

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTIONControl No: 560 Department or Agency: Alabama Medicaid AgencyRule No: 560-X-37-01Rule Title: General

New Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? no

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? yes

Is there another, less restrictive method of regulation available that could adequately protect the public? no

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? no

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? no

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? yes

Does the proposed rule have an economic impact? no

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer: Stephanie Lindsay

Date: 12/19/17

ALABAMA MEDICAID AGENCY

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Medicaid Agency

RULE NO. & TITLE: 560-X-37-.01 - General

INTENDED ACTION: Amend Rule No. 560-X-37-.01

SUBSTANCE OF PROPOSED ACTION: The above referenced rule is being amended to reflect changes to 42 C.F.R. Part 438.

TIME, PLACE, MANNER OF PRESENTING VIEWS: Written or oral comments may be submitted to the Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624. Agency business hours are 8:00 a.m. to 5:00 p.m. Monday through Friday.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: Written/Oral comments concerning this change must be received by the Alabama Medicaid Agency no later than February 2, 2018.

CONTACT PERSON AT AGENCY: Stephanie Lindsay, Administrative Secretary, Alabama Medicaid Agency, 501 Dexter Avenue, Post Office Box 5624, Montgomery, Alabama 36103-5624. Phone: (334) 242-5833.



Stephanie McGee Azar
Commissioner

Rule No. 560-X-37-01 General

(1) The Medicaid Agency may, at its discretion, and in consultation with local communities, organize and develop area specific systems as part of an overall managed care system.

(a) Flexibility. Since community needs and resources differ from area to area, the Medicaid Agency will maintain the flexibility to design plans which are consistent with local needs and resources.

(b) Waiver Programs. Plans may be either voluntary or mandatory pursuant to waiver(s) granted by the Centers for Medicare and Medicaid Services (CMS) ~~or the Office of State Health Reform Demonstration~~. Some plans may start as voluntary and subsequently become mandatory. All required federal waivers and/or approvals must be obtained by the Medicaid Agency before any system or contract can become effective.

(c) State Plan Programs. Amendments to the state plan must be approved by CMS before any system or contract can become effective.

(d) Models. The Medicaid Agency may utilize one or more managed care systems established in 42 C.F.R. Part 438 or approved by CMS, including but not limited to, health maintenance organizations (HMO), managed care organizations (MCO), prepaid ambulatory health plans (PAHPs), prepaid Inpatient health plans (PIHP), primary care case management systems (PCCM), and/or primary care case management entities (PCCM entity). It is anticipated that managed care will be accomplished through a combination of primary care case management systems (PCCM), health maintenance organizations (HMO), managed care organizations (MCO), prepaid Inpatient health plans, and regional care organizations (RCO).

(e) Purpose. The purposes of managed care are to:

- (i) Ensure needed access to health care;
- (ii) Provide health education;
- (iii) Promote continuity of care;
- (iv) Strengthen the patient/physician relationship; and
- (v) Achieve cost efficiencies.

~~(2)(a) Any managed care system established shall comply with the approved Alabama State Plan for Medical Assistance, Alabama Medicaid Administrative Code, the Alabama Medicaid Provider Manual and/or operational protocols, all other guidelines of Medicaid program areas, all state and federal laws and regulations, and any federally approved waivers in effect in the geographical areas of the State in which the system is operational and providing medical services to eligible Medicaid enrollees.~~

~~(b) The regulations of CMS at 42 CFR Parts 430, 432, 434, 438, 440, and 447, as promulgated in 67 Federal Register 40988 (June 14, 2002) and 68 Federal Register 3586 (January 24, 2003), and as may be subsequently amended, are adopted by reference. Copies of these regulations may be obtained from the US Government Printing Office, Washington, DC 20402 or at www.gpo.gov/su_docs/aces/aces140.html. Copies are also available from Medicaid at a cost of \$7.00.~~

(2) Any established managed care system shall comply with the following:

- (a) the Alabama Medicaid State Plan and any award letters, waivers or other directives or permissions approved by CMS for operation of the managed care system;
- (b) the Federal Medicaid Act, Title XIX of the Social Security Act, the Children's Health Insurance Program (CHIP), established by Title XXI of the Social Security Act, and the Affordable Care Act, and their implementing regulations published in the Code of Federal Regulations (CFR), except as waived by CMS, including, but not limited to, 42 C.F.R. Parts 430, 432, 434, 438, 440, and 447, and as may be subsequently amended;
- (c) any state law implementing or directing the implementation of the managed care system;
- (d) Alabama Medicaid Administrative Code;
- (e) the Alabama Medicaid Provider Manual and/or operational protocols, any Agency written policy, written procedure, written interpretation or other written guidance, including operational memos, manuals, interpretations, and Agency written communications; and
- (f) all other applicable state and federal laws and regulations.

