage; and

(8) 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 household income without covering children with a lower household 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) [Reserved]

(d) *Citizenship and immigration status.* All individuals seeking coverage under a separate child health plan must make a declaration of United States citizenship or satisfactory immigration status. Such declaration may be made by an adult member of the individual's household, an authorized representative, as defined in § 435.923 of this chapter (referenced at § 457.340), or if the individual is a minor or incapacitated, someone acting responsibly for the individual provided that such individual attests to having knowledge of the individual's status.

(e) *Residency.* (1) Residency for a non-institutionalized child who is not a ward of the State must be determined in accordance with § 435.403(i) of this chapter.

(2) Residency for a targeted low-income pregnant woman defined at 2112 of the Act must be determined in accordance with § 435.403(h) of this chapter.

(3) A State may not—

(i) Impose a durational residency requirement;

(ii) Preclude the following individuals from declaring residence in a State—

(A) 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 or caretaker at the time of placement; or

(B) A child who is a ward of a State, regardless of where the child lives

(4) In cases of disputed residency, the State must follow the process described in § 435.403(m) of this chapter.

(f) *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) [Reserved]

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001, 77 FR 17214, Mar. 23, 2012; 81 FR 86463, Nov. 30, 2016]

§ 457.330 Application.

The State shall use the single, streamlined application used by the State in accordance with paragraph (b) of § 435.907 of this chapter, and otherwise comply with such section, except that the terms of § 435.907(c) of this chapter (relating to applicants seeking coverage on a basis other than modified adjusted gross income) do not apply.

[77 FR 17215, Mar. 23, 2012]

§ 457.340 Application for and enrollment in CHIP.

(a) *Application and renewal assistance, availability of program information, and Web site.* The terms of §§ 435.905, 435.906, 435.908, and 435.1200(f) of this chapter apply equally to the State in administering a separate CHIP.

(b) *Use of Social Security number.* The terms of §§ 435.910 and 435.907(e) of this chapter regarding the provision and use of Social Security Numbers and non-applicant information apply equally to the State in administering a separate CHIP.

(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 determination of eligibility.* (1) The terms in § 435.912 of this chapter apply equally to CHIP, except that standards for transferring electronic accounts to other insurance affordability programs are pursuant to § 457.350 and the standards for receiving applications from other insurance affordability programs are pursuant to § 457.348 of this part.

(2) In applying timeliness standards, the State must define ''date of application'' and must count each calendar day from the date of application to the day the agency provides notice of its eligibility decision.

(3) In the case of individuals subject to a period of uninsurance under this part, the state must identify and implement processes to facilitate enrollment of CHIP-eligible children who have satisfied a period of uninsurance (as described under § 457.805). To minimize burden on individuals, a state may not require a new application or information already provided by a family immediately preceding the beginning of a waiting period. States must also ensure that the proper safeguards are in place to prevent a disruption in coverage for children transitioning from coverage under another insurance affordability program after the completion of a period of uninsurance.

(e) *Notice of eligibility determinations.* The State must provide each applicant or enrollee with timely and adequate written notice of any decision affecting his or her eligibility, including an approval, denial or termination, or suspension of eligibility, consistent with §§ 457.315, 457.348, and 457.350. The notice must be written in plain language; and accessible to persons who are limited English proficient and individuals with disabilities, consistent with § 435.905(b) of this chapter and § 457.110.

(1) *Content of eligibility notice.* (i) Any notice of an approval of CHIP eligibility must include, but is not limited to, the following—

(A) The basis and effective date of eligibility;

(B) The circumstances under which the individual must report and procedures for reporting, any changes that may affect the individual's eligibility;

(C) Basic information on benefits and services and if applicable, any premiums, enrollment fees, and cost sharing required, and an explanation of how to receive additional detailed information on benefits and financial responsibilities; and

(D) Information on the enrollees' right and responsibilities, including the opportunity to request a review of matters described in § 457.1130.

(ii) Any notice of denial, termination, or suspension of CHIP eligibility must include, but is not limited to the following—

(A) The basis supporting the action and the effective date,

(B) Information on the individual's right to a review process, in accordance with § 457.1180;

(iii) In the case of a suspension or termination of eligibility, the State must provide sufficient notice to enable the child's parent or other caretaker to take any appropriate actions that may be required to allow coverage to continue without interruption.

(2) The State's responsibility to provide notice under this paragraph is satisfied by a combined eligibility notice, as defined in § 457.10, provided by an Exchange or other insurance affordability program in accordance with paragraph (f) of this section, except that, if the information described in paragraph (e)(1)(i)(C) of this section is not included in such combined eligibility notice, the State must provide the individual with a supplemental notice of such information, consistent with this section.

(f) *Coordination of notices with other programs.* The State must—

(1) Include in the agreement into which the State has entered under § 457.348(a) that for individuals who are transferred between the State and another insurance affordability program in accordance with § 457.348 or § 457.350, the State, Exchange or other insurance affordability program will provide, to the maximum extent feasible, a combined eligibility notice to individuals, as well as to multiple members of the same household included on the same application or renewal form.

(2) For individuals and other household members who will not receive a combined eligibility notice, include appropriate coordinated content, as defined in § 457.10, in any notice provided by the State in accordance with paragraph (e)(1) of this section.

(g) *Effective date of eligibility.* A State must specify a method for determining the effective date of eligibility for CHIP, which can be determined based on the date of application or through

any other reasonable method that ensures coordinated transition of children between CHIP and other insurance affordability programs as family circumstances change and avoids gaps or overlaps in coverage.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001; 77 FR 17215, Mar. 23, 2012; 78 FR 42312, July 15, 2013; 81 FR 86464, Nov. 30, 2016]

§ 457.342 Continuous eligibility for children.

(a) A State may provide continuous eligibility for children under a separate CHIP in accordance with the terms of § 435.926 of this chapter, and subject to a child remaining ineligible for Medicaid, as required by section 2110(b)(1) of the Act and § 457.310 (related to the definition and standards for being a targeted low-income child) and the requirements of section 2102(b)(3) of the Act and § 457.350 (related to eligibility screening and enrollment).

(b) In addition to the reasons provided at § 435.926(d) of this chapter, a child may be terminated during the continuous eligibility period for failure to pay required premiums or enrollment fees required under the State plan, subject to the disenrollment protections afforded under section 2103(e)(3)(C) of the Act (related to premium grace periods) and § 457.570 (related to disenrollment protections).

[81 FR 86464, Nov. 30, 2016]

§ 457.343 Periodic renewal of CHIP eligibility.

The renewal procedures described in § 435.916 of this chapter apply equally to the State in administering a separate CHIP, except that the State shall verify information needed to renew CHIP eligibility in accordance with § 457.380 of this subpart, shall provide notice regarding the State's determination of renewed eligibility or termination in accordance with § 457.340(e) of this subpart and shall comply with the requirements set forth in § 457.350 of this subpart for screening individuals for other insurance affordability programs and transmitting such individuals' electronic account and other relevant information to the appropriate program.

[77 FR 17215, Mar. 23, 2012]

§ 457.348 Determinations of Children's Health Insurance Program eligibility by other insurance affordability programs.

(a) *Agreements with other insurance affordability programs.* The State must enter into and, upon request, provide to the Secretary one or more agreements with an Exchange and the agencies administering other insurance affordability programs as are necessary to fulfill the requirements of this section, including a clear delineation of the responsibilities of each program to—

(1) Minimize burden on individuals seeking to obtain or renew eligibility or to appeal a determination of eligibility for one or more insurance affordability program;

(2) Ensure compliance with paragraphs (b) and (c) of this section and § 457.350;

(3) Ensure prompt determination of eligibility and enrollment in the appropriate program without undue delay, consistent with the timeliness standards established under § 457.340(d), based on the date the application is submitted to any insurance affordability program, and

(4) Provide for coordination of notices with other insurance affordability programs, consistent with § 457.340(f), and an opportunity for individuals to submit a joint review request, as defined in § 457.10, consistent with § 457.351.

(5) Provide for a combined appeals decision by an Exchange or Exchange appeals entity (or other insurance affordability program or appeals entity) for individuals who requested an appeal of an Exchange-related determination in accordance with 45 CFR part 155 subpart F (or of a determination related to another program) and an appeal of a denial of CHIP eligibility which is conducted by an Exchange or Exchange appeals entity (or other program or appeals entity) in accordance with the State plan.

(b) *Provision of CHIP for individuals found eligible for CHIP by another insurance affordability program.* If a State accepts final determinations of CHIP eligibility made by another insurance affordability program, for each individual determined so eligible by the other insurance affordability program (including as a result of a decision made by an Exchange appeals entity authorized by the State to adjudicate reviews of CHIP eligibility determinations), the State must—

(1) Establish procedures to receive, via secure electronic interface, the electronic account containing the determination of CHIP eligibility and notify such program of the receipt of the electronic account;

(2) Comply with the provisions of § 457.340 to the same extent as if the application had been submitted to the State; and

(3) Maintain proper oversight of the eligibility determinations made by the other program.

(c) *Transfer from other insurance affordability programs to CHIP.* For individuals for whom another insurance affordability program has not made a determination of CHIP eligibility, but who have been screened as potentially CHIP eligible by such program (including as a result of a decision made by an Exchange or other program appeals entity), the State must—

(1) Accept, via secure electronic interface, the electronic account for the individual and notify such program of the receipt of the electronic account;

(2) Not request information or documentation from the individual in the individual's electronic account, or provided to the State by another insurance affordability program or appeals entity;

(3) Promptly and without undue delay, consistent with the timeliness standards established under § 457.340(d), determine the CHIP eligibility of the individual, in accordance with § 457.340, without requiring submission of another application and, for individuals determined not eligible for CHIP, comply with § 457.350(i) of this section;

(4) Accept any finding relating to a criterion of eligibility made by such program or appeals entity, without further verification, if such finding was made in accordance with policies and procedures which are the same as those applied by the State in accordance with § 457.380 or approved by it in the agreement described in paragraph (a) of this section; and

(5) Notify such program of the final determination of the individual's eligibility or ineligibility for CHIP.

(d) *Certification of eligibility criteria.* The State must certify for the Exchange and other insurance affordability programs the criteria applied in determining CHIP eligibility.

[77 FR 17215, Mar. 23, 2012, as amended at 78 FR 42312, July 15, 2013; 81 FR 86464, Nov. 30, 2016]

§ 457.350 Eligibility screening and enrollment in other insurance affordability programs.

(a) *State plan requirement.* The State plan shall include a description of the coordinated eligibility and enrollment procedures used, at an initial and any follow-up eligibility determination, including any periodic redetermination, to ensure that:

(1) Only targeted low-income children are furnished CHIP coverage under the plan; and

(2) Enrollment is facilitated for applicants and enrollees found to be potentially eligible for other insurance affordability programs in accordance with this section.

(b) *Screening objectives.* A State must, promptly and without undue delay, consistent with the timeliness standards established under § 457.340(d), identify potential eligibility for other insurance affordability programs of any applicant, enrollee, or other individual who submits an application or renewal form to the State which includes sufficient information to determine CHIP eligibility, or whose eligibility is being renewed due to a change in circumstance in accordance with § 457.343 or who is determined not eligible for CHIP in accordance to a review conducted in accordance with subpart K of this part, as follows:

(1) Medicaid on the basis of having household income at or below the applicable modified adjusted gross income standard, as defined in § 435.911(b) of this chapter;

(2) Medicaid on another basis, as indicated by information provided on the application or renewal form provided;

(3) Eligibility for other insurance affordability programs.

(c) *Income eligibility test.* To identify the individuals described in paragraphs (b)(1) and (b)(3) of this section, a State must apply the methodologies used to determine household income described in § 457.315 of this subpart or such methodologies as are applied by such other programs.

(d) [Reserved]

(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) *Applicants found potentially eligible for Medicaid based on modified adjusted gross income.* For individuals identified in paragraph (b)(1) of this section, the State must—

(1) Promptly and without undue delay, consistent with the timeliness standards established under § 457.340(d) of this subpart, transfer the individual's electronic account to the Medicaid agency via a secure electronic interface; and

(2) Except as provided in § 457.355 of this subpart, find the applicant ineligible, provisionally ineligible, or suspend the applicant's application for CHIP unless and until the Medicaid application for the applicant is denied; and

(3) Determine or redetermine eligibility for CHIP, consistent with the timeliness standards established under § 457.340(d) of this subpart, if—

(i) The State is notified, in accordance with § 435.1200(d)(5) of this chapter that the applicant has been found ineligible for Medicaid; or

(ii) The State is notified prior to the final Medicaid eligibility determination that the applicant's circumstances have changed and another screening shows that the applicant is no longer potentially 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;

(2) Children placed on a waiting list or for whom action on their application is otherwise deferred are transferred to other insurance affordability programs in accordance with paragraph (i) of this section; and

(3) Families are informed that a child may be eligible for other insurance affordability programs, while the child is on a waiting list for a separate child

health program or if circumstances change, for Medicaid.

(i) *Individuals found potentially eligible for other insurance affordability programs.* For individuals identified in paragraph (b)(3) of this section, including during a period of uninsurance imposed by the State under § 457.805, the State must—

(1) Promptly and without undue delay, consistent with the timeliness standards established under § 457.340(d), transfer the electronic account to the applicable program via a secure electronic interfaces.

(2) In the case of individuals subject to a period of uninsurance under § 457.805 and transferred to another insurance affordability program in accordance with paragraph (i)(1) of this section, the State must—

(i) Notify such program of the date on which such period ends and the individual is eligible to enroll in CHIP; and

(ii) Consistent with § 457.340(e), provide the individual with—

(A) An initial notice that the individual is not currently eligible to enroll in the State's separate child health plan and the reasons therefor; the date on which the individual will be eligible to enroll in the State's separate child health plan; and that the individual's account has been transferred to another insurance affordability program for a determination of eligibility to enroll in such program during the period of underinsurance. Such notice also must contain coordinated content informing the individual of the notice being provided to the other insurance affordability program per paragraph (i)(3)(i) of this section and the impact that the individual's eligibility to enroll in the State's separate child health plan will have on the individual's eligibility for such other program.

(B) Prior to the end of the individual's period of uninsurance (sufficient to enable the individual to disenroll from the insurance affordability program to which the individual's account was transferred per paragraph (i)(1) of this section), notice reminding the individual of the information described in paragraph (i)(2)(A) of this section, as appropriate.

(3) In the case of individuals subject to a period of uninsurance under this part, the state must notify such program of the date on which such period ends and the individual is eligible to enroll in CHIP.

(j) *Applicants potentially eligible for Medicaid on a basis other than modified adjusted gross income.* For individuals identified in paragraph (b)(2) of this section, the State must—

(1) Promptly and without undue delay, consistent with the timeliness standards established under § 457.340(d) of this subpart, transfer the electronic account to the Medicaid agency via a secure electronic interface;

(2) Complete the determination of eligibility for CHIP in accordance with § 457.340 or evaluation for potential eligibility for other insurance affordability programs in accordance with paragraph (b) of this section.

(3) Include in the notice of CHIP eligibility or ineligibility provided under § 457.340(e), as appropriate, coordinated content relating to—

(i) The transfer of the individual's electronic account to the Medicaid agency per paragraph (j)(1) of this section;

(ii) The transfer of the individual's account to another insurance affordability program in accordance with paragraph (i)(1) of this section, if applicable; and

(iii) The impact that an approval of Medicaid eligibility will have on the individual's eligibility for CHIP or another insurance affordability program, as appropriate.

(4) Dis-enroll the enrollee from CHIP if the State is notified in accordance with § 435.1200(d)(5) of this chapter that the applicant has been determined eligible for Medicaid.

(k) A State may enter into an arrangement with the Exchange for the entity that determines eligibility for CHIP to make determinations of eligibility for advanced premium tax credits and cost sharing reductions, consistent with 45 CFR 155.110(a)(2).

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001; 67 FR 61974, Oct. 2, 2002; 77 FR 17216, Mar. 23, 2012; 78 FR 42312, July 15, 2013; 81 FR 86465, Nov. 30, 2016]

§ 457.351 Coordination involving appeals entities for different insurance affordability programs.

(a) The terms of § 435.1200(g) of this chapter apply equally to the State in administering a separate CHIP. References to a ''fair hearing'' and ''joint fair hearing request'' in § 435.1200(g) of this chapter are treated as references to a ''review'' under subpart K of this part and to a ''joint appeal request'' as defined in § 457.10. Reference to ''expedited review of a fair hearing request consistent with § 431.221(a)(1)(ii) of this chapter'' is considered a reference to ''expedited review of an eligibility or enrollment matter under § 457.1160(a)''. Reference to § 435.1200(b)(3), (c), (d) and (e) are treated as a reference to § 457.348(b), (c) and (d) and § 457.350(c), respectively.

(b) [Reserved]

[81 FR 86466, Nov. 30, 2016]

§ 457.353 Monitoring and evaluation of screening process.

States must establish a mechanism and monitor to evaluate the screen and enroll process described at § 457.350 of this subpart to ensure that children who are:

(a) Screened as potentially eligible for other insurance affordability programs are enrolled in such programs, if eligible; or

(b) Determined ineligible for other insurance affordability programs are enrolled in CHIP, if eligible.

[77 FR 17216, Mar. 23, 2012]

§ 457.355 Presumptive eligibility for children.

