MANAGED CARE REQUIREMENTS RELATED TO 42 CFR 438

I. Definitions (42 CFR 438.2)

The following definitions apply to this contract.

a. **Applicant** means a Medicaid beneficiary, or a person who is eligible to be a Medicaid beneficiary who makes an inquiry about voluntarily enrolling in the MI Choice program, or is in the process of voluntarily enrolling in the MI Choice program, but is not currently an enrollee or participant of a specific PAHP. The Michigan Department of Health and Human Services (MDHHS) also uses the term potential enrollee to describe an applicant.

b. **Capitation payment** means a payment MDHHS makes periodically to the Grantee on behalf of each participant enrolled under this contract for the provision of MI Choice services. MDHHS makes the payment regardless of whether the particular participant receives services during the period covered by the payment.

c. **Cold Call Marketing** means any unsolicited personal contact by the PAHP with a potential participant for marketing as defined in 438.104(a).

d. **Comprehensive risk contract** means a risk contract between MDHHS and the PAHP that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

   i. Outpatient hospital services.
   ii. Rural health clinic services.
   iii. FQHC services.
   iv. Other laboratory and X-ray services.
   v. Nursing facility (NF) services.
   vi. Early and periodic screening, diagnostic, and treatment (EPSDT) services.
   vii. Family planning services.
   viii. Physician services.
   ix. Home health services.

e. **Enrollee** means a Medicaid recipient currently enrolled in the PAHP in the MI Choice program. MDHHS also uses the term participant to describe an enrollee.

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

g. **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.

h. **Health insuring organization (HIO)** means a county operated entity, that in exchange for capitation payments, covers services for beneficiaries—
   i. Through payments to, or arrangements with, providers;

- **ii.** Under a comprehensive risk contract with the State; and
- **iii.** Meets the following criteria—
  1. First became operational prior to January 1, 1986; or
  2. Is described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990) and section 205 of the Medicare Improvements for Patients and Providers Act of 2008.

i. **Long-term services and supports (LTSS)** means services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

j. **Managed Care Program** means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act.

k. **Marketing** means any communication, from a PAHP to an individual who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the individual to enroll in that particular PAHP's Medicaid product, or either to not enroll in, or to disenroll from, another PAHP's Medicaid product.

l. **Marketing Materials** means materials produced in any medium, by or on behalf of a PAHP that can reasonably be interpreted as intended to market to individuals.

m. **Network Provider** means any provider, group of providers, or entity that has a network provider agreement with a PAHP, or a subcontractor, and receives Medicaid funding directly or indirectly to order, refer, or render covered services as a result of the contract between MDHHS and the PAHP. A network provider is not a subcontractor by virtue of the network provider agreement.

n. **Non-risk contract** means a contract under which the Grantee—
- **i.** Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and
- **ii.** May be reimbursed by the State at the end of the contract period based on the incurred costs, subject to the specified limits.

o. **Participant** means a Medicaid recipient currently enrolled in a PAHP in the MI Choice Waiver Program.

p. **Potential Enrollee** means a Medicaid beneficiary, or a person who is eligible to be a Medicaid beneficiary who makes an inquiry about voluntarily enrolling in the MI Choice program, or is in the process of voluntarily enrolling in the MI Choice program, but is not currently an enrollee or participant of a specific PAHP. MDHHS also uses the term applicant to describe a potential enrollee.

q. Prepaid ambulatory health plan (PAHP) means an entity that:
   i. Provides MI Choice services to enrollees under contract with MDHHS, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;
   ii. 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
   iii. Does not have a comprehensive risk contract.
   iv. For purposes of this document, the PAHP is also the Grantee.

r. Prevalent Non-English Language is one that is spoken as the primary language by more than 5% of the Grantee's enrollees.

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

t. 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 beneficiaries.

u. Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:
   i. A physician assistant.
   ii. A nurse practitioner.
   iii. A certified nurse-midwife.

v. Provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the service.

w. Risk contract means a contract between the State and the Grantee under which the Grantee
   i. Assumes risk for the cost of the services covered under the contract; and
   ii. Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

x. Subcontractor means an individual or entity that has a contract with the PAHP that relates directly or indirectly to the performance of the PAHP's obligations under its contract with MDHHS. A network provider is not a subcontractor by virtue of the network provider agreement with the PAHP.

II. Enrollment Discrimination Prohibited (42 CFR 438.3(d))

a. The PAHP accepts individuals eligible for enrollment in the order in which they apply, according to the waiting list priority categories, up to the limits set under the contract in

Attachment Q.

b. The PAHP will not, based on health status, or need for health care services, discriminate against individuals eligible to enroll.

c. The PAHP will not discriminate against individuals eligible to enroll based on race, color, national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation, gender identity, or disability.

III. Coverage of Additional Services (42 CFR 438.3(e))

The Grantee may cover, for enrollees, services in addition to those covered under the MI Choice contract as long as the Grantee voluntarily agrees to provide them, although the cost of these services cannot be included when determining the capitation payments for the MI Choice program. (This Federal requirement replaces services previously known as Gap-filling and Temporarily Ineligible Participant (TIP) services in previous contracts.)

IV. Choice of Providers (42 CFR 438.3(l))

The PAHP must allow each enrollee to choose his or her network provider to the extent possible and appropriate.

V. Record Inspection, Retention, and Audits (42 CFR 438.3(h), (u), and (m))

a. The PAHP must allow the State, CMS, the Office of Inspector General, the Comptroller General, and their designees to, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of the audit period, whichever is later.

b. The PAHP and its network providers must retain for a period of no less than ten years the following information, as applicable:

- **i.** Enrollee grievance and appeal records in 42 CFR 438.416
- **ii.** Base data in 42 CFR 438.5(c)
- **iii.** Medical Loss Ratio reports in 42 CFR 438.8(k), and
- **iv.** The data, information, and documentation specified in 42 CFR 438.604, 438.606, 438.608, and 438.610.

c. The PAHP must submit audited financial reports specific to the Medicaid contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

VI. Medical Loss Ratio (MLR) Reporting Requirements (42 CFR 438.8)

a. The PAHP must calculate and report a MLR in accordance with this section.

b. Definitions. As used in this section, the following terms have the indicated meanings:

- **i.** *Credibility adjustment* means an adjustment to the MLR for a partially credible PAHP to account for a difference between the actual and target MLRs that may be due to

random statistical variation.

ii. _Full credibility_ means a standard for which the experience of a PAHP is determined to be sufficient for the calculation of a MLR with a minimal chance that the difference between the actual and target medical loss ratio is not statistically significant. A PAHP that is assigned full credibility (or is fully credible) will not receive a credibility adjustment to its MLR.

iii. _Member months_ mean the number of months an enrollee or a group of enrollees is covered by the PAHP over a specified period, such as a year.

iv. _MLR reporting year_ means a period of 12 months consistent with the rating period selected by the State.

v. _No credibility_ means a standard for which the experience of a PAHP is determined to be insufficient for the calculation of a MLR. A PAHP that is assigned no credibility (or is non-credible) will not be measured against any MLR requirements.

vi. _Non-claims costs_ means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e.ii) of this section); expenditures on activities that improve health care quality (as defined in paragraph (e.iii) of this section); or licensing and regulatory fees, or Federal and State taxes (as defined in paragraph (f.ii) of this section).

