State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Solicitation

NUMBER	PAGE
BMS14028	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
BOB KILPATRICK
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES
ROOM 251
350 CAPITOL STREET
CHARLESTON, WV
25301-3709 304-558-1737

DATE PRINTED
05/22/2014

BID OPENING DATE: 06/18/2014 BID OPENING TIME 1:30PM

LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

REQUEST FOR PROPOSAL
(RFP)

THE WEST VIRGINIA PURCHASING DIVISION, ON BEHALF OF THE WV DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES, IS SOLICITING PROPOSALS TO PROVIDE A ENROLLMENT BROKERAGE SERVICES FROM A QUALIFIED VENDOR FOR THE MEDICAID MANAGED CARE PROGRAM IN ACCORDANCE WITH THE ATTACHED SPECIFICATIONS.

ATTACHMENTS INLCUDE:

1. BMS14028 REQUEST FOR PROPOSAL
2. ATTACHMENT A: VENDOR RESPONSE SHEET
3. ATTACHMENT B: MANDATORY SPECIFICATION CHECKLIST
4. ATTACHMENT C: COST SHEET
5. EXHIBIT A: STATE DOCUMENTS
6. EXHIBIT B: CODE OF FEDERAL REGULATIONS
7. HIPAA BUSINESS ASSOCIATE ADDENDUM
8. BID BOND PREPARATION INSTRUCTIONS AND SAMPLE FORM
9. PURCHASING AFFIDAVIT
10. VENDOR PREFERENCE CERTIFICATIONS

****
PLEASE NOTE: A MANDATORY PRE-BID MEETING IS SCHEDULED FOR 6/5/2014 AT 1:30PM EST AT THE BUREAU'S OFFICES AT 350 CAPITOL STREET, ROOM 251, CHARLESTON, WV, 25301
****

SIGNATURE	TELEPHONE	DATE
TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO SOLICITATION, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Solicitation

NUMBER	PAGE
BMS14028	2

ADDRESS CORRESPONDENCE TO ATTENTION OF:
BOB KILPATRICK
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES
ROOM 251
350 CAPITOL STREET
CHARLESTON, WV
25301-3709 304-558-1737

DATE PRINTED
05/22/2014

BID OPENING DATE: 06/18/2014 BID OPENING TIME 1:30PM

LINE	QUANTITY	UOP	CAT NO.	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	1	LS		948-74		

PER THE ATTACHED SPECIFICATIONS

****** THIS IS THE END OF RFQ BMS14028 ****** TOTAL:

SIGNATURE	TELEPHONE	DATE
TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO SOLICITATION, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

REQUEST FOR PROPOSAL

West Virginia Bureau for Medical Services
RFP # BMS14028

TABLE OF CONTENTS

SECTION ONE: GENERAL INFORMATION

1. Purpose: The West Virginia Department of Administration, Purchasing Division (hereinafter referred to as the "Purchasing Division") is soliciting proposals pursuant to West Virginia Code §5A-3-10b for the West Virginia Department of Health and Human Resources ("DHHR"), West Virginia Bureau for Medical Services (hereinafter referred to as the "Agency" or "BMS") to provide **enrollment broker services** from a qualified Vendor for the Medicaid Managed Care program in accordance with the attached specifications.

2. By signing and submitting its proposal, the successful Vendor agrees to be bound by all the terms contained in this Request for Proposal ("RFP").

   An RFP is generally used for the procurement of services in situations where price is not the sole determining factor and the award will be based on a combination of cost and technical factors (Best Value). Through its proposal, the bidder offers a solution to the objectives, problem, or need specified in the RFP, and defines how it intends to meet (or exceed) the RFP requirements.

3. Schedule of Events:

   Vendor's Written Questions Submission Deadline.....6/9/2014
   Mandatory Pre-bid Conference (see Instruction to Vendors).....6/5/2014
   Addendum Issued (by).....6/11/2014
   Bid Opening Date.....6/18/2014
   Oral Presentation *(Agency Option)* ..... TBD

REQUEST FOR PROPOSAL

West Virginia Bureau for Medical Services
RFP # BMS14028

SECTION TWO: INSTRUCTIONS TO VENDORS SUBMITTING BIDS

Instructions begin on next page.

INSTRUCTIONS TO VENDORS SUBMITTING BIDS

1. **REVIEW DOCUMENTS THOROUGHLY:** The attached documents contain a solicitation for bids. Please read these instructions and all documents attached in their entirety. These instructions provide critical information about requirements that if overlooked could lead to disqualification of a Vendor's bid. All bids must be submitted in accordance with the provisions contained in these instructions and the Solicitation. Failure to do so may result in disqualification of Vendor's bid.

