FFP is necessary because a State is out of compliance with Federal requirements, in accordance with §430.35, the decision also specifies—

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

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

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

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

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

Sec.

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 separate Children's Health Insurance Program agency;

(*3*) The Basic Health Program agency;

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

(*5*) 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; 89 FR 22865, Apr. 2, 2024]

§ 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 Medicaid Advisory Committee and Beneficiary Advisory Council.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State Plan requirements for establishment and ongoing operation of a public Medicaid Advisory Committee (MAC) with a dedicated Beneficiary Advisory Council (BAC) comprised of current and former Medicaid beneficiaries, their family members, and

caregivers, to advise the State Medicaid agency on matters of concern related to policy development, and matters related to the effective administration of the Medicaid program.

(b) *State plan requirement.* The State plan must provide for a MAC and a BAC that will advise the director of the single State Agency for the Medicaid program on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(c) *Selection of members.* The Director of the single State Agency for the Medicaid program must select members for the MAC and BAC for a term of length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis. The State must create a process for recruitment and selection of members and publish this information on the State's website as specified in paragraph (f).

(d) *MAC membership and composition.* The membership of the MAC must be composed of the following percentage and representative categories of interested parties in the State:

(1) For the period from July 9, 2025 through July 9, 2026, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2026 through July 9, 2027, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

(2) The remaining committee members must include representation of at least one from each of the following categories:

(A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries.

(B) Clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care. This includes providers or administrators of primary care, specialty care, and long-term care.

(C) As applicable, participating Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2, or a health plan association representing more than one such plans; and

(D) Other State agencies that serve Medicaid beneficiaries (for example, foster care agency, mental health agency, health department, State agencies delegated to conduct eligibility determinations for Medicaid, State Unit on Aging), as ex-officio, non-voting members.

(e) *Beneficiary Advisory Council.* The State must form and support a BAC, which can be an existing beneficiary group, that is comprised of: individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid), to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(1) The MAC members described in paragraph (d)(1) of this section must also be members of the BAC.

(2) The BAC must meet separately from the MAC, on a regular basis, and in advance of each MAC meeting to ensure BAC member preparation for each MAC meeting.

(f) *MAC and BAC administration.* The State agency must create standardized processes and practices for the administration of the MAC and the BAC that are available for public review on the State website. The State agency must—

(1) Develop and publish, by posting publicly on its website, bylaws for governance of the MAC and BAC along with a current list of members. States will also post publicly the past meeting minutes of the MAC and BAC meetings, including a list of meeting attendees. States will give BAC members the option to include their names in the membership list and meeting minutes that will be posted publicly.

(2) Develop and publish by posting publicly on its website a process for MAC and BAC member recruitment and selection along with a process for selection of MAC and BAC leadership;

(3) Develop, publish by posting publicly on its website, and implement a regular meeting schedule for the MAC

and BAC; the MAC and BAC must each meet at least once per quarter and hold off-cycle meetings as needed. Each MAC and BAC meeting agenda must include a time for members and the public (if applicable) to disclose conflicts of interest.

(4) Make at least two MAC meetings per year open to the public and those meetings must include a dedicated time during the meeting for the public to make comments. BAC meetings are not required to be open to the public, unless the State's BAC members decide otherwise. The public must be adequately notified of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance of the date of the meeting.

(5) Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have, at a minimum, telephone dial-in option at the MAC and BAC meetings for its members. If the MAC or BAC meeting is deemed open to the public, the State must offer at a minimum a telephone dial-in option for members of the public;

(6) Ensure that the meeting times and locations for MAC and BAC meetings are selected to maximize member attendance and may vary by meeting; and

(7) Facilitate participation of beneficiaries by ensuring that that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, and communications with individuals with disabilities are as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 80, 84 and 92, respectively.