(3) Any managed care system or respective network provider shall comply with all applicable federal and state laws, rules, and regulations, including, but not limited to:

- (a) Age Discrimination Act of 1975, as amended, 42 U.S.C. § 6101, *et seq.*;
- (b) Age Discrimination in Employment Act of 1967, 29 U.S.C. §§ 621 – 634;
- (c) Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. § 12101, *et seq.*;
- (d) Byrd Anti-Lobbying Amendment, 31 U.S.C. § 1352, 45 C.F.R. § 2543.87;
- (e) Clean Air Act, 42 U.S.C. § 7401, *et seq.*;
- (f) Debarment and Suspension 45 CFR § 74 Appendix A (8) and Executive Order (E.O.) 12549 and 12689;
- (g) Equal Employment Opportunity, E.O. 11246, as amended by E.O. 11375, amending E.O. 11246 and as supplemented by 41 C.F.R., Part 60;

- (h) Equal Pay Act of 1963, 29 USC § 206(d);
- (i) Federal Water Pollution Control Act, as amended, 33 U.S.C. § 1251, *et seq.*;
- (j) Immigration Reform and Control Act of 1986, 8 U.S.C. § 1324b;
- (k) Rights to inventions made under a contract or agreement, 45 C.F.R. § 2543.85;
- (l) Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 794;
- (m) Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. § 2000d, *et seq.*;
- (n) Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e;
- (o) Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. § 1681; and
- (p) Section 1557 of the Patient Protection and Affordable Care Act.

~~(3) Any managed care system or provider shall comply with all federal and state laws, rules and regulations relating to discrimination and equal employment opportunity, Titles VI and VII of the Civil Rights Act of 1964, as amended, the Federal Age Discrimination Act, Section 504 of the Rehabilitation Act of 1973, and Americans with Disabilities Act of 1990.~~

- (4) The Medicaid Agency's contract with the managed care system must, at a minimum:
 - (a) include the applicable standard contract provisions of 42 C.F.R. § 438.3;
 - (b) include all applicable provisions required by 42 C.F.R. Part 438;
 - (c) include any provisions required by state or federal laws or regulations;
 - (d) be approved by CMS in accordance with to 42 C.F.R. § 438.3(a).

~~(5) Each managed care system must comply with the information requirements contained in 42 C.F.R. § 438.10. Unless otherwise specified in the manage care system contract or elsewhere by the Medicaid Agency, Prevalent Languages shall mean the fifteen (15) most spoken languages in the state as determined by the most recent United States Census.~~

~~(6) The Medicaid Agency must have policies and procedures in place to ensure that its obligations under 42 C.F.R. § 438 Subpart B are met. Further, Medicaid Agency employees must comply with the state ethics laws including, but not limited to, Code of Alabama (1975), Sections 36-25-5, -7, -8, -11, -12, and -13.~~

~~(7) Every managed care system must establish policies and procedures, which shall be subject to the Medicaid Agency's sole approval, to ensure that its obligations under its contract with the Medicaid Agency and 42 C.F.R. Subparts D and E are met. In addition, the Medicaid Agency must~~

establish policies and procedures to monitor the managed care system's performance of its obligations.

(8) Every managed care system must establish, subject to the Medicaid Agency's sole approval, a grievance system. Such grievance system must, at a minimum:

- (a) comply with the applicable provisions of 42 C.F.R. § 438 Subpart F; and
- (b) comply with any other applicable state or federal laws and regulations.

(4) The terminology and definitions in this chapter may be referenced in their entirety in 42 CFR 438.2. An abbreviated list follows:

(a) *Capitation payment* means a payment the state agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the state plan.

(b) *Capitated risk contract* means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the services listed in Rule 560 X 37 .03 (2).

(c) *Federally qualified HMO* means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

(d) *Health care professional* means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(e) *Health insuring organization (HIO)* means a county operated entity that in exchange for capitation payments covers services for recipients through payments to, or arrangements with, providers under a comprehensive risk contract with the state.