The State may provide coverage under a separate child health program for children determined by a qualified entity to be presumptively eligible for the State's separate CHIP in the same manner and to the same extent as permitted under Medicaid under § 435.1101 and § 435.1102 of this chapter.

[81 FR 86466, Nov. 30, 2016]

§ 457.360 Deemed newborn children.

(a) *Basis*. This section implements section 2112(e) of the Act.

(b) *Eligibility*. (1) The State must provide CHIP to children from birth until the child's first birthday without application if—

(i) The child's mother was eligible for and received covered services for the date of the child's birth under the State plan as a targeted low-income pregnant woman in accordance with section 2112 of the Act; and

(ii) The child is not eligible for Medicaid under § 435.117 of this chapter.

(2)(i) The State may provide coverage under this section to children who are not eligible for Medicaid under § 435.117 from birth until the child's first birthday without application if the requirement in paragraph (b)(2)(ii) of this section is met and if, for the date of the child's birth, the child's mother was eligible for and received covered services under—

(A) The State plan as a targeted low-income child;

(B) CHIP coverage in another State; or

(C) Coverage under the State's demonstration under section 1115 of the Act as a Medicaid or CHIP population.

(ii) For purposes of paragraph (b)(2)(i) of this section, the State may only elect the optional populations described if it elects to cover the corresponding optional populations in Medicaid under § 435.117(b)(2)(ii) of this chapter.

(3) The child is deemed to have applied and been determined eligible under the State's separate CHIP State plan effective as of the date of birth, and remains eligible regardless of changes in circumstances (except if the child dies or ceases to be a resident of the State or the child's representative requests a voluntary termination of the child's eligibility) until the child's first birthday.

(c) *CHIP identification number*. (1) The CHIP identification number of the mother serves as the child's identification number, and all claims for covered services provided to the child may be submitted and paid under such number, unless and until the State issues a separate identification number for the child.

(2) The State must issue a separate CHIP identification number for the child prior to the effective date of any termination of the mother's eligibility or prior to the date of the child's first

birthday, whichever is sooner, except that the State must issue a separate CHIP identification number for the child if the mother was covered in another State at the time of birth.

[81 FR 86466, Nov. 30, 2016]

§ 457.370 Alignment with Exchange initial open enrollment period.

The terms of § 435.1205 apply equally to the State in administering a separate CHIP, except that the State shall make available and accept the application described in § 457.330, shall accept electronic accounts as described in § 457.348, and furnish coverage in accordance with § 457.340.

[78 FR 42312, July 15, 2013]

§ 457.380 Eligibility verification.

(a) *General requirements.* Except where law requires other procedures (such as for citizenship and immigration status information), the State may accept attestation of information needed to determine the eligibility of an individual for CHIP (either self-attestation by the individual or attestation by an adult who is in the applicant's household, as defined in § 435.603(f) of this subchapter, or family, as defined in section 36B(d)(1) of the Internal Revenue Code, an authorized representative, or if the individual is a minor or incapacitated, someone acting responsibly for the individual) without requiring further information (including documentation) from the individual.

(b) *Status as a citizen, national or a non-citizen.* (1) Except for newborns identified in § 435.406(a)(1)(iii)(E) of this chapter, who are exempt from any requirement to verify citizenship, the agency must—

(i) Verify citizenship or immigration status in accordance with § 435.956(a) of this chapter, except that the reference to § 435.945(k) is read as a reference to paragraph (i) of this section; and

(ii) Provide a reasonable opportunity period to verify such status in accordance with § 435.956(a)(5) and (b) of this chapter and provide benefits during such reasonable opportunity period to individuals determined to be otherwise eligible for CHIP.

(2) [Reserved]

(c) *State residents.* If the State does not accept self-attestation of residency, the State must verify residency in accordance with § 435.956(c) of this chapter.

(d) *Income.* If the State does not accept self-attestation of income, the State must verify the income of an individual by using the data sources and following standards and procedures for verification of financial eligibility consistent with § 435.945(a), § 435.948 and § 435.952 of this chapter.

(e) *Verification of other factors of eligibility.* For eligibility requirements not described in paragraphs (c) or (d) of this section, a State may adopt reasonable verification procedures, consistent with the requirements in § 435.952 of this chapter, except that the State must accept self-attestation of pregnancy unless the State has information that is not reasonably compatible with such attestation.

(f) *Requesting information.* The terms of § 435.952 of this chapter apply equally to the State in administering a separate CHIP.

(g) *Electronic service.* Except to the extent permitted under paragraph (i) of this section, to the extent that information sought under this section is available through the electronic service described in § 435.949 of this chapter, the State must obtain the information through that service.

(h) *Interaction with program integrity requirements.* Nothing in this section should be construed as limiting the State's program integrity measures or affecting the State's obligation to ensure that only eligible individuals receive benefits or its obligation to provide for methods of administration that are in the best interest of applicants and enrollees and are necessary for the proper and efficient operation of the plan.

(i) *Flexibility in information collection and verification.* Subject to approval by the Secretary, the State may modify the methods to be used for collection of information and verification of information as set forth in this section, provided that such alternative source will reduce the administrative costs and burdens on individuals and States

while maximizing accuracy, minimizing delay, meeting applicable requirements relating to the confidentiality, disclosure, maintenance, or use of information, and promoting coordination with other insurance affordability programs.

(j) *Verification plan*. The State must develop, and update as modified, and submit to the Secretary, upon request, a verification plan describing the verification policies and procedures adopted by the State to implement the provisions set forth in this section in a format and manner prescribed by the Secretary.

[77 FR 17216, Mar. 23, 2012, as amended at 81 FR 86466, Nov. 30, 2016]

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]

§ 457.496 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms.* For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a State plan or a Managed Care Entity (MCE) (as defined at § 457.10) that contracts with the State plan. State plans must meet the requirements of § 457.480.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a State plan or a MCE that contracts with a State plan. State plans must meet the requirements at § 457.480.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits has the meaning defined in section 1905(r) of the Act and must be provided in accordance with section 1902(a)(43) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined under the terms of the State plan in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the State plan as being or not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or generally applicable State guidelines). Medical/surgical benefits include long term care services.

Mental health benefits means benefits for items or services that treat or otherwise address mental health conditions, as defined under the terms of the State plan in accordance with applicable Federal and State law, and consistent with generally recognized independent standards of current medical practice. Standards of current medical practice can be based on the most current version of the DSM, the most current version of the ICD, or generally applicable State guidelines. The term includes long term care services.

State Plan has the meaning assigned at §§ 457.10 and 457.50.

Substance use disorder benefits means benefits for items or services for substance use disorder, as defined under the terms of the State plan in accordance with applicable Federal and State law, and consistent with generally recognized independent standards of current medical practice. Standards of current medical practice can be based on the most current version of the DSM, the most current version of the ICD, or generally applicable State guidelines. The term includes long term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under the State plan. (*See* paragraph (d)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) *State plan providing EPSDT benefits.* (1) A State child health plan is deemed to be in compliance with this section if—

(i) The State elects in the State child health plan to cover Secretary-approved coverage defined in § 457.450(a) that includes all EPSDT benefits, as defined in section 1905(r) of the Act, in accordance with the requirement applied under section 1905(r)(5) of the Act to provide necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, as well as the informing and administrative requirements under 1902(a)(43) of the Act and the approved State Medicaid plan; and

(ii) The State child health plan does not exclude EPSDT benefits for any particular condition, disorder, or diagnosis.

(2) The child health plan must include a description of how the State will comply with paragraph (b)(1)(i) of this section.

(3) If a State has elected in its state plan to cover EPSDT benefits only for certain populations enrolled in the state child health plan, the State is deemed compliant with this section only with respect to such children.

(c) *Parity requirements for aggregate lifetime and annual dollar limits.* This paragraph (c) details the application of the parity requirements for aggregate lifetime and annual dollar limits. A State plan that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (c)(1), (2), or (4) of this section.

(1) *Plan with no limit or limits on less than one-third of all medical/surgical benefits.* If a State plan does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(2) *State plans with a limit on at least two-thirds of all medical/surgical benefits.* If a State plan includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is more restrictive than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (d)(3)(iii) of this section prohibiting separately accumulating cumulative financial requirements.)

(3) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this paragraph (c), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the State plan for the State plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the State plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(4) *Plan not described in this section*—(i) *In general.* A State plan that is not described in paragraph (c)(1) or (2) of this section for aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or

substance use disorder benefits that is no more restrictive than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (c)(4)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur for such benefits, taking into account any other applicable restrictions under the plan.

(ii) *Weighting*. For purposes of this paragraph (c)(4), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (c)(3) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(d) *Parity requirements for financial requirements and treatment limitations*—(1) *Clarification of terms*—(i) *Classification of benefits*. When reference is made in this paragraph (d) to a classification of benefits, the term ''classification'' means a classification as described in paragraph (d)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation*. When reference is made in this paragraph (d) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. *See* paragraph (d)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation*. When reference is made in this paragraph (d) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(2) *General parity requirement*—(i) *General rule*. A State plan or a MCE that contracts with CHIP through its State plan that provides both medical/surgical benefits and mental health or substance use disorder benefits, including when such benefits are delivered through an MCE, may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (d)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (d)(3) of this section; the application of the rules of this paragraph (d)(2) to nonquantitative treatment limitations is addressed in paragraph (d)(4) of this section.

(ii) *Classifications of benefits used for applying rules*. If a State plan provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (d)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, the same reasonable standards must apply to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a State plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this

paragraph (d) apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (d):

(A) *Inpatient*. Benefits furnished on an inpatient basis.

(B) *Outpatient*. Benefits furnished on an outpatient basis. See special rules for office visits in paragraph (d)(3)(iii) of this section.

(C) *Emergency care*. Benefits for emergency care.

(D) *Prescription drugs*. Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (d)(3)(iii) of this section.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining ''substantially all'' and ''predominant''*—(A) *Substantially all*. For purposes of this paragraph (d), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant*. (*1*) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (d)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(*2*) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the State plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a State plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on plan payments*. For purposes of this paragraph (d), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all State plan payments and combinations of MCE payments for medical/surgical benefits in the classification expected to be paid under the plan or MCE or combination that contracts with the State plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements*. For any deductible, the dollar amount of a State plan payments includes all plan payments for claims that would be subject to the deductible if it had not been satisfied. In accordance with the cumulative cost-sharing maximum in § 457.560, or any other out-of-pocket maximum in the State plan, the dollar amount of plan payments includes all State plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any

other thresholds at which the rate of health plan payment changes.

(E) *Determining the dollar amount of State plan payments.* Subject to paragraph (d)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a State plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) *Special rules*—(A) *Multi-tiered prescription drug benefits.* If a State plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (d)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the health plan satisfies the parity requirements of this paragraph (d) for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(B) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (d), a State plan may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (d)(3)(ii)(B). After the sub-classifications are established, the State plan may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (d)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (d)(3)(ii)(B) are:

(*1*) Office visits (such as physician visits); and

(*2*) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(iii) *No separate cumulative financial requirements.* A State plan may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(4) *Nonquantitative treatment limitations*—(i) *General rule.* A State plan may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the terms of the CHIP State plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards for provider admission to participate in a network, including reimbursement rates;

(E) Plan methods for determining usual, customary, and reasonable charges;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment;

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage; and

(I) Standards for providing access to out-of-network providers.

(5) *Application to out-of-network providers.* Any State plan providing access to out-of-network providers for medical/surgical benefits within a classification must use processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for mental health or substance use disorder benefits that are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for medical/surgical benefits.

(e) *Availability of plan information*—(1) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations made under a State plan including when benefits are furnished through a MCE contractor for mental health or substance use disorder benefits must be made available by the plan administrator (or the State offering the coverage) to any current enrollee or potential enrollee or contracting provider upon request. Health plans operating in compliance with § 438.236(c) of this chapter will be deemed compliant with the requirements in this paragraph (e).

(2) *Reason for any denial.* The reason for any denial under a health plan of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available by the plan administrator or the State to the enrollee.

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (e)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law.

(f) *Applicability*—(1) *State plans.* The requirements of this section apply to State plans offering medical/surgical benefits and mental health or substance use disorder benefits to their enrollees including when benefits are furnished under a contract with MCEs. If, under an arrangement or arrangements to provide State plan benefits any enrollee can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section apply separately for each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any enrollee can simultaneously receive from the State.

(i) *Standard for defining benefits.* States must indicate the standard used for defining the following benefits in the State plan:

(A) Medical/surgical benefits.

(B) Mental health benefits.

(C) Substance use disorder benefits.

(ii) [Reserved]

(2) *Scope.* This section does not—

(i) Require a State plan or a MCE that contracts with a State plan to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a State plan or a MCE that contracts with a State plan for one or more mental health conditions or substance use disorders does not require the plan or health insurance coverage under this section to provide benefits for any other mental health condition or substance use disorder;

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the State plan or a MCE that contracts with a CHIP State plan except as specifically provided in paragraphs (c) and (d) of this section.

(g) *Compliance dates*—(1) *In general.* State plans (including those that contract with a MCE) must comply with the requirements of this section no later than October 2, 2017.

(2) [Reserved]

[81 FR 18842, Mar. 30, 2016]

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 household 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

household 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, § 447.53, or § 447.54 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 household 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 household 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; 78 FR 42312, July 15, 2013]

§ 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 household 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 household 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 household 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 household 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 household 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 ensure that disenrollment policies, such as policies related to non-payment of premiums, do not present barriers to the timely determination of eligibility and enrollment in coverage of an eligible child in the appropriate insurance affordability program. A State may not—

(1) Establish a premium lock-out period that exceeds 90-days in accordance with § 457.10 of this part.

(2) Continue to impose a premium lock-out period after a child's past due premiums have been paid.

(3) Require the collection of past due premiums or enrollment fees as a condition of eligibility for reenrollment once the State-defined lock out period has expired, regardless of the length of the lock-out period.

(d) 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).

[66 FR 2681, Jan. 11, 2001, as amended at 78 FR 42312, July 15, 2013]

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 2015, 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.

[66 FR 2670, Jan. 11, 2001, as amended at 76 FR 9246, Feb. 17, 2011]

§ 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 prior to FY 2009.

(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.

[66 FR 2670, Jan. 11, 2001, as amended at 76 FR 9246, Feb. 17, 2011]

§ 457.609 Process and calculation of State allotments for a fiscal year after FY 2008.

(a) *General*. For each of the 50 States and the District of Columbia and for each Commonwealth and Territory with an approved State child health plan, the State allotments for FY 2009 through FY 2015 are determined by CMS as described in paragraphs (b) through (g) of this section. Unless otherwise indicated in this section, the reference to ''State'' refers to the 50 States and the District of Columbia and the Commonwealths and Territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands).

(b) *Amounts available for allotment*. The total amounts available for allotment for each fiscal year are as follows:

(1) FY 2009: $10,562,000,000.

(2) FY 2010: $12,520,000,000.

(3) FY 2011: $13,459,000,000.

(4) FY 2012: $14,982,000,000.

(5) FY 2013: $17,406,000,000.

(6) FY 2014: $19,147,000,000.

(7) FY 2015, for the period beginning October 1, 2014 and ending March 31, 2015, the following amounts are available for allotment:

(i) $2,850,000,000.

(ii) 15,361,000,000.

(8) FY 2015, for the period beginning April 1, 2013 and ending on September 30, 2013, $2,850,000,000.

(c) *Determination of a State allotment for FY 2009*—(1) *For the 50 States and the District of Columbia*. From the amount in paragraph (b)(1) of this section as appropriated for the fiscal year under section 2104(a) of the Act, subject to paragraph (e) related to proration, and paragraph (c)(3) of this section relating to coordination of funding, the allotment for FY 2009 is equal to 110 percent of the highest of the following amounts for each State and the District of Columbia:

(i) The total Federal payments to the State under title XXI of the Act for FY 2008 as reported by the State and certified to the Secretary through the November 2008 submission of the quarterly expenditure reports, Forms CMS–21 (OMB # 0938–0731) and CMS–64 (OMB # 0938–0067), multiplied by the allotment increase factor determined under paragraph (f) of this section.

(ii) The amount allotted to the State for FY 2008, multiplied by the allotment increase factor determined under paragraph (f) of this section;

(iii) The projected total Federal payments to the State under title XXI of the Act for FY 2009, subject to paragraph (c)(1)(iv) of this section, as determined based on the February 2009 projections certified by the State to CMS by no later than March 31, 2009.

(iv) In the case of a State described in section 2105(g) of the Act and electing the option under paragraph (4) of such section, for purposes of the projections described in paragraph (c)(1)(iii) of this section, such projections would include an amount equal to the difference between the following amounts:

(A) the amount of Federal payments for the expenditures described in section 2105(g)(4)(B) of the Act made after February 4, 2009 that would have been paid to the State if claimed at the enhanced Federal medical assistance percentage determined under section 2105(b) of the Act.

(B) the amount of Federal payments for the expenditures described in section 2105(g)(4)(B) of the Act made after February 4, 2009 that would have been paid to the State if claimed at the Federal medical assistance percentage defined in section 1905(b) of the Act; during the recession adjustment period described in section 5001(h) of the American Recovery and Reinvestment Act of 2009 (ARRA), as amended the Federal medical assistance percentage is as determined for the State under section 5001 of ARRA.