vii. _Partial credibility_ means a standard for which the experience of a PAHP is determined to be sufficient for the calculation of a MLR but with a non-negligible chance that the difference between the actual and target medical loss ratios is statistically significant. A PAHP that is assigned partial credibility (or is partially credible) will receive a credibility adjustment to its MLR.

c. The State mandates a minimum MLR for each PAHP. The minimum MLR is equal to or higher than 85 percent and is calculated and reported for each MLR reporting year by the PAHP, consistent with this section.

d. The MLR experienced for each PAHP in an MLR reporting year is the ratio of the numerator (as defined in paragraph (e) of this section) to the denominator (as defined in paragraph (f) of this section). A MLR may be increased by a credibility adjustment, in accordance with paragraph (h) of this section.

e. Numerator

i. The numerator of a PAHP's MLR for a MLR reporting year is the sum of the PAHP's incurred claims (as defined in (e.ii) of this section); the PAHP's expenditures for activities that improve health care quality (as defined in paragraph (e.iii) of this section); and fraud prevention activities (as defined in paragraph (e.iv) of this section).

ii. Incurred claims

MANAGED CARE REQUIREMENTS RELATED TO 42 CFR 438

1. Incurred claims must include the following:

   a. Direct claims that the PAHP paid to providers (including under capitated contracts with network providers) for services or supplies covered under the contract and services meeting the requirements of §438.3(e) provided to enrollees.

   b. Unpaid claims liabilities for the MLR reporting year, including claims reported that are in the process of being adjusted or claims incurred but not reported.

   c. Withholds from payments made to network providers.

   d. Claims that are recoverable for anticipated coordination of benefits.

   e. Claims payments recoveries received as a result of subrogation.

   f. Incurred but not reported claims based on past experience, and modified to reflect current conditions, such as changes in exposure or claim frequency or severity.

   g. Changes in other claims-related reserves.

   h. Reserves for contingent benefits and the medical claim portion of lawsuits.

2. Amounts that must be deducted from incurred claims include the following:

   a. Overpayment recoveries received from network providers.

   b. Prescription drug rebates received and accrued.

3. Expenditures that must be included in incurred claims include the following:

   a. The amount of incentive and bonus payments made, or expected to be made, to network providers.

   b. The amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses. The amount of fraud reduction expenses must not include activities specified in paragraph (e.iv) of this section.

4. Amounts that must either be included in or deducted from incurred claims include, respectively, net payments or receipts related to State mandated solvency funds.

5. Amounts that must be excluded from incurred claims:

   a. Non-claims costs, as defined in paragraph (b) of this section, which include the following:

      i. Amounts paid to third party vendors for secondary network savings.

ii. Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.

iii. Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in §438.3(e) and provided to an enrollee.

iv. Fines and penalties assessed by regulatory authorities.

b. Amounts paid to the State as remittance under paragraph (j) of this section.

c. Amounts paid to network providers under to §438.6(d).

6. Incurred claims paid by one PAHP that is later assumed by another entity must be reported by the assuming PAHP for the entire MLR reporting year and no incurred claims for that MLR reporting year may be reported by the ceding PAHP.

iii. Activities that improve health care quality must be in one of the following categories:

1. A PAHP activity that meets the requirements of 45 CFR 158.150(b) (Activities that improve health care quality) and is not excluded under 45 CFR 158.150(c).

2. A PAHP activity related to any EQR-related activity as described in §438.358(b) and (c).

3. Any PAHP expenditure that is related to Health Information Technology and meaningful use, meets the requirements placed on issuers found in 45 CFR 158.151, and is not considered incurred claims, as defined in paragraph (e.ii) of this section.

iv. Fraud prevention activities. PAHP expenditures on activities related to fraud prevention as adopted for the private market at 45 CFR part 158. Expenditures under this paragraph must not include expenses for fraud reduction efforts in paragraph (e.ii.3.b) of this section.

f. Denominator

i. Required elements. The denominator of a PAHP's MLR for a MLR reporting year must equal the adjusted premium revenue. The adjusted premium revenue is the PAHP's premium revenue (as defined in paragraph (f.ii) of this section) minus the PAHP's Federal, State, and local taxes and licensing and regulatory fees (as defined in paragraph (f.iii) of this section) and is aggregated in accordance with paragraph (i) of this section.

ii. Premium revenue includes the following for the MLR reporting year:

1. State capitation payments, developed in accordance with §438.4, PAHP for all enrollees under a risk contract approved under §438.3(a), excluding payments made under §438.6(d).

2. State-developed one-time payments, for specific life events of enrollees.

3. Other payments to the PAHP approved under §438.6(b)(3).

4. Unpaid cost-sharing amounts that the PAHP could have collected from enrollees under the contract, except those amounts the PAHP can show it made a reasonable, but unsuccessful, effort to collect.

5. All changes to unearned premium reserves.

6. Net payments or receipts related to risk sharing mechanisms developed in accordance with §438.5 or §438.6.

iii. Federal, State, and local taxes, licensing and regulatory fees for the MLR reporting year include:

1. Statutory assessments to defray the operating expenses of any State or Federal department.

2. Examination fees in lieu of premium taxes as specified by State law.

3. Federal taxes and assessments allocated to PAHPs, excluding Federal income taxes on investment income and capital gains and Federal employment taxes.

4. State and local taxes and assessments including:

a. Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State or locality directly.

b. Guaranty fund assessments.

c. Assessments of State or locality industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

d. State or locality income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

e. State or locality premium taxes plus State or locality taxes based on reserves, if in lieu of premium taxes.

5. Payments made by a PAHP that are otherwise exempt from Federal income taxes, for community benefit expenditures as defined in 45 CFR 158.162(c), limited to the highest of either:

a. Three percent of earned premium; or

b. The highest premium tax rate in the State for which the report is being submitted, multiplied by the PAHP's earned premium in the State.

iv. The total amount of the denominator for a PAHP which is later assumed by another entity must be reported by the assuming PAHP for the entire MLR reporting year and no amount under this paragraph for that year may be reported by the ceding PAHP.

g. Allocation of expense

i. General requirements

1. Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.

2. Expenditures that benefit multiple contracts or populations, or contracts other than those being reported, must be reported on a pro rata basis.

ii. Methods used to allocate expenses

1. Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results.

2. Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.

3. Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.

h. Credibility adjustment

i. A PAHP may add a credibility adjustment to a calculated MLR if the MLR reporting year experience is partially credible. The credibility adjustment is added to the reported MLR calculation before calculating any remittances, if required by the State as described in paragraph (j) of this section.

ii. A PAHP may not add a credibility adjustment to a calculated MLR if the MLR reporting year experience is fully credible.

iii. If a PAHP's experience is non-credible, it is presumed to meet or exceed the MLR calculation standards in this section.

iv. On an annual basis, CMS will publish base credibility factors for PAHPs that are developed according to the following methodology:

1. CMS will use the most recently available and complete managed care encounter

data or FFS claims data, and enrollment data, reported by the states to CMS. This data may cover more than 1 year of experience.

2. CMS will calculate the credibility adjustment so that a PAHP receiving a capitation payment that is estimated to have a medical loss ratio of 85 percent would be expected to experience a loss ratio less than 85 percent 1 out of every 4 years, or 25 percent of the time.

3. The minimum number of member months necessary for a PAHP's medical loss ratio to be determined at least partially credible will be set so that the credibility adjustment would not exceed 10 percent for any partially credible PAHP. Any PAHP with enrollment less than this number of member months will be determined non-credible.