(f) *Managed care organization (MCO)* means an entity that has, or is seeking to qualify for, a comprehensive risk contract as defined in 42 CFR, Part 438, and that is a federally qualified HMO that meets the requirements of 42 CFR, Part 489, Subpart I.

(g) *Nonrisk contract* means a contract under which the contractor is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in 42 CFR, Section 447.362.

(h) *Prepaid ambulatory health plan (PAHP)* means an entity that provides medical services to enrollees under contract with the state agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use state plan payment rates; does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and does not have a comprehensive risk contract.

(i) *Prepaid inpatient health plan (PIHP)* means an entity that provides medical services to enrollees under contract with the state agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use state plan payment rates; provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and does not have a comprehensive risk contract.

(j) *Primary care* means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the state in which the practitioner furnishes them.

(k) *Primary care case management* means a system under which a PCCM contracts with the state to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

(l) *Primary care case manager (PCCM)* means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services.

(m) *Primary medical provider (PMP)* means a family practitioner, general practitioner, internist, or pediatrician, an entity that provides or arranges for PMP coverage for services, consultation, or referrals 24 hours a day, seven days a week.

(n) *Risk contract* means a contract under which the contractor assumes risk for the cost of the services covered under the contract; and incurs loss if the cost of furnishing the services exceeds the payments under the contract.

(o) *Regional Care Organization (RCO)* means an organization of health care providers contracting with the Medicaid Agency to provide a comprehensive package of Medicaid benefits to Medicaid beneficiaries within a defined region of the state and that meets the requirements set forth in the law.

(5) The contract requirements in this chapter may be referenced in their entirety in 42 CFR 438.6. An abbreviated list follows:

(a) The CMS Regional Office must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in 438.806.

(b) Payments under risk contracts must be based on actuarially sound capitation rates that have been developed in accordance with generally accepted actuarial principles and practices; and are appropriate for the populations to be covered, and the services to be furnished under the contract.

(c) All contracts in this chapter must comply with all applicable federal and state laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972; the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act.

Physician incentive plans (PIP) do not apply to contracts in this chapter.

All MCO and PIHP contracts must provide for compliance with the requirements of 422.128 for maintaining written policies and procedures for advance directives. The entity subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable state law.

(f) PCCM contracts must meet the following requirements:

(i) Provide for reasonable and adequate hours of operation, including 24 hour availability of information, referral, and treatment for emergency medical conditions.

(ii) Restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(iii) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(iv) Prohibit discrimination in enrollment, disenrollment, and reenrollment, based on the recipient's health status or need for health care services.

____ (v) Provide that enrollees have the right to disenroll from their PCCM in accordance with 438.56 (e).

____ (6) The information requirements in this chapter may be referenced in their entirety in 42 CFR 438.10. An abbreviated list follows:

____ (a) *Enrollee* means a Medicaid recipient who is currently enrolled in an MCO, PIHP, PAHP, or PCCM in a given managed care program.

____ (b) *Potential enrollee* means a Medicaid recipient who is subject to mandatory enrollment or may voluntarily elect to enroll in a given managed care program, but is not yet an enrollee of a specific MCO, PIHP, PAHP, or PCCM.

____ (c) Each state enrollment broker must provide all enrollment notices, informational materials, and instructional materials relating to enrollees and potential enrollees in a manner and format that may be easily understood.

____ (d) The state must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

____ (e) The state must establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the state. *Prevalent* means a non-English language spoken by a significant number of potential enrollees and enrollees in the state.

____ (f) The state and each managed care entity must make available written information in the prevalent non-English languages.

____ (g) The state must notify enrollees and potential enrollees and require each managed care entity to notify its enrollees that oral interpretation is available for any language and written information is available in prevalent languages.

____ (7) The provider discrimination prohibitions in this chapter may be found in their entirety in 42 CFR 438.12. An abbreviated list follows:

____ (a) A managed care entity may not discriminate for the participation, reimbursement, or indemnification of any provider who is acting within the scope of his license or certification under applicable state law, solely on the basis of that license or certification. If a managed care entity declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

____ (b) In all contracts with health care professionals, a managed care entity must comply with the requirements in 438.214.

____ (8) The enrollment requirements in this chapter may be found in their entirety in 42 CFR 438.50 through 438.66. An abbreviated list follows:

____ (a) A state plan that requires Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the state imposes the requirement as part of a demonstration project under section 1115 of the Act; or under a waiver granted under section 1915(b) of the Act.

