# ATTACHMENT B

## Compliance Determination Activities for Individual Regulatory Provisions

The preceding protocol showed how documents should be reviewed and interviews should be conducted in order to address multiple regulatory provisions. This appendix contains the same document review and potential interview questions as the protocol, but displays them according to the individual regulatory provision or provisions they are intended to address. For each regulatory provision or group of provisions, the information is presented as follows:

1. Regulatory provisions are presented first in shaded boxes like this.
2. Information to be obtained (as needed) from the State Medicaid agency,
3. Documents for potential review, and
4. Potential interview questions of MCO/PIHP personnel.

Gaps in the numbering of the regulations reflect the inclusion of only those subpart C, D and F regulations that specify requirements that MCOs or PIHPs must meet.

In certain instances, this attachment also includes notes to reviewers to help understand the intent and interpretation of individual document review or interview activities.

# Subpart C - Enrollee Rights and Protections

## §438.100 Enrollee rights.

**(a)** ***General rule.*** The State must ensure that--

**(1)** Each MCO and each PIHP has written policies regarding the enrollee rights specified in this section; and

**(2)** Each MCO, PIHP, . . . complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take into account those rights when furnishing services to enrollees.

**(b)** ***Specific rights.***

**(1)** ***Basic requirement.*** The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraph (b)(2) and (b)(3) of this section.

**(2)** An enrollee of an MCO, PIHP, . . . has the following rights: The right to--

**(i)** Receive information in accordance with 438.10. ***(Section 438.10 is stated below.)***

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## §438.10 Information requirements.

**(a)** ***Terminology.*** As used in this section, the following terms have the indicated meanings:

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

*Enrollee* means a Medicaid recipient who is currently enrolled in a MCO, PIHP. . . in a given managed care program.

**(b)** ***Basic rule.*** Each . . . MCO, PIHP, . . . must provide all enrollment notices, informational materials, and instructional materials relating to enrollees and potential enrollees in a manner and format that may be easily understood.

**(c)** ***Language.*** The State must:

**(1)** Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. "Prevalent" means a non-English language spoken by a significant number or percentage of potential enrollees and enrollees in the State.

**(2)** [This paragraph contains a requirement for the State, not the MCO/PIHP.]

**(3)** Require each MCO, PIHP, . . . to make its written information available in the prevalent, non-English languages in its particular service area.

**(4)** . . require each MCO, PIHP, . . . to make those services [i.e., oral interpretation services] available free of charge to the each potential enrollee and enrollee. This applies to all non-English languages, not just those the State identifies as prevalent.

**(5)** . . . require each MCO, PIHP, . . . to notify its enrollees--

**(i)** That oral interpretation is available for any language and written information is available in prevalent languages; and

**(ii)** How to access those services.

**(d)** ***Format.***

**(1)** Written material must--

**(i)** Use easily understood language and format;

**(ii)** Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

**(2)** All enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats.

**(e)** ***Information for potential enrollees.*** **[The requirements of this paragraph pertain to the State Medicaid agency or its contracted representative, not to MCOs or PIHPs.]**

**(f)** ***General information for all enrollees of MCOs, PIHPs, . . .*** Information must be made available to MCO, PIHP, . . . enrollees as follows:

**(1)** [Requirement pertains to State, not to MCOs or PIHPs.]

**(2)** The State, its contracted representative, or the MCO, PIHP, . . . must notify all enrollees of their right to request and obtain the information listed in paragraph (f)(6) of this section, (and (g) of this section if applicable) at least once a year.

**(3)** The State, its contracted representative, or the MCO, PIHP, . . . must furnish to each of its enrollees the information listed in paragraph (f)(6) of this section, (and (g) of this section if applicable) within a reasonable time after the MCO, PIHP, . . . receives, from the State or its contracted representative, notice of the recipient's enrollment.

**(4)** The MCO, PIHP, . . . must give each enrollee written notice of any change (that the State defines as "significant") in the information specified in paragraph (f)(6) of this section, (and section (g) of this section if applicable) at least 30 days before the intended effective date of the change.

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

**(6)** The following information must also be provide to all enrollees:

**(i)** Names, locations, telephone numbers of, and non-English languages spoken by current network providers in the enrollee's service area, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

**(ii)** Any restrictions on the enrollee's freedom of choice among network providers.

[Note: Related provisions addressing the free choice of providers for family planning services are included herein.]

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**431.51 Free choice of providers**

**(a)** Statutory basis**.** * * *

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

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

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

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**(iii)** Enrollee rights and responsibilities, as specified in §438.100

**(iv)** Information on grievance and fair hearing procedures, and . . .the information specified in §438.10(g)(i)

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

**(vi)** Procedures for obtaining benefits, including authorization requirements.

**(vii)** The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.

**(viii)** The extent to which, and how, after-hours and emergency coverage are provided, including**:**

**(A)** What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in §438.114 (a). (***Section 438.114 definitions listed below.***)

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**438.114 Emergency and post-stabilization services**

**(a)** ***Definitions.*** As used in this section--

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

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

(2) Serious impairment to bodily functions; or

(3) Serious dysfunction of any bodily organ or part.

*Emergency services* means covered inpatient and outpatient services that are--

(1) Furnished by a provider qualified to furnish emergency services; and

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

*Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

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**(B)** The fact that prior authorization is not required for emergency services.

**(C)** The process and procedures for obtaining emergency services, including use of the 911-telephone system or its local equivalent.

**(D)** The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and post-stabilization services covered under the contract.

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

**(ix)** The post-stabilization care service rules set forth at 422.113(c) of this chapter. ***(Section 422.113(c) is stated below.)***

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**422.113(c) Maintenance care and post-stabilization care services.**

**(1)** Definition. [This is the same as shown above.]

**(2)** M+C organization financial responsibility. The M+C organization—

**(i)** Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the M+C organization that re pre-approved by a plan provider or other M+C organization representative;

**(ii)** Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization care services;

**(iii)** Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

**(A)** The M+C organization does not respond to a request for pre-approval within 1hour;

**(B)** The M+C organization cannot be contacted; or

**(C)** The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the M+C organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue care of the patient until a plan physician is reached or one of the criteria in § 422.113(c)(3) is met; and

**(iv)** Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the M+C organization.

**(3)** End of M+C organization's financial responsibility. The M+C organization's financial responsibility for post-stabilization care services it has not approved ends when—

**(i)** A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

**(ii)** A plan physician assumes responsibility for the enrollee's care through transfer;

**(iii)** An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or

**(iv)** The enrollee is discharged.

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**(x)** Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

**(xi)** Cost sharing, if any.

**(xii)** How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost-sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP… does not cover because of moral or religious objections, the MCO, PIHP. . . need not furnish information on how and where to obtain the service. The State must furnish information about how and where to obtain the service.

**(g)** ***Specific Information Requirements for enrollees of MCOs and PIHPs.*** In addition to the requirements in §438.10(c), MCOs and PIHPs must provide the following information to their enrollees:

**(1)** Grievance, appeal, and fair hearing procedures and time frames, as provided in §§438.400 through 438.424, in a State-developed or State-approved description, that must include:

**(i)** For State fair hearing--

**(A)** The right to hearing;

**(B)** The method for obtaining a hearing; and

**(C)** The rules that govern representation at the hearing.

**(ii)** The right to file grievances and appeals.

**(iii)** The requirements and timeframes for filing a grievance or appeal.

**(iv)** The availability of assistance in the filing process.

**(v)** The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

**(vi)** The fact that, when requested by the enrollee--

**(A)** Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the time frames specified for filing; and

**(B)** The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

**(vii)** Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

**(2)** Advance Directives, as set forth in § 438.6(i)(2) of this chapter. **[Compliance with requirements for advance directives are addressed as part of the provisions of § 438.100(b)(2)(iv) pertaining to enroll participation in treatment decisions.]**

**(3)** Additional information that is available upon request, including:

**(i)** Information on the structure and operation of the MCO or PIHP.

**(ii)** Physician incentive plans as set forth in § 438.6(h) of this chapter. [Section 438.6(h) is included below.]

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**438.6 Contract requirements**

**(h) Physician incentive plans. (1) MCO, PIHP… must provide for compliance with the requirements ser forth in §§ 422.208 and 422.210 of this chapter.**

**(2) In applying the provsions of §§ 422.208 and 422.210 of this chapter, references to "M+C organization", "CMS", and "Medicare beneficiaries" must be read as references to "MCO, PIHP…", "State agency", and "Medicaid recipients", respectively.**

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**(i)** ***Special rules: States with mandatory enrollment under State plan authority--***

**(1)** ***Basic rule.*** If the State plan provides for mandatory enrollment under § 438.50, the State or its contracted representative must provide information on MCOs, and PCCMs (as specified in paragraph (i)(3) of this section), either directly or through the MCO or PCCM.

**(2)** ***When and how the information must be furnished.*** The information must be furnished as follows:

**(i)** For potential enrollees, at the time the potential enrollee is first required to enroll in a mandatory enrollment program.

**(ii)** For enrollees, annually and upon request.

**(iii)** In a comparative, chart-like format.

**(3)*Required* information**. Some of the information is the same as the information required for potential enrollees under paragraph (e) of this section and for enrollees under paragraph (f) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (i)(2) of this section, and includes the following for each contracting MCO. . .

**(i)** The MCO's. . . service area.

**(ii)** The benefits covered under the contract.

**(iii)** Any cost sharing imposed by the MCO . . .

**[Note: Related provisions addressing cost sharing are included herein.]**

**438.106 Liability for payment**
Each MCO, PIHP …must provide that its Medicaid enrollees are not held liable for any of the following:
(a) The MCO's, PIHP's …debts, in the event of the entity's insolvency.
(b) Covered services provided to the enrollee, for which—
(1) The State does not pay the MCO, PIHP… or
(2) The State, or the MCO, PIHP …does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.
(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO, PIHP… provided the services directly.

**438.108 Cost sharing**
The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

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**(iv)** To the extent available, quality and performance indicators, including enrollee satisfaction.

***Information to be obtained from the State:*** Obtain from the State Medicaid agency information on:

1) the language(s) that State Medicaid agency has determined are prevalent in the MCO's/PIHP's geographic service area.
2) any requirements the State has issued to the MCO/PIHP specifying a standard for the reading level of written materials prepared for Medicaid enrollees;
3) the State's decision about whether or not the MCO is to notify all enrollees at least once a year of their right to request and obtain the information listed in paragraph (f)(6) and paragraph (g);
4) the State's decision about whether the MCO is to furnish to each of its Medicaid enrollees the information listed in paragraph (f)(6) and paragraph (g) within a reasonable time after the MCO/ PIHP receives, from the State or its contracted representative, notice of the recipient's enrollment;
5) information on how the State has defined a "significant change" in the information MCOs and PIHPs are required to give enrollees pursuant to §438.10(f) and (g).
6) whether or not the MCO/PIHP is part of a State managed care initiative that employs mandatory enrollment of beneficiaries in the MCO or PIHP under 1932(a)(1)(A) of the Act. If the MCO/PIHP is part of such a mandatory enrollment managed care initiative, obtain information from the State on the State's decision about whether the State or the MCO is to provide potential enrollees with the information contained in §438.10(i).
7) IF the MCO/PIHP is part of a mandatory managed care initiative in the State AND IF the State had directed the MCO to provide comparative information on disenrollment as part of a chart-like comparison of MCOs, and PIHPs, obtain the State Medicaid agency's definition of "disenrollment rate."

8) whether or not the State agency has chosen to give providers the right to challenge the failure of an MCO or PIHP to cover a contracted service.
9) any applicable State laws pertaining to enrollee rights.

***Document Review:***

- If the MCO/PIHP is part of a mandatory managed care initiative in the State AND IF the State has directed the MCO to do so, (see #6 and #7 in *"Information to be obtained from the State*," above) review a copy of the MCO's/PIHP's marketing policies and procedures and other administrative policies and procedures. Determine the extent to which the MCO/PIHP has policies and procedures for providing, in a comparative, chart-like format that facilitates comparison of MCOs and PIHPs, information on: 1) the MCO's/PIHP's service area, 2) benefits covered under the Medicaid contract, 3) any cost sharing imposed by the MCO/PIHP, and 4) to the extent available, quality and performance indicators for the MCO/PIHP, including, but not limited to, disenrollment rates (as defined by the State), and enrollee satisfaction.

- If the State has directed the MCO/PIHP to notify all enrollees at least once a year of their right to request and obtain the information listed in paragraph (f)(6) and paragraph (g), review printed materials and any other media used by the MCO/PIHP to communicate to enrollees their rights. For example, enrollee rights should be located in enrollee handbooks, new enrollee information packets or marketing materials. There may also be separate communications to enrollees on their rights. Review a copy of the MCO's/PIHP's statement of enrollee rights (for either Medicaid enrollees or all MCO/PIHP enrollees). Determine the extent to which the MCO/PIHP has policies and procedures for notifying these enrollees, at least once a year, of their right to request and obtain the following information:
  - Names, locations, telephone numbers of, and non-English languages spoken by current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.
  - Any restrictions on the enrollee's freedom of choice among network providers, except family planning services.
  - Enrollee rights and responsibilities, as specified in §438.100.
  - Information on grievance, appeal, and fair hearing procedures and time frames, including:
    (i) For State fair hearing--
      (A) The right to hearing;
      (B) The method for obtaining a hearing; and
      (C) The rules that govern representation at the hearing.
    (ii) The right to file grievances and appeals.
    (iii) The requirements and time frames for filing a grievance or appeal.
    (iv) The availability of assistance in the filing process.
    (v) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

(vi) The fact that, when requested by the enrollee--

(A)Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the time frames specified for filing; and

(B) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(vii) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

- 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.
- Procedures for obtaining benefits, including authorization requirements.
- The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.
- The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in §438.114 (a). [Section 438.114 definitions listed below:]

**********

**438.114 Emergency and post-stabilization services**

**(a)** *Definitions.* As used in this section--

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

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

**(2)** Serious impairment to bodily functions.

**(3)** Serious dysfunction of any bodily organ or part.

*Emergency services* means covered inpatient or outpatient services that are as follows:

**(1)** Furnished by a provider qualified to furnish emergency services.

**(2)** Needed to evaluate or stabilize an emergency medical condition.

*Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

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(B) The fact that prior authorization is not required for emergency services.

(C) The process and procedures for obtaining emergency services, including use of the 911-telephone system or its local equivalent.

(D) The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and post-stabilization services covered under the contract.

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

- The post-stabilization care service rules set forth at § 422.113(c) of this chapter. [Section 422.113(c) is stated below.]

**********

**422.113(c) Maintenance care and post-stabilization care services.**

**(1)** Definition. [This is the same as shown above.]

**(2)** M+C organization financial responsibility. The M+C organization—

**(i)** Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the M+C organization that re pre-approved by a plan provider or other M+C organization representative;

**(ii)** Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization care services;

**(iii)** Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

**(A)** The M+C organization does not respond to a request for pre-approval within 1hour;

**(B)** The M+C organization cannot be contacted; or

**(C)** The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the M+C organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue care of the patient until a plan physician is reached or one of the criteria in § 422.113(c)(3) is met; and

**(iv)** Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the M+C organization.

**(3)** End of M+C organization's financial responsibility. The M+C organization's financial responsibility for post-stabilization care services it has not approved ends when—

**(i)** A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

**(ii)** A plan physician assumes responsibility for the enrollee's care through transfer;

**(iii)** An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or

**(iv)** The enrollee is discharged.

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- Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.
- Cost sharing, if any, except services may not be denied for an inability to pay the cost sharing.
- How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost-sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP… does not cover because of moral or religious objections, the MCO, PIHP, . . . need not furnish information on how and where to obtain the service. The State must furnish information about how and where to obtain the service.
- adult enrollees with written information on advance directives policies, and include a description of applicable State law.
- information on physician incentive plans
- additional information available upon request, including information on the structure and operation of the MCO or PIHP.

- If the State has required the MCO/PIHP to <u>furnish</u> to each of its Medicaid enrollees the information listed in paragraph (f)(6) and paragraph (g) within a reasonable time after the MCO/ PIHP receives, from the State or its contracted representative, notice of the recipient's enrollment, review the content of the following documents to determine the extent to which the MCO/PIHP has communicated the information below:
  - Enrollee handbooks,
  - Enrollee identification cards,
  - Marketing materials,
  - New enrollee orientation materials and curriculum,
  - Periodic and annual enrollee communications, and
  - Enrollee rights and responsibilities statements, if separate and distinct from the five previously noted documents.

**[*Note to reviewers:* The information need not be present in all these documents, but must be present in some combination of these or similar documents in such as way that guarantees that the information found in §438.10(f)(6) and (g) has been communicated to all Medicaid enrollees within a reasonable time after the MCO/PIHP receives notification of the Medicaid beneficiaries' enrollment in the MCO/PIHP.]**

  - Names, locations, telephone numbers of, and non-English languages spoken by current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.
  - Any restrictions on the enrollee's freedom of choice among network providers.
  - Enrollee rights and responsibilities, as specified in §438.100.

- Information on grievance, appeal, and fair hearing procedures and time frames, including:
  (i) For State fair hearing--
    (A) The right to hearing;
    (B) The method for obtaining a hearing; and
    (C) The rules that govern representation at the hearing.
  (ii) The right to file grievances and appeals.
  (iii) The requirements and time frames for filing a grievance or appeal.
  (iv) The availability of assistance in the filing process.
  (v) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.
  (vi) The fact that, when requested by the enrollee--
    (A)Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the time frames specified for filing; and
    (B) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.
  (vii) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.
- 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.
- Procedures for obtaining benefits, including authorization requirements.
- The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.
- The extent to which, and how, after-hours and emergency coverage are provided, including:
  (A) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in §438.114 (a).[Section 438.114 definitions listed below:]

**********

**438.114 Emergency and post-stabilization services**

**(a)** *Definitions.* As used in this section--

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

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

**(2)** Serious impairment to bodily functions.

**(3)** Serious dysfunction of any bodily organ or part.

*Emergency services* means covered inpatient or outpatient services that are as follows:

**(1)** Furnished by a provider qualified to furnish emergency services.

**(2)** Needed to evaluate or stabilize an emergency medical condition.

*Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

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(B) The fact that prior authorization is not required for emergency services.

(C) The process and procedures for obtaining emergency services, including use of the 911-telephone system or its local equivalent.

(D) The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and post-stabilization services covered under the contract.

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

- The post-stabilization care service rules set forth at 422.113(c) of this chapter. [Section 422.113(c) is stated below.]

**********

**422.113(c) Maintenance care and post-stabilization care services.**

**(1)** Definition. [This is the same as shown above.]

**(2)** M+C organization financial responsibility. The M+C organization—

**(i)** Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the M+C organization that re pre-approved by a plan provider or other M+C organization representative;

**(ii)** Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization care services;

**(iii)** Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

**(A)** The M+C organization does not respond to a request for pre-approval within 1hour;

**(B)** The M+C organization cannot be contacted; or

**(C)** The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the M+C organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue care of the patient until a plan physician is reached or one of the criteria in § 422.113(c)(3) is met; and

**(iv)** Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the M+C organization.

**(3)** End of M+C organization's financial responsibility. The M+C organization's financial responsibility for post-stabilization care services it has not approved ends when—

**(i)** A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

**(ii)** A plan physician assumes responsibility for the enrollee's care through transfer;

**(iii)** An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or

**(iv)** The enrollee is discharged.

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- Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.
- Cost sharing, if any.
- How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP… does not cover because of moral or religious objections, the MCO, PIHP… need not furnish information on how and where to obtain the service. The State must furnish information about how and where to obtain the service.
- adult enrollees with written information on advance directives policies, and include a description of applicable State law.
- information on physician incentive plans
- additional information available upon request, including information on the structure and operation of the MCO or PIHP.

Also determine the extent to which the above information:

- is available in the languages that predominate in the MCO enrollment areas;
- is written in easily understood language and printed in easily understood format; and
- is available in alternative formats that accommodate individuals who are visually impaired or have other special needs

- Review results of data collection and analysis conducted by the MCO to monitor complaints, grievances, or requests to change providers, to conduct enrollee surveys, or other MCO/PIHP sources of enrollee information to assess the extent to which they detect violations of any of the above enrollee rights.

- If the MCO/PHP has been directed to furnish the information in §438.10(f)(6) and (g) to enrollees, review enrollee communications policies and procedures to determine the extent to which the MCO/PIHP plans for and disseminates the information: 1) within a reasonable time after the MCO/PIHP is notified of the enrollee's enrollment; 2) upon

request; and 3) annually as a notification of enrollees' right to request and obtain information from the MCO/PIHP.

- Review marketing, enrollment and other informational and instructional materials relating to enrollment, enrollee handbooks, new enrollee materials, statements of enrollee rights, and other written materials routinely prepared for Medicaid enrollees and potential enrollees. Determine the extent to which:
    - materials are likely to be understandable to enrollees at a fourth-grade reading level (or at another level determined by the State Medicaid agency - See #2 in "*Information to be obtained from the State Medicaid agency,"* above);
    - materials are printed in a easy-to-read font (such as 14 point), with frequent headings, and short, simple explanations of key concepts;
    -technical or legal language is avoided whenever possible;
    - materials are available in the language(s) that have been identified as the prevalent language(s) for the MCO's/PIHP's particular service area;
    - basic enrollee information is also available in alternative formats (e.g., large print, Braille formats or recorded cassettes) for individuals with limited reading proficiency or visual impairment; and
    - there are mechanisms to inform enrollees and potential enrollees about how to obtain oral interpreter services free of charge if they have limited proficiency in English.

- Review the MCO's/PIHP's enrollee services and health care management polices and procedures to determine the extent to which the MCO/PIHP makes interpreter services available free of charge, including the use of sign interpreters for persons with hearing impairments and use of Braille for persons with impaired vision. Look for a list of oral interpreter services and other accommodations (such as teletypewriter or TTY communications for enrollee services) that are available to individuals whose primary language is not English or who are hearing or visually impaired. Determine the extent to which:
    - oral interpretation services are available free of charge to meet the needs of all Medicaid enrollees.
    - the MCO/PIHP provides instructions to its enrollees and potential enrollees on how to obtain information in the appropriate language and how to access interpreter services.