4. The minimum number of member months necessary for a PAHP's medical loss ratio to be determined fully credible will be set so that the minimum credibility adjustment for any partially credible PAHP would be greater than 1 percent. Any PAHP with enrollment greater than this number of member months will be determined to be fully credible.

5. A PAHP with a number of enrollee member months between the levels established for non-credible and fully credible plans will be deemed partially credible, and CMS will develop adjustments, using linear interpolation, based on the number of enrollee member months.

6. CMS may adjust the number of enrollee member months necessary for a PAHP's experience to be non-credible, partially credible, or fully credible so that the standards are rounded for the purposes of administrative simplification. The number of member months will be rounded to 1,000 or a different degree of rounding as appropriate to ensure that the credibility thresholds are consistent with the objectives of this regulation.

i. PAHPs will aggregate data for all Medicaid eligibility groups covered under the contract with the State unless the State requires separate reporting and a separate MLR calculation for specific populations.

j. If required by the State, a PAHP must provide a remittance for an MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 85 percent or higher if set by the State as described in paragraph (c) of this section.

k. Reporting requirements

i. MDHHS requires each PAHP to submit a report to the State that includes at least the following information for each MLR reporting year:

1. Total incurred claims.

2. Expenditures on quality improving activities.

3. Expenditures related to activities compliant with §438.608(a)(1) through (5), (7), (8) and (b).
4. Non-claims costs.
5. Premium revenue.
6. Taxes, licensing and regulatory fees.
7. Methodology(ies) for allocation of expenditures.
8. Any credibility adjustment applied.
9. The calculated MLR.
10. Any remittance owed to the State, if applicable.
11. A comparison of the information reported in this paragraph with the audited financial report required under §438.3(m).
12. A description of the aggregation method used under paragraph (i) of this section.
13. The number of member months.

ii. A PAHP must submit the report required in paragraph (k)(i) of this section within 12 months of the end of the MLR reporting year.

iii. PAHPs must require any third party vendor providing claims adjudication activities to provide all underlying data associated with MLR reporting to that PAHP within 180 days of the end of the MLR reporting year or within 30 days of being requested by the PAHP, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting.

l. MDHHS, in its discretion, may exclude a PAHP that is newly contracted with the State from the requirements in this section for the first year of the PAHP's operation. Such PAHPs will be required to comply with the requirements in this section during the next MLR reporting year in which the PAHP is in business with the State, even if the first year was not a full 12 months.

m. In any instance when MDHHS makes a retroactive change to the capitation payments for a MLR reporting year where the report has already been submitted to the State, the PAHP must re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.

n. PAHPs must attest to the accuracy of the calculation of the MLR in accordance with requirements of this section when submitting the report required under paragraph (k) of this section.

VII. Information Requirements (42 CFR 438.10)

a. Definitions. As used in this section, the following terms have the indicated meanings:

- **i.** *Limited English proficient (LEP)* means potential enrollees and enrollees who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English may be LEP and may be eligible to receive language assistance for a particular type of service, benefit, or encounter.
- **ii.** *Prevalent* means a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are LEP.
- **iii.** *Readily accessible* means electronic information and services that comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.

b. PAHPs must provide the required information in this section to each enrollee.

c. Enrollee information required in this section may not be provided electronically by the State, or PAHP unless all of the following are met:

- **i.** The format is readily accessible;
- **ii.** The information is placed in a location on the State or PAHP's Web site that is prominent and readily accessible;
- **iii.** The information is provided in an electronic form which can be electronically retained and printed;
- **iv.** The information is consistent with the content and language requirements of this section; and
- **v.** The enrollee is informed that the information is available in paper form without charge upon request and the PAHP provides it upon request within 5 business days.

d. Each PAHP must have in place mechanisms to help enrollees and potential enrollees understand the requirements and benefits of the plan.

e. Language and Format

- **i.** Each PAHP must make oral interpretation available in all languages and written translation available in each prevalent non-English language. All written materials for potential enrollees must include taglines in the prevalent non-English languages in the State, as well as large print, explaining the availability of written translations or oral interpretation to understand the information provided. Large print means printed in a font size no smaller than 18 point.
- **ii.** Each PAHP must make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, available in the prevalent non-English languages in its particular service area. Written materials must also be made available in alternative formats upon request of the potential enrollee or enrollee at no cost. Auxiliary aids and services must also be made available upon

request of the potential enrollee or enrollee at no cost. Written materials must include taglines in the prevalent non-English languages in the state, as well as large print, explaining the availability of written translation or oral interpretation to understand the information provided and the toll-free and TTY/TDY telephone number of the PAHP's member/customer service unit. Large print means printed in a font size no smaller than 18 point.

iii. Each PAHP must make interpretation services available to each potential enrollee and make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language. Oral interpretation requirements apply to all non-English languages, not just those that the State identifies as prevalent.

iv. Each PAHP must notify potential enrollees and enrollees:

1. That oral interpretation is available for any language and written translation is available in prevalent languages;

2. That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

3. How to access the services in paragraphs (e)(iv)(1) and (2) of this section.

v. Each PAHP must provide all written materials for potential enrollees and enrollees consistent with the following:

1. Use easily understood language and format.

2. Use a font size no smaller than 12 point.

3. Be available in alternative formats and through the provision of auxiliary aids and services in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

4. Include a large print tagline and information on how to request auxiliary aids and services, including the provision of the materials in alternative formats. Large print means printed in a font size no smaller than 18 point.

f. Information for potential enrollees.

i. The PAHP must provide the information specified in paragraph (f.ii) of this section to each potential enrollee, either in paper or electronic form as follows:

1. At the time the potential enrollee first becomes eligible to enroll in the MI Choice program; and

2. Within a timeframe that enables the potential enrollee to use the information in choosing among available PAHPs.

ii. The information for potential enrollees must include, at a minimum, all of the following:

1. Information about the potential enrollee's right to disenroll consistent with the requirements of §438.56 and which explains clearly the process for exercising this disenrollment right, as well as the alternatives available to the potential enrollee based on their specific circumstance;

2. The basic features of managed care;

3. Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program. For mandatory and voluntary populations, the length of the enrollment period and all disenrollment opportunities available to the enrollee must also be specified;

4. The service area covered by each PAHP;

5. Covered benefits including:

a. Which benefits are provided by the PAHP; and

b. Which, if any, benefits are provided directly by the State.

c. For a counseling or referral service that the PAHP does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service;

6. The provider directory information required in paragraphs (h) of this section;

7. The requirements for each PAHP to provide adequate access to covered services, including the network adequacy standards established in §438.68;

8. The PAHP's responsibilities for coordination of enrollee care; and

9. To the extent available, quality and performance indicators for each PAHP, including enrollee satisfaction.

g. Information for all enrollees of PAHPs:

i. The PAHP must make a good faith effort to give written notice of termination of a contracted provider, within 15 calendar days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

ii. The State must notify all enrollees of their right to disenroll consistent with the requirements of §438.56 at least annually. Such notification must clearly explain the process for exercising this disenrollment right, as well as the alternatives available to the enrollee based on their specific circumstance

h. Information for enrollees PAHPs - Enrollee handbook

i. Each PAHP must provide each enrollee an enrollee handbook, within a reasonable time after receiving notice of the beneficiary's enrollment, which serves a similar function as the summary of benefits and coverage described in 45 CFR 147.200(a).

ii. The content of the enrollee handbook must include information that enables the enrollee to understand how to use the managed care program effectively. This information must include at a minimum:

1. Benefits provided by the PAHP.

2. How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided.

a. In the case of a counseling or referral service that the PAHP does not cover because of moral or religious objections, the PAHP must inform enrollees that the service is not covered by the PAHP.

b. The PAHP must inform enrollees how they can obtain information from the State about how to access the services described in paragraph (h)(ii)(2)(a) of this section.