(2) *For the Commonwealths or Territories.* (i) From the amount in paragraph (b)(1) of this section, as appropriated for the FY 2009 under section 2104(a) of the Act, subject to paragraph (e) of this section related to proration, and paragraph (c)(3) of this section relating to coordination of funding, an amount equal to the highest amount of Federal payments made to the Commonwealth or Territory under title XXI of the Social Security Act for any fiscal year occurring during the period for FY 1999 through FY 2008, multiplied by the allotment increase factor determined under paragraph (f) of this section, plus the additional amount for the fiscal year specified in paragraph (c)(2)(ii) of this section.

(ii) *Additional Amounts for FY 2009.* From the amount appropriated for the fiscal year under section 2104(c)(4)(B) of the Act, the additional amount for each Commonwealth or Territory is equal to $40,000,000 multiplied by the following percentage as specified in section 2104(c)(2) of the Act:

(A) For Puerto Rico, 91.6 percent.

(B) For Guam, 3.5 percent.

(C) For the Virgin Islands, 2.6 percent.

(D) For American Samoa, 1.2 percent.

(E) For the Northern Mariana Islands, 1.1 percent.

(3) *Coordination of CHIP Funding for FY 2009.* The amount of the CHIP allotment for FY 2009 available for payment for a States' expenditures may be reduced by the amounts appropriated and obligated before April 1, 2009 for States' FY 2009 allotments, FY 2006 allotments redistributed to the State in FY 2009 determined under section 2104(k) of the Act, and the amounts of additional FY 2009 shortfall allotments determined under section 2104(l) of the Act.

(d) *Determination of a State allotment for FY 2010 through FY 2015*—(1) *General.* Subject to the provisions of paragraph (e) of this section relating to proration and paragraph (g) of the section relating to increases in a fiscal year allotment for approved program expansions, the State allotments for FY 2010 through FY 2015 are determined as follows.

(2) *Determination of a State Allotment for FY 2010.* (i) For the 50 States and the District of Columbia, and for the Commonwealths and Territories subject to paragraph (d)(2)(ii) of this section, the State allotment for FY 2010 is equal to the product of the following:

(A) The sum of:

(*1*) The State Allotment for FY 2009, as determined under paragraph (c) of the section.

(*2*) The amount of any Federal payments made as redistributions of unexpended FY 2006 allotments under section 2104(k) of the Act.

(*3*) The amount of any Federal payments made as additional FY 2009 allotments under section 2104(l) of the Act.

(*4*) The amount of any Federal payments made as contingency fund payments for FY 2009 under section 2104(n) of the Act.

(B) The State allotment increase factor for FY 2010 as determined under paragraph (f) of the section.

(ii) In determining the amount of the FY 2010 allotment for each Commonwealth and Territory, for purposes of determining the amount of the FY 2009 allotment under paragraph (d)(2)(i)(A)(1) of this section, the amount of such FY 2009 allotment will not include the additional amount determined under paragraph (c)(2)(ii).

(3) *Determination of a State Allotment for FY 2011.* For the 50 States and the District of Columbia, and the Commonwealths and Territories, the State allotment for FY 2011 is equal to the product of:

(i) The amount of Federal payments attributable and countable toward the available State allotments in FY 2010, including:

(A) Any amount redistributed to the State in FY 2010, and

(B) Any Federal payments made as contingency fund payments for FY 2010 under section 2104(n) of the Act.

(ii) The State allotment increase factor for FY 2011 as determined under paragraph (f) of the section.

(4) *Determination of a State Allotment for FY 2012.* For the 50 States and the District of Columbia, and the Commonwealths and Territories, the State allotment for FY 2012 is equal to the product of:

(i) The sum of:

(A) The State Allotment for FY 2011, as determined under paragraph (d)(3) of this section.

(B) The amount of any Federal payments made as contingency fund payments for FY 2011 under section 2104(n) of the Act.

(ii) The State allotment increase factor for FY 2012 as determined under paragraph (f) of this section.

(5) *Determination of a State Allotment for FY 2013*. For the 50 States and the District of Columbia, and the Commonwealths and Territories, the State allotment for FY 2013 is equal to the product of:

(i) The amount of Federal payments attributable and countable toward the available State allotments in FY 2012, including:

(A) Any amount redistributed to the State in FY 2012, and

(B) Any Federal payments made as contingency fund payments for FY 2012 under section 2104(n) of the Act.

(ii) The State allotment increase factor for FY 2013 as determined under paragraph (f) of the section.

(6) *Determination of a State Allotment for FY 2014*. For the 50 States and the District of Columbia, and the Commonwealths and Territories, the State allotment for FY 2014 is equal to the product of:

(i) The sum of:

(A) The State Allotment for FY 2013, as determined under paragraph (d)(5) of this section.

(B) The amount of any Federal payments made as contingency fund payments for FY 2013 under section 2104(n) of the Act.

(ii) The State allotment increase factor for FY 2014 as determined under paragraph (f) of this section.

(7) *Determination of a State Allotment for FY 2015*—(i) *General*. There are two State allotments for FY 2015; one for the period beginning October 1, 2014 and ending March 31, 2015 and the second beginning April 1, 2015 and ending September 30, 2015. These State allotments are determined for each of the 50 States and the District of Columbia, and the Commonwealths and Territories.

(ii) The State allotment for FY 2015 for the period October 1, 2014 and ending March 31, 2015 is determined as the product of the following:

(A) The first half ratio determined as the amount in paragraph (d)(7)(ii)(A)(*1*) of this section divided by the amount in paragraph (d)(7)(ii)(A)(*2*) of this section as follows:

(*1*) $18,211,000,000 (calculated as the sum of the amount in paragraph (b)(7)(i) of this section, $2,850,000,000 (appropriated in section 2104(a)(18)(A) of the Act) and the amount in paragraph (b)(7)(ii) of this section, $15,361,000,000 (appropriated in section 108 of Pub. L. 111–3, as amended by section 10203 of Pub. L. 111–148)).

(*2*) $21,061,000,000, determined as the sum of the amount determined in paragraph (*1*) of this section, $18,211,000,000, and $2,850,000,000, the amount in paragraph (b)(8) of this section, as appropriated in section 2104(a)(18)(B) of the Act, as amended by section 10203 Of Public Law 111–148.

(B) The product of:

(*1*) The amount of Federal payments attributable and countable toward the total amount of available State allotments in FY 2014, to include:

(*i*) Any amount redistributed to the State in FY 2014; and

(*ii*) Any Federal payments made as contingency fund payments for FY 2014 under section 2104(n) of the Act.

(*2*) The State allotment increase factor for FY 2015 as determined under paragraph (f) of this section.

(iii) The State allotment for FY 2015 for the period April 1, 2015 and ending September 30, 2015 is determined as the product of the following:

(A) $2,850,000,000 the amount in paragraph (b)(8) of this section, as appropriated in section 2104(a)(18)(B) of the Act; and

(B) The ratio determined as the amount in paragraph (d)(7)(iii)(B)(*1*) of this section divided by the amount in paragraph (d)(7)(iii)(B)(*2*) of this section:

(*1*) The amount of the State allotment determined in paragraph (d)(7)(ii) of this section.

(*2*) The total of all the State allotments determined in paragraph (d)(7)(ii) of this section.

(e) *Proration*. (1) If for a fiscal year the sum of the State allotments for the 50 States and the District of Columbia,

and the State allotments for the Commonwealths and Territories (not including the additional amount for FY 2009 determined under paragraph (c)(2)(ii) of this section), exceeds the total amount available for allotment for the fiscal year in paragraph (b) of this section, the amount of the allotment for each of the 50 States and the District of Columbia, and for each of the Commonwealths and Territories (not including the additional amount for FY 2009 determined under paragraph (c)(2)(ii) of this section) will be reduced on a proportional basis as indicated in paragraph (e)(2) of this section.

(2) The amount of the allotment for each of the 50 States and the District of Columbia, and for each of the Commonwealths and Territories (not including the additional amount for FY 2009 determined in paragraph (c)(2)(ii) of this section) is equal to the product of:

(i) The percentage determined by dividing the amount in paragraph (e)(2)(i)(A) by the amount in paragraph (e)(2)(i)(B) of this section.

(A) The amount of the State allotment for each of the 50 States and the District of Columbia, and for each of the Commonwealths and Territories (not including the additional amount for FY 2009 determined under paragraph (c)(2)(ii) of this section).

(B) The sum of the amounts for each of the 50 States and the District of Columbia, and the Commonwealths and Territories in paragraph (e)(2)(i) of this section.

(ii) The total amount available for allotment for the fiscal year under paragraph (b) of this section.

(f) *Allotment increase factor*. The allotment increase factor for a fiscal year is equal to the product of the following:

(1) Per capita health care growth factor. The per capita health care growth factor for a fiscal year is equal to 1 plus the percentage increase in the projected per capita amount of the National Health Expenditures from the calendar year in which the previous fiscal year ends to the calendar year in which the fiscal year involved ends, as most recently published by CMS before the beginning of the fiscal year involved.

(2) *Child Population Growth Factor* (CPGF). The CPGF for a fiscal year is equal to 1 plus the percentage increase (if any) in the population of children in the State from July 1 in the previous fiscal year to July 1 in the fiscal year involved, as determined by CMS based on the most recent published estimates of the Census Bureau available before the beginning of the fiscal year involved plus 1 percentage point. For purposes of determining the CPGF for FY 2009 for the Commonwealths and Territories only, in applying the previous sentence, ''United States'' is substituted for ''the State''.

(g) *Increase in State allotment for the 50 States and the District of Columbia for FY 2010 through FY 2015 to account for approved program expansions*. In the case of the 50 States and the District of Columbia, the State allotment for FY 2010 through FY 2015, as determined in accordance with the provisions of this section, may be increased under the following conditions and amounts:

(1) The State has submitted to the Secretary, and has approved by the Secretary a State plan amendment or waiver request relating to an expansion of eligibility for children or benefits under title XXI of the Act that becomes effective for a fiscal year (beginning with FY 2010 and ending with FY 2015).

(2) The State has submitted to the Secretary, before the August 31 preceding the beginning of the fiscal year, a request for an expansion allotment adjustment under this paragraph for such fiscal year that specifies.

(i) The additional expenditures that are attributable to the eligibility or benefit expansion provided under the amendment or waiver described in paragraph (g)(1) of this section, as certified by the State and submitted to the Secretary by not later than August 31 preceding the beginning of the fiscal year.

(ii) The extent to which such additional expenditures are projected to exceed the allotment of the State or District for the year.

(3) Subject to paragraph (e) of this section relating to proration, the amount of the allotment of the State or District under this section for such

fiscal year shall be increased by the excess amount described in paragraph (g)(2)(i)of this section. A State or District may only obtain an increase under paragraph (g)(2)(ii) of this section for an allotment for FY 2010, FY 2012, or FY 2014.

(h) *CHIP Fiscal Year Allotment Process.* As determined by the Secretary, the CHIP allotments for a fiscal year may be published as Preliminary Allotments or Final Allotments in the FEDERAL REGISTER.

[76 FR 9246, Feb. 17, 2011]

§ 457.610 Period of availability for State allotments prior to FY 2009.

The amount of a final allotment prior to FY 2009, 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.

[66 FR 2670, Jan. 11, 2001, as amended at 76 FR 9249, Feb. 17, 2011]

§ 457.611 Period of availability for State allotments for a fiscal year after FY 2008.

The amount of a final allotment for a fiscal year after FY 2008, as determined under § 457.609 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 2-year period of availability, beginning with the fiscal year of the final allotment and ending with the end of the succeeding fiscal year following the fiscal year.

(Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

[76 FR 9249, Feb. 17, 2011]

§ 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) [Reserved]

(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.

[65 FR 33622, May 24, 2000, as amended at 81 FR 86466, Nov. 30, 2016]

§ 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 §§ 431.800 through 431.1010 of this chapter (related to the PERM and MEQC programs); §§ 433.312 through 433.322 of this chapter (related to Overpayments); § 433.38 of this chapter (Interest charge on disallowed claims of FFP); §§ 430.40 through 430.42 of this chapter (Deferral of claims for FFP and Disallowance of claims for FFP); § 430.48 of this chapter (Repayment of Federal funds by installments); §§ 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 State's CHIP programs in the same manner as they apply to State's Medicaid programs.

(b) HHS Regulations in 45 CFR subtitle A:

Part 16—Procedures of the Departmental Appeals Board.

45 CFR part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (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; 75 FR 73976, Nov. 30, 2010; 77 FR 31513, May 29, 2012; 81 FR 3012, Jan. 20, 2016; 82 FR 31187, July 5, 2017]

§ 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 75, that establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

(1) Cost sharing or matching, 45 CFR 75.306; and

(2) Financial reporting, 45 CFR 75.341.

[65 FR 33622, May 24, 2000, as amended at 75 FR 48852, Aug. 11, 2010; 81 FR 3012, Jan. 20, 2016]

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) Section 2101(a) of the Act, which sets forth that the purpose of title XXI is to provide funds to States to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage;

(2) Sections 2107(a), (b) and (d) of the Act, which set forth requirements for strategic planning, reports, and program budgets; and

(3) 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, except that § 457.730 does not apply to Medicaid expansion programs. Separate child health programs that provide benefits exclusively through managed care organizations may meet the requirements of § 457.730 by requiring the managed care organizations to meet the requirements of § 457.1233(d)(2).

[66 FR 2683, Jan. 11, 2001, as amended at 85 FR 25635, May 1, 2020]

§ 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]

§ 457.730 Beneficiary access to and exchange of data.

(a) *Application Programming Interface to support CHIP beneficiaries.* A State must implement and maintain a standards-based Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of the current individual beneficiary or the beneficiary's personal representative, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the beneficiary.

(b) *Accessible content.* A State must make the following information accessible to its current beneficiaries or the beneficiary's personal representative through the API described in paragraph (a) of this section:

(1) Data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and beneficiary cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(2) Encounter data no later than 1 business day after receiving the data from providers, other than MCOs, PIHPs, or PAHPs, compensated on the basis of capitation payments;

(3) Clinical data, including laboratory results, if a State maintains any such data, no later than one (1) business day after the data is received by the State; and

(4) Information, about covered outpatient drugs and updates to such information, including, where applicable, preferred drug list information, no later than one (1) business day after the effective date of the information or updates to such information.

(c) *Technical requirements.* A State implementing an API under paragraph (a) of this section:

(1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215;

(2) Must conduct routine testing and monitoring, and update as appropriate, to ensure the API functions properly, including assessments to verify that the API technology is fully and successfully implementing privacy and security features such as, but not limited to, those required to comply with HIPAA privacy and security requirements in 45 CFR parts 160 and 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;

(3) Must comply with the content and vocabulary standard requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are applicable to the data type or element, as appropriate; and

(ii) Content and vocabulary standards at 45 CFR part 162 and § 423.160 of this chapter where required by law, or where such standards are applicable to the data type or element, as appropriate.

(4) May use an updated version of any standard or all standards required under paragraphs (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 170.215, the National Coordinator

has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Use of the updated version of a standard does not disrupt an end user's ability to access the data described in paragraph (b) of this section through the API described in paragraph (a) of this section.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, a State must make publicly accessible, by posting directly on its website or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum the information listed in this paragraph. For the purposes of this section, ''publicly accessible'' means that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps, such as a fee for access to the documentation; a requirement to receive a copy of the material via email; a requirement to register or create an account to receive the documentation; or a requirement to read promotional material or agree to receive future communications from the organization making the documentation available;

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations that an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* A State may deny or discontinue any third-party application's connection to the API required under paragraph (a) of this section if the State:

(1) Reasonably determines, consistent with its security risk analysis under 45 CFR part 164 subpart C, that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of protected health information on the State's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which beneficiaries seek to access their electronic health information as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) *Beneficiary resources regarding privacy and security.* A State must provide in an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former beneficiaries seeking to access their health information held by the State CHIP agency, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application including secondary uses of data, and the importance of understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of OCR and FTC, and how to submit a complaint to:

(i) The HHS Office for Civil Rights (OCR); and

(ii) The Federal Trade Commission (FTC).

(g) *Data availability.* (1) The State must comply with the requirements in paragraphs (a) through (f) of this section beginning January 1, 2021 with regard to data:

(i) With a date of service on or after January 1, 2016; and

(ii) That are maintained by the State.

(2) [Reserved]

[85 FR 25636, May 1, 2020]

§ 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) Household income as a percentage of the Federal poverty level as described in paragraph (b) of this section.

(b) *Reportable household 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 household 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]

§ 457.760 Access to published provider directory information.

(a) The State must implement and maintain a publicly accessible, standards-based Application Programming Interface (API) that is conformant with the technical requirements at § 457.730(c), excluding the security protocols related to user authentication and authorization and any other protocols that restrict the availability of this information to particular persons or organizations, the documentation requirements at § 457.730(d), and is accessible via a public-facing digital endpoint on the State's website.

(b) The API must provide a complete and accurate directory of—

(1) The State's provider directory information including provider names, addresses, phone numbers, and specialties, updated no later than 30 calendar days after the State receives provider directory information or updates to provider directory information.

(2) [Reserved]

(c) This section is applicable beginning January 1, 2021.

[85 FR 25637, May 1, 2020]

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.

(a) *State plan requirements.* 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.