- Review enrollee handbooks, new enrollee materials, statements of enrollee rights, and other written materials routinely prepared for Medicaid enrollees. Determine the extent to which:
    - materials are available in at least the language(s) that the Sate has determined predominate in the MCO's/PIHP's service area; and
    - basic enrollee information is also available in alternative formats (i.e., large print, Braille formats or recorded) as indicated.

- Review the MCO's/PIHP's enrollee services and health care management polices and procedures to determine the extent to which the MCO/PIHP has provisions to
  - give each enrollee written notice of any change (that the State defines as "significant") in the information specified in paragraph (f)(6) of this section, at least 30 days before the intended effective date of the change.
  - must make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

- Review provider network materials, such as contracts, procedure manuals, performance expectations, oversight procedures and tools, to determine the extent to which the MCO/PIHP informs affiliated providers of their obligations to comply with enrollee rights (including enrollee rights to information) when rendering care and services to enrollees

- Review provider and staff orientation materials and manuals and continuing education curricula, and other human resources policies and procedures to determine the extent to which the MCO:
  - has polices and practices in place to assist persons with limited-English proficiency including providing sufficient access to proficient interpreters, and dissemination of written policies on the use of interpreters;
  - provides information to providers on how to access oral interpreter services.

***Potential Interview Questions:***

Interview enrollee services staff, provider/contractor services staff and (optionally) providers/contractors to: 1) confirm that the MCO/PIHP is effectively implementing policies and procedures to effectively communicate with enrollees about their rights, and in particular their rights to information, and 2) supplement what has been learned through document review. Potential questions to ask during interviews with these individuals or groups include:

MCO/PIHP Leadership

1. What information is your MCO/PIHP required to disseminate to Medicaid enrollees? How often is your MCO/PIHP required to make this information available?

2. How does your MCO/PIHP give each enrollee written notice of any change (that the State defines as "significant") in the information specified above, at least 30 days before the intended effective date of the change? How does the State define "significant?" Have you made any such "significant" changes in the last year?

3. How does your MCO/PIHP give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who receives his or her primary care from, or is seen on a regular basis by, the terminated provider? Have you terminated the contract of any providers in the last year?

4. How do you ensure that your staff and affiliated providers comply with Federal and State laws that pertain to enrollee rights?

Enrollee Services Staff

1. What information is routinely provided to Medicaid enrollees? What is the process for disseminating information to new and existing enrollees? How often is information distributed to existing enrollees? In what format is this information presented?

2. Describe or provide copies of the formats in which information is presented to enrollees.

3. In what languages or alternative formats are enrollee materials and information presented? How was it determined that materials were needed in different languages?

4. Does the MCO/PIHP need written materials in alternative formats for the visually impaired? How did the MCO/PIHP determine this?

5. Describe the procedure for handling calls to the MCO/PIHP from non-English speaking enrollees. What instruction or guidance is available for providers that may need interpretation assistance to provide care and services to assigned enrollees?

6. To what extent is the MCO/PIHP responsible for responding to requests for information for potential Medicaid enrollees?

7. How does the MCO/PIHP inform enrollees (and potential enrollees, if applicable) about how to obtain oral interpreter services if they have limited proficiency in English?

8. Are there any benefits that an enrollee is entitled to under the Medicaid program, but that are not made available through the MCO contract? What are those benefits? How are enrollees made aware of the Medicaid program benefits that are outside the scope of services available through the MCO?

9. How does the MCO/PIHP ascertain the primary language spoken by individual Medicaid enrollees?

10. Are enrollees provided with a listing of primary care providers? Does the listing include providers' non-English language capabilities?

11. Does your MCO/PIHP give written notice of termination of a contracted provider to enrollees who receive primary care from, or are seen on a regular basis by, the terminated providers? How is this accomplished? Have you had to make any such notifications in the last year?

12. Does your MCO/PIHP give enrollees any notice of significant changes change in the information specified above? When and how does this occur? Have you had to make any such notifications in the last year?

13. Does your MCO/PIHP give enrollees any anotice of significant changes in the information specified above? When and how does this occur? Have you had to make any such notifications in the last year?

Provider/Contractor Services Staff (individual and institutional)

1. How does the MCO/PIHP inform its individual and institutional providers about enrollee rights and responsibilities? How does the MCO/PIHP monitor for compliance with these rights by its providers?

2. To what extent, if any, does the MCO/PIHP supply providers with information on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCO/PIHP?

3. Does the MCO/PIHP require providers to have access to oral interpreter services? Does the MCO/PIHP supply providers with guidance or assistance in accessing oral interpreter services if necessary?

Providers/Contractors **(OPTIONAL)**

1. When the MCO's/PIHP's enrollees present for services, do they appear to have a clear understanding of their rights and responsibilities? Their benefits? How to obtain services?

2. Does the MCO/PIHP provide you with information on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCO/PIHP?

3. How often do you and your staff have to assist enrollees with understanding the materials provided by the MCO/PIHP?

4. Does the MCO/PIHP require providers to have access to oral interpreter services? Does the MCO/PIHP provide your office with guidance or assistance is accessing interpreter services if necessary?

## §438.100 Enrollee rights (cont.)

**(a)** ***General rule.*** The State must ensure that--

**(1)** Each MCO and each PIHP has written policies regarding the enrollee rights specified in this section; and

**(2)** Each MCO, PIHP, . . . complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take into account those rights when furnishing services to enrollees.

**(b)** ***Specific rights.***

**(1)** ***Basic requirement.*** The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraph (b)(2) and (b)(3) of this section.

**(2)** An enrollee of an MCO, PIHP, . . . has the following rights: The right to--

**(ii)** Be treated with respect and with due consideration for his or her dignity and privacy;

***Document Review:***

- Review and MCO/PIHP statement(s) of enrollee rights and determine the extent to which it contains a right to be treated with respect, dignity, and consideration for enrollee privacy.

- Review staff and provider orientation, education, and training curricula and materials; and other provider and staff communication tools and methods identified by the MCO staff to determine the extent to which these documents address how staff and providers are to treat all enrollees with respect, dignity and consideration for enrollee privacy.

- Review data collection and analysis tools used by the MCO to monitor complaints, grievances, or requests to change providers, and to conduct enrollee surveys, to assess the extent to which they explicitly include provisions that address respect, dignity and enrollee privacy.

- Review credentialing and recredentialing policies and procedures to determine the extent to which the MCO's credentialing and recredentialing of health care professionals include site visits to offices and facilities. If so, do policies and procedures for conducting site visits include a general assessment of the privacy of examining rooms and other protections of patients privacy; e.g., places that enrollees can be interviewed about medical, financial or other issues without being overheard by other patients?

***Potential Interview Questions:***

Organization Leaders

1. How does the MCO/PIHP ensure that its own facilities and those of its affiliated providers comply with enrollee rights such as: treatment with respect, dignity and consideration for privacy, confidentiality of information? Provide examples.
2. What processes are in place to ensure that staff observe the MCO's/PIHP's policies and procedures on privacy and confidentiality of enrollee information?

3. What does the MCO/PIHP do to raise staff awareness of its policies on nondiscriminatory behavior towards enrollees? How are staff monitored to determine that they comply with these policies?

Provider/Contractor Services Staff (individual and institutional)

1. How does the MCO/PIHP ensure that its own facilities and those of its affiliated providers comply with enrollee rights to treatment with respect, dignity and consideration for privacy? Provide examples.

2. How does the MCO/PIHP ensure that enrollees are not discriminated against in its own facilities and those of its affiliated providers when seeking health care services consistent with their covered benefits?

3. Describe the MCO's/PIHP's credentialing and oversight process for primary care providers, other health care professionals and institutional providers. What is encompassed by reviews and evaluations of these providers? Do these processes involve visits to the providers' care delivery sites?

Enrollee Services Staff

1. How does the MCO/PIHP ensure that its own facilities and those of its affiliated providers comply with enrollee rights to treatment with respect, dignity and consideration for privacy? Provide examples.

## §438.100 Enrollee rights (cont.)

**(a)** ***General rule.*** The State must ensure that--

**(1)** Each MCO and each PIHP has written policies regarding the enrollee rights specified in this section; and

**(2)** Each MCO, PIHP, . . . complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take into account those rights when furnishing services to enrollees.

**(b)** ***Specific rights.***

**(1)** ***Basic requirement.*** The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraph (b)(2) and (b)(3) of this section.

**(2)** An enrollee of an MCO, PIHP, . . . has the following rights: The right to--

**(iii)** Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in §438.10(f)(6)(xii).)

***Note to reviewers:*** See related § 438.102 and its exception clause, below:

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## §438.102 Provider-enrollee communications

**(a)** ***General rules.***

**(1)** An MCO, PIHP. . . may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

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

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

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

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

**(2)** Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP… that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, . . . objects to the service on moral or religious grounds.

**(b)** ***Information requirements: MCO, PIHP. . . responsibility.***

**(1)** An MCO, PIHP…that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

**(i)** To the State--

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

**(ii)** Consistent with the provisions of § 438.10--

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO, PIHP . . . to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(f)(4) requires the MCO, PIHP,. . . to furnish the information at least 30 days before the effective date of the policy.)

**(2)** As specified in § 438.10(e) and (f), the information that MCOs, PIHPs, . . must furnish to enrollees does not include how and where to obtain the service excluded under paragraph (a)(2) of this section.

**(c)** ***Information requirements: State responsibility.*** [This paragraph contains State requirements; not MCO/PIHP requirements.]

**(d)** ***Sanction.*** [This paragraph contains State requirements; not MCO/PIHP requirements.]

***Information to be obtained from the State:*** Obtain from the State Medicaid agency information on whether or not the MCO/PIHP has documented to the State any moral or religious objection

to providing, reimbursing for, or providing coverage of, a counseling or referral service for a particular Medicaid service or services.

***Document Review:***

- If the MCO/PIHP has identified to the State Medicaid agency any moral or religious objection to providing, reimbursing for, or providing coverage of, a counseling or referral service for a particular service or services (See information to be obtained from the State, above), determine the extent to which the MCO/PIHP:
  - informs potential enrollees of this, before and during enrollment; and
  - informs enrollees within 90 days after adopting any such policy change.

- Review new member packets, statement of enrollee rights, and other member information materials to determine the extent to which the MCO/PIHP informs all Medicaid enrollees of their right to receive information on available treatment options and alternatives in a manner appropriate to the enrollee's condition and ability to understand.

- Review provider orientation, education, and training curricula and materials; and other provider communication tools and methods identified by the MCO staff to determine the extent to which these documents address Medicaid enrollees' right to receive information on available treatment options and alternatives in a manner appropriate to the enrollee's condition and ability to understand.

- Review provider orientation, education, and training curricula and materials; and other provider communication tools and methods identified by the MCO staff to determine the extent to which these documents clearly state that the provider may, without any constraint from the MCO/PIHP, advise or advocate on behalf of an enrollee who is his or her patient, for the following:
  - The enrollee's health status, medical care or treatment options, including any alternative treatment that may be self-administered.
  - Any information the enrollee needs in order to decide among all relevant treatment options.
  - The risks, benefits, and consequences of treatment or non-treatment.
  - The enrollee's right to participate in decisions regarding his or her halth care, including the right to refuse treatment, and to express preferences about future treatment decisions.

- Review the MCO's/PIHP's standard contracts with providers to determine the extent to which the contracts place limits on a provider's ability to counsel or advise a Medicaid enrollee about:
  - The enrollee's health status, medical care or treatment options, including any alternative treatment that may be self-administered.
  - Any information the enrollee needs in order to decide among all relevant treatment options.
  - The risks, benefits, and consequences of treatment or non-treatment.

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

(Such contract provisions would not be allowed unless the MCO/PIHP has cited a moral or religious objection to counseling for a particular service or services and has provided written information to the State Medicaid agency on this - See information to be obtained from the State, above).

***Potential Interview Questions:***

Organization Leaders

1. Does your MCO/PIHP have any moral or religious objection to providing, reimbursing for, or providing coverage of, a counseling or referral service for a particular Medicaid service or services? If so, how do you inform potential enrollees and current enrollees of this?

2. How does the MCO/PIHP ensure that providers share information on available treatment options and alternatives with enrollees? Does this include alternatives and options that are outside, as well as within, the Medicaid contract's scope of benefits?

3. What steps does the MCO/PIHP take to ensure that enrollees receive information on available treatment options and alternatives *in a manner appropriate to their condition and ability to understand?*

Provider/Contractor Services Staff

1. Are providers encouraged to share information on available treatment options and alternatives with enrollees? If so, what methods are used?

2. What processes are in place for monitoring providers to determine that they are providing information on available treatment options and alternatives?

Providers/Contractors **(OPTIONAL)**

1. Does the MCO/PIHP place any limits on your ability to counsel or advise a Medicaid enrollee on treatment options that may be appropriate for the enrollee's condition or disease?

2. Does the MCO encourage providers to share with enrollees information on available treatment options and alternatives? Does this include options and alternatives that are within as well as those outside the scope of the enrollees' benefits? If so, how does the MCO/PIHP do this?

**(a)** ***General rule.*** The State must ensure that--

**(1)** Each MCO and each PIHP has written policies regarding the enrollee rights specified in this section; and

**(2)** Each MCO, PIHP, . . . complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take into account those rights when furnishing services to enrollees.

**(b)** ***Specific rights.***

**(1)** ***Basic requirement.*** The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraph (b)(2) and (b)(3) of this section.

**(2)** An enrollee of an MCO, PIHP, . . . has the following rights: The right to--

**(iv)** Participate in decisions regarding his or her health care, including the right to refuse treatment.

**(v)** Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

**Note: Section 438.10(g)(2) requires that MCO and PIHP enrollees receive information on advance directives. Because of the relationship of advance directives to decisions regarding health care, these provisions are discussed in this section.**

438.10(g) states that, ". . .MCOs and PIHPs must provide to their enrollees, information on (2) Advance directives, as set forth in §438.6(i)(2)."

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**438.6(i)Advance directives.**

(1) All MCO and PIHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures with respect to advance directives. ***(Note: Section* 422.128(a) *requires that each organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in Subpart I of part 489 of this chapter. Subpart I of part 489.102 (d) requires adherence to § 417.436 requirements which are stated below.)***

**(2)** The MCO or PIHP must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

**(3)** The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

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**417.436(d)** ***Advance directives.*** (1) An HMO or CMP must maintain written policies and procedures concerning advance directives, as defined in § 489.100 of this chapter[1], with respect to all adult individuals receiving medical care by or through the HMO or CMP and are required to:

[1] Section 489.100 states, "*Advance directive* means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated."

(i) Provide written information to those individuals concerning-

(A) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individuals option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law; and

(B) The HMO's or CMP's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the HMO or CMP cannot implement an advance directive as a matter of conscience. At a minimum, this statement should:

*(1)* Clarify any differences between-institution wide conscience objections and those that may be raised by individual physicians;

*(2)* Identify the state legal authority permitting such objection; and

*(3)* Describe the range of medical conditions or procedures affected by the conscience objection.

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the HMO or CMP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(iii) Document in the individual's medical record whether or not the individual has executed an advance directive;

(iv) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(v) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives;

(vi) Provide for the education of staff concerning its policies and procedures on advance directives; and

(vii) Provide for community education regarding advance directives that may include material required in paragraph (d)(1)(i)(A) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the HMO or CMP. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment,

and describe applicable State law concerning advance directives. An HMO or CMP must be able to document its community education efforts.

(2) The HMO or CMP - (i) Is not required to provide care that conflicts with an advance directive.

(ii) Is not required to implement an advance directive if, as a matter of conscience, the HMO or CMP cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(3) The HMO or CMP must inform individuals that complaints concerning non-compliance with the advance directive may be filed with the State survey and certification agency.

***Information to be obtained from the State:***

1) a written description of any State law(s) concerning advance directives. The written description may include information from State statutes on advance directives, regulations that implement the statutory provisions, opinions rendered by State courts and other States administrative directives. **[*Note to reviewers:* Each State Medicaid agency is required under Federal regulations at CFR 431.20 to develop such a description of State laws and to distribute it to all MCOs. Revisions to this description as a result of changes in State law are to be sent to MCOs no later than 60 days from the effective date of the change in State law.]**

2) information on whether or not the MCO/PIHP has documented to the State any moral or religious objection to fulfilling the regulatory provisions pertaining to advance directives.

***Document Review:***

- Review enrollee orientation/new member materials, enrollee handbooks, statement of enrollee rights, and other member information materials and communications to enrollees, such as newsletters or brochures; to determine the extent to which the MCO/PIHP:
  - informs all Medicaid enrollees of their right to participate in decisions regarding their health care, including the right to refuse treatment;
  - informs all Medicaid enrollees of their right to be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation;
  - at the time of each enrollee's initial enrollment, provides adult enrollees with written information on advance directives policies, including: their rights under State law to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individuals option, advance directives.
  - at the time of each enrollee's initial enrollment, if there is any limitation on the MCO's or PIHP's ability (as a matter of conscience) to implement advance directives, provides enrollees with a clear and concise statement of any such limitations, including:
    *(1)* Specification of any differences between-institution wide conscience objections and those that may be raised by individual physicians;
    *(2)* Identification of the state legal authority permitting such objection; and
    *(3)* Description of the range of medical conditions or procedures affected by the conscience objection.

- informs individuals that complaints concerning non-compliance with the advance directive may be filed with the State survey and certification agency.

- Review the HMO's/PIHP's written policies and procedures concerning advance directives and determine the extent to which they contain provisions that:
  - require documentation in each adult enrollee's medical record whether or not the individual has executed an advance directive;
  - protect against the provision of care conditioned upon execution of an advance directive or discrimination against an individual based on whether or not the individual has executed an advance directive.
  - address situations in which an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive. Determine the extent to which the MCOs'/PIHP's polices and procedures for advance directives in such situations provide:
    - that the MCO or PIHP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law.
    - for follow-up procedures to ensure that the information is given to the individual directly at the appropriate time; i.e., once he or she is no longer incapacitated or unable to receive such information. **[*Note to reviewers:* The MCO continues to have an obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information.]**
  - limit the MCO/PIHP from implementing the advance directive requirements as a matter of conscience. If such a limitation is present, determine the extent to which there is a clear and precise statement of the limitation, including at a minimum:
    - any differences between-institution wide conscience objections and those that may be raised by individual physicians;
    - the state legal authority permitting such objection; and
    - the range of medical conditions or procedures affected by the conscience objection.
  - reflect and ensure compliance with the requirements of State law.

- Review provider and staff documents including:
  - staff handbooks (for enrollee services, utilization management, and provider services in particular);
  - provider contracts and manuals;
  - practice guidelines and utilization management guidelines;
  - medical record-keeping policies and procedures; and
  - provider organization policy reviews or audits, to assess the extent to which the MCO/PIHP has taken steps to ensure that staff and providers are informed of and act in accord with the enrollees' right to participate in his or her own health care and advance directives.

- Review staff handbooks (enrollee services, utilization management, providers services), provider contracts and manuals; provider and staff orientation and education curriculum and assess the extent to which the MCO/PIHP educates its staff concerning policies and procedures on advance directives.

- Review documentation of the MCO's/PIHP's community education initiatives regarding advance directives. **[*Note to reviewers:* An HMO or PIHP must be able to document its community education efforts. However, community education may be implemented by the MCO/PIHP by itself or in concert with other providers or entities. Further, the same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives.]**

***Potential Interview Questions:***

Organization Leaders

1. To what extent does the MCO/PIHP allow enrollees to participate in care and treatment decisions? Describe.

2. Does the MCO have any limitations in implementing State and Federal laws pertaining to advance directives? If so, what are these?

Provider/Contractor Services Staff

1. What requirements does the MCO/PIHP have for providers/contractors relative to enrollee advance directives? How is it determined that providers/contractors are meeting the MCO's/PIHP's requirements?

Case Managers/Care Coordinators

1. To what extent does the MCO/PIHP allow enrollees to participate in care and treatment decisions? Describe some of the ways in which this is accomplished.

Enrollee Services Staff

1. To what extent does the MCO/PIHP allow enrollees to participate in care and treatment decisions? Describe some of the ways in which this is accomplished.

2. To what extent are Medicaid enrollees informed at the time of enrollment of their right to accept or refuse treatment and to execute an advance directive and the MCO's/PIHP's policies on implementation of that right?

## §438.100 Enrollee rights (cont.)

**(a)** ***General rule.*** The State must ensure that--

**(1)** Each MCO and each PIHP has written policies regarding the enrollee rights specified in this section; and

**(2)** Each MCO, PIHP, . . . complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take into account those rights when furnishing services to enrollees.

**(b)** ***Specific rights.***

**(1)** ***Basic requirement.*** The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraph (b)(2) and (b)(3) of this section.

**(3)** An enrollee of an MCO, PIHP also has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.

**[*Note to reviewers:* Compliance with this provision will be determined in part by the compliance determination activities for §§438.206 through 438.210. In addition, the following document review and interviewing activities are additionally specified for relevant sections of §§438.206 through 438.210 that pertain to MCO/PIHP responsibilities for having written policies regarding the enrollee rights specified in this section and ensuring that its staff and affiliated providers take into account those rights when furnishing services to enrollees.]**

***Document Review:***

- Review printed materials and any other media used by the MCO/PIHP to communicate to enrollees their rights or other guarantees of service delivery to Medicaid enrollees; e.g., enrollee handbooks, new enrollee information packets or marketing materials, or separate communications to enrollees on their rights. Determine the extent to which there are written provisions addressing the right of Medicaid enrollees to have:
  - (For females) direct access to a women's health specialist within the MCO's/PIHP's network for women's routine and preventive health care services as well as a primary care provider (438.206(b)(2)).
  - A second opinion from a qualified health care professional within the network, or outside the network, if necessary, at no cost to the enrollee (438.206(b)(3)).
  - Services available 24 hours per day, seven days a week, when medically necessary (438.206(c)(1)(iii)).
  - Provider hours of operation that are as good as those offered to commercial enrollees (438.206(c)(1)(ii)).
  - Timely access to care and member services in accordance with State standards (taking into account the urgency of the need for services) (438.206(c)(1)).
  - An identification of those with special health care need (438.208(c)(1)).
  - (For individuals with special health care needs ):
  - an assessment of their need for a course of treatment or regular care monitoring (438.208(c)(2);
  - direct access to a specialist as appropriate for the enrollee's condition and identified needs, if there is determined to be a special condition that requires a course of treatment or regular care monitoring) (438.208(c)(4)).