3. The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

4. Procedures for obtaining benefits, including any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

5. The extent to which, and how, after-hours and emergency coverage are provided, including:

a. What constitutes an emergency medical condition and emergency services.

b. The fact that prior authorization is not required for emergency services.

c. The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

6. Any restrictions on the enrollee's freedom of choice among network providers.

7. The extent to which, and how, enrollees may obtain benefits from out-of-network providers.

8. Enrollee rights and responsibilities, including the elements specified in §438.100.

9. Grievance, appeal, and fair hearing procedures and timeframes, consistent with subpart F of this part, in a State-developed or State-approved description. Such

information must include:

a. The right to file grievances and appeals.

b. The requirements and timeframes for filing a grievance or appeal.

c. The availability of assistance in the filing process.

d. The right to request a State fair hearing after PAHP has made a determination on an enrollee's appeal that is adverse to the enrollee.

e. The fact that, when requested by the enrollee, benefits that the PAHP seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing, and that the enrollee may be required to pay the cost of services furnished while the appeal or state fair hearing is pending if the final decision is adverse to the enrollee.

10. How to exercise an advance directive, as set forth in §438.3(j). For PAHPs, information must be provided only to the extent that the PAHP includes any of the providers described in §489.102(a) of this chapter.

11. How to access auxiliary aids and services, including additional information in alternative formats or languages.

12. The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees.

13. Information on how to report suspected fraud or abuse;

14. Any other content required by the State.

iii. Information required by this paragraph to be provided by a PAHP will be considered to be provided if the PAHP:

1. Mails a printed copy of the information to the enrollee's mailing address;

2. Provides the information by email after obtaining the enrollee's agreement to receive the information by email;

3. Posts the information on the Web site of the PAHP and advises the enrollee in paper or electronic form that the information is available on the Internet and includes the applicable Internet address, provided that enrollees with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or

4. Provides the information by any other method that can reasonably be expected to result in the enrollee receiving that information.

iv. The PAHP must give each enrollee notice of any change that the State defines as significant in the information specified in this paragraph (h), at least 30 days before

the intended effective date of the change.

i. Information for all enrollees of PAHPs - Provider Directory

i. Each PAHP must make available in paper form upon request and electronic form, the following information about its network providers:

1. The provider's name as well as any group affiliation.
2. Street address(es).
3. Telephone number(s).
4. Web site URL, as appropriate.
5. Specialty, as appropriate.
6. Whether the provider will accept new enrollees.
7. The provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office, and whether the provider has completed cultural competence training.
8. Whether the provider's office/facility has accommodations for people with physical disabilities, including offices, exam room(s) and equipment.

ii. The provider directory must include the information in paragraph (i)(1) of this section for each of the following provider types covered under the contract:

1. Physicians, including specialists;
2. Hospitals;
3. Pharmacies;
4. Behavioral health providers; and
5. LTSS providers, as appropriate.

iii. Information included in a paper provider directory must be updated at least monthly and electronic provider directories must be updated no later than 30 calendar days after the PAHP receives updated provider information.

iv. Provider directories must be made available on the PAHP's Web site in a machine-readable file and format as specified by the Secretary.

VIII. Disenrollment: Requirements and Limitations (42 CFR 438.56)

a. Disenrollment requested by the PAHP:

i. The PAHP may request disenrollment of a participant for reasons specified in Attachment K of this contract.

ii. The PAHP may not request disenrollment because of:
1. an adverse change in the enrollee's health status,
2. the enrollee's utilization of medical services,
3. the enrollee’s diminished mental capacity, or
4. the enrollee’s uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the PAHP seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees).

iii. The PAHP will document reasons for requesting disenrollment within the case record as specified in Attachment K of this contract. MDHHS will periodically evaluate disenrollment reasons to assure all requested disenrollments are for reasons allowed by contract.

b. Disenrollment requested by the enrollee.

i. An enrollee may request disenrollment as follows:

1. For cause, at any time.

2. Without cause, at the following times:

a. During the 90 days following the date of the beneficiary's initial enrollment into the PAHP or during the 90 days following the date the State sends the beneficiary notice of that enrollment, whichever is later.

b. At least once every 12 months thereafter.

c. Upon automatic reenrollment when a beneficiary was automatically reenrolled after a disenrollment based solely because the enrolee lost their Medicaid eligibility for a period of two months or less, if the temporary loss of Medicaid eligibility has caused the beneficiary to miss the annual disenrollment opportunity.

d. When the State imposes the intermediate sanction specified in §438.702(a)(4).

c. Procedures for disenrollment

i. The enrollee (or his or her representative) must submit an oral or written request, to the PAHP to process disenrollment requests.

ii. The following are cause for disenrollment:

1. The enrollee moves out of PAHP's service area.

2. Because of moral or religious objections, the PAHP does not cover the service the enrollee seeks.

3. The enrollee needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the provider network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

4. For enrollees that use MLTSS, the enrollee would have to change their residential, institutional, or employment supports provider based on that provider's change in status from an in-network to an out-of-network provider with the PAHP and, as a result, would experience a disruption in their residence or employment.

5. Other reasons, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's care needs.

iii. PAHP action on request.

1. The PAHP may either approve a request for disenrollment by or on behalf of an enrollee or the PAHP must refer the request to the State.

2. If the PAHP fails to make a disenrollment determination so that the enrollee can be disenrolled within the timeframes specified in paragraph (d)(i) of this section, the disenrollment is considered approved.

iv. State agency action on request.

1. For a request received directly from the enrollee, or one referred by the PAHP, the State agency must take action to approve or disapprove the request based on the following:

a. Reasons cited in the request.

b. Information provided by the PAHP at the agency's request.

c. Any of the reasons specified in paragraph (c)(ii) of this section.

v. Use of the PAHP's grievance procedures.

1. MDHHS requires that the enrollee seek redress through the PAHP's grievance system before MDHHS will make a determination on the enrollee's request.

2. The PAHP’s grievance process must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in paragraph (d)(i) of this section.

3. If, as a result of the grievance process, the PAHP approves the disenrollment,

MDHHS is not required to make a determination in accordance with paragraph (c)(iv) of this section.

d. Timeframe for disenrollment determinations.

i. Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the PAHP refers the request to the State.

ii. If the PAHP or MDHHS (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (d)(i) of this section, the disenrollment is considered approved for the effective date that would have been established had MDHHS or the PAHP complied with paragraph (d)(i) of this section.

e. Automatic reenrollment: The PAHP may reenroll a beneficiary who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less, provided the beneficiary continues to meet MI Choice program eligibility criteria.

IX. <u>Free Exercise of Rights (42 CFR 438.100(c))</u>

The Grantee must assure 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 PAHP and its providers or the State agency treat the participant.