____ (b) The state plan must specify the types of entities with which the state contracts; whether the payment method is fee for service or capitated; whether it contracts on a comprehensive risk basis; and the process the state uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the state plan has been implemented.

(e) The plan must provide assurances that the state meets applicable requirements of section 1903(m) of the Act for MCOs; section 1905(t) of the Act for PCCMs; and section 1932(a)(1)(A) of the Act for the state's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(d) The state must provide assurances that, in implementing the state plan managed care option; it will not require the following groups to enroll in an MCO or PCCM: Medicare eligible recipients;

Indians who are members of federally recognized tribes, except when the MCO or PCCM is the Indian Health Service or an Indian health program operated under a contract, grant, etc., with the Indian Health Service;

Children under 19 years of age who are eligible for SSI under title XVI; eligible under section 1902(e)(3) of the Act; in foster care or out of home placement; receiving foster care or adoption assistance; or receiving services through a community based care system.

(e) The state must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity accept all those seeking enrollment under the program.

(f) For recipients who do not choose an MCO or PCCM during their enrollment period, the state must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(g) The process must seek to preserve existing provider recipient relationships and relationships with providers that have traditionally served Medicaid recipients.

(h) An *existing provider recipient relationship* is one in which the provider was the main source of Medicaid services for the recipient during the previous year.

(i) A provider is considered to have *traditionally served* Medicaid recipients if it has experience in serving the Medicaid population.

(9) The recipient choice requirements in this chapter may be found in their entirety in 42 CFR 438.52. An abbreviated list follows:

(a) A state that requires Medicaid recipients to enroll in an MCO, PIHP, PAHP or PCCM system must give those recipients a choice of at least two entities.

(b) A state may limit a rural area recipient to a single managed care entity with the exceptions noted in 438.52(b).

(c) A state may limit recipients to a single HIO if the recipient has a choice of at least two primary care providers within the entity.

(d) A state's limitation on an enrollee's freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment noted in 438.56.

(10) The disenrollment requirements and limitations in this chapter may be found in their entirety in 42 CFR 438.56. An abbreviated list follows:

(a) The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PIHP, a PAHP, or a PCCM.

(b) All contracts must specify the reasons for which the entity may request disenrollment of an enrollee.

_____ (e) The entity may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs.

_____ (d) All contracts must specify the methods by which the entity assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

_____ (e) All contracts must specify that a recipient may request disenrollment for cause at any time or without cause at the following times:

_____ (i) During the 90 days following the date of the recipient's initial enrollment with the entity or the date the state sends the recipient notice of the enrollment, whichever is later.

_____ (ii) At least once every 12 months thereafter.

_____ (iii) Upon automatic reenrollment if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

_____ (f) Recipients (or their representatives) must submit oral or written requests for disenrollment to the state agency or the managed care entity (if the state permits the entity to process such requests).

_____ (g) The following are cause for disenrollment:

_____ (i) The enrollee moves out of the entity's service area.

_____ (ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

_____ (iii) The enrollee needs related services to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

_____ (iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

_____ (h) The state agency must complete the determination on the recipient's (or the entity's) request so that the effective date of disenrollment is no later than the first day of the second month following the month in which the recipient (or the entity) files the request.

_____ (11) The state must have in effect safeguards against conflict of interest on the part of employees and agents of the state who have responsibilities relating to the managed care contracts. Medicaid employees must comply with the state ethics laws including, but not limited to, Code of Alabama (1975), Sections 36-25-5, 7, 8, 11, 12, and 13.

_____ (12) The state must ensure that no payment is made to a provider other than the managed care entity for services available under the contract between the state and the entity. Medicaid ensures compliance with 438.60 through the systematic plan code determination at the detail level of a claim.

_____ (13) The state must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of a managed care entity whose contract is terminated and for any Medicaid enrollee who is disenrolled from an entity for any reason other than ineligibility for Medicaid.

(14) The state must have in effect procedures for monitoring the entity's operations, including at a minimum, operations related to the following:

Recipient enrollment and disenrollment.

Processing of grievances and appeals.

Violations subject to intermediate sanctions.

Violations of the conditions for FFP.

All other conditions of the contract as appropriate.