- An ongoing source of primary care appropriate to their needs (438.208 (b)(1)).
- A person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee (438.208 (b)(1)).
- Coordination of the services the MCO/PIHP provides with services the enrollee receives from other MCOs or PIHPs (438.208 (b)(2)).
- Appropriate and confidential exchange of information among providers.
- Written notice of any decision by the MCO or PIHP to deny a service authorization request, or to authorize a service in an amount, duration or scope less than requested (438.210 (c)).
- Notice of service authorization decisions as expeditiously as the enrollee's health condition requires and within a State-established timeframes that that may not exceed 14 calendar days after receipt of a request for service, or may not be later than 3 working days if the provider indicates or the MCO/PIHP determines that following the ordinary timeframes could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function, with possible extensions of up to 14 days if requested by the enrollee or the MCO/PIHP (MCOs/PIHPs must justify the request for extension to the State Medicaid agency upon request) (438.210(d)).

- Review staff and provider orientation, education, and training curricula and materials; and other provider and staff communication tools and methods identified by the MCO staff to determine the extent to which these documents address how staff and affiliated providers are to take into account each of the above rights when furnishing services to enrollees.

- Review results of data collection and analysis conducted by the MCO to monitor complaints, grievances, or requests to change providers, to conduct enrollee surveys, or other MCO/PIHP sources of enrollee information to assess the extent to which they detect violations of any of the above enrollee rights.

***Potential Interview Questions:***

Enrollee Services Staff

1. How does the MCO/PIHP monitor for compliance with enrollee rights to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional? What are the most recent results of this monitoring?

Provider/Contractor Services Staff (individual and institutional)

1. How does the MCO/PIHP inform its individual and institutional providers about enrollee rights to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional? How does the MCO/PIHP monitor for compliance with these rights by its providers?

## §438.100 Enrollee rights (cont.)

**(a)** ***General rule.*** The State must ensure that--

**(1)** Each MCO and each PIHP has written policies regarding the enrollee rights specified in this section; and

**(2)** Each MCO, PIHP, . . . complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take into account those rights when furnishing services to enrollees.

**(b)** ***Specific rights.***

**(1)** ***Basic requirement.*** The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraph (b)(2) and (b)(3) of this section.

**(2)** An enrollee of an MCO, PIHP also has the right to--

**(vi)** Request and receive a copy of his or her medical records, and to request that they be amended or corrected, as specified in 45 CFR § 164.524 and 164.526.

***Note to reviewers:*** **The Office of Civil Rights (OCR) within the Department of Health and Human Services is charged with enforcement of the confidentiality requirements of 45 CFR parts 160 and 164. As a result, compliance with these provisions will not be addressed in this protocol.**

***Document Review:***

- Review new member information packets, any statement of enrollee rights, and other member information materials to determine the extent to which the MCO informs all Medicaid enrollees, in writing, of their right to request and receive a copy of their medical records, and to request that they be amended or corrected.

- Review enrollee services policies and procedures, enrollee handbooks, statements of enrollee rights or other forms of enrollee communications to determine the extent to which the MCO/PIHP has written policies and procedures through which an enrollee can request and receive a copy of his or her medical records, and to request that they be amended or corrected.

- Review provider contracts and procedure manuals to determine the extent to which the MCO/PIHP informs providers about, and has procedures in place to enforce, enrollee rights to request and receive a copy of their medical records, and to request that they be amended or corrected.

***Potential Interview Questions:***

Enrollee Services Staff

1. How do enrollees obtain access to their medical records maintained by the MCO/PIHP, including records maintained by providers/contractors from whom the enrollee has received services?

2. How are enrollees informed of their right to request and receive a copy of their medical records, and to request that they be amended or corrected?

3. Has the MCO/PIHP received any complaints about an enrollee's inability to timely access their medical records? If yes, what was the volume and nature of the complaints? How were they resolved?

Provider/Contractor Services Staff

1. How are the MCO's/PIHP's network providers informed of enrollees' right to request and receive a copy of their medical records, and to request that they be amended or corrected?

## §438.100 Enrollee rights (cont.)

**438.100(d)** ***Compliance with other Federal and State laws.*** The State must ensure that each MCO, PIHP,. . . complies with any other applicable Federal or State laws (such as: the Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and Titles II and III of the Americans with Disabilities Act; and other laws regarding privacy and confidentiality.

*Note to reviewers:* **Many Federal laws (including some of those cited above) are enforced by agencies other than CMS or State agencies. However, to the extent feasible and appropriate, assessment of compliance should be addressed as a part of compliance monitoring. For example, site visits to individual practitioners' offices can include a general assessment of physical accessibility.**

***Information to be obtained from the State:*** Obtain from the State Medicaid agency the identification of all State laws that pertain to enrollee rights and with which the State Medicaid agency requires its MCOs to comply.

***Document Review:***

- Review the MCO's/PIHP's standard contracts with providers or a sample of provider contracts to ascertain if the contracts require compliance with Federal and State laws specified by the State.

- Review the MCO's/PIHP's credentialing and recredentialing policies and procedures to determine if site visits to individual provider's offices are conducted. If site visits are conducted, do they include a general assessment of physical accessibility? Review the criteria the MCO/PIHP uses to determine its network of institutional providers. Do the MCO's/PIHP's policies and procedures for network affiliates include requirements for physical accessibility of facilities?

- Review the MCO's/PIHP's written administrative policies, provider contracts and manuals, and staff handbooks, to assess the extent to which the MCO acknowledges its responsibilities to comply with applicable Federal and State laws. A review of these documents should look for the presence of statements citing the MCO's/PIHP's intent to comply with the specific Federal and State laws identified by the State, such as: 1)Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; 2) Section 504 of the Rehabilitation Act of 1973; 3) the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; 4) Titles II and III of the Americans with Disabilities Act; 5) Section 542 of the Public Health Service Act (pertaining to nondiscrimination against substance abusers); and 6) Title 45, Part 46 of the Code of Federal Regulations, pertaining to research involving human subjects. In addition, look for statements documenting policies and procedures that the MCO/PIHP will follow to report any observed violations and refer any enrollee complaints to the appropriate agency for resolution.

***Potential Interview Questions:***

Organization Leaders

1. What steps do MCO/PIHP leaders take to ensure compliance with Federal and State laws on enrollee rights?

2. Has the MCO/PIHP ever been found non-compliant with any Federal and State laws on enrollee rights? If yes, in what area, and what steps were taken to clear the violation?

3. If a provider/contractor is found to be in violation of any Federal and State laws on enrollee rights, how does the MCO/PIHP respond?

4. To what extent does the MCO/PIHP orient new staff to Federal and State laws on enrollee rights that must be observed during day-to-day operations? How does the MCO/PIHP remind staff of the importance of observing these laws during interactions with other employees and with enrollees?

5. Describe the steps taken by the MCO/PIHP when staff report, or are involved in a violation of Federal or State laws on enrollee rights.

Provider/Contractor Services Staff (individual and institutional)

1. What steps does the MCO/PIHP take to ensure that providers/contractors are aware of and in compliance with applicable Federal and State laws on enrollee rights?

2. If a provider/contractor is found in violation of any Federal and State laws on enrollee rights, what action is taken by the MCO/PIHP?

Enrollee Services Staff

1. Does the MCO/PIHP orient staff to the Federal and State laws on enrollee rights that must be observed during day-to-day operations? Does the MCO/PIHP remind staff of the importance of observing these laws during interactions with other employees and with enrollees?

2. Describe the procedure for handling an enrollee complaint involving a perceived violation of their rights.

# Subpart D--Quality Assessment and Performance Improvement

## Access Standards

### 438.206 Availability of services

**(b)** ***Delivery network.*** The State must ensure, through its contracts, that each MCO, and each PIHP consistent with the scope of the PIHP's contracted services, meets the following requirements:

**(1)** Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO and PIHP must consider the following:

**(i)** The anticipated Medicaid enrollment.

**(ii)** The expected utilization of services, considering Medicaid enrollee characteristics and health care needs.

**(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.

**(v)** The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.

***Note to Reviewers*:** Because enrollee needs, the types of providers used by an organization to meet those needs, and other factors such as patterns of transportation usage can vary by State and MCO or PIHP, determinations of compliance with this standard will generally focus on: 1) the extent to which the MCO meets any explicit provider network standards defined by the State Medicaid agency, and 2) the MCO's/PIHP's own service planning activities and basic assumptions used in determining that its network is adequate to serve Medicaid beneficiaries in a given area.

***Information to be obtained from the State Medicaid agency*:**
Obtain from the State Medicaid agency information on whether or not:
1) The State agency has required the MCO or PIHP to adhere to any explicit standards for provider network adequacy, such as prescribed primary physician/enrollee ratios or specialist/enrollee ratios;
2) The State agency has in place any time or distance standards for beneficiary travel to access covered services in Medicaid fee-for-service; and
3) There are any State laws requiring MCOs and PIHPs to make specific types of providers available for the provision of certain services.

***Document Review:***

- Review the MCO's/PIHP's service and provider network[2] planning documents and provider directories.
  - Did the MCO/PIHP project the number and types (in terms of training, experience, and specialization) of providers it needs to serve Medicaid enrollees?
  - Did the MCO/PIHP base its projections of the necessary numbers and types of providers on sound information about its projected Medicaid enrollment, including the considerations listed below?
  - Its anticipated Medicaid enrollment,
  - The expected utilization of services of its Medicaid enrollees, considering Medicaid enrollee characteristics and health care needs including, at a minimum, age and prevalence of health conditions;
  - The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services;
  - The number of network providers who are not accepting new Medicaid patients; and
  - The geographic location of Medicaid providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for enrollees with disabilities.
- Did the assumptions and methodologies used by the MCO/PIHP in planning its provider network appear reasonable, and have face validity? **[*Note to reviewers:* Consistent with information obtained on whether or not the State agency has established any explicit standards for provider network adequacy such as prescribed primary physician/enrollee ratios, the MCO/PIHP could base its assumptions on national or regional norms, its own past experience, State-established standards or guidelines, or other reasonable sources of information.]**
- Did the assumptions and methodologies address: (1) types of providers who may serve as primary care provider; and (2) the extent to which network providers serve only the MCO's/PIHP's enrollees or are available to the MCO's/PIHP's enrollees on less than a full-time basis? **[*Note to reviewers*: Simple counts of providers, or even providers reportedly accepting new Medicaid patients, are insufficient to establish capacity. Rather, the assessment of capacity necessarily should consider the volume of services being furnished to patients other than the MCO's /PIHP's enrollees.]**
- Did the assumptions and methodologies also identify situations in which different types of providers will be used to provide the same service: e.g., psychiatrists, psychologists, clinical social workers, and psychiatric nurses to provide mental health services or internists, family medicine physicians, OB/GYNs and nurse practitioners to provide primary care? Is the MCO's/PIHP's proposed use of such providers consistent with any

[2]An MCO's provider network consists of all provider employees and facilities of the organization, if any, along with any providers who have entered into written agreements to serve the organization's enrollees.

State laws requiring MCOs and PIHPs, when applicable, to make specific types of providers available?

- Are all contracted services (other than emergency care) generally available within the organization's network?
- Are network providers generally located within the MCO's/PIHP's approved service area? An acceptable exception would be, for example, when an organization operating solely in a non-metropolitan area makes a service (other than primary care and emergency care) available outside the area if it is unable to contract with a sufficient number of providers within the area. An other permissible exception would be if an MCO or PIHP contracts with a service provider(s) outside of its service area if, for reasons of geography, it would be easier for some of its enrollees to reach that provider than it would be for them to reach a comparable provider located within the service area.
- Is the provider network geographically structured so that Medicaid enrollees residing in the service area do not have to travel an unreasonable distance, beyond what is customary under the Medicaid fee-for-service program in that State, to obtain a covered service? **[*Note to reviewers:* Compare estimates of travel time to any time or distance standards established by the State Medicaid agency for beneficiary travel to obtain covered services in Medicaid fee-for-service.]**
- For service areas or parts of service areas where Medicaid enrollees are expected to rely heavily upon public transportation, is the MCO's/PIHP's network structured so that providers are accessible using public transportation within the same time frames as enrollees who have their own means of transportation (unless the MCO or PIHP ensures access through alternative means, such as home visits)?
- Do enrollees with disabilities have an appropriate choice of accessible providers?
- Does the MCO's/PIHP's provider network appear sufficient to provide adequate access to covered services and to meet the needs of its Medicaid enrollees?

- Review the MCO's/PIHP's provider contracts, contracting and non-contracting provider selection criteria, and procedures for monitoring the provider network to determine the extent to which:
  - The MCO's/PIHP's provider network described in its Medicaid marketing, member services, and service planning documents are supported by written provider agreements;
  - Whenever provider contracts allow providers to further subcontract with other providers for the provision of services to enrollees, does the subcontract require that the provider hold its subcontractor to the same requirements that the MCO requires of the provider contracting directly with the MCO?

***Potential Interview Questions:***

Organization Leaders

1. Describe the MCO's/PIHP's process for assessing the needs for providers to deliver each type of covered service and need for major specialties within each type. What issues were considered in the assessment process?

2. How does the MCO/PIHP determine the adequacy of its network to serve its Medicaid enrollees?

3. What assumptions and methodologies are used to project the number, type (in terms of training, experience and specialization) and location of primary care providers and specialists necessary to serve its anticipated Medicaid enrollees?

Provider/Contractor Services Staff

1. Describe the MCO/PIHP credentialing and recredentialing process. Is this different for Medicaid providers?

2. How is it determined that providers are geographically accessible to Medicaid enrollees and physically accessible to enrollees with disabilities?

3. Describe the processes for monitoring the provider network to determine that Medicaid requirements pertaining to timeliness, availability and accessibility are being met. What are the most recent findings from this process?

Enrollee Services Staff

1. What processes does the MCO/PIHP take to monitor availability and accessibility of services to Medicaid enrollees? What are the most recent findings from this process?

2. Is there any information that is routinely collected and monitored to determine that care and services are being rendered to Medicaid enrollees in a timely manner? What are the most recent findings of this monitoring?

**438.206(b)** ***Delivery network.*** The State must ensure, through its contracts, that each MCO, and each PIHP consistent with the scope of the PIHP's contracted services, meets the following requirements. . .

**(2)** Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

***Document Review*:**

- Review administrative policies and procedures, new enrollee materials, enrollee handbooks, and other enrollee information materials to determine the extent to which the MCO/PIHP:
  - Permits and informs Medicaid enrollees that female Medicaid enrollees are allowed "direct access" to a women's health specialist within the MCO's/PIHP's network for routine and preventive women's health care services. "Direct access" means that the MCO/PIHP may not require the woman to obtain any referral, or prior authorization as a precondition to seeking or receiving care from a women's health specialist.
  - Identifies those providers in its network that it considers to be "women's health specialist" and to whom female Medicaid enrollees may have direct access. **[*Note to reviewers:* Women's health specialists may include gynecologists, certified nurse midwives, or other qualified health care professionals.]**
  - Allows women to have both a designated primary care provider and direct access to a women's health specialist, without requiring the woman to choose a women's health specialist as her primary care provider.

***Potential Interview Questions:***
None recommended.

**438.206(b)*Delivery network.*** The State must ensure, through its contracts, that each MCO, and each PIHP consistent with the scope of the PIHP's contracted services, meets the following requirements. . .

**(3)** Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

**(4)** If the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PIHP must adequately and timely cover these services out of network for the enrollee for as long as the MCO or PIHP is unable to provide them.

**(5)** Requires out-of-network providers to coordinate with the MCO or PIHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

***Document Review*:**
- Review the MCO's/PIHP's administrative policies and procedures pertaining to service authorization and coverage, utilization management and use of out-of-network providers. Determine the extent to which the MCO/PIHP has procedures for providing Medicaid enrollees with:
  - A second opinion -- at no cost to the enrollee -- from a qualified health care professional within the network, or outside the network if a qualified health care professional is not available within the network

- Timely and adequate coverage of necessary medical services covered under the contract from out-of-network providers whenever the network is unable to provide necessary medical services and for as long as the MCO or PIHP is unable to provide them.

- Review the MCO's/PIHP's administrative policies and procedures pertaining to use of out-of-network providers. Determine the extent to which the MCO/PIHP:
  - Requires out-of-network providers to coordinate with the MCO/PIHP with respect to payment; and
  - Ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

- Review the MCO's/PIHP's new member materials, enrollee handbooks, and other enrollee information materials to determine the extent to which the MCO/PIHP informs Medicaid enrollees of:
  - the availability -- at no cost to the enrollee -- of a second opinion from a qualified health care professional within the network or outside the network if a qualified health care professional is not available within the network;
  - timely and adequate coverage of necessary medical services covered under the contract from out-of-network providers whenever the network is unable to provide necessary medical services and for as long as the MCO or PIHP is unable to provide them.

***Potential Interview Questions:***

Organization Leaders

1. Approximately what proportion of Medicaid enrollee provider encounters are made to out-of-network providers? If this is a significant percent, what are the reasons for this?

2. How do you pay out-of-network providers? Do you receive claim or encounter data from out-of- network providers similar to the claim or encounter data that you receive from your network providers?

3. How does your MCO/PIHP ensure that any costs to the Medicaid enrollee for out-of-network services is no greater than the costs the Medicaid enrollee would incur if they used a network provider for the same service?

Enrollee Services Staff

1. Are Medicaid enrollee requests for out-of-network providers tracked? How often do Medicaid enrollees request services from out-of-network providers? What are their reasons for requesting out-of-network providers?
2. How often do Medicaid enrollees receive services from out-of-network providers?

Information System Personnel

1. How does your IS track services provided by and/or reimbursed to out-of-network providers?

2. Is there any routinely collected and available data on use of out-of-network providers (excluding Point of Service-related use)? Is data on use of out-of-network providers separately available for Medicaid enrollees?

Provider and Contractor Service Staff

1. How often in the last year has your MCO/PIHP had to arrange for services or reimbursements to out-of -network providers?

Utilization Management Staff

1. What procedures must a Medicaid enrollee follow if he/she wishes to receive a second opinion? For what types of services are second opinions available?

**438.206(b)** The State must ensure, through its contracts, that each MCO, and each PIHP consistent with the scope of the PIHP's contracted services, meets the following requirements.

**(6)** Demonstrates that its providers are credentialed as required by § 438.214.

***Note:*** **Establishing whether or not the MCO/PIHP credentials its providers as required by § 438.214 will be addressed in the compliance determination activities for § 438.214.**

**438.206(c)** ***Furnishing of services.*** The State must ensure that each MCO and each PIHP contract complies with the requirements of this paragraph.

**(1)** ***Timely access.*** Each MCO and each PIHP must--

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

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

**(iii)** Makes services available 24 hours a day, 7 days a week when medically necessary.

**(iv)** Establish mechanisms to ensure compliance.

**(v)** Monitor providers regularly to determine compliance.

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

***Information to be obtained from the State Medicaid agency*:** Obtain a copy of the State Medicaid agency's standards for timely enrollee access to care and services required of Medicaid MCOs and PIHPs.

***Document Review*:**

- Review the MCO's/PIHP's standards for timely access to care and services for Medicaid enrollees to determine the extent to which they meet or exceed standards established by the State Medicaid agency.

- Review provider contracts, manuals and orientation programs as well as credentialing policies and procedures to determine the extent to which the MCO informs affiliated (network) providers of its standards.

- Review the MCO's/PIHP's service area and strategic planning documents such as: Medicaid enrollee needs assessments, provider network planning documents, provider selection criteria, provider contracts, and provider/contractor office/facility review criteria and subsequent audit results. Look for evidence in these documents that the MCO/PIHP:
  - Makes services available 24 hours per day, seven days per week, when medically necessary.
  - Offers provider hours of operation that do not discriminate against Medicaid enrollees relative to other enrollees; i.e., provider hours of operation for Medicaid enrollees are no less than the provider hours of operation offered to the MCO's/PIHP's commercial enrollees.

- Review enrollee services policies and procedures, MCO/PIHP informational materials prepared for new Medicaid enrollees, and other Medicaid member/enrollee information and educational materials to determine the extent to which they contain provisions that document the availability of health care services 24 hours per day/ seven days per week, when medically necessary.

- Review documents identified by MCO/PIHP staff during the interview process that show how the MCO/PIHP ensures compliance and continuously monitors its network providers and member services for compliance with the Medicaid timeliness of access standards. **[*Note to reviewers:* Acceptable MCO/PIHP mechanisms for monitoring compliance include, but are not limited to:**
  - **surveys of Medicaid enrollees,**
  - **analysis of Medicaid enrollee complaints and grievances,**
  - **provider self-reports of appointment and in-office waiting times, supplemented by random calls or audits, and**
  - **for the MCO's/PIHP's own services, test calls and ongoing monitoring of telephone abandonment rates (i.e., the percentage of callers who terminate a call before reaching an MCO/PIHP representative).]**

During this review, determine:

- the extent to which the MCO/PIHP evaluates access and availability for all Medicaid services the MCO/PIHP is responsible for providing under its contract [***Note to reviewers:*** By this we mean, for example, that an MCO/PIHP should not exclude specialty services and only evaluate primary care services. Neither should an MCO/PIHP base its monitoring solely on general surveys of its enrolled population that do not yield information on availability of specialty or other services or do not provide a sufficient sample of Medicaid enrollees requiring such services.]
- if these monitoring procedures and tools identified any problem(s) with access that required corrective action.