X. <u>Anti-gag Clause (42 CFR 438.102(a))</u>

A PAHP may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of a participant who is his or her patient.

a. For the participant's health status, medical care, or treatment options, including an alternative treatment that may be self-administered.

b. For any information the participant needs in order to decide among all relevant treatment options.

c. For the risks, benefits, and consequences of treatment or non-treatment.

d. For the participant's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

XI. <u>Moral or Religious Objections (42 CFR 438.102(b))</u>

a. The PAHP may object to a service on moral or religious grounds. When the PAHP would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service but objects based on moral or religious grounds, the PAHP must furnish information about the services it does not cover as follows:

i. To the State

1. With its application for a Medicaid contract.

2. Whenever it adopts the policy during the term of the contract.

ii. Consistent with the provisions of §438.10, to enrollees, within 90 days after adopting the policy for any particular service.

iii. The PAHP must furnish the information at least 30 days before the effective date of the policy.

iv. As specified in §438.10(g)(2)(ii)(A) and (B), the PAHP must inform enrollees how they can obtain information from the State about how to access the service excluded under this section.

XII. Marketing Activities State Approval (42 CFR 438.104)

a. The Grantee must not distribute any marketing materials without first obtaining MDHHS approval. Before approving any marketing material, the Grantee will adequately assure MDHHS the content of the material is accurate and does not mislead, confuse, or defraud applicants, participants, or MDHHS.

b. Marketing materials will be closely monitored during Administrative Quality Assurance Reviews, and at any other time MDHHS staff deems appropriate.

c. The Grantee must comply with the information requirements of 438.10 to ensure that before enrollment the participant receives the accurate oral and written information he or she needs to make an informed decision on whether to enroll. Marketing materials cannot contain any assertion or statement (whether written or oral) that:

i. The participant must enroll in the PAHP in order to obtain benefits or in order not to lose benefits.

ii. That the Grantee is endorsed by CMS, the Federal or State government or similar entity.

iii. Marketing requirements must include the following:

1. That the entity distributes the materials to its entire service area as indicated in the contract.

2. That the entity does not seek to influence enrollment in conjunction with the sale or offering of any private insurance.

3. That the entity does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

XIII. Liability for Payment (42 CFR 438.106)

Each PAHP must provide that its Medicaid enrollees are not held liable for any of the following:

a. The PAHP's debts, in the event of the entity's insolvency.

b. Covered services provided to the enrollee, for which:

- **i.** The State does not pay the PAHP; or

- **ii.** The State or PAHP does not pay the individual or health care provider that furnished the services under a contractual, referral, or other arrangement.

c. Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the PAHP covered the services directly.

XIV. Member Advisory Committee (42 CFR 438.110)

The PAHP must establish and maintain a member advisory committee that is comprised of a reasonably representative sample of the PAHP's enrollees or other individuals representing those enrollees.

XV. Provider Network (42 CFR 438.206)

a. The Grantee must maintain a network of appropriate providers that is:

- **i.** Supported by written agreements

- **ii.** Sufficient to provide adequate access to all services covered under the contract

b. In establishing and maintaining the provider network, the Grantee must consider each of the following:

- **i.** The anticipated participant enrollments

- **ii.** The expected utilization of services, taking into consideration the characteristics and health care needs of the specific participants served

- **iii.** The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services

- **iv.** The number of network providers who are not accepting new Medicaid patients, and the geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

c. Each waiver agency uses an open bid process to contract with qualified providers in their service area that are willing to furnish MI Choice services. MDHHS requires each waiver agency to have a provider network with capacity to serve at least 125% of their monthly slot utilization for each MI Choice service, and at least two providers for each MI Choice service. This assures network capacity as well as choice of providers. When providers cannot assure this choice within 30 miles or 30 minutes travel time for each enrollee, they may request a rural area exception from the Department.

d. If the Grantee is unable to provide necessary medical services covered under the contract to a particular participant the Grantee must adequately and timely cover these services out of network for the participant, for as long as the Grantee is unable to provide them within the network. Since there is no cost to the participant for the Grantee's in-network services, there may be no cost to the participant for medically-necessary services provided out-of-network.

e. The Grantee shall ensure timely access to MI Choice services for each participant as specified in Attachment I of the contract, and require the same of its subcontracted providers.

f. The Grantee and its providers must offer hours of operation that are no less than the hours of operation available to non-Medicaid eligible individuals and other individuals not enrolled in the MI Choice program, but served by either the Grantee or the provider.

g. MI Choice services must be available 24 hours per day, 7 days per week when medically necessary. This requirement shall not be construed as a requirement to provide MI Choice services 24 hours per day, 7 days per week.

h. The Grantee must:

i. Establish mechanisms to ensure network providers comply with the timely access requirements specified in IX.a through IX.f above.

ii. Monitor contracted providers regularly to determine compliance.

iii. Take corrective action if there is a failure to comply with these requirements.

XVI. <u>Coordination and Continuity of Care (42 CFR 438.208)</u>

a. Each PAHP must implement procedures to deliver care to and coordinate services for all enrollees. These procedures must meet requirements defined in Attachment K of this contract and must do the following:

i. Ensure that each enrollee has an ongoing source of care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee. The enrollee must be provided information on how to contact their designated person or entity;

ii. Coordinate the services the PAHP furnishes to the enrollee:

1. Between settings of care, including appropriate discharge planning for short term and long-term hospital and institutional stays;

2. With the services the enrollee receives from any other MCO, PIHP, or PAHP;

3. With the services the enrollee receives in FFS Medicaid; and

4. With the services the enrollee receives from community and social support

providers.

iii. Share with the State or other MCOs, PIHPs, and PAHPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities;

iv. Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards; and

v. Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

b. Each PAHP must implement mechanisms to comprehensively assess each enrollee to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring as specified in Attachment K of this contract.

c. The PAHP must assist each participant with developing a person-centered service plan (PCSP) as defined in Attachment K of this contract. The PCSP must be:

i. Developed by an individual meeting LTSS service coordination requirements with enrollee participation, and in consultation with any providers caring for the enrollee:

ii. Developed by a person trained in person-centered planning using a person-centered process and plan as defined in 42 CFR 441.301(c)(1) and (2);

iii. Approved by the PAHP in a timely manner;

iv. In accordance with any applicable State quality assurance and utilization review standards; and

v. Reviewed and revised upon reassessment of functional need, at least every 12 months, or when the enrollee's circumstances or needs change significantly, or at the request of the enrollee per 42 CFR 441.301(c)(3).

XVII. Coverage and Authorization of Services (42 CFR 438.210)

a. PAHPs are required to authorize and furnish MI Choice services in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under Medicaid Fee for Service programs and options.

b. The PAHP:

i. Must ensure the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished.

ii. May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the participant.

iii. May place appropriate limits on a service on the basis of medical necessity or for the

purpose of utilization control, provided that the services furnished can reasonably achieve their purpose, and are authorized in a manner that reflects the participant's ongoing need for such services and supports.

iv. And its subcontractors have in place, and follow, written policies and procedures for the authorization of services.

v. Must have mechanisms to ensure consistent application of review criteria for authorization decisions.

vi. Must consult with the requesting provider for medical services when appropriate.

vii. Must authorize LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan.

viii. Must use individuals with appropriate expertise in addressing the participant's medical, behavioral health or LTSS needs to make decisions to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested.

c. Notice of adverse benefit determination.

i. The PAHP must notify the requesting provider, and give the enrollee written notice of any decision by the PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested.

ii. The participant's notice must meet the requirements of §438.404.

d. Each PAHP must adhere to the following timeframes for decisions and notices:

i. For standard authorization decisions, provide notice as expeditiously as the participant's condition requires, not to exceed 12 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

1. The enrollee, or the provider, requests extension; or

2. The PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

ii. Expedited authorization decisions

1. The PAHP shall make an expedited authorization decision when the standard authorization timeframe could seriously jeopardize the participant's life, health, or ability to attain, maintain, or regain maximum function as indicted by a provider or the PAHP.