(b) *Limitations.* (1) A state may not, under this section, impose a period of uninsurance which exceeds 90 days from the date a child otherwise eligible for CHIP is disenrolled from coverage under a group health plan.

(2) A waiting period may not be applied to a child following the loss of eligibility for and enrollment in Medicaid or another insurance affordability program.

(3) If a state elects to impose a period of uninsurance following the loss of

coverage under a group health plan under this section, such period may not be imposed in the case of any child if:

(i) The premium paid by the family for coverage of the child under the group health plan exceeded 5 percent of household income;

(ii) The child's parent is determined eligible for advance payment of the premium tax credit for enrollment in a QHP through the Exchange because the ESI in which the family was enrolled is determined unaffordable in accordance with 26 CFR 1.36B–2(c)(3)(v).

(iii) The cost of family coverage that includes the child exceeds 9.5 percent of the household income.

(iv) The employer stopped offering coverage of dependents (or any coverage) under an employer-sponsored health insurance plan;

(v) A change in employment, including involuntary separation, resulted in the child's loss of employer-sponsored insurance (other than through full payment of the premium by the parent under COBRA);

(vi) The child has special health care needs; or

(vii) The child lost coverage due to the death or divorce of a parent.

[78 FR 42313, July 15, 2013, as amended at 81 FR 86466, Nov. 30, 2016]

§ 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) *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) Any waiting period imposed under the state child health plan prior to the provision of child health assistance to a targeted low-income child under the state plan shall apply to the same extent to the provision of a premium assistance subsidy for the child and shall not exceed 90 days.

(2) States must permit the same exemptions to the required waiting period for premium assistance as specified under the state plan at § 457.805(a)(2), and § 457.805(a)(3) for the provision of child health assistance to a targeted low-income child.

(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.

[66 FR 2684, Jan. 11, 2001, as amended at 78 FR 42313, July 15, 2013]

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.

(x) Sections 1902(a)(77) and 1902(kk) of the Act relating to provider and supplier screening, oversight, and reporting requirements.

(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.

[66 FR 2685, Jan. 11, 2001, as amended at 76 FR 5970, Feb. 2, 2011]

§ 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 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 part 75, as applicable.

(c) All contracts under this part must include provisions that define a sound and complete procurement contract, as required by 45 CFR part 75, as applicable.

[81 FR 27897, May 6, 2016]

§ 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) *MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities.* The contract requirements for MCOs, PAHPs, PIHPs, PCCMs, and PCCM entities are provided in § 457.1201.

(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.

[66 FR 2685, Jan. 11, 2001, as amended at 81 FR 27897, May 6, 2016]

§ 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.

§ 457.990 Provider and supplier screening, oversight, and reporting requirements.

The following provisions and their corresponding regulations apply to a State under title XXI of the Act, in the same manner as these provisions and regulations apply to a State under title XIX of the Act:

(a) Section 455.107.

(b) Part 455, subpart E, of this chapter.

(c) Sections 1902(a)(77) and 1902(kk) of the Act pertaining to provider and supplier screening, oversight, and reporting requirements.

[76 FR 5970, Feb. 2, 2011, as amended at 84 FR 47857, Sept. 10, 2019]

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]

Subpart L—Managed Care

SOURCE: 81 FR 27897, May 6, 2016, unless otherwise noted.

GENERAL PROVISIONS

§457.1200 Basis, scope, and applicability.

(a) *Statutory basis*. This subpart implements the following sections of the Act:

(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.

(2) Section 2103(f)(3) and 2107(e)(1)(M) of the Act, which apply certain provisions of Title XIX related to Medicaid managed care to CHIP.

(3) Sections 2107(b) and 2107(e)(2) of the Act, which relate to program integrity.

(b) *Scope*. This subpart sets forth requirements for the provision of services through MCOs, PIHPs, PAHPs, and PCCM entities, as defined in §457.10.

(c) *Applicability*. The requirements of this subpart apply to child health assistance provided under a separate child health program operating a managed care delivery system. Regulations relating to managed care that are applicable to a Medicaid expansion program are found at part 438 of this chapter.

§457.1201 Standard contract requirements.

(a) *CMS review*. The State must submit all MCO, PAHP, PIHP, PCCM, and PCCM entity contracts for review in the form and manner established by CMS.

(b) *Entities eligible for comprehensive risk contracts*. The State may enter into a comprehensive risk contract only with the entities specified in §438.3(b)(1) through (3) of this chapter.

(c) *Payment*. The final capitation rates for all MCO, PIHP or PAHP contracts must be identified and developed, and payment must be made in accordance with §438.3(c) of this chapter, except that the requirement for preapproval of contracts does not apply, and contract rates must be submitted to CMS upon request of the Secretary.

(d) *Enrollment discrimination prohibited*. Contracts with MCOs, PAHPs, PIHPs, PCCMs and PCCM entities must comply with prohibitions on enrollment discrimination in accordance with §438.3(d) of this chapter, except that §438.3(d)(2) of this chapter (related to voluntary enrollment) does not apply.

(e) *Services that may be covered by an MCO, PIHP, or PAHP*. An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with §438.3(e) of this chapter.

(f) *Compliance with applicable laws and conflict of interest safeguards*. Contracts with MCOs, PAHPs, PIHPs, PCCMs or

PCCM entities must comply with Federal laws and regulations in accordance with § 438.3(f) of this chapter.

(g) *Inspection and audit of records and access to facilities.* Contracts with MCOs, PIHPs, PAHPs, PCCMs or PCCM entities must allow for the inspection and audit of records and access to facilities in accordance with § 438.3(h) of this chapter.

(h) *Physician incentive plans.* If a contract with an MCO, PAHP, or PIHP provides for a physician incentive plan, it must comply with § 438.3(i) of this chapter (which cross references §§ 422.208 and 422.210 of this chapter).

(i) *Subcontractual relationships and delegations.* The state must ensure, through its contracts with MCOs, PIHPs, and PAHPs, that any contract or written agreement that the MCO, PIHP, or PAHP has with any individual or entity that relates directly or indirectly to the performance of the MCOs, PIHPs, or PAHPs obligations under its contract comply with § 457.1233(b) (which cross references § 438.230 of this chapter).

(j) *Choice of network provider.* The contract must allow each enrollee to choose his or her network provider in accordance with § 438.3(l) of this chapter.

(k) *Audited financial reports.* Contracts with MCOs, PAHPs, and PIHPs must comply with the requirements for submission of audited financial reports in § 438.3(m) of this chapter.

(l) *Parity in mental health and substance use disorder benefits.* Contracts with MCOs, PAHPs, and PIHPs must comply with the requirements of § 457.496.

(m) *Additional rules for contracts with PCCMs.* Contracts with PCCMs must comply with the requirements of § 438.3(q) of this chapter, except that the right to disenroll is in accordance with § 457.1212.

(n) *Additional rules for contracts with PCCM entities.* (1) States must submit PCCM entity contracts to CMS for review.

(2) Contracts with PCCMs must comply with the requirements of paragraph (o) of this section; § 457.1207; § 457.1240(b) (cross-referencing § 438.330(b)(2), (b)(3), (c), and (e) of this chapter); § 457.1240(e) (cross-referencing § 438.340 of this chapter); and § 457.1250(a) (cross-referencing § 438.350 of this chapter).

(o) *Attestations.* Contracts with MCO, PAHP, PIHP, PCCM or PCCM entities must include an attestation to the accuracy, completeness, and truthfulness of claims and payment data, under penalty of perjury.

(p) *Guarantee not to avoid costs.* Contracts with an MCO, PAHP, PIHP, PCCM or PCCM entities must include a guarantee that the MCO, PAHP, PIHP, PCCM or PCCM entity will not avoid costs for services covered in its contract by referring enrollees to publicly supported health care resources.

(q) *Recordkeeping requirements.* Contracts with MCOs, PIHPs, and PAHPs, must comply with the recordkeeping requirements of § 438.3(u) of this chapter.

[81 FR 27897, May 6, 2016, as amended at 82 FR 40, Jan. 3, 2017]

§ 457.1203 Rate development standards and medical loss ratio.

(a) A state must use payment rates based on public or private payment rates for comparable services for comparable populations, consistent with actuarially sound principles as defined at § 457.10. This requirement for using actuarially sound principles to develop payment rates does not prohibit a state from implementing value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services; such alternate payment models should be developed using actuarially sound principles to the extent applicable.

(b) A State may establish higher rates than permitted under paragraph (a) of this section if such rates are necessary to ensure sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

(c) The rates must be designed to reasonably achieve a medical loss ratio standard, calculated in accordance with the provisions of § 438.8 of this chapter, that—

(1) Is equal to at least 85 percent for the rate year; and

(2) Provides for reasonable administrative costs.

(d) 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 (a), (b), or (c) of this section.

(e) The state must comply with the requirements related to medical loss ratios in accordance with the terms of § 438.74 of this chapter, except that the description of the reports received from the MCOs, PIHPs and PAHPs under § 438.8(k) of this chapter will be submitted independently, and not with the actuarial certification described in § 438.7 of this chapter.

(f) The state must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the requirements § 438.8 of this chapter.

[81 FR 27897, May 6, 2016, as amended at 82 FR 40, Jan. 3, 2017]

§ 457.1206 Non-emergency medical transportation PAHPs.

(a) For purposes of this section Non-Emergency Medical Transportation (NEMT) Prepaid Ambulatory Health Plan (PAHP) means an entity that provides only NEMT services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(b) The following requirements and options apply to NEMT PAHPs, NEMT PAHP contracts, and States in connection with NEMT PAHPs, to the same extent that they apply to PAHPs, PAHP contracts, and States in connection with PAHPs.

(1) All contract provisions in § 457.1201 except those set forth in § 457.1201(h) (related to physician incentive plans) § 457.1201(l) (related to mental health parity).

(2) The information requirements in § 457.1207.

(3) The provision against provider discrimination in § 457.1208.

(4) The State responsibility provisions in §§ 457.1212 and 457.1214, and § 438.62(a) of this chapter, as cross-referenced in § 457.1216.

(5) The provisions on enrollee rights and protections in §§ 457.1220, 457.1222, 457.1224, and 457.1226.

(6) The PAHP standards in § 438.206(b)(1) of this chapter, as cross-referenced by §§ 457.1230(a), 457.1230(d), and 457.1233(a), (b) and (d).

(7) An enrollee's right to a State review under subpart K of this part.

(8) Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in § 438.610 of this chapter, as cross referenced by § 457.1285.

(9) Requirements relating to contracts involving Indians, Indian Health Care Providers, and Indian managed care entities in § 457.1209.

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM, and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of § 438.10 of this chapter, except that the terms of § 438.10(c)(2), (g)(2)(xi)(E), and (g)(2)(xii) of this chapter do not apply.

[85 FR 72842, Nov. 13, 2020]

§ 457.1208 Provider discrimination prohibited.

The state must ensure through its contracts that each MCO, PIHP, and PAHP follow the requirements related to the prohibition on provider discrimination in § 438.12 of this chapter.

§ 457.1209 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care provider (IHCP), and Indian managed care entities (IMCE).

The State must follow, and ensure through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follows, the requirements related to Indians, IHCPs, and IMCEs in accordance with the terms of § 438.14 of this chapter.

STATE RESPONSIBILITIES

§ 457.1210 Enrollment process.

(a) *Default enrollment process.* (1) If a state uses a default enrollment process

to assign beneficiaries to a MCO, PIHP, PAHP, PCCM, or PCCM entity, the process must:

(i) Assign beneficiaries to a qualified MCO, PIHP, PAHP, PCCM or PCCM entity. To be qualified, the MCO, PIHP, PAHP, PCCM or PCCM entity must:

(A) Not be subject to the intermediate sanction described in § 438.702(a)(4) of this chapter.

(B) Have capacity to enroll beneficiaries.

(ii) Maximize continuation of existing provider-beneficiary relationships. An ''existing provider-beneficiary relationship'' is one in which the provider was the main source of CHIP services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, encounter data, or through contact with the beneficiary.

(iii) If the approach in paragraph (a)(1)(ii) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered.

(2) The State may consider additional reasonable criteria to conduct the default enrollment process, including the previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria that support the objectives of the managed care program.

(3) The State must send a confirmation of the enrollee's managed care enrollment to the enrollee within 5 calendar days of the date such enrollment is processed by the State. The confirmation must clearly explain the enrollee's right to disenroll within 90 days from the effective date of the enrollment.

(b) *Priority for enrollment.* The state must have an enrollment system under which beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM, or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(c) *Informational notices.* A State must provide an informational notice to each potential enrollee who may enroll in an MCO, PIHP, PAHP, PCCM, or PCCM entity. Such notice must:

(1) Include the MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities available to the potential enrollee;

(2) Explain how to select an MCO, PIHP, PAHP, PCCM, or PCCM entity;

(3) Explain the implications of making or not making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity;

(4) Explain the length of the enrollment period as well as the disenrollment policies in § 457.1212; and

(5) Comply with the information requirements in § 457.1207 and accessibility standards established under § 457.340.

[81 FR 27897, May 6, 2016, as amended at 82 FR 40, Jan. 3, 2017]

§ 457.1212 Disenrollment.

The State must comply with and ensure, through its contracts, that each MCO, PAHP, PIHP, PCCM and PCCM entity complies with the disenrollment requirements in accordance with the terms of § 438.56 of this chapter, except that references to fair hearings should be read to refer to reviews as described in subpart K of this part.

§ 457.1214 Conflict of interest safeguards.

The State must have in effect safeguards against conflict of interest in accordance with the terms of § 438.58 of this chapter, except that references to § 438.54(b) should be read to refer to the enrollment processes described in § 457.1210(a).

[82 FR 40, Jan. 3, 2017]

§ 457.1216 Continued services to enrollees.

The State must follow the requirements related to continued services to enrollees in accordance with the terms of § 438.62 of this chapter.

§457.1218 Network adequacy standards.

The State must develop network adequacy standards in accordance with the terms of §438.68 of this chapter, and, ensure through its contracts, that each MCO, PAHP, and PIHP meets such standards.

ENROLLEE RIGHTS AND PROTECTIONS

§457.1220 Enrollee rights.

The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follow the enrollee rights requirements in accordance with the terms of §438.100 of this chapter.

§457.1222 Provider-enrollee communication.

The State must ensure, through its contracts, that each MCO, PIHP, and PAHP protects communications between providers and enrollees in accordance with the terms of §438.102 of this chapter.

§457.1224 Marketing activities.

The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, and PCCM entity follows the requirements related to marketing activities in accordance with the terms of §438.104 of this chapter, except §438.104(c) of this chapter related to state agency review does not apply.

§457.1226 Liability for payment.

The State must ensure, through its contracts, that enrollees of MCOs, PIHPs, and PAHPs are not held liable for services or debts of the MCO, PIHP, or PAHPs in accordance with the terms of §438.106 of this chapter.

§457.1228 Emergency and poststabilization services.

The State must ensure that emergency and poststabilization care services are available and accessible to enrollees in accordance with the terms of §438.114 of this chapter.

[82 FR 40, Jan. 3, 2017]

MCO, PIHP, AND PAHP STANDARDS

§457.1230 Access standards.

(a) *Availability of services.* The State must ensure that the services are available and accessible to enrollees in accordance with the terms of §438.206 of this chapter.

(b) *Assurances of adequate capacity and services.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP has adequate capacity to serve the expected enrollment in accordance with the terms of §438.207 of this chapter.

(c) *Coordination and continuity of care.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP complies with the coordination and continuity of care requirements in accordance with the terms of §438.208 of this chapter, except that the applicability date in §438.208(d) does not apply.

(d) *Coverage and authorization of services.* The State must ensure, through its contracts, that each MCO, PIHP or PAHP complies with the coverage and authorization of services requirements in accordance with the terms of §438.210 of this chapter, except that the following do not apply: §438.210(a)(5) of this chapter (related to medical necessity standard); §438.210(b)(2)(iii) of this chapter (related to authorizing LTSS), and §438.210(f) (relating to the applicability date).

[81 FR 27897, May 6, 2016, as amended at 82 FR 40, Jan. 3, 2017]

§457.1233 Structure and operation standards.

(a) *Provider selection.* The State must ensure, through its contracts, that each MCO, PIHP or PAHP complies with the provider selection requirements as provided in §438.214 of this chapter.

(b) *Subcontractual relationships and delegation.* The State must ensure, through its contracts, that each MCO, PIHP, PAHP, and PCCM entity complies with the subcontractual relationships and delegation requirements as provided in §438.230 of this chapter.

(c) *Practice guidelines.* The state must ensure, through its contracts, that each MCO and, when applicable, each PIHP and PAHP, complies with the

practice guidelines requirements as provided in § 438.236 of this chapter.

(d) *Health information systems.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the health information systems requirements as provided in § 438.242 of this chapter, except that the applicability date in § 438.242(e) of this chapter does not apply. The State is required to submit enrollee encounter data to CMS in accordance with § 438.818 of this chapter.

(e) *Privacy protections.* The state must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the privacy protections as provided in § 457.1110.

[81 FR 27897, May 6, 2016, as amended at 82 FR 40, Jan. 3, 2017; 85 FR 25637, May 1, 2020; 85 FR 72842, Nov. 13, 2020]

QUALITY MEASUREMENT AND IMPROVEMENT; EXTERNAL QUALITY REVIEW

§ 457.1240 Quality measurement and improvement.