- Review the documentation of any instances found through the above monitoring processes, tools or other processes in which the MCO/PIHP failed to meet standards set by the State for timeliness of access to care or member services. Determine the extent to which the MCO/PIHP:
  - initiated corrective action; and
  - assessed the effectiveness of corrective action.

***Potential Interview Questions:***

Organization Leaders

1. Describe how the MCO/PIHP monitors for compliance with its Medicaid standards for timely access to care and services.

2. How does the MCO/PIHP ensure the 24 hours per day, 7 day per week availability of Medicaid services included in its contract with the State when medically necessary?

3. How does the MCO/PIHP determine that the individual and institutional providers it contracts with have sufficient capacity to make services available when medically appropriate 24 hour per day, 7 days per week to Medicaid enrollees?

4. How does the MCO/PIHP ensure that its provider network's hours of operation do not discriminate against Medicaid enrollees; i.e., are not different for Medicaid enrollees than for commercial enrollees?

5. How big of a problem is inappropriate use of emergency rooms by your Medicaid enrollees?

6. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

Provider/Contractor Services Staff (individual and institutional)

1. Does the MCO/PIHP continuously monitor its provider network for compliance with established standards on timeliness of access to all care and member services? If yes, how, and what are the most recent findings?

2. Is corrective action initiated when providers are not in compliance with established standards for timeliness of access to care and member services? Are the corrective actions assessed for effectiveness?

Case Managers and Care Coordinators

1. To what extent are services offered through the MCO/PIHP available to Medicaid enrollees and others coordinating care 24 hours per day, 7 days per week when medically necessary?

2. What types of services require pre-authorization?

Provider/Contractor Services Staff

1. Are MCO/ PIHP and provider services available 24 hours a day, 7 days a week, when medically necessary?

2. Are the hours of operation of the provider network serving Medicaid enrollees different from the hours of operation of the provider network serving other enrollees? If so, why?

Providers/Contractors (individual and institutional) (OPTIONAL)

1. Are your hours of operation for Medicaid enrollees different from the hours of operation for other MCO/PIHP enrollees? If so, why?

Enrollee Services Staff

1. Are MCO/ PIHP and provider services available 24 hours a day, 7 days a week, when medically appropriate?

2. How frequently do enrollee services staff receive complaints about provider hours of operations not being available to enrollees when medically necessary?

3. Does the MCO/PIHP conduct surveys, focus groups or other activities to receive the feedback of Medicaid enrollees? If so, what are the most recent findings about Medicaid enrollee perceptions about availability of MCO/PIHP and provider services?

Quality Assessment and Performance Improvement (QAPI) Program Leader(s) and Staff

1. Have any recent QAPI activities been implemented to monitor the MCO's/PIHP's compliance with its established standards for timeliness of access to care and member services? **[*Note to reviewers:* This is not a requirement for compliance with this standard, but will be assessed as part of determining compliance with regulations at § 438.240. It is included under this standard only as a way to identify methods**

**(which otherwise may go undetected) that the MCO/PIHP may have used to monitor compliance with the standards.]**

2. What are the results of these QAPI activities?

**438.206(c)(2)** ***Cultural considerations.*** Each MCO and PIHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

***Information to be obtained from the State Medicaid agency*:** Obtain from the State Medicaid agency:

1) Descriptive information on the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

2) The requirements the State has communicated to the MCO/PIHP with respect to how the MCO/PIHP is expected to participate in the State's efforts to promote the delivery of services in a culturally competent manner.

***Potential Interview Questions:***

Organization Leaders

1. What have been the State Medicaid agency's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds? How has your MCO/PIHP participated in these efforts? What documentation exists describing your efforts and the results of your efforts?

***Document Review*:**

- Review Medicaid enrollee new member materials, enrollee handbooks, enrollee educational materials and other enrollee materials and any other documentation of the MCO's /PIHP's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds consistent with the State's efforts. Is there evidence that the MCO/PIHP has participated in the State's efforts?

# 438.208 Coordination and continuity of care.

**(a)** ***Basic requirement.***

**(*1*)** ***General rule.*** Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure through its contracts, that each MCO and PIHP complies with the requirements of this section.

***(2) PIHP exception.*** For PIHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PIHP is required to--

**(i)** Meet the primary care requirements of paragraph (b)(1) of this section; and

**(ii)** Implement mechanisms for the screenings and assessments specified in paragraphs (c) of this section.

***(3) Exception for MCOs that serve dually eligible enrollees.***

**(i)** For an MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare+Choice plan, the State determines to what extent that an MCO must meet the primary care coordination, identification, assessment, and treatment planning provisions of paragraphs (b) and (c) of this section.

**(ii)** The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

**(b)** ***Primary care and coordination of health care services for all MCO and PIHP enrollees.*** Each MCO and PIHP must implement procedures to deliver primary care to and coordinate health care services for all MCO and PIHP enrollees. These procedures must meet State requirements and must do the following:

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

**(2)** Coordinate the services the MCO or PIHP furnishes to the enrollee with the services the enrollee receives from any other MCO, PIHP, or PAHP.

**(3)** Share with other MCOs, PIHPs, and PAHPs serving the enrollee with special health care needs the results of its identification and assessment of the enrollee's needs to prevent duplication of those activities.

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

**(c)** ***Additional services for enrollees with special health care needs.***

**(1) Identification.** The State must implement mechanisms to identify persons with special health care needs to MCOs and PIHPs, as those persons are defined by the State. These identification mechanisms must—

**(i)** Must be specified in the State's quality improvement strategy in § 438.202; and

**(ii)** May use State staff, the State's enrollment broker, or the State's MCOs and PIHPs.

**(2**) Assessment. Each MCO and PIHP must implement mechanisms to assess each Medicaid enrollee identified by the State (through the mechanism specified in papragraph (c)(1) of this section) and identified to the MCO or PIHP by the State as having special health care needs in order to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. The assessment mechanisms must use appropriate health care professionals.

**(3) Treatment plans.** If the State requires MCOs and POIHPs to produce a treatment plans for enrollees with special health care needs who are determined through

assessment to need a course of treatment or regular care monitoring, the treatment plan must be—

**(i)** Developed by the enrollee's primary care provider with enrollee participation, and in consultation with any specialists caring for the enrollee;

**(ii)** Approved by the MCO or PIHP in a timely manner, if this approval is required by the MCO or PIHP; and

**(iii)** In accord with any applicable State quality assurance and utilization review standards.

**(4) Direct access to specialists.** For enrollees with speoical health care needs determined through an assessment by appropriate health care professionals (consistent with § 438.208(c)(2)) to need a course of treamtne or regular care monitoring, each MCO and PIHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.

***Notes to reviewers:***

(1) The Office of Civil Rights (OCR) within the Department of Health and Human Services is charged with enforcement of the confidentiality requirements of 45 CFR parts 160 and 164. As a result, compliance with these provisions will not be addressed in this protocol.

(2) There are many different ways in which a MCO can provide care coordination. Traditionally, many health maintenance organizations (HMOs) and similar entities have used a gatekeeper model of care coordination, in which the enrollee's usual source of primary care serves as the entry point for all other medical care services (often a distinct entry point was established for mental health and substance abuse services). While this model is still used, some MCOs have systems under which a health care professional other than the enrollee's usual source of primary care, such as a case manager, coordinates needed services. A case manger can be an individual health care professional or a team of health care professionals.

In monitoring for compliance with the requirements for care coordination, note that an MCO/PIHP may establish different coordination mechanisms for different types of enrollees. For example, care coordination for most enrollees might be provided by the enrollee's primary care provider, while a case manager might coordinate care of enrollees with complex needs, chronic illnesses or functional disabilities.

***Information to be obtained from the State*:** Obtain from the State Medicaid agency:

1) The definition or specifications used by the State to identify individuals with special health care needs.
2) The mechanisms used by the State to identify to the MCO/PIHP those enrollees with special health care needs.

3) Information about whether the MCO/PIHP to be reviewed has been required by the State to implement mechanisms to identify persons with special health care needs using the State's definition of a person with a special health care needs.
4) The State requirements for MCO/PIHP assessment mechanisms to assess each Medicaid enrollee identified by the State to the MCO/PIHP as having special health care needs in order to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring.
5) Information about whether the MCO/PIHP to be reviewed has been required by the State to produce a treatment plan for enrollees with special health care needs who are determined through assessment to need a course of treatment or regular care monitoring.
6) The State requirements for MCO/PIHP care coordination.
7) ***If the organization to be reviewed is a PIHP,*** information about whether the PIHP to be reviewed has been required by the State to ensure that each enrollee has 1) an ongoing source of primary care appropriate to his or her needs and 2) a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee; and
8) ***If the organization to be reviewed is an MCO that serves enrollees who are also enrolled in a Medicare+Choice plan and also receive Medicare benefits,*** information from the State about the extent to which the MCO/PIHP has been required by the State to implement:
   - Procedures to deliver primary care to and coordinate health care services for all MCO/PIHP enrollees and ensure that each enrollee has: 1) an ongoing source of primary care appropriate to his or her needs; and 2) a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.
   - For enrollees determined through assessment to need a course of treatment or regular care monitoring, a mechanism that ensures that:
     (1) the enrollee may directly access a specialist (for example, through a standing referral or approved number of visits) as is appropriate for the enrollee's condition and identified needs.
     (2) a treatment plan that, if required by the MCO or PIHP, is developed by the enrollee's primary care provider in consultation with the specialist caring for the enrollee, and is
       (i) developed with enrollee participation;
       (ii) approved by the MCO/PIHP in a timely manner, if this approval is required; and
       (iii) in accordance with the State's quality assurance and utilization review standards.
9) The State's quality assurance and utilization review standards.

***Document Review*:**

- **If the State requires the MCO/PIHP to *identify* persons with special health care needs**, review the State's mechanisms to identify persons with special health care needs and the MCO's/PIHP's procedures for implementing the identification mechanisms to determine the extent to which the MCO/PIHP:
  - Has in place and implements procedures to identify those Medicaid enrollees who have a special health care need; and

- Uses and operationalizes the State's definition of an enrollee with a special health care need.

- Review the MCO's/PIHP's Medicaid enrollee services policies and procedures, Medicaid enrollee handbooks, care management/coordination policies and procedures, provider procedure manuals, and any clinical practice guidelines adopted by the MCO/PIHP and determine the extent to which the MCO/PIHP has in place and implements mechanisms to assess Medicaid enrollees who have been identified to the MCO/PIHP by the State as having special health care need to identify any ongoing special conditions or the enrollee that require a course of treatment or regular care monitoring.

- Review the MCO's/PIHP's procedures to provide care to enrollees who have ongoing special conditions and who require a course of treatment or regular care monitoring. Determine the extent to which the MCO's/PIHP's policies and procedures:
- Allow an enrollee (as appropriate for the enrollee's condition and identified needs) to directly access a specialist (for example, through a standing referral or approved number of visits); and
- Ensure that a treatment plan (if required by the MCO or PIHP) is:
  1) developed by the enrollee's primary care provider in consultation with any specialists caring for the enrollee;
  2) developed with the participation of the enrollee (or his or her family if the enrollee is a child);
  3) approved by the MCO or PIHP in a timely manner, if this approval is required; and
  4) in accordance with the State's quality assurance and utilization review standards.

- Obtain a random sample of records or files of Medicaid enrollees with special health care needs and review the assessment of the enrollee needs and, if a treatment plan is required by the MCO/PIHP, their treatment plans. Determine the extent to which:
  - The enrollees' specific special health care needs were identified and assessed.
  - The enrollees (if appropriate for the enrollee's condition and identified needs) were afforded direct access a specialist (for example, through a standing referral or approved number of visits).
  - The treatment plan (if required by the MCO or PIHP) was:
    1) developed by the enrollee's primary care provider in consultation with and specialists caring for the enrollee;
    2) developed with the participation of the enrollee or his or her family, if the enrollee is a child;
    3) approved by the MCO or PIHP in a timely manner, if this approval is required; and
    4) in accordance with the State's quality assurance and utilization review standards.

- Review the MCO's/PIHP's written policies and procedures for delivering and coordinating health care to enrollees. Determine the extent to which these policies and procedures specify:

- the functions of a primary care provider;
- who may serve as enrollee primary care providers; and
- conditions under which coordination of enrollee health care may be provided by an enrollee's primary care provider and when coordination may be provided by a different practitioner.

Contain mechanisms to ensure that:
- each enrollee has an ongoing source of primary care appropriate to his or her needs;
- each enrollee has a person or entity formally designated as primarily responsible for coordinating the health services furnished to the enrollee;
- the MCO/PIHP coordinates the services it furnishes to the enrollee with services the Medicaid enrollee receives from any other MCO or PIHP; and
- the results of its identification and assessment of enrollee needs are shared with other MCOs and PIHPs from which the enrollee may be receiving services, so that these activities need not be duplicated (e.g., information sharing between physical health providers and mental health and substance abuse providers (e.g., with respect to prescribed medications).

- Review the MCO's/PIHP's policies on enrollees' use of health care providers, new enrollee (member) orientation information, enrollee handbooks, enrollee educational materials and provider procedure manuals to determine the extent to which an ongoing relationship with a usual source of primary care is being made available to providers and enrollees.

- Review enrollee and provider documents such as provider procedure manuals and enrollee handbooks to determine the extent to which policies on care coordination are communicated to enrollees and providers. Specifically review the documents to determine the extent to which it is communicated that each Medicaid enrollee is to have: 1) an ongoing source of primary care appropriate to his or her needs; and 2) a person or entity formally designated as primarily responsible for coordinating their health care services. If an MCO has different mechanisms for providing coordination of care for different types of enrollees (e.g. primary care providers for most enrollees, but full-time non-physician case managers for enrollees with special health care needs) determine the extent to which these arrangements are clearly described in the enrollee and provider materials.

- Review a sample of records of Medicaid enrollees receiving care coordination /case management services to determine the extent to which the MCO/PIHP coordinates its services with services the enrollee receives from any other MCOs and PIHPs.

***Potential Interview Questions:***

Organization Leaders

1. How are "individuals with special health care needs" defined by the State Medicaid agency? Has your MCO/PIHP developed any other operational definition or definitions of individuals with special health care needs? If yes, what is/are these and how were they developed? How do they differ from the State definition?

2. Does the State Medicaid agency require your MCO/PIHP to identify Medicaid enrollees with special health care needs?

3. How are individuals with special health care needs - including both individuals with special health care needs identified by this MCO/PIHP and those identified by the State Medicaid agency or its agent - identified and tracked within your MCO/PIHP?

4. What mechanisms does your MCO/PIHP have in place to assess Medicaid enrollees with special health care needs? How are the assessment activities conducted?

5. Who may serve as enrollee primary care providers?

6. What steps does the MCO/PIHP take to promote Medicaid enrollees' ongoing relationship with a usual source of primary care?

7. What process(es) is/are used to coordinate services for enrollees? Are there different types of care coordination mechanisms for different types of enrollees? If so, what are these?

8. If your MCO/PIHP establishes separate coordination of care for medical services and mental health and substance abuse services, how does it ensure exchange of necessary information between providers?

9. How does the MCO/PIHP ensure coordination of its services with services enrollees may receive from other MCOs, PIHPs, or PAHPs?

10. Under what circumstances may Medicaid enrollees have direct access to specialists?

11. How does your MCO/PIHP manage the provision or any specialty care services currently not provided in-network?

12. Does your MCO/PIHP require written treatment plans to be developed for enrollees? If yes, under what circumstances are written treatment plans required?

Case Managers and Care Coordinators

1. Does this MCO/PIHP identify Medicaid enrollees with special health care needs? If yes, what mechanisms have been implemented to conduct the identification activities?

2. How are Medicaid enrollees with special health care needs - including both any individuals with special health care needs identified by your MCO/PIHP and any identified by the State Medicaid agency or its agent - identified and tracked within your MCO/PIHP?

3. What mechanisms does your MCO/PIHP have in place to assess Medicaid enrollees with special health care needs? How are the assessment activities conducted?

4. Does this MCO/PIHP require written treatment plans to be developed for enrollees with ongoing special conditions that require a course of treatment or regular care monitoring? If yes, how is it decided which Medicaid enrollees will receive a written treatment plan?

5. If treatment plans are required by this MCO/PIHP, how does the MCO/PIHP ensure that treatment plans for individuals with special health care needs address the needs identified by the assessment?

6. Describe the treatment planning process for individuals with special health care needs and the process for determining and assuring appropriate use of specialists.

7. Within the last year, how many treatment plans have been developed? How many requests for treatment plans have been denied? What were the reasons for these denials? How many treatment plans have been denied?

8. What process(es) is/are used to coordinate services for enrollees? Are their different types of care coordination mechanisms for different types of enrollees? If so, how are these different and how do they work?

9 Who is responsible for coordinating the care of individuals with special health care needs?

10. What are the procedures for coordinating the services that the MCO/PIHP furnishes to the enrollee with services the Medicaid enrollee receives from any other MCOs, PIHPs, or PAHPs?

11. If the MCO/PIHP establishes separate coordination of care for medical services and mental health and substance abuse services, how does the MCO/PIHP ensure exchange of necessary information between providers?

Enrollee Services Staff

1. Does this MCO/PIHP identify Medicaid enrollees with special health care needs? If yes, how is this implemented?

2. How are Medicaid enrollees with special health care needs - including both any individuals with special health care needs identified by your MCO/PIHP and any identified by the State Medicaid agency or its agent - identified and tracked within your MCO/PIHP?

3. What mechanisms does your MCO/PIHP have in place to assess Medicaid enrollees with special health care needs? How are the assessment activities conducted?

4. What proportion of Medicaid enrollees have an ongoing source of primary care?

5. What proportion of Medicaid enrollees have a person or entity formally designated as primarily responsible for coordinating their health care services?

6. What proportion of Medicaid enrollees with special health care needs has a person or entity formally designated as primarily responsible for coordinating their health care services?

Provider/Contractor Services Staff

1. How are primary care providers serving enrollees with special health care needs made aware of and involved in procedures for:
   - assessing these individuals?
   - ensuring that their treatment plans address the needs identified by the assessment?
   - treatment planning and determining and assuring appropriate use of specialists?
   - coordinating their care with care provided by other MCOs and PIHPs serving the enrollee?

2. How are specialty providers serving enrollees with special health care needs made aware of and involved in procedures for:
   - assessing individuals with special health care needs?
   - ensuring that treatment plans address the needs identified by the assessment?
   - treatment planning?
   - coordinating the care of individuals with special health care needs with the care provided by other MCOs and PIHPs serving the enrollee?

## 438.210 Coverage and authorization of services

**(b)** ***Authorization of services*.** For the processing of requests for initial and continuing authorizations of services, each contract must require--

**(1)** That the MCO or PIHP and its subcontractors have in place, and follow, written policies and procedures.

**(2)** That the MCO or PIHP--

**(i)** Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

**(ii)** Consult with the requesting provider when appropriate.

**(3)** That any decision to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollees's condition or disease.

**(c)** ***Notice of adverse action.*** Each contract must provide for the MCO or PIHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO or PIHP to deny a service authorization request, or to authorize a service in an amount, duration or scope that is less than requested. The notice must meet the requirements of §438.404, except that the notice to the provider need not be in writing.

**(d)** ***Timeframe for decisions.*** Each MCO or PIHP contract must provide for the following decisions and notices:

***(1) Standard authorization decisions.*** For standard authorization decisions, provide notice as expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extensdion of up to 14 additional calendar days, if—

**(i)** The enrollee, of the provider, requests extension: or

**(ii)** The MCO, PIHP,… justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

***(2) Expedited authorization decisions.***

**(i)** For cases in which a provider indicates, or the MCO or PIHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability attain, maintain, or regain maximum function, the MCO or PIHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.

**(ii)** The MCO or PIHP may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO or PIHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

**(e)** ***Compensation for utilization management activities.*** Each contract must provide that, consistent with §438.6(h), and §422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

**[Note: Related provisions addressing coverage and authorization of emergency services are included herein.]**

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**438.114 Emergency and post-stabilization services**

**(a)** ***Definitions.*** As used in this section--

*Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson,

with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in --

(1) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(2) Serious impairment to bodily functions; or

(3) Serious dysfunction of any bodily organ or part.

*Emergency services* means covered inpatient or outpatient services that are--

(1) Furnished by a provider qualified to furnish emergency services.

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

*Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

**(b)** ***Coverage and payment: General rule.*** The following entities are responsible for coverage and payment of emergency services and post-stabilization care services.

**(1)** The MCO, PIHP, . . .

**(c)** ***Coverage and payment: Emergency services.***

**(1)** The entities identified in paragraph (b) of this section--

**(i)** Must cover and pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PIHP, …and

**(ii)** May not deny payment for treatment obtained under either of the following circumstances:

**(A)** An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2) and (3) of the definition of "emergency medical condition" in paragraph (a) of this section.

**(B)** A representative of the MCO, PIHP,. . . instructs the enrollee to seek emergency services.

**(d)** ***Additional rules for emergency services.***

**(1)** The entities specified in paragraph (b) of this section may not--

**(i)** Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

**(ii)** Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, PIHP,… or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

**(2)** An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

**(3)** The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently

stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

**(e)** ***Coverage and payment: Post-stabilization care services.*** Post-stabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to "M+C organization" must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section.

**(f)** ***Applicability to PIHPs . . .*** To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP. . . is responsible, the rules under this section apply.

***Note to reviewers:*** The requirement in § 438.210(c) that "The notice must meet the requirements of § 438.404. . . ." will be addressed in the section addressing 438.404.

***Information to be obtained from the State:*** Obtain from the State Medicaid agency the State-established standards for MCO/PIHP processing of standard authorization decisions.