2. The PAHP must make an expedited authorization decision as expeditiously as the participant's health condition requires, and no later than 72 hours after the

receipt of the request for services.

3. The PAHP may extend the 72 hour time period by up to 14 calendar days if the participant requests an extension, or if the PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the participant's interest.

e. Neither MDHHS nor the PAHP may structure compensation to individuals or entities that conduct utilization management activities to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

XVIII. Practice Guidelines (42 CFR 438.236)

a. Each PAHP shall adopt practice guidelines that meet the following requirements:

i. Are based on valid and reliable clinical evidence or a consensus of providers in the particular field.

ii. Consider the needs of the enrollees.

iii. Are adopted in consultation with contracting health care professionals.

iv. Are reviewed and updated periodically as appropriate.

b. Each PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

c. The PAHP shall ensure that decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

XIX. Quality Assessment and Performance Improvement Program (42 CFR 438.330)

a. Definitions

i. *Access*, as it pertains to external quality review, means the timely use of services to achieve optimal outcomes, as evidenced by the PAHP successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under §438.68 (Network adequacy standards) and §438.206 (Availability of services).

ii. *External quality review (EQR)* means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that a PAHP or their contractors furnish to Medicaid beneficiaries.

iii. *External quality review organization (EQRO)* means an organization that meets the competence and independence requirements set forth in §438.354, and performs EQR, other EQR-related activities as set forth in §438.358, or both.

iv. *Financial relationship means—*

1. A direct or indirect ownership or investment interest (including an option or non-

vested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means, and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

2. A compensation arrangement with an entity.

v. *Health care services* means all Medicaid services provided by a PAHP under contract with the State Medicaid agency in any setting, including but not limited to medical care, behavioral health care, and long-term services and supports.

vi. *Outcomes* mean changes in patient health, functional status, satisfaction or goal achievement that result from health care or supportive services.

vii. *Quality,* as it pertains to EQR, means the degree to which a PAHP increases the likelihood of desired outcomes of its enrollees through:

1. Its structural and operational characteristics.

2. The provision of services consistent with current professional, evidenced-based-knowledge.

3. Interventions for performance improvement.

viii. *Validation* means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

b. General rules

i. Each PAHP must establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees that includes the elements identified in paragraph (c) of this section.

ii. The PAHP must modify its quality improvement plan if CMS specifies performance measures and performance improvement projects (PIPs) to include in the standard measures identified and PIPs required by the State in accordance with paragraphs (d) and (e) of this section.

c. Basic elements of quality assessment and performance improvement programs. The comprehensive quality assessment and performance improvement program described in paragraph (b) of this section must include at least the following elements:

i. Performance improvement projects in accordance with paragraph (e) of this section.

ii. Collection and submission of performance measurement data in accordance with paragraph (d) of this section.

iii. Mechanisms to detect both underutilization and overutilization of services.

iv. Mechanisms to assess the quality and appropriateness of care furnished to

enrollees using LTSS, including assessment of care between care settings and a comparison of services and supports received with those set forth in the enrollee's treatment/service plan; and

v. Participate in efforts to prevent, detect, and remediate critical incidents (consistent with assuring enrollee health and welfare per §§441.302 and 441.730(a) of this chapter) that are based, at a minimum, on the requirements on the State for home and community-based waiver programs per §441.302(h) of this chapter.

d. The PAHP must include in its quality management plan, the standard performance measures identified by CMS and MDHHS.

i. These performance measures will include measures relating to qualify of life, rebalancing, and community integration activities for MI Choice participants.

ii. Annually, the PAHP will measure and report to MDHHS its performance using the standard measures required by CMS and MDHHS.

e. Performance improvement projects.

i. Each PAHP will conduct performance improvement projects, including those required by CMS in accordance with paragraph (b)(ii) of this section, that focus on both clinical and nonclinical areas.

ii. Each performance improvement project must be designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction, and must include the following elements:

1. Measurement of performance using objective quality indicators.

2. Implementation of interventions to achieve improvement in the access to and quality of care.

3. Evaluation of the effectiveness of the interventions based on the performance measures in paragraph (e)(ii)(1) of this section.

4. Planning and initiation of activities for increasing or sustaining improvement.

iii. MDHHS requires each PAHP to report the status and results of each project conducted per paragraph (e)(i) of this section annually.

XX. State Review of the Accreditation Status of the PAHP (42 CFR 438.332)

a. Each PAHP shall inform MDHHS whether it has been accredited by a private independent accrediting entity.

b. Each PAHP that has received accreditation by a private independent accrediting entity must authorize the private independent accrediting entity to provide MDHHS a copy of its most recent accreditation review, including:

i. Accreditation status, survey type, and level (as applicable);

ii. Accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings; and

iii. Expiration date of the accreditation.

XXI. <u>Grievance and Appeal System, Statutory basis, definitions, and applicability (42 CFR 438.400)</u>

a. Statutory basis. This subpart is based on the following statutory sections:

i. Section 1902(a)(3) of the Act requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

ii. Section 1902(a)(4) of the Act requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

iii. Section 1932(b)(4) of the Act requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

b. Definitions. As used in this subpart, the following terms have the indicated meanings:

i. *Adverse benefit determination* means any of the following:

1. The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit.

2. The reduction, suspension, or termination of a previously authorized service.

3. The denial, in whole or in part, of payment for a service.

4. The failure to provide services in a timely manner.

5. The failure of the PAHP to act within the timeframes provided in §438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals.

6. For a resident of an area with only on PAHP, the denial of an enrollee's request to exercise his or her right, under §438.52(b)(2)(ii), to obtain services outside the network.

7. The denial of an enrollee's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other enrollee financial liabilities.

ii. *Appeal* means a review by a PAHP of an adverse benefit determination.

iii. *Grievance* means an expression of dissatisfaction about any matter other than an adverse benefit determination. Grievances may include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights regardless of whether remedial action is requested. Grievance includes an enrollee's right to dispute an extension of time proposed by the PAHP to make an authorization decision.

iv. *Grievance and appeal system* means the processes the PAHP implements to handle appeals of an adverse benefit determination and grievances, as well as the processes to collect and track information about them.

v. *State fair hearing* means the process set forth in subpart E of part 431 of this chapter.

XXII. Grievance and Appeal System, General Requirements (42 CFR 438.402)

a. Each PAHP must have a grievance and appeal system in place for enrollees.

b. Each PAHP may have only one level of appeal for enrollees.

c. Filing requirements

i. Authority to file

1. An enrollee may file a grievance and request an appeal with the PAHP. An enrollee may request a State fair hearing after receiving notice under §438.408 that the adverse benefit determination is upheld.

a. Deemed exhaustion of appeals processes. In the case of a PAHP that fails to adhere to the notice and timing requirements in §438.408, the enrollee is deemed to have exhausted the PAHP's appeals process. The enrollee may initiate a State fair hearing.

b. External medical review. The State may offer and arrange for an external medical review if the following conditions are met.

i. The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

ii. The review must be independent of both the State and PAHP.

iii. The review must be offered without any cost to the enrollee.

iv. The review must not extend any of the timeframes specified in §438.408 and must not disrupt the continuation of benefits in §438.420.