2. **MANDATORY TERMS:** The Solicitation may contain mandatory provisions identified by the use of the words "must," "will," and "shall." Failure to comply with a mandatory term in the Solicitation will result in bid disqualification.

3. **PREBID MEETING:** The item identified below shall apply to this Solicitation.

☐ A pre-bid meeting will not be held prior to bid opening.

☐ A **NON-MANDATORY PRE-BID** meeting will be held at the following place and time:

☑ A **MANDATORY PRE-BID** meeting will be held at the following place and time:
Thursday, June 5, 2014 at 1:30pm EST, at:

Department of Health and Human Resources, Bureau for Medical Services
350 Capitol Street, Room 251
Charleston, WV 25301
(Vendors should arrive early enough to go through security check).

All Vendors submitting a bid must attend the mandatory pre-bid meeting. Failure to attend the mandatory pre-bid meeting shall result in disqualification of the Vendor's bid. No one person attending the pre-bid meeting may represent more than one Vendor.

An attendance sheet provided at the pre-bid meeting shall serve as the official document verifying attendance. The State will not accept any other form of proof or documentation to verify attendance. Any person attending the pre-bid meeting on behalf of a Vendor must list on the attendance sheet his or her name and the name of the Vendor he or she is representing. Additionally, the person attending the pre-bid meeting should include the Vendor's E-Mail address, phone number, and Fax number on the attendance sheet. It is the Vendor's responsibility to locate the attendance sheet and provide the required information. Failure to complete the attendance sheet as required may result in disqualification of Vendor's bid.

All Vendors should arrive prior to the starting time for the pre-bid. Vendors who arrive after the starting time but prior to the end of the pre-bid will be permitted to sign in, but are charged with knowing all matters discussed at the pre-bid.

Questions submitted at least five business days prior to a scheduled pre-bid will be discussed at the pre-bid meeting if possible. Any discussions or answers to questions at the pre-bid meeting are preliminary in nature and are non-binding. Official and binding answers to questions will be published in a written addendum to the Solicitation prior to bid opening.

4. **VENDOR QUESTION DEADLINE:** Vendors may submit questions relating to this Solicitation to the Purchasing Division. Questions must be submitted in writing. All questions must be submitted on or before the date listed below and to the address listed below in order to be considered. A written response will be published in a Solicitation addendum if a response is possible and appropriate. Non-written discussions, conversations, or questions and answers regarding this Solicitation are preliminary in nature and are non-binding.

Question Submission Deadline: Monday, June 9, 2014 by 5:00pm EST

Submit Questions to: Robert P Kilpatrick, Senior Buyer
2019 Washington Street, East
Charleston, WV 25305
Fax: (304) 558-4115
(Vendors should not use this fax number for bid submission)
Email: robert.p.kilpatrick@wv.gov

5. **VERBAL COMMUNICATION:** Any verbal communication between the Vendor and any State personnel is not binding, including that made at the mandatory pre-bid conference. Only information issued in writing and added to the Solicitation by an official written addendum by the Purchasing Division is binding.

6. **BID SUBMISSION:** All bids must be signed and delivered by the Vendor to the Purchasing Division at the address listed below on or before the date and time of the bid opening. Any bid received by the Purchasing Division staff is considered to be in the possession of the Purchasing Division and will not be returned for any reason. The Purchasing Division will not accept bids, modification of bids, or addendum acknowledgment forms via e-mail. Acceptable delivery methods include hand delivery, delivery by courier, or facsimile. The bid delivery address is:

Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

The bid should contain the information listed below on the face of the envelope or the bid maynot be considered:

SEALED BID: _____
BUYER: Robert P Kilpatrick, File 22
SOLICITATION NO.: BMS14028
BID OPENING DATE: June 18, 2014
BID OPENING TIME: 1:30pm EST
FAX NUMBER: 304-558-3970

In the event that Vendor is responding to a request for proposal, the Vendor shall submit one original technical and one original cost proposal plus 8 convenience copies of each to the Purchasing Division at the address shown above. Additionally, the Vendor should identify the bid type as either a technical or cost proposal on the face of each bid envelope submitted in response to a request for proposal as follows:

BID TYPE: ☐ Technical
☐ Cost

7. **BID OPENING:** Bids submitted in response to this Solicitation will be opened at the location identified below on the date and time listed below. Delivery of a bid after the bid opening date and time will result in bid disqualification. For purposes of this Solicitation, a bid is considered delivered when time stamped bythe official Purchasing Division time clock.