(a) *Scope.* This section sets forth requirements related to quality assessment and performance improvement that the State must meet in contracting with an MCO, PIHP, PAHP, or certain PCCM entities.

(b) *Quality assessment and performance improvement program.* (1) The State must require, through its contracts, that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees, in accordance with the requirements and standards in § 438.330 of this chapter, except that the terms of § 438.330(d)(4) of this chapter (related to dually eligible beneficiaries) do not apply.

(2) In the case of a contract with a PCCM entity described in paragraph (f) of this section, § 438.330(b)(2) and (3), (c), and (e) of this chapter apply.

(c) *State review of the accreditation status of MCOs, PIHPs, and PAHPs.* The State must review the accreditation status of each MCO, PIHP, and PAHP in accordance with the requirements as set forth in § 438.332 of this chapter.

(d) *Managed care quality rating system.* The State must determine a quality rating or ratings for each MCO, PIHP, and PAHP in accordance with the requirements set forth in § 438.334 of this chapter, except that the terms of § 438.334(c)(2)(i) and (c)(3) of this chapter (related to consultation with the Medical Care Advisory Committee) do not apply.

(e) *Managed care quality strategy.* The State must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished CHIP enrollees as described in § 438.340 of this chapter, except that the reference to consultation with the Medical Care Advisory Committee described in § 438.340(c)(1)(i) of this chapter does not apply.

(f) *Applicability to PCCM entities.* For purposes of paragraphs (b) and (e) of this section and § 457.1250(a), a PCCM entity described in this paragraph is a PCCM entity whose contract with the State provides for shared savings, incentive payments or other financial reward for improved quality outcomes.

[81 FR 27897, May 6, 2016, as amended at 82 FR 40, Jan. 3, 2017; 85 FR 72842, Nov. 13, 2020]

§ 457.1250 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must follow all applicable external quality review requirements as set forth in §§ 438.350 (except for references to § 438.362), 438.352, 438.354, 438.356, 438.358, 438.360 (only with respect to nonduplication of EQR activities with private accreditation) and § 438.364 of this chapter. In the case of a contract with a PCCM entity described in § 457.1240(f), § 438.350 (except for references to § 438.362) of this chapter applies.

(b) A State may amend an existing EQRO contract to include the performance of EQR-related activities and/or EQR in accordance with paragraph (a) of this section.

[81 FR 27897, May 6, 2016, as amended at 82 FR 40, Jan. 3, 2017]

GRIEVANCE SYSTEM

§ 457.1260 Grievance system.

(a) *Statutory basis and definitions*—(1) *Statutory basis.* This section implements section 2103(f)(3) of the Act, which provides that the State CHIP

must provide for the application of section 1932(a)(4), (a)(5), (b), (c), (d), and (e) of the Act (relating to requirements for managed care) to coverage, State agencies, enrollment brokers, managed care entities, and managed care organizations. Section 1932(b)(4) of the Act requires managed care plans to establish an internal grievance procedure under which an enrollee, or a provider on behalf of such an enrollee, may challenge the denial of coverage of or payment for covered benefits.

(2) *Definitions*. The following definitions from §438.400(b) of this chapter apply to this section—

(i) Paragraphs (1) through (5) and (7) of the definition of ''adverse benefit determination''; and

(ii) The definitions of ''appeal'', ''grievance'', and ''grievance and appeal system''.

(b) *General requirements*. (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions of §438.402(a), (b), and (c)(2) and (3) of this chapter with regard to the establishment and operation of a grievances and appeals system.

(2) An enrollee may file a grievance and request an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State external review in accordance with the terms of subpart K of this part after receiving notice under paragraph (e) of this section that the adverse benefit decision is upheld by the MCO, PIHP, or PAHP.

(3) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State external review in accordance with the terms of subpart K of this part, on behalf of an enrollee. When the term ''enrollee'' is used throughout this section, it includes providers and authorized representatives consistent with this paragraph (b).

(c) *Timely and adequate notice of adverse benefit determination*. (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at §438.404(a) and (b)(1), (2), and (5) of this chapter (regarding the content of the notice of an adverse benefit determination).

(2) In addition to the requirements referenced in paragraph (c)(1) of this section, the notice must explain:

(i) The enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal described at §438.402(b) of this chapter referenced in paragraph (b)(1) of this section, and the right to request a State external review in accordance with the terms of subpart K of this part; and

(ii) The procedures for the enrollee to exercise his or her rights provided under this paragraph (c).

(3) The MCO, PIHP, or PAHP must provide timely written notice to the enrollee of the adverse benefit determination. The terms of §§438.404(c)(6) and 438.210(d)(2) of this chapter apply in the circumstances of expedited service authorization decisions.

(d) *Handling of grievances and appeals*. The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at §438.406 of this chapter.

(e) *Resolution and notification: Grievances and appeals*. (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at §438.408(b) (relating to the timeframe for resolution of grievances and appeals), (c)(1) and (2) (the extension of timeframes for resolution of grievances and appeals), (d) (relating to the format of the notice of resolution for grievances and appeals), and (e)(1) (relating to the content of the notice of resolution for grievances and appeals) of this chapter.

(2) Each MCO, PIHP, or PAHP must resolve each grievance and 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 paragraph (e).

(3) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State external review in accordance with the terms of subpart K of this part.

(4) For appeals not resolved wholly in favor of an enrollee, in addition to the information required under paragraph (e)(1) of this section and § 438.408(e)(1) of this chapter, the content of the notice of appeal resolution must include the enrollee's right to request a State external review in accordance with the terms of subpart K of this part, and how to do so.

(5) Except as provided in paragraph (e)(3) of this section, an enrollee may request a State external review only after receiving notice that the MCO, PIHP, or PAHP is upholding the adverse benefit determination. The State must provide enrollees no less than 90 calendar days and no more than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution to request a State external review. The parties to the State external review include the MCO, PIHP, or PAHP, as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

(f) *Expedited resolution of appeals.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.410 of this chapter.

(g) *Information about the grievance and appeal system to providers and subcontractors.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.414 of this chapter.

(h) *Recordkeeping requirements.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.416 of this chapter.

(i) *Effectuation of reversed appeal resolutions.* If the MCO, PIHP, or PAHP, or the result of a State external review, in accordance with the terms of subpart K of this part, reverses a decision to deny, limit, or delay services, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

[85 FR 72842, Nov. 13, 2020]

SANCTIONS

§ 457.1270 Sanctions.

(a) *General.* The State must comply with §§ 438.700 through 438.704, 438.706(c) and (d), and 438.708 through 438.730 of this chapter.

(b) *Optional imposition of temporary management.* Except as provided in paragraph (c) of this section, the State may impose temporary management under § 438.702(a)(2) of this chapter as referenced in paragraph (a) of this section, only if it finds (through onsite surveys, enrollee or other complaints, financial status, or any other source) any of the following:

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700 of this chapter (as referenced in paragraph (a) of this section), or that is contrary to any of the requirements of this subpart.

(2) There is substantial risk to enrollees' health.

(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 of this chapter as referenced in paragraph (a) of this section.

(ii) Until there is an orderly termination or reorganization of the MCO.

(c) *Required imposition of temporary management.* 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 this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3) of this chapter as referenced in paragraph (a) of this section, and must notify the affected enrollees of their right to terminate enrollment.

[85 FR 72843, Nov. 13, 2020]

§ 457.1280 Conditions necessary to contract as an MCO, PAHP, or PIHP.

(a) The State must assure that any entity seeking to contract as an MCO, PAHP, or PIHP 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 MCO, PAHP, and PIHP compliance with all applicable Federal and State statutes, regulations, and standards.

(2) Prohibit MCOs, PAHPs, and PIHPs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of the MCO, PAHP, or PIHP for the purpose of influencing the individual to enroll with the entity.

(3) Include a mechanism for MCOs, PAHPs, and PIHPs to report to the State, to CMS, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors, providers, or enrollees of an MCO, PAHP, or PIHP 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 MCOs, PIHPs, and PAHPs at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent or abusive activity.

[66 FR 2685, Jan. 11, 2011. Redesignated and amended at 81 FR 27900, May 6, 2016]

§ 457.1285 Program integrity safeguards.

The State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of §§ 438.604(a)(2) and 438.608(d)(4) of this chapter do not apply.

[85 FR 72844, Nov. 13, 2020]

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: 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.

§ 460.3 Part D program requirements.

PACE organizations offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor, as defined in § 423.4 of this chapter, must abide by all applicable Part D program requirements in part 423 of this chapter.

[84 FR 25671, June 3, 2019]

§ 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.

Service, as used in this part, means all services that could be required under § 460.92, including items and drugs.

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; 86 FR 6131, Jan. 19, 2021]

Subpart B—PACE Organization Application and Waiver Process

§ 460.10 Purpose.

(a) *Applications*. This subpart sets forth the application procedures for the following:

(1) An entity that seeks approval from CMS as a PACE organization.

(2) A PACE organization that seeks to expand its service area or to add a new PACE center.

(3) A PACE organization that seeks to expand its service area and to add a new PACE center.

(b) *Waiver*. This subpart sets forth 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).

[84 FR 25671, June 3, 2019]

§ 460.12 Application requirements.

(a) *Submission of application*. An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area and/or add a PACE center site must submit to CMS a complete application in the form and manner specified by CMS that describes how the entity or PACE organization meets all requirements in this part.

(b) *State assurance*. (1) An entity's application to become a PACE organization must include an assurance from the State administering agency of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.

(2) A PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the State administering agency of the State in which the program is located indicating that the State is willing to amend the PACE program agreement to include the new site and/or expand the PACE organization's service area.

(c) *Service area designation*. (1) An entity submitting an application to become a PACE organization or a PACE organization submitting an application seeking to expand its service area must describe the proposed service area in its application.

(2) 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.

(d) *Service area and/or PACE center site expansion*. CMS and the State administering agency will only approve a service area expansion or PACE center site expansion after the PACE organization has successfully completed its

first trial period audit and, if applicable, has implemented an acceptable corrective action plan.

[84 FR 25671, June 3, 2019]

§ 460.14 [Reserved]

§ 460.16 [Reserved]

§ 460.18 CMS evaluation of applications.

CMS evaluates an application on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained by CMS or the State administering agency through on-site visits or any other means.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25671, June 3, 2019]

§ 460.20 Notice of CMS determination.

(a) *Time limit for notification of determination.* Within 90 days, or 45 days for applications set forth in § 460.10(a)(2), after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS:

(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.

(b) *Complete application.* An application is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial.

(c) *Additional information requested.* If CMS determines that an application is not complete because it does not include sufficient information to make a determination, CMS will request additional information within 90 days, or 45 days for applications set forth in § 460.10(a)(2), after the date of submission of the application.

(1) The time limits in paragraph (a) of this section do not begin until CMS receives all requested information and the application is complete.

(2) If more than 12 months elapse between the date of initial submission of the application and the entity's response to the CMS request for additional information, the entity must update the application to provide the most current information and materials related to the application.

(d) *Deemed approval.* An entity's application to become a PACE organization is deemed approved if CMS fails to act on the complete application within 90 days, after the later of the following dates:

(1) The date the application is submitted by the organization.

(2) The date CMS receives all requested additional information.

(e) *Date of submission.* For purposes of the time limits 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25672, June 3, 2019]

§ 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) A PACE organization, or an entity submitting an application to become a PACE organization, must submit its waiver request through the State administering agency for initial review.

(1) The State administering agency forwards a PACE organization's waiver requests to CMS along with any concurrence, concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may:

(i) Submit a waiver request as a document separate from the application by submitting it first to the State administering agency which, in turn, will forward the waiver request to CMS indicating the State's concurrence, concerns or conditions regarding the waiver request; or

(ii) Submit a waiver request directly to CMS in conjunction with the application. This request must include a letter from the State administering agency indicating the State's concurrence, concerns or conditions regarding the waiver request.

(b) CMS evaluates a waiver request from a PACE organization or PACE applicant 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 onsite 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, as amended at 71 FR 71334, Dec. 8, 2006; 84 FR 25672, June 3, 2019]

§ 460.28 Notice of CMS determination on waiver requests.

(a) *General.* Within 90 days after receipt of a complete waiver request, CMS takes one of the following actions, in the form and manner specified by CMS:

(1) Approves the waiver request.

(2) Conditionally approves the waiver request and notifies the PACE applicant.

(3) Denies the waiver request and notifies the PACE organization or PACE applicant of the basis for the denial.

(b) *Additional information requested.* A waiver request is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial. If CMS determines that the waiver request is not complete because it does not include sufficient information to make a determination, CMS will request additional information from the PACE organization or PACE applicant. The 90-day time limit in paragraph (a) of this section will start when CMS receives the complete waiver request.

(c) *Waiver approval.* A waiver request is deemed approved if CMS fails to act on the request within 90 days after CMS receives a complete waiver request.

(d) *Withdrawal of CMS approval for good cause.* (1) CMS in consultation with the State administering agency may withdraw approval of a waiver for good cause.

(2) If the waiver approval is withdrawn, CMS must notify the PACE organization or PACE applicant and the State administering agency that approval of a waiver has been withdrawn and the reason for doing so and must specify the effective date of the withdrawal in the notice.

[84 FR 25672, June 3, 2019]

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 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 state's Medicaid capitation rate or Medicaid payment rate methodology, 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; 84 FR 25672, June 3, 2019]

§ 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.

(a) 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:

(1) 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.

(2) Involuntarily disenrolls a participant in violation of § 460.164.

(3) Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid beneficiaries, 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.

(4) 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 beneficiaries whose medical condition or history indicates a need for substantial future medical services.

(5) Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.

(6) Misrepresents or falsifies information that is furnished—

(i) To CMS or the State under this part; or

(ii) To an individual or any other entity under this part.

(7) 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.

(8) Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.

(9) 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.

(10) Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.

(b) If CMS or the State administering agency makes a determination that could lead to termination of a PACE program agreement under § 460.50, CMS may impose any of the sanctions specified at §§ 460.42 and 460.46.

[64 FR 66279, Nov. 24, 1999, as amended at 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018; 84 FR 25672, June 3, 2019]

§ 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 maximum amounts specified in paragraphs (a)(1) through (4) of this section. These amounts will be adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) and updated amounts specified in 45 CFR part 102.

(1) For each violation regarding enrollment or disenrollment specified in § 460.40(a)(3) or (4), $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(a)(5), $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(a)(6)(i), $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).

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25672, June 3, 2019]

§ 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, including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018]

§ 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.

§ 460.56 Procedures for imposing sanctions and civil money penalties.

CMS provides notice and a right to request a hearing according to the procedures set forth in either of the following:

(a) Section 422.756(a) and (b) of this chapter if CMS imposes a suspension of enrollment or payment under § 460.42 or § 460.48(b).

(b) Section 422.756(e)(2)(v) of this chapter if CMS imposes civil money penalties under § 460.46.

[86 FR 6132, Jan. 19, 2021]

Subpart E—PACE Administrative Requirements

§ 460.60 PACE organizational structure.

(a) *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.

(b) *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 improvement program.

(c) *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) Except as provided in paragraph (d) of this section, 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.

(d) *Change of ownership*. A PACE organization planning a change of ownership must comply with all requirements in 42 CFR part 422, subpart L, and must notify CMS and the State administering agency, in writing, at least 60 days before the anticipated effective date of the change.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71334, Dec. 8, 2006; 84 FR 25673, June 3, 2019]

§ 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) A quality improvement program as described in § 460.130.

(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; 84 FR 25673, June 3, 2019]

§ 460.63 Compliance oversight requirements.

A PACE organization must adopt and implement effective compliance oversight requirements, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance oversight program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(a) If the PACE organization discovers evidence of misconduct related to payment or delivery of items or services, it must conduct a timely, reasonable inquiry into that conduct.

(b) The PACE organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation.

(c) The PACE organization should have procedures to voluntarily self-report potential fraud or misconduct related to the PACE program to CMS and the State administering agency.

[84 FR 25673, June 3, 2019]

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) *General qualification requirements.* Each member of the PACE organization's staff (employee or contractor) that has direct contact with participants 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 working with a frail or elderly population or, if the individual has less than 1 year of experience but meets all other requirements under paragraph (a) of this section, must receive appropriate training from the PACE organization on working with a frail or elderly population upon hiring.

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization 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, as amended at 84 FR 25673, June 3, 2019]

§ 460.66 Training.

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.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006; 84 FR 25673, June 3, 2019]

§ 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;

(3) If the PACE organization determines that an individual's contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug, or alcohol abuse or use;

(4) Who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property; or

(5) Who have been convicted of specific crimes for any offense described in section 1128(a) of the Social Security Act.

(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; 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018; 84 FR 25673, June 3, 2019]

§ 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 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.

(6) With respect to an individual who is contracting as a program director or medical director or to be part of the interdisciplinary team as set forth at § 460.60(a) and (b) and § 460.102(b), the contract must specify that the individual agrees to:

(i) Perform all the duties related to its position as specified in this part.

(ii) Participate in interdisciplinary team meetings as required.

(iii) Be accountable to the PACE organization.

(iv) 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(c).

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006; 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018; 84 FR 25673, June 3, 2019]

§ 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 that includes, 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) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact as required under § 460.64(a)(5).