2. With the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair

hearing, on behalf of an enrollee. When the term “enrollee” is used throughout this section, it includes providers and authorized representatives consistent with this paragraph, with the exception that providers cannot request continuation of benefits as specified in §438.420(b)(5).

ii. Timing

1. Grievance. An enrollee may file a grievance with the PAHP **at any time**.

2. Appeal. Following receipt of a notification of an adverse benefit determination by the PAHP, an enrollee has **60 calendar days** from the date on the adverse benefit determination notice to file a request for an appeal to the PAHP.

iii. Procedures

1. Grievance. The enrollee may file a grievance either orally or in writing with the PAHP.

2. Appeal. The enrollee may request an appeal either orally or in writing. Further, unless the enrollee requests an expedited resolution, an oral appeal must be followed by a written, signed appeal.

XXIII. Grievance and Appeal System, Timely and Adequate Notice of Adverse Benefit Determination (42 CFR 438.404)

a. The PAHP must give enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below and in §438.10.

b. The notice must explain the following:

i. The adverse benefit determination the PAHP has made or intends to make.

ii. The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

iii. The enrollee's right to request an appeal of the adverse benefit determination, including information on exhausting the PAHP's one level of appeal described at §438.402(b) and the right to request a State fair hearing consistent with §438.402(c).

iv. The procedures for exercising the rights specified in this paragraph (b).

v. The circumstances under which an appeal process can be expedited and how to request it.

vi. The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances, under which the

enrollee may be required to pay the costs of these services.

c. The PAHP must mail the notice within the following timeframes:

i. For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the following timeframes:

1. **Advance notice.** The PAHP must send a notice at least 10 days before the date of action, except as permitted under (c)(i)(2) and (c)(i)(3).

2. **Exceptions from advance notice.** The PAHP may send a notice not later than the date of action if

a. The agency has factual information confirming the death of an enrollee;

b. The agency receives a clear written statement signed by an enrollee that:

i. He or she no longer wishes services; or

ii. Gives information that requires termination or reduction of services and indicates that he or she understands that this must be the result of supplying that information;

iii. The enrollee has been admitted to an institution where he is ineligible under the plan for further services;

iv. The enrollee's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address;

v. The agency establishes the fact that the enrollee has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth;

vi. A change in the level of medical care is prescribed by the enrollee’s physician;

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

viii. The date of action will occur in less than 10 days.

c. **Notice in cases of probable fraud.** The agency may shorten the period of advance notice to 5 days before the date of action if:

i. The agency has facts indicating that action should be taken because of probable fraud by the enrollee; and

ii. The facts have been verified, if possible, through secondary sources.

ii. For denial of payment, at the time of any action affecting the claim.

iii. For standard service authorization decisions that deny or limit services, within the timeframe specified in §438.210(d)(1).

iv. If the PAHP meets the criteria set forth for extending the timeframe for standard service authorization decisions consistent with §438.210(d)(1)(ii), it must:

1. Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

2. Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

v. For service authorization decisions not reached within the timeframes specified in §438.210(d) (which constitutes a denial and is thus an adverse benefit determination), on the date that the timeframes expire.

vi. For expedited service authorization decisions, within the timeframes specified in §438.210(d)(2).

XXIV. Grievance and Appeal System, Handling of Grievances and Appeals (42 CFR 438.406)

a. In handling grievances and appeals, each PAHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

b. A PAHP's process for handling enrollee grievances and appeals of adverse benefit determinations must:

i. Acknowledge receipt of each grievance and appeal.

ii. Ensure that the individuals who make decisions on grievances and appeals are individuals:

1. Who were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

2. Who, if deciding any of the following, are individuals who have the appropriate clinical expertise in treating the enrollee's condition or disease:

a. An appeal of a denial that is based on lack of medical necessity.

b. A grievance regarding denial of expedited resolution of an appeal.

c. A grievance or appeal that involves clinical issues.

3. Who take into account all comments, documents, records, and other information

submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination.

iii. Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

iv. Provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments. The PAHP must inform the enrollee of the limited time available for this sufficiently in advance of the resolution timeframe for appeals as specified in §438.408(b) and (c) in the case of expedited resolution.

v. Provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the PAHP (or at the direction of the PAHP) in connection with the appeal of the adverse benefit determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in §438.408(b) and (c).

vi. Include, as parties to the appeal

1. The enrollee and his or her representative; or

2. The legal representative of a deceased enrollee's estate.

XXV. Grievance and Appeal System, Resolution and Notification (42 CFR 438.408)

a. Each PAHP must resolve each grievance and appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within the timeframes specified in this section.

b. Specific timeframes

i. Standard resolution of grievances. For standard resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the PAHP receives the grievance.

ii. Standard resolution of appeals. For standard resolution of an appeal and notice to the affected parties no longer than 30 calendar days from the day the PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

iii. Expedited resolution of appeals. For expedited resolution of an appeal and notice to affected parties, no longer than 72 hours after the PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

c. Extension of timeframes.

i. The PAHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if

1. The enrollee requests the extension; or

2. The PAHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

ii. Requirements following extension. If the PAHP extends the timeframes not at the request of the enrollee, it must complete all of the following:

1. Make reasonable efforts to give the enrollee prompt oral notice of the delay.

2. Within 2 calendar days give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision.

3. Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

iii. Deemed exhaustion of appeals processes. In the case of a PAHP that fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the PAHP's appeals process. The enrollee may initiate a State fair hearing.

d. Format of notice

i. Grievances. The PAHP will use the state-established method to notify an enrollee of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at §438.10.

ii. Appeals.

1. For all appeals, the PAHP must provide written notice of resolution in a format and language that, at a minimum, meet the standards described at §438.10.

2. For notice of an expedited resolution, the PAHP must also make reasonable efforts to provide oral notice.

e. Content of notice of appeal resolution. The written notice of the resolution must include the following:

i. The results of the resolution process and the date it was completed.

ii. For appeals not resolved wholly in favor of the enrollees

1. The right to request a State fair hearing and how to do so.

2. The right to request and receive benefits while the hearing is pending, and how to make the request.

3. That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the PAHP's adverse benefit determination.

f. Requirements for State fair hearings

i. Availability. An enrollee may request a State fair hearing only after receiving notice that the PAHP is upholding the adverse benefit determination.

1. Deemed exhaustion of appeals processes. In the case of a PAHP that fails to adhere to the notice and timing requirements in §438.408, the enrollee is deemed to have exhausted the PAHP's appeals process. The enrollee may initiate a State fair hearing.

2. External medical review. The State may offer and arrange for an external medical review if the following conditions are met.

a. The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

b. The review must be independent of both the State and PAHP.

c. The review must be offered without any cost to the enrollee.

d. The review must not extend any of the timeframes specified in §438.408 and must not disrupt the continuation of benefits in §438.420.

ii. The enrollee must request a State fair hearing no later than 120 calendar days from the date of the PAHP's notice of resolution.

iii. The parties to the State fair hearing include the PAHP, as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

XXVI. Grievance and Appeal System, Expedited Resolution of Appeals (42 CFR 438.410)

a. Each PAHP must establish and maintain an expedited review process for appeals, when the PAHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

b. The PAHP must ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

c. Action following denial of a request for expedited resolution. If the PAHP denies a request for expedited resolution of an appeal, it must

i. Transfer the appeal to the timeframe for standard resolution in accordance with §438.408(b)(2).

ii. Follow the requirements in §438.408(c)(2).