(g) *MAC and BAC participation and scope.* The MAC and BAC participants must have the opportunity to advise the director of the single State Agency for the Medicaid program on matters related to policy development and matters related to the effective administration of the Medicaid program. At a minimum, the MAC and BAC must determine, in collaboration with the State, which topics to provide advice on related to—

(1) Additions and changes to services;

(2) Coordination of care;

(3) Quality of services;

(4) Eligibility, enrollment, and renewal processes;

(5) Beneficiary and provider communications by State Medicaid agency and Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2;

(6) Cultural competency, language access, health equity, and disparities and biases in the Medicaid program;

(7) Access to services; and

(8) Other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as determined by the MAC, BAC, or State.

(h) *State agency staff assistance, participation, and financial help.* The single State Agency for the Medicaid program must provide staff to support planning and execution of the MAC and the BAC to include—

(1) Recruitment of MAC and BAC members;

(2) Planning and execution of all MAC and BAC meetings and the production of meeting minutes that include actions taken or anticipated actions by the State in response to interested parties' feedback provided during the meeting. The minutes are to be posted on the State's website within 30 calendar days following each meeting. Additionally, the State must produce and post on its website an annual report as specified in paragraph (i) of this section; and

(3) The provision of appropriate support and preparation (providing research or other information needed) to the MAC and BAC members who are Medicaid beneficiaries to ensure meaningful participation. These tasks include—

(i) Providing staff whose responsibilities are to facilitate MAC and BAC member engagement;

(ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAC; and

(iii) Attendance by at least one staff member from the single State Agency for the Medicaid program's executive staff at all MAC and BAC meetings.

(i) *Annual report.* The MAC, with support from the State, must submit an annual report describing its activities, topics discussed, and recommendations. The State must review the report and include responses to the recommended actions. The State agency must then—

(1) Provide MAC members with final review of the report;

(2) Ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAC, as well as the State's responses to the recommendations; and

(3) Post the report to the State's website. States have 2 years from July 9, 2024 to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.

(j) *Federal financial participation.* FFP is available at 50 percent of expenditures for the MAC and BAC activities.

(k) *Applicability dates.* Except as noted in paragraphs (d)(1) and (i)(3) of this section, the requirements in paragraphs (a) through (j) of this section are applicable July 9, 2025.

[89 FR 40861, May 10, 2024; 89 FR 53501, June 27, 2024]

§ 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 minimum retention period for such records, and the conditions under which those records must be provided or made available.

(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 all of the following:

(1) Individual records on each applicant and beneficiary that contain all of the following:

(i) All information provided on the initial application submitted through any modality described in § 435.907 of this chapter by, or on behalf of, the applicant or beneficiary, including the signature on and date of application.

(ii) The electronic account and any information or other documentation received from another insurance affordability program in accordance with § 435.1200(c) and (d) of this chapter.

(iii) The date of, basis for, and all documents or other evidence to support any determination, denial, or other adverse action, including decisions made at application, renewal, and as a result of a change in circumstance, taken with respect to the applicant or beneficiary, including all information provided by, or on behalf of, the applicant or beneficiary, and all information obtained electronically or otherwise by the agency from third-party sources.

(iv) The provision of, and payment for, services, items and other medical assistance, including the service or item provided, relevant diagnoses, the date that the service or item was provided, the practitioner or provider rendering, providing or prescribing the

service or item, including their National Provider Identifier, and the full amount paid or reimbursed for the service or item, and any third-party liabilities.

(v) Any changes in circumstances reported by the individual and any actions taken by the agency in response to such reports.

(vi) All renewal forms and documentation returned by, or on behalf of, a beneficiary, to the Medicaid agency in accordance with § 435.916 of this chapter, regardless of the modality through which such forms are submitted, including the signature on the form and date received.

(vii) All notices provided to the applicant or beneficiary in accordance with § 431.206 and §§ 435.917 and 435.918 of this chapter.

(viii) All records pertaining to any fair hearings requested by, or on behalf of, the applicant or beneficiary, including each request submitted and the date of such request, the complete record of the hearing decision, as described in § 431.244(b), and the final administrative action taken by the agency following the hearing decision and date of such action.

(ix) The disposition of income and eligibility verification information received under §§ 435.940 through 435.960 of this chapter, including evidence that no information was returned from an electronic data source.