(5) Have been oriented to the PACE program.

(6) Agree to abide by the philosophy, practices, and protocols of the PACE organization.

(c) 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.

(d) Personal care attendants must exhibit competency before performing personal care services independently.

[67 FR 61505, Oct. 1, 2002, as amended at 71 FR 71335, Dec. 8, 2006; 81 FR 80562, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018; 84 FR 25674, June 3, 2019]

§ 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 and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4.)

(ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(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) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a PACE facility, but only if the waiver will not adversely affect the health and safety of the patients.

(3) A PACE center may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(4) When a sprinkler system is shut down for more than 10 hours in a 24-hour period, the PACE must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(c) [Reserved]

(d) *Standard: Building Safety*. Except as otherwise provided in this section, a PACE center must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5 and TIA 12–6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a PACE center.

(2) If application of the Health Care Facilities Code required under paragraph (d) of this section would result in unreasonable hardship for the PACE center, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy 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*. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[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; 81 FR 26898, May 4, 2016; 81 FR 64026, Sept. 16, 2016]

§ 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.

(d) *COVID–19 Vaccination of PACE organization staff*. The PACE organization must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID–

19. The completion of a primary vaccination series for COVID–19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or participant contact, the policies and procedures must apply to the following PACE organization staff, who provide any care, treatment, or other services for the PACE organization and/or its participants:

(i) PACE organization employees;

(ii) Licensed practitioners providing services on behalf of the PACE organization;

(iii) Students, trainees, and volunteers providing services on behalf of the PACE organization; and

(iv) Individuals who provide care, treatment, or other services on behalf of the PACE organization, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following PACE organization staff:

(i) Staff who exclusively provide telehealth or telemedicine services for the PACE organization and/or its participants and who do not have any direct contact with participants and other PACE organization staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the PACE organization and/or its participants and who do not have any direct contact with participants and other PACE organization staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the PACE organization and/or its participants;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID–19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the PACE organization has granted, an exemption from the staff COVID–19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID–19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the

staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the PACE organization's COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID–19.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006; 86 FR 61618, Nov. 5, 2021]

§ 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, Nov. 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, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken in the home by at least 5 percent of the individuals in the PACE organization's service area.

(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 not use the following marketing practices, which are prohibited:

(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, unless the gifts are of nominal value as defined in CMS guidance, are offered to all potential enrollees without regard to whether they enroll in the PACE program, and are not in the form of cash or other monetary rebates.

(4) Marketing by any individual or entity that is directly or indirectly compensated by the PACE organization based on activities or outcomes unless the individual or entity has been appropriately trained on PACE program requirements, including but not limited to, subparts G and I of this part.

(i) PACE organizations are responsible for the activities of contracted individuals or entities who market on their behalf.

(ii) PACE organizations that choose to use contracted individuals or entities for marketing purposes must develop a method to document training has been provided.

(5) Unsolicited door-to-door marketing or other unsolicited means of direct contact, including calling or emailing a potential or current participant without the individual initiating the contact.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25674, June 3, 2019]

§ 460.84 Emergency preparedness.

The Program for the All-Inclusive Care for the Elderly (PACE) organization must comply with all applicable Federal, State, and local emergency preparedness requirements. The PACE organization must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The PACE organization must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address participant population, including, but not limited to, the type of services the PACE organization has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or

the public. Policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and participants, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect participant health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered participants under the PACE center(s) care during and after an emergency. If on-duty staff and sheltered participants are relocated during the emergency, the PACE must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the PACE center, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) The procedures to inform State and local emergency preparedness officials about PACE participants in need of evacuation from their residences at any time due to an emergency situation based on the participant's medical and psychiatric conditions and home environment.

(5) A means to shelter in place for participants, staff, and volunteers who remain in the facility.

(6) A system of medical documentation that preserves participant information, protects confidentiality of participant information, and secures and maintains the availability of records.

(7) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(8) The development of arrangements with other PACE organizations, PACE centers, or other providers to receive participants in the event of limitations or cessation of operations to maintain the continuity of services to PACE participants.

(9) The role of the PACE organization under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(10)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.

(ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.

(iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

(c) *Communication plan.* The PACE organization must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for staff; entities providing services under arrangement; participants' physicians; other PACE organizations; and volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) PACE organization's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for participants under the organization's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release participant information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of participants under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PACE organization's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing*. The PACE organization must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program*. The PACE organization must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

(v) If the emergency preparedness policies and procedures are significantly updated, the PACE must conduct training on the updated policies and procedures.

(2) *Testing*. The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following:

(i) Participate in a full-scale exercise that is community-based or;

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise every 2 years; or

(B) If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

(e) *Integrated healthcare systems*. If a PACE is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the PACE may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, participant populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4)

of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64026, Sept. 16, 2016, as amended at 84 FR 51816, Sept. 30, 2019]

§ 460.86 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter.

(b) If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

[83 FR 16756, Apr. 16, 2018]

Subpart F—PACE Services

§ 460.90 PACE benefits under Medicare and Medicaid.

If a Medicare beneficiary or Medicaid beneficiary 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.

(a) The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(1) All Medicare-covered services.

(2) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(3) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

(b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account:

(1) The participant's current medical, physical, emotional, and social needs; and

(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.

[86 FR 6132, Jan. 19, 2021]

§ 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) 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.

(b) Experimental medical, surgical, or other health procedures.

(c) 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; 86 FR 6132, Jan. 19, 2021]

§ 460.98 Service delivery.

(a) *Access to services.* A PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.

(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care. These services must be furnished in accordance with § 460.70(a).

(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, mental or physical disability, or source of payment.

(4) Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

(5) The PACE organization must document, track and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.

(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 services furnished by a primary care provider as defined in § 460.102(c) 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; 84 FR 25674, June 3, 2019; 85 FR 37243, June 19, 2020; 86 FR 6132, Jan. 19, 2021]

§ 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 PACE organizations are obligated to cover. Rather, they are non-emergency services that the PACE organization 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; 84 FR 25674, June 3, 2019]

§ 460.102 Interdisciplinary team.

(a) *Basic requirement.* A PACE organization must meet the following requirements:

(1) Establish an interdisciplinary team, composed of members that fill the roles described in paragraph (b) of this section, 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 members qualified to fill, at minimum, the following roles, in accordance with CMS guidelines. One individual may fill two separate roles on the interdisciplinary team where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.

(1) Primary care provider.

(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 provider.* (1) Primary medical care must be furnished to a participant by any of the following:

(i) A primary care physician.

(ii) A community-based physician.

(iii) A physician assistant who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.

(iv) A nurse practitioner who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.

(2) Each primary care provider 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 following:

(i) The initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery.

(ii) Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(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 any individual with direct knowledge of or contact with the participant, including the following:

(A) Other team members.

(B) Participants.

(C) Caregivers.

(D) Employees.

(E) Contractors.

(F) Specialists.

(G) Designated representatives.

(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation polices established by the medical director.

(e) *Team member qualifications.* The PACE organization must ensure that all members of the interdisciplinary team have appropriate licenses or certifications under State law, act within the scope of practice as defined by State laws, and meet the requirements set forth in § 460.71.

(f) *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; 84 FR 25674, June 3, 2019; 86 FR 6132, Jan. 21, 2021]

§ 460.104 Participant assessment.

(a) *Initial comprehensive assessment*—(1) *Basic requirement.* The interdisciplinary team must conduct an initial in-person comprehensive assessment on each participant. The assessment must be completed in a timely manner in order to meet the requirements in paragraph (b) of this section.

(2) *Members present.* As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the

participant in person and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care provider

(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) *Additional professional disciplines.* At the recommendation of the interdisciplinary team, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the initial comprehensive assessment process.

(4) *Initial comprehensive assessment criteria.* The initial in-person comprehensive assessment must at a minimum include the evaluation of:

(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.* Within 30 days of the date of enrollment, the interdisciplinary team must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire interdisciplinary team. In developing the plan of care:

(1) If the interdisciplinary team determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care.

(2) 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) *Semi-annual reassessment.* On at least a semi-annual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

(1) Primary care provider.

(2) Registered nurse.

(3) Master's-level social worker.

(4) Other team members that the primary care provider, registered nurse and Master's-level social worker determine are actively involved in the development or implementation of the participant's plan of care.

(d) *Unscheduled reassessments.* In addition to semi-annual 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 (c) of this section must conduct an in-person reassessment.

(2) *In response to a service determination request.* In accordance with § 460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service determination request, and may conduct reassessments as determined necessary for approved services.

(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; 84 FR 25674, June 3, 2019; 86 FR 6132, Jan. 19, 2021]

§ 460.106 Plan of care.

(a) *Basic requirement*. Within 30 days of the date of enrollment, the interdisciplinary team members specified in § 460.104(a)(2) must develop a comprehensive plan of care for each participant based on the initial comprehensive assessment findings.

(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.

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify each intervention and how it will be implemented.

(5) Identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25675, June 3, 2019]

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) Prior to and upon enrollment in the PACE organization.

(ii) 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 helped 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.

(4) To contact 1–800–MEDICARE for information and assistance, including to make a complaint related to the quality of care or the delivery of a service.

(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 have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

(4) To receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

(5) To disenroll from the program at any time and have such disenrollment be effective the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment as set forth in § 460.162(a).

(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; 84 FR 25675, June 3, 2019; 86 FR 6132, Jan. 19, 2021]

§ 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, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization's service area.

(2) Display the PACE participant rights in a prominent place in the PACE center.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25675, June 3, 2019]

§ 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 improvement program.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25675, June 3, 2019]

§ 460.121 Service determination process.

(a) *Written procedures.* Each PACE organization must have formal written procedures for identifying and processing service determination requests in accordance with the requirements of this Part.

(b) *What is a service determination request*—(1) *Requests that constitute a service determination request.* Except as provided in paragraph (b)(2) of this section, the following requests constitute service determination requests:

(i) A request to initiate a service.

(ii) A request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service.

(iii) A request to continue coverage of a service that the PACE organization is recommending be discontinued or reduced.

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care.

(c) *Who can make a service determination request.* Any of the following individuals can make a service determination request:

(1) The participant.

(2) The participant's designated representative.

(3) The participant's caregiver.

(d) *Method for making a service determination request.* An individual may make a service determination request as follows:

(1) Either orally or in writing.

(2) To any employee or contractor of the PACE organization that provides

direct care to a participant in the participant's residence, the PACE center, or while transporting participants.

(e) *Processing a service determination request.* (1) Except as provided in paragraph (e)(2) of this section, the PACE organization must bring a service determination request to the interdisciplinary team as expeditiously as the participant's condition requires, but no later than 3 calendar days from the time the request is made.

(2) If a member of the interdisciplinary team is able to approve the service determination request in full at the time the request is made, the PACE organization—

(i) Must fulfill all of the following:

(A) Notice of the decision to approve a service determination request requirements specified in paragraph (j)(1) of this section.

(B) Effectuation requirements specified in paragraph (k) of this section.

(C) Recordkeeping requirements specified in paragraph (m) of this section.

(ii) Is not required to process the service determination request in accordance with paragraphs (f) through (i), (j)(2), and (*l*) of this section.

(f) *Who must review a service determination request.* The full interdisciplinary team must review and discuss each service determination request and decide to approve, deny, or partially deny the request based on that review.

(g) *Interdisciplinary team decision making.* The interdisciplinary team must consider all relevant information when evaluating a service determination request, including, but not limited to, the findings and results of any reassessments required in paragraph (h) of this section, as well as the criteria specified in §460.92(b).

(h) *Reassessments in response to a service determination request.* (1) If the interdisciplinary team expects to deny or partially deny a service determination request, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment before the interdisciplinary team makes a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.

(2) The interdisciplinary team may conduct a reassessment prior to approving a service determination request, either in-person or through the use of remote technology, if the team determines that a reassessment is necessary.

(i) *Notification timeframe.* Except as provided in paragraph (i)(1) of this section, when the interdisciplinary team receives a service determination request, it must make its decision and notify the participant or their designated representative of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the interdisciplinary team receives the request.

(1) *Extensions.* The interdisciplinary team may extend the timeframe for review and notification by up to 5 calendar days if either of the following occur:

(i) The participant or other requestor listed in paragraph (c)(2) or (3) of this section requests the extension.

(ii) The extension is in the participant's interest because the interdisciplinary team needs additional information from an individual not directly employed by the PACE organization that may change the interdisciplinary team's decision to deny a service. The interdisciplinary team must document the circumstances that led to the extension and demonstrate how the extension is in the participant's best interest.

(2) *Notice of extension.* When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative in writing. The notice must explain the reason(s) for the delay and must be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe.

(j) *Notification requirements*—(1) *Notice of decisions to approve a service determination request.* If the interdisciplinary team makes a determination to approve a service determination request, it must provide the participant or the designated representative either

oral or written notice of the determination. Notice of any decision to approve a service determination request must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

(2) *Notice of decisions to deny a service determination request.* If the interdisciplinary team decides to deny or partially deny a service, it must provide the participant or the designated representative both oral and written notice of the determination. Notice of any denial must—

(i) State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language.

(ii) Inform the participant or designated representative of his or her right to appeal the decision under § 460.122.

(iii) Describe 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.

(iv) For a Medicaid participant, inform the participant of both of the following, as specified in § 460.122(e)(1):

(A) His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.

(B) The conditions for continuing to receive disputed services.

(k) *Effectuation requirements.* If the interdisciplinary team approves a service determination request, in whole or in part, the PACE organization must provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. The interdisciplinary team must explain when the participant may expect to receive the service in accordance with paragraph (j)(1) of this section.

(l) *Effect of failure to meet the processing timeframes.* 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.

(m) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for service determination requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

[86 FR 6132, Jan. 19, 2021]

§ 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 request to initiate, modify or continue a service must first be processed as a service determination request under § 460.121 before the PACE organization can process an appeal under this section.

(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 service determination request or request for 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 §§ 460.121(i) and (m).

(2) How a participant or their designated representative files an appeal,

including procedures for accepting oral and written appeal requests.

(3) Documentation of a participant's appeal.

(4) Review of an appeal by an appropriate third party reviewer or committee. An appropriate third party reviewer or member of a review committee must be an individual who meets all of the following:

(i) Appropriately credentialed in the field(s) or discipline(s) related to the appeal.

(ii) An impartial third party who meets both of the following:

(A) Was not involved in the original action.

(B) Does not have a stake in the outcome of the appeal.

(5) The distribution of written or electronic materials to the third party reviewer or committee that, at a minimum, explain all of the following:

(i) Services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98.

(ii) The need to make decisions in a manner consistent with how determinations under section 1862(a)(1)(A) of the Act are made.

(iii) The rules in § 460.90(a) that specify that certain limitations and conditions applicable to Medicare or Medicaid or both benefits do not apply.

(6) 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.

(7) Maintenance of confidentiality of appeals.

(d) *Opportunity to submit evidence.* A PACE organization must give all parties involved in the appeal 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) *Notification.* A PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal.

(1) *Notice of a favorable decision.* Notice of any favorable decision must explain the conditions of the approval in understandable language.

(2) *Notice of partially or fully adverse decisions.* (i) Notice of any denial must—

(A) State the specific reason(s) for the denial;

(B) Explain the reason(s) why the service would not improve or maintain the participant's overall health status;

(C) Inform the participant of his or her right to appeal the decision; and

(D) Describe the external appeal rights under § 460.124.

(ii) At the same time the decision is made, the PACE organization must also notify the following:

(A) CMS.

(B) The State administering agency.

(h) *Actions following a favorable decision.* 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.

(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 improvement program.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006; 84 FR 25675, June 3, 2019; 86 FR 6134, Jan. 19, 2021]

§ 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.

(a) *Appeal rights under Medicare.* Medicare participants have the right to a reconsideration by an independent review entity.

(1) A written request for reconsideration must be filed with the independent review entity within 60 calendar days from the date of the decision by the third party reviewer under § 460.122.

(2) The independent outside entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract.

(3) If the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization.

(b) *Appeal rights under Medicaid.* Medicaid participants have the right to a State Fair Hearing as described in part 431, subpart E, of this chapter.

(c) *Appeal rights for dual eligible participants.* Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in paragraph (a) of this section or the State Fair Hearing process described in paragraph (b) of this section.

[86 FR 6134, Jan. 19, 2021]

Subpart H—Quality Improvement

§ 460.130 General rule.

(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality 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.

(d) 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 460.132 Quality improvement plan.

(a) *Basic rule.* A PACE organization must have a written quality improvement plan that is collaborative and interdisciplinary in nature.

(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 improvement activities.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 460.134 Minimum requirements for quality improvement program.

(a) *Minimum program requirements.* A PACE organization's quality 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 460.136 Internal quality improvement activities.

(a) *Quality 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 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 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 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 improvement activities, including providing information about their satisfaction with services.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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 improvement plan.

(c) Provide input related to ethical decisionmaking, including end-of-life

issues and implementation of the Patient Self-Determination Act.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

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 State administering agency 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 beneficiary. 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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 in the form and manner specified by CMS and make the documentation available for review.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006; 84 FR 25676, June 3, 2019]

§ 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 beneficiary 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. If a Medicaid-only or private pay participant becomes eligible for Medicare after enrollment in PACE, the participant will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from the participant's PACE organization.