XXVII. Grievance and Appeal System, Information to Providers and Subcontractors (42 CFR 438.414)

The PAHP must provide information specified in §438.10(g)(2)(xi) about the grievance and appeal system to all providers and subcontractors at the time they enter into a contract.

XXVIII. Grievance and Appeal System, Recordkeeping Requirements (42 CFR 416)

a. The PAHPs must maintain records of grievances and appeals and must review the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

b. The record of each grievance or appeal must contain, at a minimum, all of the following information:

- **i.** A general description of the reason for the appeal or grievance.
- **ii.** The date received.
- **iii.** The date of each review or, if applicable, review meeting.
- **iv.** Resolution at each level of the appeal or grievance, if applicable.
- **v.** Date of resolution at each level, if applicable.
- **vi.** Name of the covered person for whom the appeal or grievance was filed.

c. The record must be accurately maintained in a manner accessible to the state and available upon request to CMS.

XXIX. Grievance and Appeal System, Continuation of Benefits (42 CFR 438.420)

a. Definition. As used in this section *Timely files* means files for continuation of benefits on or before the later of the following:

- **i.** Within 10 calendar days of the PAHP sending the notice of adverse benefit determination.
- **ii.** The intended effective date of the PAHP's proposed adverse benefit determination.

b. The PAHP must continue the enrollee's benefits if all of the following occur:

- **i.** The enrollee files the request for an appeal timely in accordance with §438.402(c)(1)(ii) and (c)(2)(ii);
- **ii.** The appeal involves the termination, suspension, or reduction of previously authorized services;
- **iii.** The services were ordered by an authorized provider;

iv. The period covered by the original authorization has not expired; and

v. The enrollee timely files for continuation of benefits.

c. Duration of continued or reinstated benefits. If, at the enrollee's request, the PAHP continues or reinstates the enrollee's benefits while the appeal or state fair hearing is pending, the benefits must be continued until one of following occurs:

i. The enrollee withdraws the appeal or request for state fair hearing.

ii. The enrollee fails to request a state fair hearing and continuation of benefits within 10 calendar days after the PAHP sends the notice of an adverse resolution to the enrollee's appeal under §438.408(d)(2).

iii. A State fair hearing office issues a hearing decision adverse to the enrollee.

d. Enrollee responsibility for services furnished while the appeal or state fair hearing is pending. If the final resolution of the appeal or state fair hearing is adverse to the enrollee, that is, upholds the PAHP's adverse benefit determination, the PAHP may recover the cost of services furnished to the enrollee while the appeal and state fair hearing was pending, to the extent that they were furnished solely because of the requirements of this section.

XXX. Grievance and Appeal System, Effectuation of Reversed Appeal Resolutions (42 CFR 438.424)

a. Services not furnished while the appeal is pending. If the PAHP or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

b. Services furnished while the appeal is pending. If the PAHP or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the PAHP must pay for those services.

XXXI. Program Integrity Requirements (42 CFR 438.608)

a. Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse. The PAHP must implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:

i. A compliance program that includes, at a minimum, all of the following elements:

1. Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and State requirements.

2. The designation of a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance

with the requirements of the contract and who reports directly to the Chief Executive Officer and the board of directors.

3. The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.

4. A system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.

5. Effective lines of communication between the compliance officer and the organization's employees.

6. Enforcement of standards through well-publicized disciplinary guidelines.

7. Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract.

ii. Provision for prompt reporting of all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.

iii. Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including all of the following:

1. Changes in the enrollee's residence;

2. The death of an enrollee.

iv. Provision for notification to the State when it receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the PAHP.

v. Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis.

vi. In the case of PAHPs that make or receive annual payments under the contract of at least $5,000,000, provision for written policies for all employees of the entity, and of any contractor or agent, that provide detailed information about the False Claims Act

and other Federal and State laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers.

vii. Provision for the prompt referral of any potential fraud, waste, or abuse that the PAHP identifies to the MDHHS Office of Inspector General.

viii. Provision for the PAHP's suspension of payments to a network provider for which the State determines there is a credible allegation of fraud in accordance with §455.23 of this chapter.

b. Disclosures. Each PAHP and any subcontractors must:

i. Provide written disclosure of any prohibited affiliation under §438.610.

ii. Provide written disclosures of information on ownership and control required under §455.104 of this chapter.

iii. Report to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the contract.

c. Treatment of recoveries made by the PAHP of overpayments to providers.

i. When the PAHP recovers payments to providers:

1. The PAHP may retain the recovered overpayment including those based upon fraud, waste or abuse.

2. The PAHP must adjust encounter data related to the recovered funds appropriately within CHAMPS within 30 days of receiving the recovered funds.

3. The PAHP must report to MDHHS all capitation payments affected by the recovered funds within 30 days of receiving the recovered funds.

4. This provision does not apply to any amount of a recovery to be retained under False Claims Act cases or through other investigations.

ii. Each PAHP must have mechanism for a network provider to report to the PAHP when it has received an overpayment, to return the overpayment to the PAHP within 60 calendar days after the date on which the overpayment was identified, and to notify the PAHP in writing of the reason for the overpayment.

iii. Each PAHP must report annually to the State on their recoveries of overpayments.

XXXII. Prohibited Affiliations (42 CFR 438.610)

a. A PAHP may not knowingly have a relationship of the type described in paragraph (c) of this section with the following:

i. An individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in non-procurement activities under regulations issued under

Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

ii. An individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation at 48 CFR 2.101, of a person described in paragraph (a)(1) of this section.

b. A PAHP may not have a relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Act.

c. The relationships described in paragraph (a) of this section, are as follows:

i. A director, officer, or partner of the PAHP.

ii. A subcontractor of the PAHP, as governed by §438.230.

iii. A person with beneficial ownership of 5 percent or more of the PAHP's equity.

iv. A network provider or person with an employment, consulting or other arrangement with the PAHP entity for the provision of items and services that are significant and material to the PAHP's obligations under this contract.

d. If a State finds that a PAHP is not in compliance with paragraphs (a) and (b) of this section, the State:

i. Must notify the Secretary of the noncompliance.

ii. May continue an existing agreement with the PAHP unless the Secretary directs otherwise.

iii. May not renew or otherwise extend the duration of an existing agreement with the PAHP unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliations.

iv. Nothing in this section must be construed to limit or otherwise affect any remedies available to the U.S. under sections 1128, 1128A or 1128B of the Act.

e. Consultation with the Inspector General. Any action by the Secretary described in paragraphs (d)(2) or (3) of this section is taken in consultation with the Inspector General.

XXXIII. Fraud and Abuse Reporting

The PAHP must report fraud and abuse information to the State. PAHPs must report the following to the State:

a. Number of complaints of fraud and abuse made to State that warrant preliminary investigation.

b. For each complaint that warrants investigation, supply the:

i. Name, ID number

- **ii.** Source of complaint
- **iii.** Type of provider
- **iv.** Nature of complaint
- **v.** Approximate dollars involved, and
- **vi.** Legal and administrative disposition of the case.