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

(c) *Retention of records.* The State plan must—

(1) Except as provided in paragraph (c)(2) of this section, provide that the records required under paragraph (b) of this section will be retained for the period when the applicant or beneficiary's case is active, plus a minimum of 3 years thereafter.

(2) For beneficiaries described in section 1917(a)(1)(B), (b)(1)(B) and (b)(1)(C) of the Act, provide that the records required under paragraph (b) of this section will be retained until the State has satisfied the requirements of section 1917(b) of the Act (relating to estate recovery).

(d) *Accessibility and availability of records.* The agency must—

(1) Maintain the records described in paragraph (b) of this section in an electronic format; and

(2) Consistent with paragraph (e) of this section, and to the extent permitted under Federal law, make the records available to the Secretary, Federal and State auditors and other parties who request and are authorized to review such records within 30 calendar days of the request (or longer period specified in the request), except when there is an administrative or other emergency beyond the agency's control.

(e) *Release and safeguarding information.* The agency must provide safeguards that restrict the use or disclosure of information contained in the records described in paragraph (b) of this section in accordance with the requirements set forth in subpart F of this part.

[89 FR 22865, Apr. 2, 2024]

§ 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) All data classes and data elements included in a content standard in 45 CFR 170.213 that are maintained by the State no later than 1 business day after the State receives the data; 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.

(5) Beginning January 1, 2027, the information in paragraph (b)(5)(i) of this section about prior authorizations for items and services (excluding drugs as defined in paragraph (b)(6) of this section), according to the timelines in paragraph (b)(5)(ii) of this section.

(i) The prior authorization request and decision, including all of the following, as applicable:

(A) The prior authorization status.

(B) The date the prior authorization was approved or denied.

(C) The date or circumstance under which the prior authorization ends.

(D) The items and services approved.

(E) If denied, a specific reason why the request was denied.

(F) Related structured administrative and clinical documentation submitted by a provider.

(ii) The information in paragraph (b)(5)(i) of this section must—

(A) Be accessible no later than 1 business day after the State receives a prior authorization request;

(B) Be updated no later than 1 business day after any status change; and

(C) Continue to be accessible for the duration that the authorization is active and at least 1 year after the prior authorization's last status change.

(6) Drugs are defined for the purposes of paragraph (b)(5) of this section as any and all drugs covered by the State.

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

(1) Must implement and maintain API technology conformant with 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (e)(1);

(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) Using the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data specified in paragraph (b) of this section or §§ 431.61, 431.70, and 431.80, through the required APIs.

(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 apps and developers through which parties seek to access electronic health information, as defined in 45 CFR 171.102, including but not limited to criteria that rely on automated monitoring and risk mitigation tools.

(f) *Reporting on Patient Access API usage.* Beginning in 2026, by March 31 of each year, a State must report to CMS the following metrics, in the form of aggregated, de-identified data, for the previous calendar year at the State level in the form and manner specified by the Secretary:

(1) The total number of unique beneficiaries whose data are transferred via the Patient Access API to a health app designated by the beneficiary; and

(2) The total number of unique beneficiaries whose data are transferred more than once via the Patient Access API to a health app designated by the beneficiary.

(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]

(h) *Applicability.* A State must comply with the requirements in paragraphs (a) through (e) and (g) of this section beginning January 1, 2021, and with the requirements in paragraph (f) of this section beginning in 2026, with regard to data:

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

(2) That are maintained by the State.

[85 FR 25634, May 1, 2020, as amended at 89 FR 8977, Feb. 8, 2024]

§ 431.61 Access to and exchange of health data for providers and payers.

(a) *Application programming interface to support data exchange from payers to providers—Provider Access API.* Beginning January 1, 2027, unless granted an extension or exemption under paragraph (c) of this section, a State must do the following:

(1) *API requirements.* Implement and maintain an application programming interface (API) conformant with all of the following:

(i) Section 431.60(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (d)(1).

(2) *Provider access.* Make the data specified in § 431.60(b) with a date of service on or after January 1, 2016, excluding provider remittances and beneficiary cost-sharing information, that are maintained by the State available to enrolled Medicaid providers via the API required in paragraph (a)(1) of this section no later than 1 business day after receiving a request from such a provider, if all the following conditions are met:

(i) The State authenticates the identity of the provider that requests access and attributes the beneficiary to the provider under the attribution process described in paragraph (a)(3) of this section.