***Document review:***

- Review the MCO's/PIHP's written service authorization policies and procedures. Determine the extent to which these policies and procedures:
  - Specify information required for making authorization decisions and the criteria to be used in making the decisions.
  - Promote consistent application of review criteria for authorization decisions.
  - Specify time frames for responding to standard requests for service authorization that are within the applicable limits set by the State Medicaid agency.
  - Assure that any decision to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested is made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.
  - Provide for consultation with the requesting provider when appropriate.
  - Provide for expedited response to requests for authorization of urgently needed services that adhere to the following time frames:

    1. For cases in which a provider indicates, or the MCO or PIHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability attain, maintain, or regain maximum function, the MCO or PIHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.

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

    - Provide for notification of the requesting provider and the enrollee of any decision by the MCO or PIHP to deny a service authorization request, or to authorize a service in an amount, duration or scope that is less than requested. Enrollee notification (but not provider notification) must be in writing.

- Review information sources identified by the MCO/PIHP such as service authorization tracking logs and other authorization record-keeping documents to determine: 1) the extent to which the MCO/PIHP complies with the State's time frames for standard and the above time frames for expedited authorization of service requests; and 2) the number and reasons for delayed expedited authorization of service requests.

- Review a sample of service authorization requests that were denied. Determine the extent to which:
    - Decisions to deny a service were made by health care professional with appropriate clinical expertise in treating the enrollee's condition or disease.
    - Requesting providers were notified of any decision to deny, limit, or discontinue authorization of services, and
    - Enrollees were notified, in writing, of any decision to deny, limit, or discontinue authorization of services.

- Review the MCO's/PIHP's contracts or agreements with employees who perform utilization management activities. Determine the extent to which compensation to these individuals or entities does not appear to be structured in such a way as to provide incentives to deny, limit, or discontinue medically necessary services to any enrollee.

- Review the MCO's/PIHP's contracts or other agreements with utilization review organizations (or other reviewers who are not employees of the MCO/PIHP who perform utilization management activities) to determine that the contracts or agreements do not include any financial incentive for denial, limitation or discontinuation of authorization for medically necessary services.

- Review the MCO's/PIHP's written policies and procedures pertaining to utilization management relative to emergency and post-stabilization services. Determine the extent to which the written policies and procedures ensure that:
    - The MCO/PIHP covers and pays for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PIHP… and regardless of whether or not the claim contains the primary care provider's authorization number.
    - The MCO/PIHP pays for treatment obtained under either of the following circumstances:
        **(A)** An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1)(2) and (3) of the definition of "emergency medical condition" in paragraph (a) of this chapter.
        **(B)** A representative of the MCO, PIHP… instructs the enrollee to seek emergency services.

- The MCO/PIHP does not limit what constitutes an emergency medical condition on the basis of lists of diagnoses or symptoms; and
- An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.
- The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the MCO/PIHP.

- Review grievance files or aggregate data related to payment/non-payment for services. Determine the extent to which there are records related to denial of payment for emergency or post-stabilization services.

***Potential Interview Questions:***

Organization Leaders

1. How big of a problem is inappropriate use of emergency rooms by your Medicaid enrollees?

2. Has your MCO/PIHP investigated a potential relationship between inappropriate emergency room use and enrollee access to routine and urgent care?

3. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

Medical Director

1. How does the MCO/PIHP monitor its compliance with the State's time frames for processing standard requests for service authorization?

2. What are the MCO's/PIHP's standards for processing expedited requests for service authorization? How does the MCO/PIHP monitor its compliance with these time frames?

2. Under what circumstances is there consultation with requesting providers when responding to service authorization requests?

4. How does the MCO/PIHP ensure consistent application of criteria used in making service authorization decisions?

5. What mechanism does the MCO/PIHP use to assure that any decision to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease?

6. How are employees and any contractors used by the MCO/PIHP to perform service authorization and utilization management financially compensated? Are they paid in any

way other than on a straight salary or per case review basis? Do their financial compensation arrangements involve the use of any financial incentives?

Utilization Management Staff

1. What types of services require pre-authorization?

2. What are the MCO's/PIHP's time frames for processing standard and expedited requests for service authorization?

3. How does the MCO/PIHP monitor its compliance with these time frames? What sources of documentation exist to provide evidence of the monitoring by the MCO/PIHP?

4. How often and under what circumstances are requesting providers consulted when the MCO/PIHP makes service authorization decisions?

5. To what extent does the MCO/PIHP assess the consistency of authorization decisions? How does the MCO/PIHP do this?

6. What is the process when a decision is being made to deny authorization for a service? Who makes the decision to deny a request to authorize a service?

7. Describe the process for notifying the requesting provider and the enrollee of any decision
   to deny, limit, or discontinue authorization of services. What information is typically included in enrollee and provider notification? What are the MCO's/PIHP's time frames for notification?

8. How big of a problem is inappropriate use of emergency rooms by your Medicaid enrollees?

9. Has your MCO/PIHP investigated a potential relationship between inappropriate emergency room use and enrollee access to routine and urgent care?

10. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

Case Managers and Care Coordinators

1. What types of services require pre-authorization?

Provider/Contractor Services Staff

1. Do contracts/agreements with individuals or organizations performing utilization review provide for any performance incentives? If yes, please describe the incentives. **[*Note to reviewers*: Look for any incentives for denying, limiting or discontinuing authorization of services.]**

2. Are network providers notified of the information ordinarily required to process an authorization request?

3. Describe the process for notifying the requesting provider of any decision to deny, limit, or discontinue authorization of services. What are the MCO's/PIHP's time frames for notification?

Enrollee Services Staff

1. How frequently do enrollee services staff receive complaints about difficulty obtaining emergency or post-stabilization services?

2. Describe the procedure for handling member calls regarding need for emergency services.

## Stucture and Operation Standards

### 438.214 Provider selection

**(a)** ***General rules.*** The State must ensure, through its contracts, that each MCO and PIHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

***(b) Credentialing and recredentialing requirements.***

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

**(c)** ***Nondiscrimination.*** MCO and PIHP provider selection policies and procedures, consistent with 438.12 ***(below)*** do not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

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### 438.12 Provider discrimination prohibited

**(a)** ***General rules.***

**(1)** An MCO, PIHP, …may not discriminate for the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO, PIHP, …declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

**(2)** In all contracts with health care professionals an MCO, PIHP, … must comply with the requirements specified in § 438.214.

**(b)** ***Construction.*** Paragraph (a) of this section may not be construed to--

**(1)** Require the MCO, PIHP, …to contract with providers beyond the number necessary to meet the needs of its enrollees;

**(2)** Preclude the MCO, PIHP, …from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

**(3)** Preclude the MCO, PIHP, …from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

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**(d)** ***Excluded providers.*** MCOs or PIHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

**(e)** ***State requirements.*** Each MCO and PIHP must comply with any additional requirements established by the State.

***Note to reviewers:*** Section 1128 of the Social Security Act (the Act) is entitled, "Exclusion of Certain Individuals and Entities from Participation in Medicare and State Health Care Programs." It addresses circumstances under which individuals and entities must and may be excluded from participation in any federal health care program, including Medicaid. Section 1128 also addresses procedures that the federal Department of Health and Human Services (DHHS) must follow, including informing State Medicaid agencies of the individual's or entity's exclusion. Section 1128A also addresses circumstances under which exclusion from federal health care programs may be undertaken, as well as circumstances under which civil monetary penalties may be imposed. Section 1128A also includes procedures for notifying State agencies when such action is taken.

***Information to be obtained from the State Medicaid agency*:** Obtain from the State information on any credentialling, recredentialing or other provider selection and retention requirements established by the State.

***Document Review*:**

- Review the MCO's/PIHP's written policies and procedures for selection and retention of providers.
- Review the MCO's/PIHP's written policies and procedures for credentialing and recredentialing of providers. Determine the extent to which:
  - Explicit policies and procedures for provider credentialling and recredentialing exist in writing. Note that written policies and procedures may not simply state that this function has been delegated to another entity without specification of what policies and procedures the delegated entity is to implement.
  - Credentialing and recredentialing policies and procedures apply to all providers that have a contract or participation agreement with the MCO/PIHP.
  - Credentialing and recredentialing policies and procedures include provisions that ensure that the MCO/PIHP does not employ or contract with providers excluded from participation in federal health care programs. **[Note to reviewers: Information on exclusions from Medicare and Medicaid may be obtained the US Department of Health and Human Service's Medicare and Medicaid Sanctions and Reinstatement**

**Report or through direct contact with the Medicaid agency or the Medicare intermediary.]**

- Credentialing and recredentialing policies and procedures include any requirements specified by the State Medicaid agency.

- Review a sample of provider files to determine the extent to which they provide evidence that:
  - The MCO's/PIHP's policies and procedures on provider credentialing and recredentialing are being implemented as written;
  - The MCO/PHP credentialing /recredentialing process has obtained information on whether or not providers have been excluded from participation in Medicare or Medicaid under section 1128 or 1128A of the Act.

- Review the MCO's/PIHP's contracts with groups to whom credentialing is delegated. (These may include provider groups or credential verification groups (CVOs). Determine the extent to which the MCO/PIHP requires these groups to perform credentialing activities that fulfil the MCO's/PHP's policies and procedures on credentialing and recredentialing.

- Review a sample of credentials files for providers who have been part of the MCO's/PIHP's network for at least three years, to determine the extent to which:
  1) The providers have undergone a process of recredentialing according to the MCO's/PHP's written policies and procedures.
  2) Information obtained during recredentialing includes at least information about any federally imposed exclusion from participation in Medicaid or Medicare.

- Review the MCO's/PIHP's service planning documents and criteria for the selection of providers, to determine that they do not discriminate against providers solely on the basis of license or certification.

- Review the MCO's/PIHP's credentialing policies and procedures, and credentialing committee or other provider review mechanism meeting minutes to determine if there is evidence that the MCO/PIHP discriminates against providers on the basis of factors such as license, certification, or nature of population served and thereby discriminates against providers who serve high-risk populations or specialize in the treatment of costly conditions.

- Review aggregate information and individual files of a sample of providers for whom the MCO/PIHP has recently denied participation. Identify the MCO's/PIHP's reasons and explanations for the denials. Determine the extent to which the MCO/PIHP gave the affected providers written notice of the reason for its decision.

- Review a sample of credentials files for practitioners who have <u>not been</u> appointed or reappointed to the MCO's/PIHP's provider network to determine if evidence exists that practitioners who serve high-risk or costly populations have been discriminated against during the provider selection and retention process.

- Review a sample of appealed recredentialing decisions to determine if evidence exists that practitioners who serve high-risk or costly populations have been discriminated against during the provider selection and retention process.

***Potential Interview Questions:***

Organization Leaders

1. What is the basis or criteria used to determine individual provider participation in the MCO's/PIHP's network?

2. What is the basis or criteria used to determine institutional or other non-individual practitioner participation in the MCO's/PIHP's network?

3. What types of providers are subject to the MCO's/PIHP's credentialing process?

4. Describe the provider credentialling process used by the MCO/PIHP.

5. What steps does the MCO/PIHP take to ensure that it does not employ or contract with providers who have been excluded from participation in Federal health care programs?

6. What steps does the MCO/PIHP take to ensure that providers who serve high-risk or costly populations are not discriminated against in the selection process, and when considering reimbursement and indemnification?

7. What criteria are the basis for denial of provider participation in the MCO's/PIHP's network?

Provider/Contractor Services Staff

1. What types of individual practitioners are subject to the MCO's/PIHP's credentialing process?

2. Describe the MCO's/PIHP's credentialing processes for individual practitioners. How often does this process take place? What items of credentials information are updated during the process? Are site visits made to providers? When and how often? How is it determined that a site visit will be made? Who is involved in the MCO's/PIHP's credentialing activities?

3. Describe the MCO's/PIHP's recredentialing processes for individual practitioners. What types of information are monitored and reviewed during the recredentialing process? What other operations of the MCO/PIHP contribute information to be used in the recredentialing process?

4. Describe the MCO's/PIHP's processes for selecting and monitoring institutional and other non- practitioner network providers. What information is reviewed as a part of this process? Are site visits made? When and how often?

5. Describe the MCO's/PIHP's credentialing and recredentialing processes for institutional providers. How frequently is re-credentialling performed? What items of information are typically reviewed during the evaluation and reevaluation process?

6. Are site visits a part of the process to credential and recredential institutional providers?

7. What other MCO/PIHP operations contribute to the evaluation of a network institutional provider?

8. What criteria are the basis for denial of provider participation in the MCO's/PIHP's network?

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. What type of information is generated through the quality improvement program to support recredentialing of individual practitioner providers?

2. What types of information does the quality improvement program provide to support the recredentialing of institutional and other non-practitioner providers?

## §438.218 Enrollee information

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204. **[Note: requirements of § 438.10 were addressed in Subpart C--Enrollee Rights and Responsibilities – in § 438.100(b)(2)(i) pertaining to the right to information.]**

**§438.224 Confidentiality** - The State must ensure, through its contracts, that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO and PIHP uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

*Note to reviewers*:
**Subpart F of part 431 specifies safeguards that State Medicaid agencies must follow in order to safeguard information of Medicaid applicants and recipients. The *Health Insurance Portability and Accountability Act of 1996 (HIPAA)* also governs MCO and PIHP (and other health care entity) responsibilities for safeguarding the confidentiality of enrollee information is. Regulations implementing HIPAA provisions were issued by the Federal government on December 28, 2000 as 45 CFR parts 160 and 164. The Department of Health and Human Service's Office of Civil Rights is responsible for enforcement of these regulations. Therefore, this protocol does not include provisions for monitoring for compliance with the HIPAA provisions pertaining to confidentiality of enrollee records.**

## §438.226 Enrollment and disenrollment

The State must ensure that each MCO and PIHP contract complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56. (Relevant sections of § 438.56 are included below*)*.

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## 438.56 Disenrollment: Requirements and limitations.

**(b)** ***Disenrollment requested by the MCO, PIHP, . . ..*** All MCO, PIHP, …contracts must--

**(1)** Specify the reasons for which the MCO, PIHP, . . .may request disenrollment of an enrollee;

**(2)** Provide that the MCO, PIHP, . . .may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except where his or her continued enrollment in the MCO, PIHP, . . .seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees); and

**(3)** Specify the methods by which the MCO, PIHP, …assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

***(c) Disenrollment requested by the enrollee.*** If the State chooses to limit disenrollment, its MCO, PIHP, …contracts must provide that a recipient may request disenrollment as follows:

**(1)** For cause, at any time.

**(2)** Without cause, at the following times:

**(i)** During the 90 days following the date of the individual's initial enrollment with the MCO, PIHP …, or the date the State sends the recipient notice of the enrollment, whichever is later

**(ii)** At least once every 12 months thereafter

**(iii)** Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

**(iv)** When the State imposes the intermediate sanction specified in § 438.702(a)(3).

**(d)** ***Procedures for disenrollment.***

**(1)** ***Request for disenrollment.*** The recipient (or his or her representative) must submit an oral or written request--

**(i)** To the State agency (or its agent); or

**(ii)** To the MCO, PIHP …, if the State permits MCOs, PIHPs, …to process disenrollment requests.

**(2)** ***Cause for disenrollment.*** The following are cause for disenrollment:

**(i)** The enrollee moves out of the MCO's, PIHP's… service area.

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

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

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

**(3)** ***MCO, PIHP… action on request.***

**(i)** An MCO, PIHP… may either approve a request for disenrollment or refer the request to the State.

**(ii)** If the MCO, PIHP, …or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

***(4) State agency action on request.*** For a request received directly from the recipient, or one referred by the MCO, PIHP, …, the State agency must take action to approve or disapprove the request based on the following:

**(i)** Reasons cited in the request.

**(ii)** Information provided by the MCO, PIHP, …at the agency's request.

**(iii)** Any of the reasons specified in paragraph (d)(2) of this section.

**(5)** ***Use of the MCO, PIHP, …grievance procedures.***

**(i)** The State agency may require that the enrollee seek redress through the MCO, PIHP's …grievance system before making a determination on the enrollee's request.

**(ii)** The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in §438.56(e)(1).

**(iii)** If, as a result of the grievance process, the MCO, PIHP… approves disenrollment, the State agency is not required to make a determination.

**(e)** ***Timeframe for disenrollment determinations.***

**(1)** Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PIHP, …files the request.

**(2)** If the MCO, PIHP, …or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraphs (e)(1) of this section, the disenrollment is considered approved.

***Information to be obtained from the State Medicaid Agency:*** Obtain information on:

1) Whether or not the State Medicaid agency allows the MCO or PIHP to process enrollee requests for disenrollment for cause and, if so, whether or not the State requires enrollees to seek redress through the MCO's or PIHP's grievance system before the State makes a determination on the enrollee's request.
2) A copy of the State-MCO contract provisions which specify the methods by which the MCO or PIHP assures the State Medicaid agency that it does not request disenrollment for reasons other than those permitted under the contract.

***Document Review*:**

- If the State allows the MCO/PIHP to process requests for disenrollment (See *Information to be obtained from the State Medicaid Agency*, above), review the MCO's/PIHP's policies and procedures pertaining to disenrollment. Determine the extent to which the MCO/PIHP policies and procedures include the following:
  - The methods contained in its contract with the State Medicaid agency by which the MCO, PIHP assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.
  - Allowance that an enrollee (or his or her representative) may submit a request for disenrollment either orally or in writing.
  - Processes for promptly submitting a copy of the request for disenrollment to the State agency upon receipt of the request
  - Acknowledgment that the MCO/PIHP may either approve a request for disenrollment or refer the request to the State.
  - Acknowledgment that if the MCO, PIHP, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.
  - Acknowledgment that the MCO/PIHP may be required to submit information pertaining to the request for disenrollment to the State Medicaid agency, when the State Medicaid agency is making the determination in response to a request for disenrollment.
  - Processes to ensure that 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 files the request.

- If the State requires that the enrollee seek redress through the MCO's/PIHP's grievance system before making a determination on the enrollee's request for disenrollment, review the

MCO's/PIHP's policies and procedures for handling grievances and determine the extent to which these policies and procedures:
  - Ensure that the grievance process must be completed in time to permit the disenrollment (if approved) to be effective no later than the first day of the second month after the month the enrollee makes the request.
  - Acknowledge that if, as a result of the grievance process, the MCO or PIHP approves the disenrollment, the State agency is not required to make a determination.

- Review the MCO's /PIHP's most recent year's requests by Medicaid enrollees for disenrollment. Review a representative sample to determine if the above procedures were followed.

- Review the MCO's /PIHP's most recent year's disenrollment rate, and review a representative sample to determine if a relationship exists between the enrollees requesting disenrollment and enrollees enrolled in the MCO/PIHP automatically or by default.

***Potential Interview Questions:***
Enrollee Services Staff

1. Describe the procedures that are followed when a request for disenrollment is received from an enrollee.

2. Is disenrollment information tracked through or by other MCO/PIHP operations (e.g., grievance process, quality improvement, administration)? How many requests by Medicaid enrollees were received last year for disenrollment? What were the cited causes?

## §438.228 Grievance systems

**(a)** The State must ensure, through its contracts, that each MCO and PIHP has in effect a grievance system that meets the requirements of subpart F of this part.

**(b)** If the State delegates to the MCO or PIHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO and PIHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

***Note to reviewers:***
1) Compliance determination activities for subpart F requirements are addressed following compliance with these subpart D provisions.
2) The "notice of action under subpart E of part 431 of this chapter" refers to the notice that must be given to a Medicaid recipient who has received an adverse decision with respect to a request for a covered service. This notice is required to inform the Medica recipient that he or she has the right to a State Fair hearing to reconsider their request for the covered service.

***Information to be obtained from the State Medicaid Agency:*** Obtain information on whether or not the State delegates to the MCO or PIHP responsibility for providing each Medicaid enrollee (who has received an adverse decision with respect to a request for a covered service) notice that informs him or her that he or she has the right to a State Fair hearing to reconsider their request for the covered service.

***Document review:***

- If the State delegates to the MCO or PIHP responsibility for providing its Medicaid enrollees notice of action under subpart E of part 431 of this chapter, obtain a list of the MCO's /PIHP's most recent year's denied service requests. Review a random sample to determine if Medicaid enrollees who were denied services were notified by the MCO/PIHP or its providers or subcontractors of their right to a State fair hearing.

***Potential Interview Questions:*** If the State delegates to the MCO or PIHP responsibility for providing its Medicaid enrollees notice of action under subpart E of part 431 of this chapter, ask the following questions:

Organization Leaders

1. How does your MCO/PIHP track requests for covered services that your MCO/PHP or its providers has denied?

3. What was the volume of denied claims for services in the most recent year?

4. How do you ensure that Medicaid enrollees who were denied services were notified of their right to a State fair hearing?

Utilization Management Staff

1. What types of services require pre-authorization?

2 Describe the process for notifying the requesting provider and the enrollee of any decision
to deny, limit, or discontinue authorization of services. What information is typically included in enrollee and provider notification? What are the MCO's/PIHP's time frames for notification?

3. How does your MCO/PIHP track requests for covered services that your MCO/PHP or its providers has denied?

4. What was the volume of denied request for services in the most recent year?

Provider/Contractor Services Staff

1. Describe the process for notifying the requesting provider of any decision to deny, limit, or discontinue authorization of services. What are the MCO's/PIHP's time frames for notification?

Enrollee Services Staff

1. Describe the process for notifying Medicaid enrollees of any decision to deny, limit, or discontinue a request for service. What are the MCO's/PIHP's time frames for notification?

## §438.230 Subcontractual relationships and delegation.

**(a)** ***General rule.*** The State must ensure, through its contracts, that each MCO and PIHP--

**(1)** Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor, and

**(2)** Meets the conditions of paragraph (b) of this section.

**(b)** ***Specific conditions.***

**(1)** Before any delegation, each MCO and PIHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

**(2)** There is a written agreement that--

**(i)** Specifies the activities and report responsibilities delegated to the subcontractor; and

**(ii)** Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

**(3)** The MCO or PIHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State laws and regulations.

**(4)** If any MCO or PIHP identifies deficiencies or areas for improvement, the MCO or PIHP and the subcontractor take corrective action.