Bid Opening Date and Time: Wednesday, June 18, 2014 at 1:30pm EST

Bid Opening Location: Department of Administration, Purchasing Division
2019 Washington Street East
Charleston, WV 25305-0130

8. **ADDENDUM ACKNOWLEDGEMENT:** Changes or revisions to this Solicitation will be made by an official written addendum issued by the Purchasing Division. Vendor should acknowledge receipt of all addenda issued with this Solicitation by completing an Addendum Acknowledgment Form, a copy of which is included herewith. Failure to acknowledge addenda may result in bid disqualification. The addendum acknowledgement should be submitted with the bid to expedite document processing.

9. **BID FORMATTING:** Vendor should type or electronically enter the information onto its bid to prevent errors in the evaluation. Failure to type or electronically enter the information may result in bid disqualification.

REQUEST FOR PROPOSAL

West Virginia Bureau for Medical Services
RFP # BMS14028

SECTION THREE: GENERAL TERMS AND CONDITIONS

Terms and conditions begin on next page.

GENERAL TERMS AND CONDITIONS:

1. **CONTRACTUAL AGREEMENT:** Issuance of a Purchase Order signed by the Purchasing Division Director, or his designee, and approved as to form by the Attorney General's office constitutes acceptance of this Contract made by and between the State of West Virginia and the Vendor. Vendor's signature on its bid signifies Vendor's agreement to be bound by and accept the terms and conditions contained in this Contract.

2. **DEFINITIONS:** As used in this Solicitation/Contract, the following terms shall have the meanings attributed to them below. Additional definitions may be found in the specifications included with this Solicitation/Contract.

   2.1 "Agency" or **"Agencies"** means the agency, board, commission, or other entity of the State of West Virginia that is identified on the first page of the Solicitation or any other public entity seeking to procure goods or services under this Contract.

   2.2 "Contract" means the binding agreement that is entered into between the State and the Vendor to provide the goods and services requested in the Solicitation.

   2.3 "Director" means the Director of the West Virginia Department of Administration, Purchasing Division.

   2.4 "Purchasing Division" means the West Virginia Department of Administration, Purchasing Division.

   2.5 "Purchase Order" means the document signed by the Agency and the Purchasing Division, and approved as to form by the Attorney General, that identifies the Vendor as the successful bidder and Contract holder.

   2.6 "Solicitation" means the official solicitation published by the Purchasing Division and identified by number on the first page thereof.

   2.7 "State" means the State of West Virginia and/or any of its agencies, commissions, boards, etc. as context requires.

   2.8 "Vendor" or **"Vendors"** means any entity submitting a bid in response to the Solicitation, the entity that has been selected as the lowest responsible bidder, or the entity that has been awarded the Contract as context requires.

3. **CONTRACT TERM; RENEWAL; EXTENSION:** The term of this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below:

☑ **Term Contract**

Initial Contract Term: This Contract becomes effective on Upon Award

and extends for a period of one (1) year(s).

Renewal Term: This Contract may be renewed upon the mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). Any request for renewal must be submitted to the Purchasing Division Director thirty (30) days prior to the expiration date of the initial contract term or appropriate renewal term. A Contract renewal shall be in accordance with the terms and conditions of the original contract. Renewal of this Contract is limited to four (4) successive one (1) year periods. Automatic renewal of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases. Attorney General approval may be required for vendor terms and conditions.

Reasonable Time Extension: At the sole discretion of the Purchasing Division Director, and with approval from the Attorney General's office (Attorney General approval is as to form only), this Contract may be extended for a reasonable time after the initial Contract term or after any renewal term as may be necessary to obtain a new contract or renew this Contract. Any reasonable time extension shall not exceed twelve (12) months. Vendor may avoid a reasonable time extension by providing the Purchasing Division Director with written notice of Vendor's desire to terminate this Contract 30 days prior to the expiration of the then current term. During any reasonable time extension period, the Vendor may terminate this Contract for any reason upon giving the Purchasing Division Director 30 days written notice. Automatic extension of this Contract is prohibited. Notwithstanding the foregoing, Purchasing Division approval is not required on agency delegated or exempt purchases, but Attorney General approval may be required.