The enrollee rights in this chapter may be found in their entirety in 42 CFR 438.100. An abbreviated list follows:

(a) The state must ensure that each managed care entity has written policies regarding the enrollee rights specified in 438.100.

(b) Each entity shall comply with any applicable federal and state laws that pertain to enrollee rights and shall ensure that its staff and providers take those rights into account when furnishing services to enrollees.

(c) An enrollee of a managed care entity has the right to:

(i) Receive information in accordance with 438.10.

(ii) Be treated with respect and with due consideration for this or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand.

(iv) Participate in decisions regarding his or her health care.

(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation.

(vi) Request and receive a copy of his or her medical records, and request that they be amended or corrected.

An enrollee of a managed care entity has the right to be furnished health care services in accordance with 438.206 through 438.210.

(e) The state must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the managed care entity and its providers treat the enrollee.

(f) The state must ensure that each entity complies with any other applicable federal and state laws.

(16) The provider-enrollee communications in this chapter may be found in their entirety in 42 CFR 438.102. An abbreviated list follows:

(a) A managed care entity may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or nontreatment.

____ (iv) The enrollee's rights to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

____ (17) The marketing activities described in this chapter may be found in their entirety in 42 CFR 438.104. An abbreviated list follows:

____ (a) *Cold-call marketing* means any unsolicited personal contact by the managed care entity for the purpose of marketing.

____ (b) *Marketing* means any communication from a managed care entity to a Medicaid recipient who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the recipient to enroll in that particular entity's Medicaid product, or either to not enroll in, or to disenroll from, another entity's Medicaid product.

____ (c) Each contract with a managed care entity must provide that the entity does not distribute any marketing materials without first obtaining state approval.

____ (18) The rules concerning liability for payment may be found in their entirety in 42 CFR 438.106. An abbreviated list follows:

____ (a) Each managed care entity must provide that its Medicaid enrollees are not held liable for any of the following:

____ (i) The entity's debts in the event of insolvency.

____ (ii) Covered services provided to the enrollee for which the state does not pay the entity, or the state or the entity does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

____ (iii) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the entity provided the services directly.

____ (19) All contracts must provide that any cost sharing imposed on Medicaid enrollees is in accordance with 447.50 through 447.60.

____ (20) The rules concerning emergency and post stabilization services may be found in their entirety in 42 CFR 438.114. An abbreviated list follows:

____ (a) *Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

____ (i) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

____ (ii) Serious impairment to bodily functions.

____ (iii) Serious dysfunction of any bodily organ or part.

____ (b) *Emergency services* means covered inpatient and outpatient services that are as follows:

____ (i) Furnished by a provider that is qualified to furnish these services.

____ (ii) Needed to evaluate or stabilize an emergency medical condition.

_____ (c) *Post stabilization care services* means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized in order to maintain the stabilized condition or to improve or resolve the enrollee's condition.

_____ (21) The solvency standards in this chapter may be found in their entirety in 42 CFR 438.116. An abbreviated list follows:

_____ (a) Each MCO, PIHP, and PAHP that is not a federally qualified HMO must provide assurances to the state showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the managed care entity's debts if the entity becomes insolvent.

_____ (b) Federally qualified HMOs are exempt from this requirement.

_____ (22) The quality assessment and performance improvement standards in this chapter may be found in their entirety in 42 CFR, 438.200. An abbreviated list follows:

_____ (a) The state must have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs.

_____ (b) The state must obtain the input of recipients and other stakeholders in the development of the strategy and make the strategy available for public comment before adopting it as final.

_____ (c) The state must ensure that MCOs, PIHPs, and PAHPs comply with standards established by the state consistent with the regulations found in 42 CFR, Part 438.

_____ (d) The state must conduct periodic reviews to evaluate the effectiveness of the strategy and update the strategy periodically as needed.

_____ (e) The state must submit to CMS a copy of the initial strategy and the revised strategy whenever significant changes are made, as well as regular reports on the effectiveness of the strategy.

_____ (23) The elements of state quality strategies in this chapter may be found in their entirety in 42 CFR 438.204. An abbreviated list follows:

_____ (a) The contracts with MCOs and PIHPs must contain procedures that:

_____ (i) Assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, and to individuals with special health care needs.

_____ (ii) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. The state must provide this information to the MCO and PIHP for each Medicaid enrollee at the time of enrollment.