***Information to be obtained from the State Medicaid Agency:*** Obtain from the State the "periodic schedule" established by the State according to which the MCO/PIHP is to monitor and formally review on an ongoing basis all subcontractor's performance of any delegated activities.

**[*Note to reviewers:* Prior to determining compliance with these provisions, first identify which, if any, functions and responsibilities required under the MCO's/PIHP's contract with the State Medicaid agency are delegated by the MCO/PIHP to any subcontractors. For this reason, questions will need to be asked of selected MCO/PIHP personnel prior to reviewing documents so that delegated activities can be identified.]**

**Initial interview questions of MCO/PIHP leaders:**

Which of the following **OR OTHER** activities are performed by (and thereby delegated to) contractors?

- Establishment or maintenance of your provider network,
- Provider credentialling,
- Initial assessments of enrollees,
- Care coordination,
- Service authorization,
- Providing information to enrollees,
- Grievance systems,
- Quality assessment and performance improvement,
- Performance measurement,
- Information systems management, and
- Others.

***Document Review:***

Separately, for each delegated activity:

- Review a sample of the MCO's/PIHP's contracts or written agreements with the entities performing the delegated activity(ies). *(Note: there should be a contract or written agreement with every entity that is performing one of these activities on behalf of the MCO.)* Review the contract or written agreement to determine the extent to which the contract or written agreement specifies:
  - The delegated activities, and which responsibilities have been delegated and which remain with the MCO/PIHP when functions are partially delegated.
  - Reporting responsibilities of the entity.
  - Requirements that the entity comply with applicable Federal and State laws and regulations.
  - Provisions for revocation of the delegation or imposition of other sanctions when there is inadequate performance.

- Review the MCO's/PIHP's written policies and procedures for the delegated activity to determine the extent to which the MCO/PIHP evaluated the entity's ability to perform the delegated activity prior to delegation. Determine from completed evaluation records or files the extent to which the MCO/PIHP:
  - Verified that the contractor is capable of performing the delegated activities; i.e., has sufficient resources and appropriately qualified staff to perform the function.
  - Approved the entity's policies and procedures with respect to the delegated function.

- Review the MCO's/PIHP's policies and procedures for that activity. Determine the extent to which there are written policies and procedures that provide for ongoing mechanisms for formal monitoring and review of the delegated functions by MCO/PIHP personnel qualified to assess the delegated function. Determine the extent to which these policies and procedures provide that the formal monitoring and review be implemented according to the "periodic schedule" established by the State.

- Review the results of the most recent review of the delegated activity. To what extent were

corrective actions identified as needed for problems or deficiencies, including procedures for assuring that the corrective action is implemented?

***Potential Interview Questions:***

Organization Leaders

1. What steps does your MCO/PIHP take to determine that an entity to which functions will be delegated is capable of performing the function? Describe any such evaluation process that your MCO/PIHP has in place.

2. Describe the MCO's/PIHP's process for identifying and selecting contractors? How is it determined that a contractor has the ability to perform the activities that are to be delegated?

3. How does your MCO/PIHP determine who will monitor and review delegate activities? How often does delegate evaluation occur? Who in your MCO/PIHP is presented with evaluation results? Who in your MCO/PIHP takes action on evaluation results?

4. For <u>each</u> of the activities that have been delegated, describe the review methodology adopted by your MCO/PIHP to oversee entities that have been delegated this activity through contracts or agreements. Has the methodology been effective in determining delegate compliance with your MCO's/PIHP's performance expectations?

Provider/Contractor Services Staff (individual and institutional)

1. What types of activities are performed by (and thereby delegated to) contractors?

2. Describe your MCO's/PIHP's process for identifying and selecting contractors? How is it determined that a contractor has the ability to perform the activities that are being delegated by the organization?

3. What steps does your MCO/PIHP take to determine that an entity to which functions will be delegated is capable of performing the function? Describe any evaluation process that your MCO/PIHP has in place.

4. For <u>each</u> of the activities that has been delegated:

- Is there any ongoing monitoring and review of entities performing delegated activities? How this is accomplished? Is the process the same for all delegates at all times? Are there any instances when your MCO/PIHP varies the monitoring process or the timing of evaluation?

- Does your MCO/PIHP perform an annual evaluation of the delegate's performance? Describe the process undertaken to conduct this evaluation. What is included in the evaluation?

- What is done with the results of delegate evaluations? Do the results of the most recent delegate evaluations specify any necessary corrective action for problems or deficiencies identified? Describe some of the recommendations made to delegates in an effort to improve performance.

- What steps does your MCO/PIHP take to assure that the delegate implements corrective actions?

- Who in the MCO/PIHP is assigned responsibility for monitoring the delegate's performance?

# Measurement and Improvement Standards

## §438.236 Practice guidelines.

**(a)** ***Basic rule.*** The State must ensure, through its contracts, that each MCO and , when applicable, each PIHP meets the requirements of this section.

**(b)** ***Adoption of practice guidelines.*** Each MCO and, when applicable, each PIHP adopts practice guidelines that meet the following requirements:

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

**(2)** Consider the needs of the MCO's or PIHP's enrollees.;
**(3)** Are adopted in consultation with contracting health care professionals.
**(4)** Are reviewed and updated periodically as appropriate.

***Document Review*:**

- For a sample of the guidelines that have been adopted by the MCO/PIHP, review the history of the guideline and the guideline's adoption by the MCO/PIHP. **[*Note to reviewers:* Each MCO/PIHP should have adopted at least two practice guidelines in order to comply with this requirement. The organizational component of the MCO/PIHP responsible for the adoption of the guideline should be able to supply documentation of the origins and evidence base for the guideline, and the process that led to its adoption by the MCO/PIHP.]** Determine the answers to the following questions:
  1) Is the guideline one that was promulgated by the Agency for HealthCare Research and Quality, expert consensus panels convened by the National Institutes of Health, medical specialty societies, or other expert body based on a review of valid and reliable clinical evidence, or a consensus of health care professionals in the particular field? If the guideline was developed by the MCO/PIHP, was it also developed based on a review of valid and reliable clinical evidence or a consensus of health care professionals in the particular field?
  2) Do the guidelines that the MCO/PIHP has adopted reflect the health needs of its enrolled population? (Compare the subject of the guidelines with the information on the health needs of the enrolled population generated by the MCO's/PIHP's QAPI program.)
  3) Was there a formal process for consulting affiliated providers about the guidelines as the guidelines were adopted?
  4) Have the guidelines been periodically reviewed and updated since their adoption by the MCO/PIHP?

- Review any administrative policies and procedures that describe the MCO's/PIHP's processes for adopting new practice guidelines. Determine the extent to which these policies and procedures ensure that all adopted guidelines:
  1) Are based on a review of valid and reliable clinical evidence or a consensus of health care professionals in the particular field.
  2) Reflect the health needs of its enrolled population.
  3) Are developed in consultation with affiliated providers.
  4) Are periodically reevaluated.

***Potential Interview Questions:***

Organization Leaders

1. What organizational component is responsible for the adoption of practice guidelines used by your MCO/PIHP?

2. How does your MCO/PIHP establish priorities for adoption of practice guidelines?

3. What guidelines has your MCO/PIHP adopted?

4. By what process were they adopted?

5. To what extent are your MCO's/PIHP's guidelines "evidence-based"?

6. How does your MCO/PIHP consider the enrolled Medicaid population's health needs in the adoption of practice guidelines?

7. How are affiliated providers consulted as guidelines are adopted and re-evaluated?

8. What mechanism(s) does your MCO/PIHP have for periodically evaluating and updating the guidelines it has adopted?

Provider/Contractor Services Staff (individual and institutional)

1. What mechanism is in place to consult affiliated providers as practice guidelines are adopted and re-evaluated?

Providers/Contractors **(OPTIONAL)**

1. Are affiliated providers/contractors consulted as practice guidelines are adopted and re-evaluated?

## §438.236 Practice guidelines.

**(c)** ***Dissemination of guidelines.*** Each MCO and PIHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

***Document Review:***

- Review provider manuals, newsletters, bulletins or other forms of communications to providers to determine the extent to which the MCO/PIHP communicates practice guidelines it has adopted to all affected providers.

- Review enrollee newsletters, enrollee health education programs, communications to enrollees participating in disease management programs, internet-based enrollee educational offerings and any other mechanisms for communicating with enrollees to determine the extent to which the MCO communicates practice guidelines to all enrollees and potential enrollees when they request them.

***Potential Interview Questions:***
Organization Leaders

1. How are practice guidelines disseminated to providers?

2. When and how are guidelines disseminated to enrollees and potential enrollees?

Provider/Contractor Services Staff (individual and institutional)

1. How are practice guidelines disseminated to providers?

Enrollee Services Staff

1. How often does your MCO/PIHP receive requests from enrollees and potential enrollees for practice guidelines? How does your MCO/PIHP respond to these requests?

Providers/Contractors (OPTIONAL)

1. How does the MCO/PIHP make providers/contractors aware of practice guidelines currently in use and those under consideration for adoption?

## §438.236 Practice guidelines.

**(d)** ***Application of guidelines.*** Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

***Document Review:***

- Review administrative policies and procedures with respect to utilization management and service authorizations to determine the extent to which they acknowledge:
  - the presence of practice guidelines adopted by the MCO/PIHP; and
  - that utilization management and service authorization decisions should be consistent with the practice guidelines adopted by the MCO/PIHP.

- Review the MCO's/PIHP's performance improvement projects and indicators to determine the extent to which any quality measurement and improvement activities that address topics also addresses by the adopted practice guidelines, are consistent with the guidelines.

- Review the MCO's/PIHP's enrollee education programs and determine the extent to which any enrollee education activities that address topics also addresses by the adopted practice guidelines are consistent with the guidelines.

***Potential Interview Questions:***
Organization Leaders

1. To what extent are the practice guidelines adopted by your MCO/PIHP a component of your MCO's/PIHP's QAPI program?

2. Is there an interface between the QAPI program and practice guidelines adoption process?

3. What steps are taken to ensure that decision-making in the areas of utilization management or coverage determinations and other functional areas are consistent with the adopted practice guidelines?

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. How does the QAPI program interface with the administrative function responsible for adopting practice guidelines?

Enrollee Services Staff

1. When and how does your MCO/PIHP disseminate practice guidelines to enrollees?

Utilization Management Staff

1. What practice guidelines has your MCO/PIHP adopted?

2. To what extent are your utilization management review guidelines (criteria) consistent with these practice guidelines? How do you promote or ensure consistency?

3. Describe how utilization management review guidelines (criteria) are modified to reflect the adoption or revision of practice guidelines. Are both sets of guidelines updated through the same process, at the same time?

## §438.240 Quality assessment and performance improvement program.

**(a)** ***General rules.***

**(1)** The State must require, through its contracts, that each MCO and PIHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

**(2) [Requirement pertains to the State; not the MCO or PIHP.]**

**(b)** ***Basic elements of MCO and PIHP quality assessment and performance improvement programs.*** At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

**(1)** Conduct performance improvement projects as described in paragraph (d) of this section *[Note: Paragraph (d) is included below]*. These projects must achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction.

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**(d)** ***Performance improvement projects.***

**(1)** MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and non-clinical areas, and that involve the following:
**(i)** Measurement of performance using objective quality indicators.
**(ii)** Implementation of system interventions to achieve improvement in quality.
**(iii)** Evaluation of the effectiveness of the interventions.
**(iv)** Planning and initiation of activities for increasing or sustaining improvement.

**(2)** Each MCO and PIHP must report the status and results of each project to the State as requested, including those that incorporate the requirements of § 438.240(a)(2). Each performance improvement project must be completed in a reasonable time period so as to generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.

***Information to be obtained from the State:*** Obtain from the State Medicaid agency:

1. Information on whether or not the State Medicaid agency has required the MCO's/PIHP's PIPs to address a specific topic or topics, or address a specific topic(s) and also use specific quality indicators identified by the State Medicaid agency.
2. The State's requirements with respect to MCO/PIHP reporting of the status and results of each PIP to the State Medicaid agency; and
3. Any reports on the status and results of the PIPs submitted by the MCO/PIHP in response to State requirements for reporting the status and results of each PIP to the State Medicaid agency.

***Document Review:***

- Review a description of the number and types of PIPs initiated, in progress, and completed by the MCO/PIHP during the review year. Determine if those PIPs meet the States' requirements for "information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year" as per §438.240 (d)(2).

- Using the EQRO protocol, "*Validating Performance Improvement Projects in Managed Care Organizations and Prepaid Health Plans,"* review documentation of the design, methods, analysis and results of each Medicaid PIP producing new information on quality of care for the year under review. Use of this validation protocol will determine compliance with the requirements specified in §438.240 (d)(1).

- Review a copy of any reports on the status and results of the PIPs submitted to the State by the MCO/PIHP in response to State requirements for reporting the status and results of each PIP to the State Medicaid agency:
  - Determine the extent to which the report(s) meet(s) the State's requirements with respect to MCO/PIHP reporting of the status and results of each PIP.
  - If the State is requiring the MCO/PIHP to address a specific topic or topics, or address a specific topic(s) and also use specific quality indicators identified by the State Medicaid agency in any performance improvement projects for the period under review, determine

the extent to which the MCO/PIHP has complied with specifications or instructions from the State pertaining to these PIP topics and/or indicators.

***Potential Interview Questions:***
Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. Does the State require your MCO/PIHP to specific topic or topics and/or indicators in your PIPs projects? If yes, what types of projects are required?

## §438.240 Quality assessment and performance improvement program.

**(b)** ***Basic elements of an MCO and PIHP quality assessment and performance improvement program.*** At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

**(2)** Submit performance measurement data as described in paragraph (c) of this section. *[Note: Paragraph (c) is included below.]*

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**(c)** ***Performance measurement.*** Annually each MCO and PIHP must--

**(1)** Measure and report to the State its performance, using standard measures required by the State including those that incorporate the requirements of § 438.204(c) and § 438.240(a)(2) *[Note: § 438.204(c) and § 438.240(a)(2) are included below.]*;

**(2)** Submit to the State, data specified by the State, that enables the State to measure the MCO's or PIHP's performance; or

**(3)** Perform a combination of the activitied described in paragraphs (c)(1) and (c)(2) of this section.

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**438.204(c)** For MCOs and PIHPs, any national performance measures and levels that may be identified and developed by CMS in consultation with States and other relevant stakeholders.

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**438.240(a)(2)** CMS, in consultation with States and other stakeholders, may specifiy performance measures and topics for performance improvement projects to e required by States in their contracts with MCOs and PIHPs.

***Information to be obtained from the State:*** Obtain from the State Medicaid agency:

1) A list of all performance measures required of the MCO/PIHP by the State for the year or years for which the review is being conducted.
2) The actual performance measures and/or performance data submitted by the MCO/PIHP to the State for the year or years for which the review is being conducted.

3) Instructions from the State on whether or not the State wishes the EQRO to validate the MCO's/PIHP's submitted performance measures. **[*Note to reviewers:* <u>This</u> protocol does not require that the performance measures that the MCO/PIHP submits to the State be validated. However, if the State does instruct the EQRO to validate the performance measures, the EQRO should do so consistent with the CMS protocol entitled, "Validating Performance Measures."]**

***Document Review*:**

- Review the performance measures and/or performance data submitted by the MCO/PIHP to the State. Determine the extent to which the MCO/PIHP submitted a measure of its performance for every performance measure required by the State, and/or all performance data specified by the State for the State to measure the MCO's/PIHP's performance, for the year or years for which the review is being conducted.

- If the State has instructed the EQRO to validate the performance measures submitted by the MCO/PIHP, do so consistent with the CMS protocol entitled, "*Validating Performance Measures."*]

***Potential Interview Questions:*** No interviews are required for monitoring for compliance with these standards. If the State (or, at the option of the State, the MCO) is not able to provide documentation of the performance measures submitted by the MCO/PIHP to the State, the MCO/PIHP must be determined to be out of compliance with this standard.

## §438.240 Quality assessment and performance improvement program.

**(b)** ***Basic elements of an MCO and PIHP quality assessment and performance improvement program.*** At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

**(3)** Have in effect mechanisms to detect both underutilization and overutilization of services.

***Document Review:***

- Review the performance measures and PIPs produced by the MCO/PIHP. Determine the extent to which these quality measurement and improvement activities, in the aggregate, can detect both over- and under-utilization.

- Review MCO/PIHP policies and procedures pertaining to utilization management. Determine the extent to which the MCO/PIHP has put in place mechanisms to detect both over- and under-utilization.

- Review documentation of the MCO's/PIHP's overall quality assessment and performance improvement program. Determine the extent to which it contains mechanisms to detect both over- and under-utilization.

- Review MCO/PIHP analytic reports and audit processes for evidence that claims, encounter data and medical records are evaluated to assess the degree of over- and under-utilization

***Potential Interview Questions:***

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. How does your MCO/PIHP detect over- and under-utilization? Provide examples of how your quality assessment and improvement program has monitored to detect under- and over-utilization.

Medical Director

1. Does the MCO/PIHP have any processes for reviewing claims, payment systems, encounter data and medical records to assess utilization of services? What reports on service utilization are regularly produced by these processes? What are the most recent findings with respect to over- and under-utilization?

Utilization Management Staff

1. What information is analyzed to detect over- and under-utilization of services? Who is involved in the analysis and review of this information? Have any trends been identified? What are the typical follow-up actions taken when either condition is discovered?

## §438.240 Quality assessment and performance improvement program.

**(b)** ***Basic elements of an MCO and PIHP quality assessment and performance improvement program.*** At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

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

***Document Review:***

- Review the performance measures and PIPs produced by the MCO/PIHP. Determine the extent to which these quality measurement and improvement activities, in the aggregate, assess the quality and appropriateness of care furnished to enrollees with special health care needs

- Review documentation of the MCO's/PIHP's overall quality assessment and performance improvement program. Determine the extent to which it contains mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

***Potential Interview Questions:***
Organization Leaders

1. How does your MCO/PIHP define enrollees with "special health care needs.?" How are these enrollees identified/ tracked within your MCO/PIHP?

2. How does your MCO/PIHP assess the quality and appropriateness of care furnished to enrollees with special health care needs?

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. How does your MCO/PIHP define enrollees with "special health care needs?" How are these enrollees identified/ tracked within your MCO/PIHP?

2. How does your MCO/PIHP assess the quality and appropriateness of care furnished to enrollees with special health care needs? Provide examples.

Medical Director

1. How does your MCO/PIHP define enrollees with "special health care needs?" How are these enrollees identified within your MCO/PIHP?

2. How does your MCO/PIHP assess the quality and appropriateness of care furnished to enrollees with special health care needs? Provide examples.

## §438.240 Quality assessment and performance improvement program.

**(e)** ***Program review by the State.***

**(1)** The State must review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. The review must include--

**(i)** The MCO's and PIHP's performance on the standard measures on which it is required to report; and

**(ii)**The results of each MCO's and PIHP's performance improvement projects.

**(2)** The State may require that an MCO or PIHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

***Information to be obtained from the State Medicaid agency*:**
Determine from the State Medicaid agency whether or not the State has required the MCO/PIHP to have in effect a process for its own evaluation of the the impact and effectiveness of its quality assessment and performance improvement (QAPI) program and, if so, how frequently the MCO/PIHP is to make such an evaluation.

***Document Review*:**

- Review the MCO's/PIHP's performance on the standard measures on which the State has required it to report, and the results of the MCO's/ PIHP's performance improvement projects. Look for evidence that these two activities have had any impact or effect, during the year under review, on the health status of Medicaid enrollees or on the quality of health care and services provided to the Medicaid enrollees.

- If the State requires the MCO to self-evaluate its QAPI program, obtain and review the MCO's/PIHP's most recent QAPI self-evaluation. Determine the extent to which the self-evaluation addresses:
  - The MCO's/PIHP's performance on standardized Medicaid performance measures that the State requires the MCO/PIHP to report.
  - The results of the MCO's/PIHP's performance improvement projects.
  - Under and over utilization.
  - The quality and appropriateness of care furnished to enrollees with special health care needs.
  - The impact and effectiveness of its quality assessment and performance improvement (QAPI) program.

***Potential Interview Questions:***

Organization Leaders

1. Does the MCO/PIHP evaluate the effectiveness of its quality assessment and performance improvement program? How often?

2. What were the findings of the MCO's/PIHP's most recent self-evaluation of its QAPI? What action did the MCO/PIHP take as a result of these findings?

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. Does the MCO/PIHP evaluate the effectiveness of its quality assessment and performance improvement program? How often?

2. Describe the evaluation process. What aspects of the program are encompassed in the evaluation?

3. What were the findings of the MCO's/PIHP's most recent self-evaluation? What action did the MCO/PIHP take as a result of these findings?

4. Is the evaluation conducted to meet the State's requirements, and if so, what is reported to the State and how often?

## §438.242 Health information systems

**(a)** ***General rule.*** The State must ensure, through its contracts, that each MCO and PIHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system must provide information on areas including, but not limited to, utilization, grievances, and disenrollments for other than loss of Medicaid eligibility.

**(b)** ***Basic elements of a health information system.*** The State must require, at a minimum, that each MCO and PIHP comply with the following:

**(1)** Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

**(2)** Ensure that data received from providers is accurate and complete by--

**(i)** Verifying the accuracy and timeliness of reported data;

**(ii)** Screening the data for completeness, logic, and consistency; and

**(iii)** Collecting service information in standardized formats to the extent feasible and appropriate.

**(3)** Make all collected data available to the State and to CMS, as required in this subpart.

***Note to reviewers:*** Assessing the adequacy of MCO/PIHP health information systems to "collect, analyze, integrate, and report data and . . . achieve the objectives of" subpart D requirements (such as performance measurement and performance improvement projects) requires technical knowledge of automated health information systems, clinical coding conventions, standardized claim and reporting forms, and routine data collection, transfer and storage practices of providers and health plans. Because such an assessment is resource intensive, reviewers who are responsible for determining compliance with these regulatory provisions should first determine from both the State Medicaid agency and the MCO/PIHP under review if the MCO/PIHP has recently undergone such an assessment of its health information system (IS). IS assessments are a routine part of validating performance measures in both the commercial and Medicaid marketplaces, as well as a routine part of validating encounter data. If the State has recently required, or if the MCO/PIHP has otherwise recently received, such an assessment of its IS, it is recommended that the EQRO performing this compliance review obtain a copy of the IS Assessment from either the State or the MCO/PIHP, and interview the entity that conducted the earlier IS assessment to obtain answers to the following questions. This will avoid a duplicate reassessment.