(ii) The beneficiary does not opt out as described in paragraph (a)(4) of this section.

(iii) Disclosure of the data is not prohibited by other applicable law.

(3) *Attribution.* Establish and maintain a process to associate beneficiaries with their enrolled Medicaid providers to enable data exchange via the Provider Access API.

(4) *Opt out and patient educational resources.* (i) Establish and maintain a process to allow a beneficiary or the beneficiary's personal representative to opt out of the data exchange described in paragraph (a)(2) of this section and to change their permission at any time. That process must be available before the first date on which the State makes beneficiary information available via the Provider Access API and at any time while the beneficiary is enrolled with the State.

(ii) Provide information to beneficiaries in plain language about the benefits of API data exchange with their providers, their opt out rights, and instructions both for opting out of data exchange and for subsequently opting in, as follows:

(A) Before the first date on which the State makes beneficiary information available through the Provider Access API.

(B) No later than 1 week after enrollment.

(C) At least annually.

(D) In an easily accessible location on its public website.

(5) *Provider resources.* Provide on its website and through other appropriate provider communications, information in plain language explaining the process for requesting beneficiary data using the Provider Access API required in paragraph (a)(1) of this section. The resources must include information about how to use the State's attribution process to associate beneficiaries with their providers.

(b) *Application programming interface to support data exchange between payers—Payer-to-Payer API.* Beginning January 1, 2027, unless granted an extension or exemption under paragraph (c) of this section, a State must do the following:

(1) *API requirements.* Implement and maintain an API conformant with all of the following:

(i) Section 431.60(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (d)(1).

(2) *Opt in.* Establish and maintain a process to allow beneficiaries or their personal representatives to opt into the State's payer to payer data exchange with the beneficiary's previous payer(s), described in paragraphs (b)(4) and (5) of this section, and with concurrent payer(s), described in paragraph (b)(6) of this section, and to change their permission at any time.

(i) The opt in process must be offered as follows:

(A) To current beneficiaries, no later than the compliance date.

(B) To new beneficiaries, no later than 1 week after enrollment.

(ii) If a beneficiary has coverage through any Medicaid MCO, prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) within the same State while enrolled in Medicaid, the State must share their opt in permission with those MCO, PIHP, or PAHP to allow the Payer-to-Payer API data exchange described in this section.

(iii) If a beneficiary does not respond or additional information is necessary, the State must make reasonable efforts to engage with the beneficiary to collect this information.

(3) *Identify previous and concurrent payers.* Establish and maintain a process to identify a new beneficiary's previous and concurrent payer(s) to facilitate the Payer-to-Payer API data exchange. The information request process must start as follows:

(i) For current beneficiaries, no later than the compliance date.

(ii) For new beneficiaries, no later than 1 week after enrollment.

(iii) If a beneficiary does not respond or additional information is necessary, the State must make reasonable efforts to engage with the beneficiary to collect this information.

(4) *Exchange request requirements.* Exchange beneficiary data with other payers, consistent with the following requirements:

(i) The State must request the data specified in paragraph (b)(4)(ii) of this section through the beneficiary's previous payers' API, if all the following conditions are met:

(A) The beneficiary has opted in, as described in paragraph (b)(2) of this section, except for data exchanges between a State Medicaid agency and its contracted MCOs, PIHPs, or PAHPs, which do not require a beneficiary to opt in.

(B) The exchange is not prohibited by other applicable law.

(ii) The data to be requested are all of the following with a date of service within 5 years before the request:

(A) Data specified in § 431.60(b), excluding the following:

(*1*) Provider remittances and enrollee cost-sharing information.

(*2*) Denied prior authorizations.

(B) Unstructured administrative and clinical documentation submitted by a provider related to prior authorizations.

(iii) The State must include an attestation with this request affirming that the beneficiary is enrolled with the State and has opted into the data exchange.

(iv) The State must complete this request as follows:

(A) No later than 1 week after the payer has sufficient identifying information about previous payers and the beneficiary has opted in.