_____ (iii) Regularly monitor and evaluate the MCO and PIHP compliance with the standards.

_____ (iv) Arrange for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered.

_____ (24) The rules concerning availability of services in this chapter may be found in their entirety in 42 CFR 438.206. An abbreviated list follows:

_____ (a) The state must ensure that all services covered under the state plan are available and accessible to enrollees of MCOs, PIHPs and PAHPs.

_____ (b) The state must ensure through its contracts that each entity, consistent with the entity's scope of contracted services, meets the following requirements:

_____ (i) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract.

_____ (ii) Considers the anticipated Medicaid enrollment.

_____ (iii) Considers the expected utilization of services, taking into account the characteristics and health care needs of specific Medicaid populations represented in the particular entity.

_____ (iv) Considers the numbers and types of providers required to furnish the contracted Medicaid services.

_____ (v) Considers the numbers of network providers who are not accepting new Medicaid patients.

_____ (vi) Considers the geographic location of providers and enrollees.

_____ (e) Each entity must do the following:

_____ (i) Meet and require its providers to meet state standards for timely access to care and services, taking into account the urgency of the need for services.

_____ (ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid fee-for-service.

_____ (iii) Make services included in the contract available 24 hours a day, seven days a week when medically necessary.

Establish mechanisms to ensure compliance by providers.

_____ (v) Monitor providers regularly to determine compliance.

_____ (vi) Take corrective action if there is a failure to comply.

_____ (25) The assurances of adequate capacity and services in this chapter may be found in their entirety in 42 CFR 438.207. An abbreviated list follows:

_____ (a) The state must ensure, through its contracts that each entity gives assurances to the state and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the state's standards for access to care.

_____ (b) Each entity must submit documentation to the state, in a format specified by the state, to demonstrate that it complies with the following requirements:

_____ (i) Offers an appropriate range of preventive, primary care, and specialty services that is adequate for the anticipated number of enrollees for the service area.

_____ (ii) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

_____ (c) Each entity must submit the documentation to the state at the time it enters into a contract with Medicaid and at any time there has been a significant change in the entity's operations that would affect capacity and services.

_____ (26) The requirements for coordination and continuity of care in this chapter may be found in their entirety in 42 CFR 438.208. An abbreviated list follows:

____ (a) Each managed care entity must implement procedures to deliver primary care and to coordinate health care service for all the entity's enrollees. These procedures must meet state requirements and must do the following:

____ (i) Ensure that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

____ (ii) Coordinate the services the entity furnishes to the enrollee with the services the enrollee receives from any other entity.

____ (iii) Share with other entities serving the enrollee with special health care needs the results of its identification and assessment of that enrollee's needs to prevent duplication of those activities.

____ (iv) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with state and federal requirements to the extent that they are applicable.

____ (27) The requirements for coverage and authorization of services in this chapter may be found in their entirety in 42 CFR 438.210. An abbreviated list follows:

____ (a) Each contract with a managed care entity must identify, define, and specify the amount, duration, and scope of each service that the entity is required to offer.

____ (b) The services identified in each entity's contract must be furnished in the same manner that recipients receive under fee for service Medicaid.

____ (c) Each contract must ensure that the services are sufficient in amount, duration, and scope to reasonably be expected to achieve the purpose for which the services were furnished.

____ (d) The entity may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of a diagnosis, type of illness, or condition of the beneficiary.

____ (28) The requirements for provider selection in this chapter may be found in their entirety in 42 CFR, 432.214. An abbreviated list follows:

____ (a) Medicaid must ensure through its contracts that each entity implements written policies and procedures for selection and retention of providers.

____ (b) Medicaid must establish a uniform credentialing and recredentialing policy that each entity must follow.

____ (c) Each entity must follow a documented process for credentialing and recredentialing of providers who have signed contracts or participation agreements with the entity.

____ (d) The entity's provider selection policies and procedures must not discriminate against particular providers that serve high risk populations or specialize in conditions that require costly treatment.

____ (e) The managed care entities may not employ or contract with providers excluded from participation in federal health care programs.

____ (f) Each entity must comply with any additional requirements established by Medicaid.

____ (29) The enrollee information requirements that the state must meet under the regulations in 438.10 constitute part of Medicaid's quality strategy at 438.204.

____ (30) Medicaid must ensure, through its contracts, for medical records and any other health and enrollment information that identifies any particular enrollee, each entity uses and discloses such information in accordance with applicable state and federal laws.