If no recent assessment of the MCO's/PIHP's IS exists, the EQRO should assess the MCO's/PIHP's IS using a comprehensive IS assessment tool such as that found in Appendix Z, which contains an example of an Information Systems Assessment Tool (ISCAT) that is used as part of the EQRO protocols on validating performance measures and encounter data.

***Information to be obtained from the State Medicaid agency:*** Obtain from the State:
1) Information on whether or not the State has required the MCO/PIHP to undergo, or has otherwise received, a recent assessment of the MCO's/PIHP's health information system (IS). If

the State has required or received such an assessment, obtain a copy of the IS Assessment from the State or the MCO/PIHP. Also obtain contact information about the person or entity that conducted the assessment and to whom follow-up questions may be addressed.

2) State specifications for data on enrollee and provider characteristics that must be collected by the MCO/PIHP;

3) State specifications for how MCOs/PIHPs are to collect data on services furnished to enrollees; i.e., whether or not the MCO/PIHP must collect encounter data or may use other methods. If the State allows the MCO/PIHP to use other methods, what are the State's requirements with respect to these "other methods?" If the State requires MCOs/PIHPs to collect encounter data and report it to the State, does the State validate this data or require it to be validated? If the data is validated, obtain a copy of the most recent validation report.

***Document Review:***

- Review a recent Information Systems Assessment and other documents describing the MCO's/PIHP's health IS. [Note: If no prior IS assessment exists, the EQRO will need to conduct its own IS assessment using an instrument such as that found in Appendix Z.] Determine the extent to which the MCO's/PIHP's health information system:
  - Collects, analyzes, and integrates data on enrollee and provider characteristics (as specified by the State);
  - Collects data on services furnished to enrollees by all components of its network through an encounter data system or other methods specified by the State;
  - Integrates enrollee and provider data from all components of its network to produce comprehensive information on enrollee needs and utilization; and
  - Reports information on: provision of services to Medicaid enrollees, grievances, and disenrollment for other than loss of Medicaid eligibility.

- Review procedures used by the MCO/PIHP to ensure the reliability of the data obtained from providers and contained within its IS, regardless of whether the MCO/PIHP compiles data within its own facilities or uses external contractors. Determine the extent to which the MCO/PIHP has in place and implements ongoing processes that:
  1) Assess the accuracy of data reported by its network providers, including comparing reported data to a sample of medical records to verify the accuracy of reported data;
  2) Assess the timeliness of data reported by its network providers; including a system for comparing reported data to a sample of medical records to assess the timeliness of transmission;
  3) Screen data reported by providers for completeness to ensure that reported data contain all data elements required by the MCO's/PIHP's standards;
  4) Screen data reported by providers for consistency and logic; and
  5) Collect information on services provided to Medicaid enrollees using standardized formats to the extent feasible and appropriate.

- Review the inventory of reports that are routinely generated by the MCO's/PIHP's information systems to support utilization management, grievance processes, enrollment services, and its quality assessment and performance improvement program. Verify that the MCO's/PIHP's IS provides information on service utilization, Medicaid grievances, and Medicaid disenrollments for other than loss of Medicaid eligibility.

- Review provider procedures manuals or contracts with health care providers to determine the extent to which expectations for data collection and reporting are outlined.

***Potential Interview Questions:***

Organization Leaders (including COO, Chief Information Systems Officer)

1. Describe the types of data collection systems that are in place to support the clinical and administrative operations of your MCO/PIHP. Specifically, what data is routinely collected to support utilization management, grievance systems, and enrollment services?

2. What processes are in place to obtain data from all components of your network (e.g., health care facilities, physician, laboratories)? To what extent does your MCO/PIHP require and receive data in standardized formats? Are there any components of your network from which you do not receive standardized (or any) information on services to enrollees?

3. How are enrollee and provider data collected and integrated across all components of your MCO's/PIHP's network? How is this used to produce comprehensive information on enrollee needs and utilization and to otherwise support management?

Information Systems Leadership and Staff

1. Is the data collected from network providers on services to enrollees subjected to accuracy and timeliness checks?

2. Describe procedures used to screen all data, both internal and external, for completeness, logic and consistency.

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. How are enrollee and provider data from all components of your MCO's/PIHP's network used in your MCO's/PIHP's quality assessment and performance improvement program? Are there any components in your network for which you do not have adequate enrollee utilization and provider data?

Provider/Contractor Services Staff (individual and institutional)

1. Does the MCO/PIHP have data collection requirements for health care facilities and physicians? How are the requirements relayed to these organizations and individuals?

2. If issues arise in the timeliness and accuracy of the data that is being collected and submitted, who notifies the health care facility or physician?

# Subpart F--Grievance System

## 438.400 Statutory basis and definitions

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

**Action** means--

In the case of an MCO or PIHP--

**(1)** The denial or limited authorization of a requested service, including the type or level of service;

**(2)** The reduction, suspension, or termination of a previously authorized service;

**(3)** The denial, in whole or in part, of payment for a service;

**(4)** The failure to provide services in a timely manner, as defined by the State;

**(5)** The failure of the MCO or PIHP to act within the timeframes provided in § 438.408(b); or [Section §438.408(b) is restated below.]

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## §438.408 Resolution and notification: Grievances and appeals.

**(b)** ***Specific timeframes.***

**(1) Standard disposition of grievances.** For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State, but may not exceed 90 days from the day the MCO or PIHP receives the grievance.

**(2) Standard resolution of appeals.** For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 45 days from the day the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

**(3) Expedited resolution of appeals.** For expedited resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 3 working days after the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

**(c)** ***Extension of timeframes.***

**(1)** The MCO or PIHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if--

**(i)** The enrollee requests the extension; or

**(ii)** The MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is a need for additional information and how the delay is in the enrollee's interest.

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**(6)** For a resident of a rural area with only one MCO, the denial of a Medicaid enrollee's request to exercise his or her right, § 438.52(b)(2)(ii), to obtain services outside the network. [Section §438.52(b)(2)(ii) is restated below.]

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## §438.52 Choice of MCOs, PIHPs, PAHPs, and PCCMs.

**(b) Exception for rural area residents.**

**(2)** A State that elects the option provided under paragraph (b)(1) of this section, must permit the recipient—

**(ii)** To obtain services from any other provider under any of the following circumstances:

**(A)** The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP… network.

**(B)** The provider is not part of the network, but is the main source of a service to the recipient, provided that—

**(1)** The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP … network as other network providers of that type.

**(2)** If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 days (after being given an opportunity to select a provider who participates).

**(C)** The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

**(D)** The recipients's primary care provider or other provider determines that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

**(E)** The State determines that other circumstances warrant out-of-network

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**Appeal** means a request for review of an action, as "action" is defined in this section.
**Grievance** means an expression of dissatisfaction about any matter other than an action, as "action" is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State Fair Hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

**[*Note to reviewers:* The above definitions apply to all of the following provisions of Subpart F, pertaining to MCO/PIHP Grievance Systems.]**

## §438.402 General requirements

**(a)** ***The grievance system.*** Each MCO and PIHP must have a system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.

**(b)** ***Filing requirements.***

**(1)** ***Authority to file.***

**(i)** An enrollee may file a grievance and an MCO or PIHP level appeal, and may request a State fair hearing.

**(ii)** A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

**(2)** ***Timing.*** The State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PIHP's notice of action. Within that timeframe--

**(i)** The enrollee or the provider may file an appeal; and

**(ii)** In a State that does not require exhaustion of MCO and PIHP level appeals, the enrollee may request a State fair hearing.

**(3)** ***Procedures.***

**(i)** The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PIHP.

**(ii)** The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

***Information to be obtained from the State.*** Obtain from the State information on:

1) The time frame during which enrollees and providers are allowed to file an appeal;
2) Whether or not the State requires enrollees to exhaust MCO/PIHP level appeals prior to requesting a State fair hearing; and
3) Whether enrollees are required or permitted to file a grievance with either the State or the MCO/PIHP or both.

***Document Review:***

- Review administrative policies and procedures pertaining to enrollee grievances, appeals and access to the State fair hearing. Determine the extent to which there are written policies and procedures that provide evidence that the MCO/PIHP has a system for resolving enrollee grievances and appeals and for providing access to the State fair hearing, including:
  - Allowing an enrollee to file a grievance, an MCO or PIHP-level appeal, and request a State fair hearing.
  - Allowing a provider, acting on behalf of the enrollee and with the enrollee's written consent, to file an appeal.
  - Prohibiting a provider from filing a grievance or requesting a State fair hearing.
  - Allowing enrollees and providers to file an appeal either orally or in writing within the time frames established by the State (See "*Information to be obtained from the State," #1, above.)*.
  - In a State that does not require exhaustion of MCO and PIHP level appeals (See "*Information to be obtained from the State," #2, above.)* allowing the enrollee to request a State fair hearing within the time frames established by the State.
  - Allowing an enrollee to file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PIHP.

  - Requiring, when either an enrollee or a provider orally files an appeal, that the oral filing be followed with a written, signed appeal, or in writing, unless an expedited resolution is requested.
- Review logs, registries, or other MCO/PIHP documentation of appeals, grievances and requests for State fair hearings made by Medicaid enrollees in the past year. Review documentation for a sample of these to determine the extent to which policies and procedures (including specified time frames) were followed in the resolution of these complaints and grievances.

***Potential Interview Questions:***

Organization Leaders

1. Who in the MCO/PIHP is responsible for the development and oversight of the appeals and grievance resolution process and access to State fair hearings?

2. What has been the volume of appeals/grievances/requests for State fair hearings in the past year and the most common areas of concern expressed by Medicaid enrollees? How has the MCO/PIHP addressed these concerns?

3. Describe the notice and appeals process for adverse actions on enrollee requests for services or payment. Elaborate on the particular steps, including time frames.

Utilization Management Staff

1. Describe the appeals process and the role of utilization management staff in the resolution process. Elaborate on the particular steps, including time frames, in which utilization management staff are involved.

2. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? Describe this process and its time frames.

Enrollee Services Staff

1. What enrollee materials contain information about the complaint and grievance processes? When are enrollees presented with this information?

2. Describe the process for handling authorization decisions that are adverse to the enrollee.

## §438.404 Notice of action

**(a)** ***Language and format*** requirements. The notice must be in writing and must meet the language and format requirements of §438.10(c) and (d) of this chapter to ensure ease of understanding. [Sections §438.10(c) and (d) are restated below.]

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### §438.10 Information requirements.

**(c)** ***Language.*** The State must:

**(1)**Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. "Prevalent" means a non-English language spoken by a significant number or percentage of potential enrollees and enrollees in the State.

**(2)** [This paragraph contains a requirement for the State; not the MCO/PIHP.]

**(3)** Require each MCO, PIHP… to make its written information available in the prevalent, non-English languages in its particular service area.

**(4)** … require each MCO, PIHP… to make those services [i.e., oral interpretation services] available free of charge to the each potential enrollee and enrollee. This applies to all non-English languages, not just those the State identifies as prevalent.

**(5)** . . . require each MCO, PIHP… to notify its enrollees--

(i) That oral interpretation is available for any language and written information is available in prevalent languages; and

(ii) How to access those services.

**(d)** ***Format.***

**(1)** Written material must--

(i) Use easily understood language and format;

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

**(2)** All enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats.

**********

***(b)*** ***Content of notice.*** The notice must explain the following:

**(1)** The action the MCO or PIHP or its contractor has taken or intends to take.

**(2)** The reasons for the action.

**(3)** The enrollee's or the provider's right to file an MCO or PIHP appeal.

**(4)** If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.

**(5)** The procedures for exercising the rights specified in this paragraph.

**(6)** The circumstances under which expedited resolution is available and how to request it.

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

***(c) Timing of notice.*** The MCO or PIHP must mail the notice within the following timeframes:

**(1)** For termination, suspension, or reduction of previously authorized Medicaid-covered service, within the time frames specified in §§431.211, 431.213, and 431.214 of this chapter. [Note: Sections §§431.211, 431.213, and 431.214 are restated below.]

**********

**§431.211 Advance notice.** The State or local agency must mail a notice at least 10 days before the date of action, except as permitted under §§431.213 and 431.214 of this subpart.

**§431.213 Exceptions from advance notice.** The agency may mail a notice no later than the date of action if--

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

**(b)** The agency receives a clear written statement signed by the recipient that--

**(1)** He no longer wishes services; or

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

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

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

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**§431.231 Reinstatement of services.**

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

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

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

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

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

**§431.214 Notice in the case of probable fraud.** The agency may shorten the period of advance notice to 5 days before the date of action if--

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

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

**********

**(2)** For denial of payment, at the time of any action affecting the claim.

**(3)** For standard service authorization decisions that deny or limit services, within the time frame specified in §438.210(d). [Section 438.210(d) is restated below.]

**********

**§438.210(d)** ***Timeframe for decisions.*** Each MCO, PIHP,… contract must provide for the following decisions and notices:

***(1) Standard authorization decisions.*** For standard authorization decisions, provide notice as expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

**(i)** The enrollee, or the provider, requests extension; or

**(ii)** The MCO, PIHP,… justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

***(2) Expedited authorization decisions.***

**(i)** For cases in which a provider indicates, or the MCO or PIHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability attain, maintain, or regain maximum function, the MCO, PIHP,… must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.

**(ii)** The MCO, PIHP,… may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP,… justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

**********

**(4)** If the MCO or PIHP extends the timeframe in accordance with §438.210(d), it must--

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

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

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

**(6)** For expedited service authorization decisions, within the timeframes specified in §438.210(d). [Section 438.210 provisions pertaining to expedited authorizations are restated below.]

**********

**§438.210(d)** ***Timeframe for decisions.*** Each MCO, PIHP,… contract must provide for the following decisions and notices:

***(2) Expedited authorization decisions.***

**(i)** For cases in which a provider indicates, or the MCO or PIHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability attain, maintain, or regain maximum function, the MCO, PIHP,… must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.

**(ii)** The MCO, PIHP,… may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP,… justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

**********

***Information to be obtained from the State*:** Obtain from the State Medicaid Agency information on the time frames within which it requires MCOs/PIHPs to make standard (initial) coverage and authorization decisions and provide written notice to requesting enrollees. These time frames will be the required time-frames within which MCOs/PIHPs must provide Medicaid enrollees with written notice of any intent to deny or limit a service (**for which previous authorization has not been given** by the MCO/PIHP) and the enrollee's right to file a MCO or PIHP appeal (or request a State fair hearing if the State does not require the enrollee to exhaust MCO/PIHP level appeals prior to requesting a State fair hearing).

***Document Review*:**

- Review administrative policies and procedures pertaining to providing Medicaid enrollees with a notice of action. Determine the extent to which there are written policies and procedures that require the MCO/PIHP, whenever it intends to deny, limit, reduce, suspend, or terminate a service or to deny payment for a service, or (for an enrollee in a rural area with only one MCO or PIHP) to deny the enrollee's request to exercise his or her right to obtain services outside the network, to:
  - Give the enrollee written notice that explains:
    - The action the MCO or PIHP or its contractor has taken or intends to take.
    - The reasons for the action.
    - The enrollee's or the provider's right to file an MCO or PIHP appeal.
    - If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.
    - The circumstances under which expedited resolution is available and how to request it.
    - 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.

- The procedures for exercising the rights to appeal, request a State fair hearing, obtain expedited resolution, and to have benefits continue pending resolution of the appeal.
- If the MCO or PIHP extends the timeframe for issuing an expedited resolution, 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
- Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date any extension expires.

- Give the enrollee written notice in accord with the following time frames:
  - **For termination, suspension, or reduction of *previously authorized* Medicaid-covered service,** the MCO/PIHP must mail a notice at least 10 days before the date of action, except as permitted below:
    *Exceptions from advance notice*. The MCO/PIHP may mail a notice no later than the date of action if--
    **(a)** The MCO/PIHP has factual information confirming the death of a recipient;
    **(b)** The MCO/PIHP receives a clear written statement signed by the recipient that--
      **(1)** He no longer wishes services; or
      **(2)** Gives information that requires termination or reduction of services and indicates that he understands that this must be the result of supplying that information;
    **(c)** The enrollee has been admitted to an institution where he or she is ineligible under the MCO's/PIHP's contract with the State for further services;
    **(d)** The enrollee's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address (but allowing that if the recipient's whereabouts become known, any discontinued service must be reinstated if his whereabouts become known during the time he is eligible for services.**]**
    **(e)** The MCO/PIHP establishes the fact that the enrollee has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth;
    **(f)** A change in the level of medical care is prescribed by the recipient's physician;
    **(g)** The notice involves an adverse determination made with regard to the preadmission screening requirements of section 1919(e)(r) of the Act; or
    **(h)** The date of action will occur in less than 10 days, in accordance with §483.12(a)(5)(ii), which provides exceptions to the 30 days notice requirements of §483.12(a)(5)(i).
    **(i)** The MCO/PIHP may shorten the period of advance notice to 5 days before the date of action if the MCO/PIHP has facts indicating that action should be taken because of probable fraud by the recipient; and the facts have been verified, if possible, through secondary sources.
  - **For denial of payment**, at the time of any action affecting the claim.

- **For standard *(initial)* service authorization decisions that deny or limit services**, within the time frame specified by the State (See *Information to be obtained from the State, above.)*
- **For expedited authorization decisions.**
  **(i)** For cases in which a provider indicates, or the MCO or PIHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability attain, maintain, or regain maximum function, the MCO or PIHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.
  **(ii)** The MCO or PIHP may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO or PIHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.
- **For standard service authorization decisions not reached within the established timeframes** (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

- Review administrative policies and procedures pertaining to providing Medicaid enrollees with translation and interpretation services during the grievance process.

- Review a sample of service authorization requests that were denied to any degree. Determine the extent to which the following items were addressed in the written notices to the enrollees notifying them of the MCO's/PIHP's intent to deny, limit, reduce, delay, or terminate a service, or deny payment for a service, or (for an enrollee in a rural area with only one MCO or PIHP) to deny the enrollee's request to exercise his or her right to obtain services outside the network:
  - The action the MCO or PIHP or its contractor has taken or intends to take.
  - The reasons for the action.
  - The enrollee's or the provider's right to file an MCO or PIHP appeal.
  - If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.
  - The circumstances under which expedited resolution is available and how to request it.
  - 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.
  - An assurance that an enrollee who files an appeal will not be treated differentially.
  - The procedures for exercising the rights to appeal, request a State fair hearing, obtain expedited resolution, and to have benefits continue pending resolution of the appeal.
  - If the MCO or PIHP extends the timeframe for issuing an expedited resolution 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.

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

- Using the same sample of denied service authorization requests, determine:
  - The timeliness of the grievance processing; and
  - The extent to which notices were written in easily understood language and in the languages prevalent in the service area.

- Using the same sample of denied service authorization requests, determine the extent to which the written notices to enrollees were provided within the following time frames:
  - **For termination, suspension, or reduction of <u>previously authorized</u> Medicaid-covered service,** the MCO/PIHP must mail a notice at least 10 days before the date of action, except as permitted below:

    *Exceptions from advance notice*. The MCO/PIHP may mail a notice no later than the date of action if--

    **(a)** The MCO/PIHP has factual information confirming the death of a recipient.

    **(b)** The MCO/PIHP receives a clear written statement signed by the recipient that--

    **(1)** He no longer wishes services, or

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

    **(c)** The enrollee has been admitted to an institution where he or she is ineligible under the MCO's/PIHP's contract with the State for further services.

    **(d)** The enrollee's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address (but allowing that if the recipient's whereabouts become known, any discontinued service must be reinstated if his whereabouts become known during the time he is eligible for services.)

    **(e)** The MCO/PIHP establishes the fact that the enrollee has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth.

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

    **(g)** The notice involves an adverse determination made with regard to the preadmission screening requirements of section 1919(e)(r) of the Act.

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

    **(i)** The MCO/PIHP may shorten the period of advance notice to 5 days before the date of action if the MCO/PIHP has facts indicating that action should be taken because of probable fraud by the recipient; and the facts have been verified, if possible, through secondary sources.

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

- **For standard (initial) service authorization decisions that deny or limit services**, within the time frame specified by the State (See *Information to be obtained from the State, above.)*
- **For expedited authorization decisions.**
  **(i)** For cases in which a provider indicates, or the MCO or PIHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability attain, maintain, or regain maximum function, the MCO or PIHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.
  **(ii)** The MCO or PIHP may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO or PIHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.
- **For standard service authorization decisions not reached within the established timeframes** (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

***Potential Interview Questions:***
None recommended.

## §438.406 Handling of grievances and appeals.

**(a)** ***General requirements.*** In handling grievances and appeals, each MCO and each PIHP must meet the following requirements:

**(1)** Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

**(2)** Acknowledge receipt of each grievance and appeal.

**(3)** Ensure that the individuals who make decisions on grievances and appeals are individuals--

**(i)** Who were not involved in any previous level of review or decision-making; and

**(ii)** Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

**(A)** An appeal of a denial that is based on lack of medical necessity.

**(B)** A grievance regarding denial of expedited resolution of an appeal.

**(C)** A grievance or appeal that involves clinical issues.

**(b)** ***Special requirements for appeals.*** The process for appeals must:

**(1)** Provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or provider requests expedited resolution.
**(2)** Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PIHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)
**(3)** Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.
**(4)** Include, as parties to the appeal--
**(i)** The enrollee and his or her representative; or
**(ii)** The legal representative of a deceased enrollee's estate.