(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; 84 FR 25676, June 3, 2019]

§ 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 that indicates that he or she is a PACE participant and that includes the phone number of the PACE organization.

(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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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) *Effective date.* A participant's voluntary disenrollment is effective on the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment.

(b) *Reasons for voluntary disenrollment.* A PACE participant may voluntarily disenroll from the program without cause at any time.

(c) *Responsibilities of PACE organization.* A PACE organization must ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status.

[84 FR 25676, June 3, 2019]

§ 460.164 Involuntary disenrollment.

(a) *Effective date.* A participant's involuntary disenrollment occurs after the PACE organization meets the requirements set forth in this section and is effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant.

(b) *Reasons for involuntary disenrollment.* A participant may be involuntarily disenrolled for any of the following reasons:

(1) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any premium due the PACE organization.

(2) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spend down liability or any amount due under the post-eligibility treatment of income process, as permitted under §§ 460.182 and 460.184.

(3) The participant or the participant's caregiver engages in disruptive or threatening behavior, as described in paragraph (c) of this section.

(4) The participant engages in disruptive or threatening behavior, as described in paragraph (c) of this section.

(5) 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.

(6) The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.

(7) The PACE program agreement with CMS and the State administering agency is not renewed or is terminated.

(8) The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers.

(c) *Disruptive or threatening behavior.* (1) For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:

(i) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or

(ii) 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.

(2) For purposes of this section, a participant's caregiver who engages in disruptive or threatening behavior exhibits behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others.

(d) *Documentation of disruptive or threatening behavior.* If a PACE organization proposes to disenroll a participant based on the disruptive or threatening behavior of the participant or the participant's caregiver, 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.

(e) *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.

(f) *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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 460.166 Disenrollment responsibilities.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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 within 30 days.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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 improvement program.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

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 amount is negotiated between the PACE organization and the State administering agency, and the amount, or the methodology used to calculate the amount, is 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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, observation of program operations;

(2) Detailed analysis of the entity's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and this part, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals.

(3) A comprehensive assessment of an organization's fiscal soundness.

(4) A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants.

(5) Any other elements that CMS or the State administering agency find necessary.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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) CMS in cooperation with the State administering agency will conduct reviews of the operations of PACE organizations as appropriate, as determined by a risk assessment of each PACE organization which takes into account the PACE organization's performance level and compliance with the significant requirements of sections 1834 and 1934 of the Social Security Act and this part.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified by CMS or the State administering agency through the following:

(1) Ongoing monitoring of the PACE organization.

(2) Reviews and audits of the PACE organization.

(3) Complaints from PACE participants or caregivers.

(4) Any other instance CMS or the State administering agency identifies programmatic deficiencies requiring correction.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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, their families, their caregivers, and their authorized representatives.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

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)(i) Participant health outcomes data.

(ii) Financial books and records.

(iii) Medical records.

(iv) Personnel records.

(2) CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at paragraph (b)(1) of this section, which may include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.

(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 do all of the following:

(1) Establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(2) Maintain all written communications received from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6).

(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) Ten years from the last entry date.

(iii) For medical records of disenrolled participants, 10 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019; 86 FR 6134, Jan. 19, 2021]

§ 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) All recommendations for services made by employees or contractors of the PACE organization, including specialists.

(5) If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service.

(6) Original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

(7) Laboratory, radiological and other test reports.

(8) Medication records.

(9) Hospital discharge summaries, if applicable.

(10) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin).

(11) Enrollment Agreement.

(12) Physician orders.

(13) Discharge summary and disenrollment justification, if applicable.

(14) Advance directives, if applicable.

(15) 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; 86 FR 6135, Jan. 19, 2021]

SUBCHAPTER F—QUALITY IMPROVEMENT ORGANIZATIONS

PART 475—QUALITY IMPROVEMENT ORGANIZATIONS

Subpart A—General Provisions

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475.1 Definitions.

Subpart B [Reserved]

Subpart C—Quality Improvement Organizations

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475.107 QIO contract awards.

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:

Case reviews means the different types of reviews that QIOs are authorized to perform. Such reviews include, but are not limited to—

(1) Beneficiary complaint reviews;

(2) General quality of care reviews;

(3) Emergency Medical Treatment and Labor Act (EMTALA) reviews;

(4) Medical necessity reviews, including appeals and DRG validation reviews; and

(5) Admission and discharge reviews.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(1) Has an ownership interest of 5 percent or more;

(2) Has an indirect ownership interest equal to 5 percent or more;

(3) 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

(4) 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, freestanding 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, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

Practitioner has the same meaning as provided in § 476.1 of this chapter.

QIO area means the defined geographic area, such as the State(s), region(s), or community(ies), in which the CMS contract directs the QIO to perform.

Quality improvement initiative has the same meaning as provided in § 476.1 of this chapter.

[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, as amended at 78 FR 75198, Dec. 10, 2013]

Subpart B [Reserved]

Subpart C—Quality Improvement Organizations

SOURCE: 78 FR 75198, Dec. 10, 2013, unless otherwise noted.

§ 475.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) and (c) of the Social Security Act as amended by section 261 of the Trade Adjustment Assistance Extension Act of 2011. This subpart defines the types of organizations that are eligible to become Quality Improvement Organizations (QIOs) and describes certain steps CMS will take in selecting QIOs.

§ 475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO contract, an organization must meet the following requirements:

(a) Have a governing body that includes at least one individual who is a representative of health care providers and at least one individual who is a representative of consumers.

(b) Demonstrate the ability to perform the functions of a QIO, including—

(1) The ability to meet the eligibility requirements and perform activities as set forth in the QIO Request for Proposal; and

(2) The ability to—

(i) Perform case reviews as described in § 475.102; and/or

(ii) Perform quality improvement initiatives as set forth in § 475.103.

(c) Demonstrate the ability to actively engage beneficiaries, families, and consumers, as applicable, in case reviews as set forth in § 475.102, and/or quality improvement initiatives as set forth in § 475.103.

(d) Demonstrate the ability to perform the functions of a QIO with objectivity and impartiality and in a fair and neutral manner.

§ 475.102 Requirements for performing case reviews.

(a) In determining whether or not an organization has demonstrated the ability to perform case review, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives and methodology to perform case reviews;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care related to case reviews;

(3) The organization's ability to take into consideration urban versus rural, local, and regional characteristics in the health care setting where the care under review was provided;

(4) The organization's ability to take into consideration evidence-based national clinical guidelines and professionally recognized standards of care; and

(5) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing case reviews; such prior experience may include prior similar case review experience.

(c) A State government that administers a Medicaid program will be considered incapable of performing case

review in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the case review will act with complete objectivity and independence from the Medicaid program.

§ 475.103 Requirements for performing quality improvement initiatives.

(a) In determining whether or not an organization has demonstrated the ability to perform quality improvement initiatives, CMS will take into consideration factors such as:

(1) The organization's proposed processes, capabilities, quantitative, and/or qualitative performance objectives, and methodology to perform quality improvement initiatives;

(2) The organization's proposed involvement of and access to physicians and practitioners in the QIO area with the appropriate expertise and specialization in the areas of health care concerning the quality improvement initiatives;

(3) The organization's access to professionals with appropriate knowledge of quality improvement methodologies and practices; and

(4) The organization's access to qualified information technology (IT) expertise.

(b) In making determinations under this section, CMS may consider characteristics such as the organization's geographic location and size. CMS may also consider prior experience in health care quality improvement that CMS considers relevant to performing quality improvement initiatives; such prior experience may include prior similar quality improvement initiative experience and whether it achieved successful results.

(c) A State government that administers a Medicaid program will be considered incapable of performing quality improvement initiative functions in an effective manner, unless the State demonstrates to the satisfaction of CMS that the State agency performing the quality improvement initiatives will act with complete objectivity and independence from the Medicaid program.

§ 475.104 [Reserved]

§ 475.105 Prohibition against contracting with health care facilities, affiliates, and payor organizations.

(a) *Basic rule.* Except as permitted under paragraph (a)(3) of this section, the following are not eligible for QIO contracts:

(1) A health care facility in the QIO area.

(2) 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 in the QIO area.

(3) A payor organization, unless the Secretary determines that—

(i) There is no other entity available for an area with which the Secretary can enter into a contract under this part; or

(ii) A payor organization is a more qualified entity to perform one or more of the functions of a QIO described in § 475.101(b), meets all other requirements and standards of this part, and demonstrates to the satisfaction of CMS that, in performing QIO activities, the payor organization will act with complete objectivity and independence from its payor program.

(b) [Reserved]

(c) *Subcontracting.* A QIO must not subcontract with a health care facility to perform any case review activities except for the review of the quality of care.

§ 475.106 [Reserved]

§ 475.107 QIO contract awards.

Subject to the provisions of § 475.105, CMS will—

(a) Ensure that all awardees meet the requirements of §§ 475.101 through 475.103, as applicable; and

(b) Award the contract to the selected organization for a specific QIO area for a period of 5 years.

PART 476—QUALITY IMPROVEMENT ORGANIZATION REVIEW

Subpart A—General Provisions

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Subpart B [Reserved]

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AUTHORITY: 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:

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.

Appointed representative means an individual appointed by a Medicare beneficiary to represent the beneficiary in the beneficiary complaint review process.

Authorized representative means an individual authorized, under State or other applicable law, to act on behalf of a Medicare beneficiary. An authorized representative has all of the rights and responsibilities of a Medicare beneficiary throughout the processing of a beneficiary complaint.

Beneficiary complaint means a complaint by a Medicare beneficiary or a Medicare beneficiary's representative alleging that the quality of Medicare covered services received by the beneficiary did not meet professionally recognized standards of care. A complaint may consist of one or more quality of care concerns.

Beneficiary complaint review means a review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare covered services provided to the beneficiary was consistent with professionally recognized standards of health care.

Beneficiary representative means an individual identified as an authorized or appointed representative of a Medicare beneficiary.

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:

(1) Has an ownership interest of 5 percent or more;

(2) Has an indirect ownership interest equal to 5 percent or more;

(3) 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

(4) 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.

General quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to a Medicare beneficiary was consistent with professionally recognized standards of health care. A general quality of care review may be carried out as a result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data.

Gross and flagrant violation means a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

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.

Immediate advocacy means an informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his or her representation has regarding the quality of Medicare covered health care received. This process involves a QIO representative's direct contact with the provider and/or practitioner.

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:

(1) A doctor or medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor, as described in section 1861(r) of the Act;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) of this definition; and

(3) An individual licensed to practice as a doctor as described in paragraph (1) of this definition in any Territory or Commonwealth of the United States of America.

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 or the Medicare administrative contractor, 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.

Provider means a health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part under Title XVIII of the Act.

QIO review means review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors.

Quality improvement initiative means any formal activity designed to serve as a catalyst and support for quality improvement that uses proven methodologies to achieve these improvements. The improvements may relate to safety, health care, health and value and involve providers, practitioners, beneficiaries, and/or communities.

Quality of care concern means a concern that care provided did not meet a professionally recognized standard of health care. A general quality of care review or a beneficiary complaint review may cover a single or multiple concerns.

Quality of care review means a review conducted by a QIO to determine whether the quality of Medicare covered services provided to beneficiaries was consistent with professionally recognized standards of health care. A quality of care review can either be a beneficiary complaint review or a general quality of care review.

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.

Significant quality of care concern means a determination by the QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

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.

Substantial violation in a substantial number of cases means a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

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; 77 FR 53682, Aug. 31, 2012; 77 FR 68559, Nov. 15, 2012; 78 FR 75199, Dec. 10, 2013]

Subpart B [Reserved]

Subpart C—Review Responsibilities of 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 bases.* 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.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a QIO and its subcontractors.

[77 FR 68560, Nov. 15, 2012]

§ 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, as determined through the resolution of oral beneficiary complaints as specified in § 476.110, written beneficiary complaints as specified in § 476.120, or the completion of general quality of care reviews as specified in § 476.160.

(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 administrative contractor, 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; 77 FR 68560, Nov. 15, 2012]

§ 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 administrative contractors, 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 § 476.78(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; 77 FR 68560, Nov. 15, 2012]

§ 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 administrative contractor, 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 administrative contractors, 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 § 411.402 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.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68560, Nov. 15, 2012]

§ 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 providers and practitioners.

(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 § 476.71.

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review.

(1) Providers must allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Providers and practitioners must 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. When the QIO does postadmission, preprocedure review, the provider must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers and practitioners must—

(i) Except as provided under §§ 476.130(b) and 476.160(b), relating to beneficiary complaint reviews and general quality of care reviews, deliver to the QIO all required information within 14 calendar days of a request. A QIO is authorized to require the receipt of the medical information earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and

circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(ii) Except if granted a waiver as described in paragraph (d) of this section, send secure transmission of an electronic version of each requested patient record to the QIO.

(A) Providers and practitioners must deliver electronic versions of patient records within 14 calendar days of the request.

(B) A QIO is authorized to require the receipt of the patient records earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and circumstances warrant earlier receipt of the patient records.

(C) A practitioner's or provider's failure to comply with the request for patient records within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(3) Providers must 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 § 411.402(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the provider has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

(5) Providers must assure, in accordance with the provisions of their agreements 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) Providers must 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 provider, 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) Hospitals must 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) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by

facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. Appeals concerning these costs are subject to the review process specified in part 405, subpart R, of this chapter.

(c) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. 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, as amended at 68 FR 67960, Dec. 5, 2003; 76 FR 51784, Aug. 18, 2011; 77 FR 53682, Aug. 31, 2012; 77 FR 68560, Nov. 15, 2012; 85 FR 59025, Sept. 18, 2020]

§ 476.80 Coordination with Medicare administrative contractors, fiscal intermediaries, and carriers

(a) *Procedures for agreements.* Medicare administrative contractor, 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 Medicare administrative contractor, 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 Medicare administrative

contractor, fiscal intermediary, or carrier and obtain approval from CMS, before it makes conclusive determinations for the Medicare program, unless CMS finds that the Medicare administrative contractor, 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 administrative contractors, 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 administrative contractors, fiscal intermediaries, and carriers, or if an agreement has not been established, the QIO's proposed administrative procedures, including any comments by the Medicare administrative contractors, 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 Medicare administrative contractor, 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 Medicare administrative contractor, fiscal intermediary, or carrier, or

(2) In the case of procedures, by the QIO, after providing opportunity for comment by the Medicare administrative contractor, fiscal intermediary, or carrier.

(e) *Role of the Medicare administrative contractor or fiscal intermediary.* (1) The Medicare administrative contractor or 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 Medicare administrative contractor or 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; 77 FR 68560, Nov. 15, 2012]

§ 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 § 411.15(g) or § 411.15(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 administrative contractors, fiscal intermediaries, and 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 administrative contractor, 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 Medicare administrative contractor, 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 administrative contractors, 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 Medicare administrative contractors, fiscal 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 478 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; 77 FR 68561, Nov. 15, 2012]

§ 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 provider or practitioner.

(a) If a provider 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 provider or practitioner has failed to comply with the requirements of 42 CFR 1004.10(c) 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 provider or practitioner, and may report the matter to the HHS Inspector General.

(b) If a QIO gives a provider or practitioner sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the provider or practitioner does not respond in a timely manner, the QIO will deny the claim. A provider or practitioner may request that the QIO reconsider its decision to deny the claim. No further appeal rights are available.

[77 FR 53683, Aug. 31, 2012]

§ 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 Medicare administrative contractor, 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 478, 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 administrative contractor, 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.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

§ 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 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.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

§ 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 administrative contractors, fiscal intermediaries, and carriers.

(b) Other QIOs; and

(c) Other public or private review organizations as may be appropriate.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

§ 476.110 Use of immediate advocacy to resolve oral beneficiary complaints.

(a) *Immediate advocacy.* A QIO may offer the option of resolving an oral complaint through the use of immediate advocacy if:

(1) The complaint is received not later than 6 months from the date on which the care giving rise to the complaint occurred.

(2) After initial screening of the complaint, the QIO makes a preliminary determination that—

(i) The complaint is unrelated to the clinical quality of health care itself but relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider; or

(ii) The complaint, while related to the clinical quality of health care received by the beneficiary, does not rise to the level of being a gross and flagrant, substantial, or significant quality of care concern.

(3) The beneficiary agrees to the disclosure of his or her name to the involved provider and/or practitioner.

(4) All parties orally consent to the use of immediate advocacy.

(5) All parties agree to the limitations on redisclosure set forth in § 480.107 of this subchapter.

(b) *Discontinuation of immediate advocacy.* The QIO or either party may discontinue participation in immediate advocacy at any time.

(1) The QIO must inform the parties that immediate advocacy will be discontinued; and

(2) The beneficiary must be informed of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

(c) *Confidentiality requirements.* All communications, written and oral, exchanged during the immediate advocacy process must not be redisclosed without the written consent of all parties.

(d) *Abandoned complaints.* If any party fails to participate or otherwise comply with the requirements of the immediate advocacy process, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that immediate advocacy will be discontinued; and

(2) Inform the Medicare beneficiary of his or her right to submit a written complaint in accordance with the procedures in § 476.120.

[77 FR 68561, Nov. 15, 2012]

§ 476.120 Submission of written beneficiary complaints.