(B) At a beneficiary's request, within 1 week of the request.

(v) The State must receive, through the API required in paragraph (b)(1) of this section, and incorporate into its records about the beneficiary, any data made available by other payers in response to the request.

(5) *Exchange response requirements.* Make available the data specified in paragraph (b)(4)(ii) of this section that are maintained by the State to other payers via the API required in paragraph (b)(1) of this section within 1 business day of receiving a request, if all the following conditions are met:

(i) The payer that requests access has its identity authenticated and includes an attestation with the request that the patient is enrolled with the payer and has opted into the data exchange.

(ii) Disclosure of the data is not prohibited by other applicable law.

(6) *Concurrent coverage data exchange requirements.* When a beneficiary has provided sufficient identifying information about concurrent payers and has opted in as described in paragraph (b)(2) of this section, a State must do the following, through the API required in paragraph (b)(1) of this section:

(i) Request the beneficiary's data from all known concurrent payers as described in paragraph (b)(4) of this section, and at least quarterly thereafter while the beneficiary is enrolled with both payers.

(ii) Respond as described in paragraph (b)(5) of this section within 1 business day of a request from any concurrent payers. If agreed upon with the requesting payer, the State may exclude any data that were previously sent to or originally received from the concurrent payer.

(7) *Patient educational resources.* Provide information to applicants or beneficiaries in plain language, explaining at a minimum: the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw that permission, and instructions for doing so. The State must provide the following resources:

(i) When requesting a beneficiary's permission for Payer-to-Payer API data exchange, as described in paragraph (b)(2) of this section.

(ii) At least annually, in appropriate mechanisms through which it ordinarily communicates with current beneficiaries.

(iii) In an easily accessible location on its public website.

(c) *Extensions and exemptions*—(1) *Extension.* (i) A State may submit a written application to request a one-time, 1-year extension of the requirements in paragraph (a) or (b) of this section (or paragraphs (a) and (b)) for its Medicaid fee-for-service (FFS) program. The written application must be submitted as part of the State's annual Advance Planning Document (APD) for Medicaid Management Information System (MMIS) operations expenditures described in part 433, subpart C, of this chapter, and approved before the compliance date for the requirements to which the State is seeking an extension. It must include all the following:

(A) A narrative justification describing the specific reasons why the State cannot satisfy the requirement(s) by the compliance date and why those reasons result from circumstances that are unique to the agency operating the Medicaid FFS program.

(B) A report on completed and ongoing State activities that evidence a good faith effort towards compliance.

(C) A comprehensive plan to meet the requirements no later than 1 year after the compliance date.

(ii) CMS grants the State's request if it determines, based on the information provided, that—

(A) The request adequately establishes a need to delay implementation; and

(B) The State has a comprehensive plan to meet the requirements no later than 1 year after the compliance date.

(2) *Exemption.* (i) A State operating a Medicaid program in which at least 90 percent of the State's Medicaid beneficiaries are enrolled in Medicaid managed care organizations, as defined in § 438.2 of this chapter, may request an exemption for its FFS program from

either or both of the following requirement(s):

(A) Paragraph (a) of this section.

(B) Paragraphs (b)(1) and (3) through (7) of this section.

(ii) The State's exemption request must:

(A) Be submitted in writing as part of a State's annual APD for MMIS operations expenditures before the compliance date for the requirements to which the State is seeking an exemption.

(B) Include both of the following:

(*1*) Documentation that the State meets the threshold for the exemption, based on enrollment data from the most recent CMS ''Medicaid Managed Care Enrollment and Program Characteristics'' (or successor) report.

(*2*) An alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.

(iii) CMS grants the exemption if the State establishes to CMS's satisfaction that the State—

(A) Meets the threshold for the exemption; and

(B) Has established an alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.