***Document Review*:**

- Review written policies and procedures pertaining to enrollee appeals and grievances to determine the extent to which they contain provisions to ensure that:
  - Enrollees are provided any reasonable assistance (including interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability) in completing forms and taking other procedural steps.
  - Each grievance and appeal is formally acknowledged.
  - Individuals who make decisions on grievances and appeals are individuals--
    **(i)** who were not involved in any previous level of review or decision-making; and
    **(ii)** who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise 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.
  - The process for appeals:
    - Provides that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or provider requests expedited resolution.
    - Provides the enrollee with a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PIHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)
    - Provide the enrollee and his or her representative with an opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.
    - Include, as parties to the appeal--
      **(i)** the enrollee and his or her representative; or
      **(ii)** the legal representative of a deceased enrollee's estate.

- Review complaint and grievance logs or other tracking mechanisms, and files to determine the extent to which the receipt of grievances and appeals are acknowledged in writing.

***Potential Interview Questions:***

Organization Leaders

1. To what extent does your MCO/PIHP provide Medicaid enrollees with assistance in completing forms and taking other procedural steps in the grievance and appeal process? How does it do this?

2. How does your MCO/PIHP treat oral requests by Medicaid enrollees to appeal actions?
3. As part of an appeal, to what extent do enrollees and their representatives have an opportunity to:
   - Present evidence; and
   - Examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

4. What are the qualifications and credentials of individuals who make decisions on grievances and appeals? How does the MCO/PIHP ensure that these individuals--
   - Were not involved in any previous level of review or decision-making; and
   - If deciding any of the following, 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?

5. Is there a process in place to monitor either the appeal and grievance process or the areas of concern identified by enrollee appeals and grievances?

Utilization Management Staff

1. What MCO/PIHP department or staff is responsible for assisting enrollees in using the MCO's/PIHP's appeal or grievance system, including completing forms, or taking other steps to resolve an appeal or grievance?

2. What are the qualifications and credentials of individuals who make decisions on grievances and appeals? How does the MCO/PIHP ensure that these individuals--
   - Were not involved in any previous level of review or decision-making; and
   - If deciding any of the following, 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?

Enrollee Services Staff

1. What MCO/PIHP department or staff are responsible for assisting enrollees to use the organization's complaint or grievance system, including completing forms, or taking other steps to resolve an appeal or grievance? What kind of assistance is made available to Medicaid enrollees?

2. What are the qualifications and credentials of individuals who make decisions on grievances and appeals? How does the MCO/PIHP ensure that these individuals--
   - Were not involved in any previous level of review or decision-making; and
   - If deciding any of the following, 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. How does your MCO/PIHP treat oral requests by Medicaid enrollees to appeal actions?

4. As part of an appeal, to what extent do enrollees and their representatives have an opportunity to:
   - Present evidence, and
   - Examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. Is there a process in place to monitor either the appeal and grievance process or the areas of concern identified by enrollee appeals and grievances?

## §438.408 Resolution and notification: Grievances and appeals

**(a)** ***Basic rule.*** The MCO or PIHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established time frames that may not exceed time frames specified in this section.

**(b)** ***Specific timeframes.***

**(1) Standard disposition of grievances.** For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State, but may not exceed 90 days from the day the MCO or PIHP receives the grievance.

**(2) Standard resolution of appeals.** For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 45 days from the day the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

**(3) Expedited resolution of appeals.** For expedited resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer

than 3 working days after the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

**(c)** ***Extension of timeframes.***

**(1)** The MCO or PIHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if--

**(i)** The enrollee requests the extension; or

**(ii)** The MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is a need for additional information and how the delay is in the enrollee's interest.

**(2)** ***Requirements following extension.*** If the MCO or PIHP extends the timeframes, it must--for any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay.

**(d)** ***Format of notice.***

**(1)** ***Grievances.*** The State must establish the method the MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance.

**(2)** ***Appeals.***

**(i)** For all appeals, the MCO or PIHP must provide written notice of disposition.

**(ii)** For notice of expedited resolution, the MCO or PIHP must also make reasonable efforts to provide oral notice.

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

**(1)** The results of the resolution process and the date it was completed.

**(2)** For appeals not resolved wholly in favor of the enrollees--

**(i)** The right to request a State fair hearing, and how to do so;

**(ii)** The right to request to receive benefits while the hearing is pending, and how to make the request; and

**(iii)** That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PIHP's action.

**(f)** ***Requirements for State fair hearings.--***

**(1)** ***Availability.*** The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days from whichever of the following dates applies--

**(i)** If the State requires exhaustion of the MCO or PIHP level appeal procedures, from the date of the MCO's or PIHP's notice of resolution; or

**(ii)** If the State does not require exhaustion of the MCO or PIHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PIHP's notice of action.

**(2)** ***Parties.*** The parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

***Information to be obtained from the State*:** Obtain from the State Medicaid Agency:

1) The State-established **standard** time frames during which the State requires MCOs/PIHPs to:
   - Dispose of a grievance and notify the affected parties of the result;

- Resolve appeals and notify affected parties of the decision; and
- Expedite and resolve appeals and notify affected parties of the decision.

2) The methods prescribed by the State that the MCO/PIHP must follow to notify an enrollee of the disposition of a grievance.
3) Information on whether or not the State requires Medicaid enrollees to exhaust MCO or PIHP level appeals before receiving a State fair hearing.

***Document Review*:**

- Review the MCO's/PIHP's written policies and procedures pertaining to grievances, standard appeals, and expedited appeals. Determine the extent to which these include provisions that:
  - Require the MCO/PIHP to dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within the State-established time frames.
  - Allow the State-specified time frames for the notice and disposition of each grievance, and notice and resolution of each appeal, to be extended if--
    - The enrollee requests the extension; or
    - The MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is a need for additional information and how the delay is in the enrollee's interest.
  - Require that, if the MCO or PIHP extends the time frames for the notice and disposition of each grievance, and notice and resolution of each appeal, it must--for any extension not requested by the enrollee--give the enrollee written notice of the reason for the delay.
  - Require the MCO or PIHP to provide written notice of disposition of all appeals. The written notice must contain:
    - The results of the resolution process and the date it was completed.
    - 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 to receive benefits while the hearing is pending, and how to make the request; and
      (3) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PIHP's action.
  - Require the MCO or PIHP to provide oral notice of resolution of expedited appeals.

- Determine from a review of records of <u>grievances</u> (and any related tracking mechanisms) the extent to which there is evidence that the MCO/PIHP complied with the following policies and procedures when responding to the grievances:
  - The MCO/PIHP disposed of each grievance and provided notice, as expeditiously as the enrollee's health condition requires, within the State-established time frames.
  - Whenever the MCO/PIHP allowed the State-specified time frames for the notice and disposition of each grievance to be extended, there is documentation that--
    - Either enrollee had requested the extension or the MCO or PIHP showed (to the satisfaction of the State agency, upon its request) that there was a need for additional information and that the delay was in the enrollee's interest.

        - For any extension not requested by the enrollee, the MCO/PIHP gave the enrollee written notice of the reason for the delay.

    - The MCO or PIHP provided notice of the resolution of all grievances in accord with the method specified by the State.

- Determine from a review of records of appeals (and any related tracking mechanisms) the extent to which there is evidence that the MCO/PIHP complied with the following policies and procedures when responding to appeals:
    - The MCO/PIHP resolved each appeal, and provided notice, as expeditiously as the enrollee's health condition requires, within the State-established time frames.
    - Whenever the MCO/PIHP allowed the State-specified time frames for the notice and resolution of each appeal to be extended there is documentation that--
        - Either enrollee had requested the extension or the MCO or PIHP showed (to the satisfaction of the State agency, upon its request) that there was a need for additional information and that the delay was in the enrollee's interest.
        - For any extension not requested by the enrollee, the MCO/PIHP gave the enrollee written notice of the reason for the delay.
    - The MCO or PIHP provided written notice of the disposition of all appeals and additionally, oral notice of resolution of all expedited appeals. All written notices contained:
        - The results of the resolution process and the date it was completed.
        - 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 to receive benefits while the hearing is pending, and how to make the request; and
            (3) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PHIP's action.

- Review a sample of grievance resolution notifications to determine the extent to which they meet the requirements specified by the State.

***Potential Interview Questions:***

Organization Leaders

1. Approximately how many grievances did the MCO/PIHP receive in the most recent reporting year?

2. Approximately how many appeals did the MCO/PIHP receive in the most recent reporting year?

3. Approximately what percent of notices of action on requests for service authorization or payment by Medicaid enrollees are appealed to the MCO/PIHP?

4. Approximately what percent of notices of action on requests for service authorization or payment by Medicaid enrollees are appealed to the State fair hearing process? Approximately what percent of these are overturned by the State?

Enrollee Services Staff

1. Describe the MCO's/PIHP's grievance resolution process.

2. Describe the MCO's/PIHP's appeal resolution process. Are Medicaid enrollees required to exhaust the MCO's/PIHP's internal appeals process before seeking and receiving a State fair hearing?

3. How is it determined that an enrollee's appeal requires expedited resolution?

4. What percent of appeal resolutions that are completely or partially adverse to Medicaid enrollees are appealed to the State fair hearing process? Of these, what percent are overturned by the State Medicaid agency?

## §438.410 Expedited resolution of appeals.

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

**(b)** ***Punitive Action.*** The MCO or PIHP must ensure that punitive action is neither taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

**(c)** ***Action following denial of a request for expedited resolution.*** If the MCO or PIHP denies a request for expedited resolution of an appeal, it must--

**(1)** Transfer the appeal to the timeframe for standard resolution in accordance with §438.408(b)(2);

**(2)** Give the enrollee prompt oral notice of the denial, and follow up within 2 calendar days with a written notice.

***Document Review*:**

- Review the MCO's/PIHP's written policies and procedures pertaining to handling of enrollee appeals. Determine the extent to which these policies and procedures require the MCO/PIHP to:
  - Establish and maintain an expedited review process for appeals, when the MCO or PIHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function.

- Ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee's appeal.
- When denying a request for expedited resolution of an appeal:
    1) Transfer the appeal to the timeframe for resolving and notifying enrollees for standard resolution of appeals, and
    2) Give the enrollee prompt oral notice of the denial followed up with a written notice within 2 calendar days.

- Determine from a review of appeal and resolution recordkeeping such as logs, files and other tracking mechanisms, the extent to which the MCO/PIHP issued expedited grievance resolution decisions--
    - As expeditiously as the enrollee's health condition requires; and
    - Within the time frames established by the State agency (See above, *Information to be obtained from the State Medicaid agency*.) or up to 14 days later if--
        - the enrollee requests the extension; or
        - the MCO/PIHP justifies (to the satisfaction of the State agency, upon request,) a need for additional information and how the delay is in the interest of the enrollee.

- Identify from the review of appeal and resolution logs, files and other tracking mechanisms, those cases where a request for expedited resolution of an appeal was denied. Determine the extent to which the MCO/PIHP:
    - Transferred the request to the time frame for standard resolution.
    - Gave the enrollee prompt oral notice of the denial of the request and followed up within 2 working days, with written notice.

***Potential Interview Questions:***

Organization Leaders

1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? Describe this process. What are the time frames for this process?

2. Are physicians allowed to request expedited appeals on behalf of an enrollee? How does the MCO/PIHP protect physicians who make such requests?

Enrollee Services Staff

1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? Describe this process. What are the timeframes defined for this process?

2. How does the MCO/PIHP notify enrollees of any denials of a request for expedited resolution?

3. Have there been any complaints by Medicaid enrollees that their requests for expedited appeals have not been acted upon timely; e.g., within three working days. If so, how many such complaints were received in the year under review?

Utilization Management Staff

1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of a grievance? Describe this process. What are the timeframes defined for this process?

2. How does the MCO/PIHP notify enrollees of any denials of a request for expedited resolution?

Provider /Contractors (OPTIONAL)

1. Have there been any instances in the most recent year under review when the MCO/PIHP took any punitive action against you for requesting an expedited resolution of an appeal on behalf of a Medicaid enrollee or for supporting an enrollee's appeal?

## §438.414 Information about the grievance system to providers and subcontractors.

The MCO or PIHP must provide the information specified at §438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract. [Section §438.10(g)(1) is restated below.]

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**§438.10(g)(1)** Grievance . . . procedures and time frames, as provided in §§438.400 through 438.424, in a State-developed or State-approved description, that must include:

**(i)** . . .

**(ii)** The right to file grievances . . .

**(iii)** The requirements and timeframes for filing a grievance . . .

**(iv)** The availability of assistance in the filing process.

**(v)** The toll-free numbers that the enrollee can use to file a grievance . . .

***Information to be obtained from the State*:** Obtain from the State Medicaid Agency information on:

1) Whether the State develops or approves the MCO's/PIHP's description of its grievance system that the MCO/PIHP is required to provide to all Medicaid enrollees. [Note that under regulations at §438.10(g)(1) the State must either develop a description for use by the MCO/PIHP or approve a description developed by the MCO/PIHP.]
2) If the States approves, rather than develops, the description of the MCO's/PIHP's grievance system, information on whether or not the State has already approved the MCO's/PIHP's description.
3) The State-specified time frames for disposition of grievances.

***Document Review*:**

- Review the MCO's/PIHP's provider contracts and procedure manuals and determine the extent to which the MCO/PIHP informs all providers and contractors, at the time they enter into a contract with the MCO/PIHP, of the grievance procedures and time frames available to Medicaid enrollees, including information on:
    - enrollees' right to file grievances;
    - requirements and time frames for filing a grievance;
    - availability of assistance to an enrollee in the filing process; and
    - toll-free numbers that an enrollee can use to file a grievance by phone.

  This information should be information that has either been prescribed or approved by the State.

- Review the description of the grievance system provided to providers and subcontractors in provider contracts and procedure manuals:
    - If the State developed the description of the MCO's/PIHP's grievance system that the MCO/PIHP must use, determine whether or not the MCO/PIHP actually used the State-developed description to inform Medicaid enrollees, providers (and potential enrollees, as appropriate) about the Medicaid grievance procedures. (See *Information to be obtained from the State Medicaid agency*, above.)
    - If the States approves, rather than develops, the description of the MCO's/PIHP's grievance system, obtain a copy of the State's approval from the MCO/PIHP (unless the State is using this compliance monitoring as the mechanism for granting its approval).
    - If the State expects the EQRO, as a part of its compliance review, to approve the MCO's/PIHP's description, determine the extent to which the MCO's/PIHP's description meets all State specifications beyond those required above. (See *Information to be obtained from the State Medicaid agency*, above.)
    - Determine the extent to which the description of the time frames for filing a grievance, and the disposition of the grievance are consistent with the time frames specified by the State.
    - Determine the extent to which the description of the procedures for filing a grievance included:
        - enrollees' right to file grievances;
        - requirements and timeframes for filing a grievance;
        - availability of assistance to an enrollee in the filing process; and
        - toll-free numbers that an enrollee can use to file a grievance by phone.

***Potential Interview Questions:***
Organization Leaders:

1. Who in your MCO/PIHP has responsibility for the proper functioning of the grievance process and the authority to require corrective action?

2. Did your State Medicaid agency develop or approve the description of your MCO's/PIHP's grievance system that your MCO/PIHP provides to Medicaid providers? Which, develop or approve? If it approved your description, how is the States' approval documented?

Provider/Contractor Services Staff (individual and institutional)

1. When are providers given information about the MCO's/PIHP's Medicaid complaint and grievance system? What is typically included in the information given to providers relative to Medicaid grievances?

## §438.416 Recordkeeping and reporting requirements.

The State must require MCOs and PIHPs to maintain records of grievances and appeals and must review the information as part of the State quality strategy.

***Document Review*:**

- Review the MCO's/PIHP's written policies and procedures on enrollee services and enrollee grievances and appeals. Determine the extent to which the MCO/PIHP has established a process for maintaining records of all grievances and appeals.

- Review the MCO's/PIHP's logs, registry or other written records of Medicaid grievances and appals. Determine the extent to which there is sufficient data on each grievance and appeal to identify the person who makes the grievance or appeal, and the date of receipt, nature, resolution, and date of resolution for each grievance and appeal.

***Potential Interview Questions:***
Organization Leaders:

1. Where in your MCO/PIHP are records on Medicaid enrollee grievances and appeals kept?

Enrollee Services Staff:

1. How are Medicaid grievances and appeals registered and tracked for resolution? Is each grievance and appeal tracked through to resolution?

2. How often is Medicaid grievance and appeal information analyzed for trends? Who receives this analysis? Does the MCO/PIHP provide any information to the State relative to its grievances and appeals?

3. How long are Medicaid grievance and appeal records retained?

4. To what extent is information on Medicaid enrollee grievances and appeals analyzed and included as part of your MCO's/PIHP's Quality Assessment and Performance Improvement Program?

Quality Assessment and Performance Improvement Program Leader(s) and Staff

1. To what extent is information on Medicaid enrollee grievances and appeals analyzed and included as part of your MCO's/PIHP's Quality Assessment and Performance Improvement Program?

## §438.420 Continuation of benefits while the MCO or PIHP appeal and the State fair hearing are pending.

**(a)** ***Terminology.*** As used in this section, "timely" filing means filing on or before the later of the following:
- **(1)** Within ten days of the MCO or PIHP mailing the notice of action.
- **(2)** The intended effective date of the MCO's or PIHP's proposed action.

**(b)** ***Continuation of benefits.*** The MCO or PIHP must continue the enrollee's benefits if-
- **(1)** The enrollee or the provider files the appeal timely;
- **(2)** The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;
- **(3)** The services were ordered by an authorized provider;
- **(4)** The original period covered by the original authorization has not expired; and
- **(5)** The enrollee requests extension of benefits.

**(c)** ***Duration of continued or reinstated benefits.*** If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of the following occurs:
- **(1)** The enrollee withdraws the appeal.
- **(2)** Ten days pass after the MCO or PIHP mails the notice, providing the resolution of the appeal against the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.
- **(3)** A State fair hearing Office issues a hearing decision adverse to the enrollee.
- **(4)** The time period or service limits of a previously authorized service has been met.

**(d)** ***Enrollee responsibility for services furnished while the appeal is pending.*** If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PIHP's action, the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in §431.230(b) of this chapter. **[Section 431.230(b) is restated below.]**

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**§431.230 Maintaining services.**

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

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**[*Note to reviewers:* Note that this provision only applies when an MCO/PIHP provider previously authorized the service <u>and</u> the Medicaid enrollee received the service <u>and</u> the enrollee requests that the services be continued. It does not apply to preservice authorization requests that are denied. This means that the mere action of filing an appeal or for a State fair hearing in a timely manner is not sufficient for benefits to be initiated.]**

***Information to be obtained from the State*:** Obtain from the State Medicaid Agency information on any time limits specified by the State that must be met by Medicaid enrolles who wish to file an appeal, request for expedited appeal or State fair hearing.

***Document Review*:**

- Review the MCO's/PIHP's written policies and procedures pertaining to appeals, continuation of benefits, and utilization management. Determine the extent to which these policies and procedures allow for a Medicaid enrollee to continue to receive previously authorized benefits if the following conditions are met:
    - The enrollee or the provider files an appeal timely.
    - The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment.
    - The services were ordered by an authorized provider.
    - The period covered by the authorization has not expired.
    - The enrollee requests extension of benefits.

    **And** until one of the following occurs:

    (1) The enrollee withdraws the appeal.

    (2) The MCO or PIHP resolves the appeal against the enrollee, unless the enrollee has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

    (3) A State fair hearing Office issues a hearing decision adverse to the enrollee.

***Potential Interview Questions:***

Enrollee Services Staff

1. What happens to enrollee benefits once continuation of benefits has been denied by the MCO/PIHP, and an appeal has been filed by the enrollee or the treating physician? Are there any mechanisms in place to continue the benefits pending the outcome of the appeal? If so, under what circumstances?

Utilization Management Staff

1. What happens to enrollee benefits once continuation of benefits has been denied by the MCO/PIHP, and an appeal has been filed by the enrollee or the treating physician? Are there any mechanisms in place to continue the benefits pending the outcome of the appeal? If so, under what circumstances?

## §438.424 Effectuation of reversed appeal resolutions.

**(a)** ***Services not furnished while the appeal is pending.*** If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

**(b)** ***Services furnished while the appeal is pending.*** If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PIHP or the State must pay for those services, in accordance with State policy and regulations.

***Information to be obtained from the State*:** Obtain from the State Medicaid Agency information on whether the State or the MCO/PIHP is required to pay for services in situation in which the MCO or PIHP, or the State fair hearing officer reversed a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending.

***Document Review*:**

- Review the MCO's/PIHP's written policies and procedures pertaining to appeals and utilization management. Determine the extent to which there are written policies and procedures to ensure that when an appeal or State fair hearing results in a reversal of a decision to deny, limit, or delay services:

  - And the services <u>were not furnished</u> while the appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

  - And the services <u>were furnished</u> while the appeal was pending, the MCO or the PIHP or the State must pay for those services, in accordance with State policy.

- Review logs and records of all grievances and appeals and requests for a State fair hearing made in the last year.
  - If the State has determined that the MCO/PIHP (as opposed to the State) must pay for the services in situations in which:
    1) Services were furnished while an appeal is pending, and
    2) The appeal or State fair hearing has upheld the provision of the benefit,

determine the extent to which enrollees filed a grievance that the MCO/PIHP failed to do so.

- Determine the extent to which enrollees made grievance that the MCO/PIHP failed to authorize or provide any disputed services promptly, and as expeditiously as the enrollee's health condition required in situation in which services were not furnished while an appeal was pending, and the MCO or PIHP or State fair hearing reversed the decision to deny, limit or delay the service.

***Potential Interview Questions:***

None recommended.

**END OF ATTACHMENT B**