(a) *Timeframe for submission of written complaints.* A QIO shall be responsible for conducting a review of any written complaint received from a Medicare beneficiary or a Medicare beneficiary's representative about the quality of health care if the complaint is received not later than 3 years from the date on which the care giving rise to the complaint occurred.

(1) A written complaint includes a complaint submitted electronically to the QIO.

(2) In those instances where a Medicare beneficiary contacts the QIO regarding a complaint but declines to

submit the complaint in writing and immediate advocacy has not been offered, the QIO may complete a general quality of care review in accordance with § 476.160 if the QIO makes a preliminary determination that the complaint involves a potential gross and flagrant, substantial or significant quality of care concern.

(b) *New concerns raised by a Medicare beneficiary*. If a Medicare beneficiary raises new concerns relating to the same complaint after the completion of the interim initial determination in § 476.130(c), the concerns will be processed as a new complaint. The QIO may process new concerns raised after the receipt of the written complaint as part of the same complaint, provided they are received prior to the completion of the interim initial determination. Even if a concern is received before the interim initial determination, the QIO can address it as a separate complaint if the QIO determines that this is warranted by the circumstances.

[77 FR 68561, Nov. 15, 2012]

§ 476.130 Beneficiary complaint review procedures.

(a) *Scope of the QIO review*. In completing its review, the QIO shall consider any information and materials submitted by the Medicare beneficiary or his or her representative and any information submitted by the provider and/or practitioner. All information obtained by the QIO that fits within the definition of ''confidential information'' under § 480.101, will be held by the QIO as confidential.

(1) The QIO's review will focus on the episode of care from which the complaint arose and address the specific concerns identified by the beneficiary and any additional concerns identified by the QIO. The QIO may separate concerns into different complaints if the QIO determine that the concerns relate to different episodes of care.

(2) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO will use available norms, best practices and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests*. (1) Upon request by the QIO, a provider or practitioner must deliver all medical information requested in response to a Medicare beneficiary complaint within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO make a preliminary determination that the complaint involves a potential gross and flagrant or substantial quality of care concern as specified in part 1004 of this title and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(2) In requesting medical information in response to a Medicare beneficiary complaint, the QIO must notify the practitioner and/or provider that the medical record is being requested in response to a beneficiary complaint, explain the practitioner's and/or provider's right to discuss the QIO's interim initial determination, and request the name of a contact person in order to ensure timely completion of the discussion.

(c) *Interim initial determination*. The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the interim initial determination within 10 calendar days of the receipt of all medical information.

(1) A practitioner and provider will be notified by telephone of the opportunity to discuss the QIO's interim initial determination with the QIO in those situations where the peer reviewer determines that the quality of services does not meet professionally recognized standards of care for any concern in the complaint. The discussion must be held no later than 7 calendar days from the date of the initial offer.

(2) The interim initial determination becomes the final initial determination if the discussion is not completed timely as a result of the practitioner's and/or provider's failure to respond.

(3) Written statements in lieu of a discussion must be received no later than 7 calendar days from the date of the initial offer.

(4) In rare circumstances, the QIO may grant additional time to complete the discussion or submission of a written statement in lieu of a discussion.

(d) *Final initial determination*. The QIO must issue written notification of its final initial determination in those cases in which the QIO has determined that care met professionally recognized standards, as well as in those cases in which the QIO determined that standards were not met and the opportunity for discussion has been completed.

(1) No later than 3 business days after completion of its review, or for cases in which the standard was not met, no later than 3 business days after the discussion or receipt of the provider's and/or practitioner's written statement, the QIO will notify (by telephone) the beneficiary and the provider/practitioner of its final initial determination and of the right to request a reconsideration of the QIO's final initial determination.

(2) Written notice of the QIO's final initial determination will be forwarded to all parties within 5 calendar days after completion of its review, and must include:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns; and

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings, including references to medical information and, if held, the discussion with the involved practitioner and/or provider.

[77 FR 68561, Nov. 15, 2012]

§ 476.140 Beneficiary complaint reconsideration procedures.

(a) *Right to request a reconsideration*. Beginning with complaints filed after July 31, 2014, a Medicare beneficiary, a provider, or a practitioner who is dissatisfied with a QIO's final initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, no later than 3 calendar days following initial notification of the QIO's determination. If the QIO is unable to accept a request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The Medicare beneficiary, or his or her representative, and the practitioner and/or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the Medicare beneficiary and the practitioner and/or provider an opportunity to provide further information. A Medicare beneficiary, a practitioner, and a provider may, but are not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision*. No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the beneficiary and the practitioner/provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon of the next calendar day that includes—

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information to the beneficiary, practitioner, and provider regarding opportunities for improving the care given to patients based on the specific findings of its review and the development of quality improvement initiatives.

[77 FR 68561, Nov. 15, 2012]

§ 476.150 Abandoned complaints and reopening rights.

(a) *Abandoned complaints*. If a Medicare beneficiary fails to participate or

otherwise comply with the requirements of the beneficiary complaint review process and the QIO does not have sufficient information to complete its review, the QIO may determine that the complaint has been abandoned and—

(1) Inform the parties that its complaint review will be discontinued; and

(2) Inform the beneficiary of his or her right to resubmit a written complaint in accordance with the procedures in § 476.120.

(b) *Reopening complaint reviews.* A QIO may reopen a Medicare beneficiary complaint review using the same procedures that the QIO would use for reopening initial denial determinations and changes as a result of DRG validation, as described in § 476.96.

[77 FR 68561, Nov. 15, 2012]

§ 476.160 General quality of care review procedures.

(a) *Scope of the QIO review.* A QIO may conduct a general quality of care review in accordance with section 1154(a)(1)(B) of the Act.

(1) A QIO may conduct general quality of care reviews based on—

(i) Concerns identified during the course of other QIO review activities;

(ii) Referrals from other sources, including but not limited to individuals, contractors, other Federal or State agencies; or

(iii) Analysis of data.

(2) The QIO's review will focus on all concerns identified by the QIO and/or identified by those who have referred or reported the concerns, with consideration being given to the episode of care related to the concerns.

(3) The QIO will use evidence-based standards of care to the maximum extent practicable. If no standard of care exists, the QIO must use available norms, best practices, and established guidelines to establish the standard that will be used in completing the review. The QIO's determination regarding the standard used is not subject to appeal.

(b) *Medical information requests.* Upon request by the QIO, a provider or practitioner must deliver all medical information requested within 14 calendar days of the request. A QIO is authorized to require the receipt of the medical information sooner if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial quality of care concern and circumstances warrant earlier receipt of the medical information. A practitioner's or provider's failure to comply with the request for medical information within the established timeframe may result in the QIO taking action in accordance with § 476.90.

(c) *Initial determination.* The QIO peer reviewer will complete the review and the practitioner and/or provider will be notified of the initial determination in writing within 10 calendar days of the receipt of all medical information.

[77 FR 68561, Nov. 15, 2012]

§ 476.170 General quality of care reconsideration procedures.

(a) *Right to request a reconsideration.* Beginning with reviews initiated after July 31, 2014, a provider or practitioner who is dissatisfied with a QIO's initial determination may request a reconsideration by the QIO.

(1) The reconsideration request must be received by the QIO, in writing or by telephone, by no later than 3 calendar days following receipt of the QIO's initial determination. If the QIO is unable to accept the request, the request must be submitted by noon of the next day the QIO is available to accept a request.

(2) The practitioner or provider must be available to answer any questions or supply any information that the QIO requests in order to conduct its reconsideration.

(3) The QIO must offer the practitioner or provider an opportunity to provide further information. A practitioner or provider may, but is not required to, submit evidence to be considered by the QIO in making its reconsideration decision.

(b) *Issuance of the QIO's final decision.* No later than 5 calendar days after receipt of the request for a reconsideration, or, if later, 5 calendar days after receiving any medical or other records needed for such reconsideration, the QIO must complete the review and notify the practitioner or provider of its decision.

(1) The QIO's initial notification may be done by telephone, followed by the mailing of a written notice by noon the next calendar day that includes:

(i) A statement for each concern that care did or did not meet the standard of care;

(ii) The standard identified by the QIO for each of the concerns;

(iii) A summary of the specific facts that the QIO determines are pertinent to its findings; and

(iv) A statement that the letter represents the QIO's final determination and that there is no right to further appeal.

(2) The QIO may provide information regarding opportunities for improving the care given to patients based on the specific findings of its review.

[77 FR 68561, Nov. 15, 2012]

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 I of this chapter for determinations under Medicare Part A and 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; 82 FR 5139, Jan. 17, 2017]

§ 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 §§ 478.18 through 478.36 and 478.48(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; 77 FR 68563, Nov. 15, 2012]

§ 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 § 478.14 has a right to a reconsideration of that determination by the QIO that made the initial denial determination.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68563, Nov. 15, 2012]

§ 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 § 478.22, 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 § 478.22 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 § 478.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68563, Nov. 15, 2012]

§ 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 § 476.98 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.

[50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68563, Nov. 15, 2012]

§ 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 § 478.40 and a final decision rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with § 478.48.

[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; 77 FR 68563, Nov. 15, 2012]

§ 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 request a hearing by an administrative law judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA).

(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*. (1) The provisions of subpart I of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart or specified in paragraph (c)(2) of this section. Except as provided in paragraph (c)(2) of this section, references in subpart I to initial determinations made by a Medicare contractor and reconsiderations made by a QIC should be read to mean initial determinations and reconsidered determinations made by a QIO.

(2) The following part 405 regulations, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999; 82 FR 5139, Jan. 17, 2017]

§ 478.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 478.40 must submit a written request to the OMHA office identified in the notice of the QIO reconsidered determination.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination, unless the time is extended for good cause as provided in § 478.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be 5 calendar days after the date on the notice, unless there is evidence to the contrary.

(3) A request is considered filed on the date it is received by OMHA.

[82 FR 5139, Jan. 17, 2017]

§ 478.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter. When two or more appellants submit a request for hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter.

(b) If the ALJ or attorney adjudicator determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, or attorney adjudicator notifies the parties 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 an 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 and the QIO that the QIO reconsidered determination is conclusive for Medicare payment purposes.

[82 FR 5139, Jan. 17, 2017]

§ 478.46 Medicare Appeals Council and judicial review.

(a) The circumstances under which the Medicare Appeals Council (Council) will review an ALJ's or attorney adjudicator's decision or dismissal are the same as those set forth at §§ 405.1102 (''Request for Council review when ALJ or attorney adjudicator issues decision or dismissal'') and 405.1110 (''Council reviews on its own motion'') of this chapter.

(b) If $2,000 or more is in controversy, a party may obtain judicial review of a Council decision, or an ALJ's or attorney adjudicator's decision if a request for review by the Council 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 Council decision or denial.

[82 FR 5140, Jan. 17, 2017]

§ 478.48 Reopening and revision of a reconsidered determination or a 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 §478.15, 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 §478.15, 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 or attorney adjudicator and Council Reopening—Applicable procedures.* The ALJ or attorney adjudicator, or the Council, whichever made the decision, may reopen and revise the decision in accordance with the procedures set forth in §405.980 of this chapter, which concerns reopenings and revised decisions under subpart I 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 attorney adjudicator, or the Council 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; 77 FR 68563, Nov. 15, 2012; 82 FR 5140, Jan. 17, 2017]

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION INFORMATION

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

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AUTHORITY: 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.

Public information means information which has been disclosed to the public.

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;

(5) Data support organizations; and

(6) CMS.

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; 76 FR 26546, May 6, 2011]

§ 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 beneficiary 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 beneficiary 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 calendar 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 administrative contractors or 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; 77 FR 68563, Nov. 15, 2012]

§ 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.

(l) Redisclosures of information that is confidential because it identifies the parties involved in immediate advocacy may occur if all parties have consented to the redisclosure, as provided for under §476.110(c) of this chapter.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999; 77 FR 68564, Nov. 15, 2012]

§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)(1) When submitting patient records to the QIO under this section, the institution or practitioner must do so consistent with the requirements in § 476.78(c) and (d) of this chapter.

(2) Reimbursement to an institution or practitioner for the cost of providing patient records is paid in accordance with § 476.78(e) of this chapter.

[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; 85 FR 59026, Sept. 18, 2020]

§ 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 non-confidential 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 to the Department all information requested by the Department in the manner and form requested. The information can include confidential and non-confidential information and requests can include those made by any component of the Department, such as CMS.

[76 FR 26547, May 6, 2011]

§ 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 §§ 476.130(d) and 476.140(b) of this chapter and 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) Except as provided under paragraph (b) of this section, all other patient and practitioner identifiers have been removed.

(2) Make disclosure to the patient or the patient's representative within 14 calendar days of receipt of the request.

(b) *Exceptions.* (1) If a request for information is in connection with an initial denial determination under section 1154(a)(2) of the Act, the QIO must provide only the information used to support that determination in accordance with the procedures for disclosure of information related to determinations under § 478.24, including relevant practitioner identifiers.

(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 or the patient's representative when the representative has been authorized or appointed to receive that information.

(2) In identifying a representative, the QIO must follow pertinent State law requirements regarding the designation of health care representatives and agents. If the patient is unable to designate a representative and the identity of the representative is not already dictated by State law, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

[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; 77 FR 68564, Nov. 15, 2012]

§ 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 beneficiary of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or reviewer as provided under this Subpart B.

(iv) A QIO is not required to obtain the consent of a practitioner or provider prior to the release of information to a beneficiary in connection with an initial denial determination or in providing a beneficiary with the QIO's findings in response to a beneficiary complaint. Information that must be specified in a QIO's final decision in a complaint review is specified in §§ 476.130(d) and 476.140(b) of this subchapter.

(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 476 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 § 478.24 of this subchapter.

(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; 77 FR 68564, Nov. 15, 2012]

§ 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)(1) A QIO must not disclose its deliberations except to—

(i) CMS; or

(ii) The Office of the Inspector General, and the Government Accountability 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.

[50 FR 15359, Apr. 17, 1985,, as amended at 76 FR 26547, May 6, 2011; 77 FR 68564, Nov. 15, 2012]

§ 480.140 Disclosure of quality review study information.

(a) A QIO must disclose 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; 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 beneficiary of the information.

(2) The beneficiary 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) A QIO must disclose quality review study information to CMS with identifiers of patients, practitioners or institutions—

(1) For purposes of quality improvement. Activities include, but are not limited to, data validation, measurement, reporting, and evaluation.

(2) As requested by CMS when CMS deems it necessary for purposes of overseeing and planning QIO program activities.

[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; 76 FR 26547, May 6, 2011]

§ 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.

§ 480.144 Access to QIO data and information.

CMS may approve the requests of researchers for access to QIO confidential information not already authorized by other provisions in 42 CFR part 480.

[76 FR 26547, May 6, 2011]

§ 480.145 Beneficiary authorization of use of confidential information.

(a) Except as otherwise provided under this part, a QIO may not use or disclose a beneficiary's confidential information without an authorization from the beneficiary. The QIO's use or disclosure must be consistent with the authorization.

(b) A valid authorization is a document that contains the following:

(1) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(2) The name or other specific identification of the QIO(s) and QIO point(s) of contact making the request to use or disclose the information.

(3) The name or other specific identification of the person(s), or class of persons, to whom the QIO(s) may disclose the information or allow the requested use.

(4) A description of each purpose of the requested use or disclosure. The statement ''at the request of the individual'' is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose.

(5) An expiration date or an expiration event that relates to the beneficiary or the purpose of the use or disclosure. The statement ''end of the QIO research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of confidential information for QIO research, including for the creation and maintenance of a research database or research repository.

(6) Signature of the individual and date. If the authorization is signed by a beneficiary's representative, a description of such representative's authority to act for the beneficiary must also be provided.

(c) In addition to those items contained in paragraph (b) of this section, the authorization must contain statements adequate to place the individual on notice of all of the following:

(1) The individual's right to revoke the authorization in writing; and

(2) Any exceptions to the right to revoke and a description of how the individual may revoke the authorization;

(3) The ability or inability of the QIO to condition its review activities on the authorization, by stating either:

(i) That the QIO may not condition the review of complaints, appeals, or payment determinations, or any other QIO reviews or other tasks within the QIO's responsibility on whether the individual signs the authorization;

(ii) The consequences to the individual of a refusal to sign the authorization when the refusal will render the QIO unable to carry out an activity.

(4) The potential for information disclosed pursuant to the authorization to be subject to either appropriate or inappropriate redisclosure by a beneficiary, after which the information would no longer be protected by this subpart.

(d) The authorization must be written in plain language.

(e) If a QIO seeks an authorization from a beneficiary for a use or disclosure of confidential information, the QIO must provide the beneficiary with a copy of the signed authorization.

(f) A beneficiary may revoke an authorization provided under this section at any time, provided the revocation is in writing, except to the extent that the QIO has taken action in reliance upon the authorization.

[77 FR 68564, Nov. 15, 2012]

PART 481 [RESERVED]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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List of CFR Sections Affected

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For changes to this volume of the CFR prior to this listing, consult the annual edition of the monthly List of CFR Sections Affected (LSA). The LSA is available at *www.govinfo.gov*. For changes to this volume of the CFR prior to 2001, see the ''List of CFR Sections Affected, 1949–1963, 1964–1972, 1973–1985, and 1986–2000'' published in 11 separate volumes. The ''List of CFR Sections Affected 1986–2000'' is available at *www.govinfo.gov*.

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