(iv) The State's exemption expires if either—

(A) Based on the 3 previous years of available, finalized Medicaid Transformed Medicaid Statistical Information System (T–MSIS) managed care and FFS enrollment data, the State's managed care enrollment for 2 of the previous 3 years is below 90 percent; or

(B)(*1*) CMS has approved a State plan amendment, waiver, or waiver amendment that would significantly reduce the percentage of beneficiaries enrolled in managed care; and

(*2*) The anticipated shift in enrollment is confirmed by the first available, finalized Medicaid T–MSIS managed care and FFS enrollment data.

(v) If a State's exemption expires under paragraph (c)(2)(iv) of this section, the State is required to do both of the following—

(A) Submit written notification to CMS that the State no longer qualifies for the exemption within 90 days of the finalization of annual Medicaid T–MSIS managed care enrollment data that demonstrates that there has been the requisite shift from managed care enrollment to FFS enrollment resulting in the State's managed care enrollment falling below the 90 percent threshold.

(B) Obtain CMS approval of a timeline for compliance with the requirements in paragraph (a) or (b) (or paragraph0s (a) and (b)) of this section within 2 years of the expiration of the exemption.

[89 FR 8977, Feb. 8, 2024]

§ 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]

§ 431.80 Prior authorization requirements.

(a) *Communicating a reason for denial.* Beginning January 1, 2026, if the State denies a prior authorization request (excluding a request for coverage of drugs as defined in § 431.60(b)(6)), in accordance with the timeframes established in § 440.230(e)(1) of this chapter, the response to the provider must include a specific reason for the denial,

regardless of the method used to communicate that information.

(b) *Prior Authorization Application Programming Interface (API).* Unless granted an extension or exemption under paragraph (c) of this section, beginning January 1, 2027, a State must implement and maintain an API conformant with § 431.60(c)(2) through (4), (d), and (e), and the standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (c)(1) that—

(1) Is populated with the State's list of covered items and services (excluding drugs, as defined in § 431.60(b)(6)) that require prior authorization;

(2) Can identify all documentation required by the State for approval of any items or services that require prior authorization;

(3) Supports a HIPAA-compliant prior authorization request and response, as described in 45 CFR part 162; and

(4) Communicates the following information about prior authorization requests:

(i) Whether the State—

(A) Approves the prior authorization request (and the date or circumstance under which the authorization ends);

(B) Denies the prior authorization request; or

(C) Requests more information.

(ii) If the State denies the prior authorization request, it must include a specific reason for the denial.

(c) *Extensions and exemptions*—(1) *Extension.* (i) A State may submit a written application to request a one-time, 1-year extension of the requirements in paragraph (b) of this section for its Medicaid FFS program. The written application must be submitted as part of the State's annual APD for MMIS operations expenditures described in part 433, subpart C, of this chapter; and approved before the compliance date in paragraph (b) of this section. It must include all the following:

(A) A narrative justification describing the specific reasons why the State cannot satisfy the requirement(s) by the compliance date and why those reasons result from circumstances that are unique to the agency operating the Medicaid FFS program.

(B) A report on completed and ongoing State activities that evidence a good faith effort towards compliance.

(C) A comprehensive plan to meet the requirements no later than 1 year after the compliance date.

(ii) CMS grants the State's request if it determines, based on the information provided, that—

(A) The request adequately establishes a need to delay implementation; and

(B) The State has a comprehensive plan to meet the requirements no later than 1 year after the compliance date.

(2) *Exemption.* (i) A State operating a Medicaid program in which at least 90 percent of the State's Medicaid beneficiaries are enrolled in Medicaid managed care organizations, as defined in § 438.2 of this chapter, may request an exemption for its FFS program from the requirements in paragraph (b) of this section.

(ii) The State's exemption request must:

(A) Be submitted in writing as part of a State's annual APD for MMIS operations expenditures before the compliance date in paragraph (b) of this section.

(B) The State's request must include both of the following:

(*1*) Documentation that the State meets the threshold for the exemption, based on enrollment data from the most recent CMS ''Medicaid Managed Care Enrollment and Program Characteristics'' (or successor) report.

(*2*) An alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.

(iii) CMS grants the exemption if the State establishes to CMS's satisfaction that the State—

(A) Meets the threshold for the exemption; and

(B) Has established an alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.