____ (31) Medicaid must ensure that each entity's contract complies with the enrollment and disenrollment requirements and limitations set forth in 438.56.

____ (32) Medicaid must ensure, through its contracts, that each entity has in effect a grievance system that meets the requirements of 438.400 through 438.424.

____ (33) The requirements concerning subcontractual relationships and delegation in this chapter may be found in their entirety in 42 CFR 438.230. An abbreviated list follows:

____ (a) Medicaid must ensure, through its contracts, that each entity oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor.

____ (b) Before any delegation, each entity must evaluate the prospective subcontractor's ability to perform the activities to be delegated.

____ (c) A written agreement between the entity and the subcontractor must specify the activities and report responsibilities delegated to the subcontractor; and must provide for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

____ (34) The requirements for practice guidelines in this chapter may be found in their entirety in 42 CFR 438.236. An abbreviated list follows:

____ (a) Medicaid must ensure, through its contracts, that each entity adopts practice guidelines that meet the following requirements:

____ (i) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field.

____ (ii) Consider the needs of the entity's enrollees.

____ (iii) Are adopted in consultation with contracting health care professionals.

____ (iv) Are reviewed and updated periodically as appropriate.

____ (35) The requirements for quality assessment and performance improvement programs in this chapter may be found in their entirety in 42 CFR 438.240. An abbreviated list follows:

____ (a) Medicaid must require, through its contracts that each entity has an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

____ (b) At a minimum, Medicaid must require that each entity comply with the following requirements:

____ (i) Conduct performance improvement projects that are designed to achieve significant improvement in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction.

____ (ii) Submit performance measurement data to Medicaid annually.

____ (iii) Have in effect mechanisms to detect both underutilization and overutilization of services.

____ (iv) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(36) The requirements for health information systems in this chapter may be found in their entirety in 42 CFR 438.242. An abbreviated list follows:

(a) Medicaid must ensure, through its contracts that each entity maintains a health information system that collects, analyzes, integrates, and reports data.

(b) The system must provide information on areas including, but not limited to, utilization, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(c) The entity must make all collected data available to Medicaid and upon request to CMS.

(37) The requirements for grievance systems in this chapter may be found in their entirety in 42 CFR 438.400. An abbreviated list follows:

(a) The Medicaid state plan provides an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(b) The Medicaid state plan provides for methods of administration that are necessary for the proper and efficient operation of the plan.

(c) Medicaid must require, through its contracts that entities establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(d) In the case of an entity, *action* means:

The denial or limited authorization of a requested service

(ii) The reduction, suspension, or termination of a previously authorized service.

(iii) The denial, in whole or in part, of payment for a service.

(iv) The failure to provide services in a timely manner as defined by the state.

(v) The failure of the entity to act within the timeframes provided in 438.408.

(e) *Appeal* means a request for review of an action, as "action" is defined above.

(f) *Grievance* means an expression of dissatisfaction about any matter other than an action, as "action" is defined above.

(38) The grievance system requirements in this chapter may be found in their entirety in 42 CFR 438.402. An abbreviated list follows:

(a) Each entity must have a system in place for enrollees that include a grievance process, an appeal process, and access to the state's fair hearing system.

(b) An enrollee, or a provider acting on behalf of the enrollee, may file an appeal, a grievance, or request a fair hearing.

(c) Medicaid will specify a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the entity's notice of action.

(39) The requirements for notice of action in this chapter may be found in their entirety in 42 CFR 438.404. An abbreviated list follows:

(a) The notice must be in writing and must meet the language and format requirements of 438.10(c) and (d) to ensure ease of understanding

(b) The notice must explain the following:

____ (i) The action the entity or its contractor has taken or intends to take.
____ (ii) The reasons for the action.
____ (iii) The enrollee's or the provider's right to file an appeal.
____ (iv) The enrollee's right to request a state fair hearing.
____ (v) The procedures for exercising the rights specified in this section.
____ (vi) The circumstances under which expedited resolution is available and how to request it.

____ (vii) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.

____ (40) The requirements for the handling of grievances and appeals in this chapter may be found in their entirety in 42 CFR 438.406. An abbreviated list follows:

____ (a) In handling grievances and appeals, each entity must meet the following requirements:

____ (i) Give enrollees any reasonable assistance in completing forms and taking other procedural steps.
____ (ii) Acknowledge receipt of each grievance and appeal.
____ (iii) Ensure that the individuals who make decisions on grievances and appeals are individuals who were not involved in any previous level of review or decision making; or are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

____ (41) The requirements for resolution and notification of grievances and appeals may be found in their entirety in 42 CFR 438.408. An abbreviated list follows:

____ (a) The managed care entity must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within the timeframes established by the state.