(iv) The State's exemption expires if either—

(A) Based on the 3 previous years of available, finalized Medicaid Transformed Medicaid Statistical Information System (T–MSIS) managed care and FFS enrollment data, the State's managed care enrollment for 2 of the previous 3 years is below 90 percent; or

(B)(*1*) CMS has approved a State plan amendment, waiver, or waiver amendment that would significantly reduce the percentage of beneficiaries enrolled in managed care; and

(*2*) The anticipated shift in enrollment is confirmed by the first available, finalized Medicaid T–MSIS managed care and FFS enrollment data.

(v) If a State's exemption expires under paragraph (c)(2)(iv) of this section, the State is required to do both of the following—

(A) Submit written notification to CMS that the State no longer qualifies for the exemption within 90 days of the finalization of annual Medicaid T–MSIS managed care enrollment data that demonstrates that there has been the requisite shift from managed care enrollment to FFS enrollment resulting in the State's managed care enrollment falling below the 90 percent threshold.

(B) Obtain CMS approval of a timeline for compliance with the requirements in paragraph (b) of this section within 2 years of the expiration of the exemption.

[89 FR 8979, Feb. 8, 2024]

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 one of the following:

(1) A termination, suspension of, or reduction in covered benefits or services, including benefits or services for which there is a current approved prior authorization;

(2) 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 to establish income eligibility in accordance with § 435.121(e)(4) or § 435.831 of this chapter;

(3) A determination that a beneficiary is subject to an increase in premiums or cost-sharing charges under subpart A of part 447 of this chapter; or

(4) A determination by a skilled nursing facility or nursing facility to transfer or discharge a resident and an adverse determination by a State regarding 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; 89 FR 8980, Feb. 8, 2024]

§ 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 mail directed to him indicating no forwarding address (see § 435.919(f)(4) of this chapter for procedures 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; 89 FR 22866, Apr. 2, 2024]

§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;

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

(vi) A prior authorization decision.

(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; 89 FR 8980, Apr. 8, 2024]

§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) [Reserved]

[44 FR 17932, Mar. 29, 1979, as amended at 78 FR 42302, July 15, 2013; 89 FR 22866, Apr. 2, 2024]

§ 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 Medicaid Advisory Committee and Beneficiary Advisory Council that operate 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.

[77 FR 11696, Feb. 27, 2012, as amended at 89 FR 40863, May 10, 2024]

§ 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 preapplication 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, 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) Beneficiaries required to be covered under §§ 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;

(ii) 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;

(iii) Beneficiaries whom States must consider to be recipients of AFDC, including those who receive adoption assistance, foster care or guardianship care, under part E of title IV of the Act, in accordance with §§ 435.145 and 436.114(e) of this subchapter, or who receive Medicaid coverage for low income families, in accordance with section 1931(b) of the Act.

(iv) Individuals required to be covered under § 435.120 of this subchapter, that is, blind or disabled individuals who, under section 1619(b) of the Act, are considered to be receiving SSI;

(v) 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;

(vi) Disabled children living at home to whom the State provides Medicaid under § 435.225 of this subchapter.

(vii) Beneficiaries required to be covered under §§ 435.115 and 436.114(f) and (h) of this subchapter, that is, those who remain eligible for 4 months of temporary Medicaid coverage because of the increased collection of spousal support under part D of title IV of the Act.

(viii) Individuals required to be covered under the QMB, SLMB, and QI eligibility groups, each separately defined in §§ 435.123 through 435.125 of this subchapter.

(ix) Adult children with disabilities, as described in 1634(c) of the Act.

(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; 87 FR 66510, Nov. 3, 2022]

§ 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 Payment Integrity Information Act (PIIA) of 2019 (Pub. L. 116–117), 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 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; 89 FR 69913, Aug. 28, 2024]

§ 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 PIIA 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, as amended at 69913, Aug. 28, 2024]

§ 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.

(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 PIIA.

[82 FR 31187, July 5, 2017, as amended at 89 FR 69913, Aug. 28, 2024]

§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

Sec.

Subpart B—Training Programs; Subprofessional and Volunteer Programs

Subpart C—Staffing and Training Expenditures

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.