____ (b) The entity may extend the timeframes by up to 14 days if the enrollee requests the extension; or the entity demonstrates that there is need for additional information and how the delay is in the enrollee's interest.

____ (42) The requirements for expedited resolution of appeals in this chapter may be found in their entirety in 42 CFR 438.410. Each entity must establish and maintain an expedited review process for appeals, when the entity determines or the provider indicates that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health.

____ (43) The managed care entity must provide the information specified at 438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

____ (44) Medicaid must require, through its contracts, each entity to maintain records of grievances and appeals and must review the information as part of the state quality strategy.

____ (45) The requirements concerning continuation of benefits (while an appeal or fair hearing is pending) in this chapter may be found in their entirety in 42 CFR 438.420. The managed care entity must continue the enrollee's benefits if:

- ____ (a) The enrollee or the provider files the appeal timely.
- ____ (b) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment.
- ____ (c) The services were ordered by an authorized provider.
- ____ (d) The original period covered by the original authorization has not expired.
- ____ (e) The enrollee requests extension of benefits.

____ (46) The requirements for effectuation of reversed appeal resolutions may be found in their entirety in 42 CFR 438.424.

____ (47) The requirements concerning fair hearings in this chapter may be found in their entirety in 42 CFR 431.200, et seq., and Chapter Three of this code. The Medicaid state plan must ensure that the regulations in these sections apply when a fair hearing is requested by an enrollee.

____ (48) The requirements concerning certifications and program integrity in this chapter may be found in their entirety in 42 CFR 438.600 through 438.610. An abbreviated list follows:

- ____ (a) When state payments to a managed care entity are based on data submitted by the entity, the state must require certification of the data as provided in 438.606.
- ____ (b) The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the state.
- ____ (c) The data submitted to the state must be certified by either the entity's chief executive officer, chief financial officer, or an individual who has been delegated the authority to sign for these officers.
- ____ (d) The certification must attest to the accuracy, completeness, and truthfulness of the submitted data.
- ____ (e) The entity must have procedures that are designed to guard against fraud and abuse.
- ____ (f) The entity must have written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable state and federal standards.
- ____ (g) The entity may not knowingly have a relationship with an individual who is debarred, suspended, or otherwise excluded from participation in state or federal health care programs.

____ (49) The requirements concerning sanctions in this chapter may be found in their entirety in 42 CFR 438.700 through 438.730. An abbreviated list follows:

- ____ (a) Medicaid must establish, through its contracts with managed care entities, intermediate provider sanctions that may be imposed upon the state's findings from onsite surveys, enrollee or other complaints, financial status, or any other source.
- ____ (b) Medicaid may impose sanctions that include the following:
 - ____ (i) Civil money penalties.
 - ____ (ii) Appointment of temporary management for the entity.
 - ____ (iii) Granting enrollees the right to terminate enrollment without cause.
 - ____ (iv) Suspension of all new enrollments after the effective date of the sanction.

_____ (v) ~~Suspension of payment for recipients enrolled after the effective date of the sanction.~~

_____ (50) ~~The requirements concerning federal financial participation (FFP) in this chapter may be found in their entirety in 42 CFR 438.602 through 438.812. An abbreviated list follows:~~

_____ (a) ~~FFP is not available in an MCO contract that does not have prior approval from CMS.~~

_____ (b) ~~Under a risk contract, the total amount Medicaid pays for carrying out the contract provisions is a medical assistance cost.~~

_____ (c) ~~Under a nonrisk contract, the amount Medicaid pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and the amount paid for the contractor's performance of other functions is an administrative cost.~~

_____ (51) ~~The requirements for timely processing of claims and cost sharing in this chapter may be found in their entirety in 42 CFR 447.45 through 447.60. An abbreviated list follows:~~

_____ (a) ~~A contract with a managed care entity must provide that the entity will meet the requirements of 447.45 and abide by those specifications.~~

_____ (b) ~~The managed care entity and its providers may, by mutual agreement, establish an alternative payment schedule, which must be stipulated in their contract.~~

Author: Jerri Jackson, Director, Managed Care Division

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