Release Order Limitations: In the event that this contract permits release orders, a release order may only be issued during the time this Contract is in effect. Any release order issued within one year of the expiration of this Contract shall be effective for one year from the date the release order is issued. No release order may be extended beyond one year after this Contract has expired.

☐ **Fixed Period Contract:** This Contract becomes effective upon Vendor's receipt of the notice to proceed and must be completed within days.

☐ **One Time Purchase:** The term of this Contract shall run from the issuance of the Purchase Order until all of the goods contracted for have been delivered, but in no event shall this Contract extend for more than one fiscal year.

☐ **Other:** See attached.

4. **NOTICE TO PROCEED:** Vendor shall begin performance of this Contract immediately upon receiving notice to proceed unless otherwise instructed by the Agency. Unless otherwise specified, the fully executed Purchase Order will be considered notice to proceed

5. **QUANTITIES:** The quantities required under this Contract shall be determined in accordance with the category that has been identified as applicable to this Contract below.

☑ **Open End Contract:** Quantities listed in this Solicitation are approximations only, based on estimates supplied by the Agency. It is understood and agreed that the Contract shall cover the quantities actually ordered for delivery during the term of the Contract, whether more or less than the quantities shown.

☑ **Service:** The scope of the service to be provided will be more clearly defined in the specifications included herewith.

☐ **Combined Service and Goods:** The scope of the service and deliverable goods to be provided will be more clearly defined in the specifications included herewith.

☐ **One Time Purchase:** This Contract is for the purchase of a set quantity of goods that are identified in the specifications included herewith. Once those items have been delivered, no additional goods may be procured under this Contract without an appropriate change order approved by the Vendor, Agency, Purchasing Division, and Attorney General's office.

6. **PRICING:** The pricing set forth herein is firm for the life of the Contract, unless specified elsewhere within this Solicitation/Contract by the State. A Vendor's inclusion of price adjustment provisions in its bid, without an express authorization from the State in the Solicitation to do so, may result in bid disqualification.

7. **EMERGENCY PURCHASES:** The Purchasing Division Director may authorize the Agency to purchase goods or services in the open market that Vendor would otherwise provide under this Contract if those goods or services are for immediate or expedited delivery in an emergency. Emergencies shall include, but are not limited to, delays in transportation or an unanticipated increase in the volume of work. An emergency purchase in the open market, approved by the Purchasing Division Director, shall not constitute of breach of this Contract and shall not entitle the Vendor to any form of compensation or damages. This provision does not excuse the State from fulfilling its obligations under a One Time Purchase contract.

8. **REQUIRED DOCUMENTS:** All of the items checked below must be provided to the Purchasing Division by the Vendor as specified below.

☑ **BID BOND:** All Vendors shall furnish a bid bond in the amount of five percent (5%) of the total amount of the bid protecting the State of West Virginia. The bid bond must be submitted with the bid. Please review attached Bid Bond Preparation Instructions/Sample Form

☐ **PERFORMANCE BOND:** The apparent successful Vendor shall provide a performance bond in the amount of . The performance bond must be issued and received by the Purchasing Division prior to Contract award. On construction contracts, the performance bond must be 100% of the Contract value.

☐ **LABOR/MATERIAL PAYMENT BOND:** The apparent successful Vendor shall provide a labor/material payment bond in the amount of 100% of the Contract value. The labor/material payment bond must be issued and delivered to the Purchasing Division prior to Contract award.

In lieu of the Bid Bond, Performance Bond, and Labor/Material Payment Bond, the Vendor may provide certified checks, cashier's checks, or irrevocable letters of credit. Any certified check, cashier's check, or irrevocable letter of credit provided in lieu of a bond must be of the same amount and delivered on the same schedule as the bond it replaces. A letter of credit submitted in lieu of a performance and labor/material payment bond will only be allowed for projects under $100,000. Personal or business checks are not acceptable.

☐ **MAINTENANCE BOND:** The apparent successful Vendor shall provide a two (2) year maintenance bond covering the roofing system. The maintenance bond must be issued and delivered to the Purchasing Division prior to Contract award.

☑ **WORKERS' COMPENSATION INSURANCE:** The apparent successful Vendor shall have appropriate workers' compensation insurance and shall provide proof thereof upon request.

☑ **INSURANCE:** The apparent successful Vendor shall furnish proof of the following insurance prior to Contract award and shall list the state as a certificate holder:

☑ **Commercial General Liability Insurance:**
$1,000,000.00 per occurrence or more.

☐ **Builders Risk Insurance:** builders risk – all risk insurance in an amount equal to 100% of the amount of the Contract.

☑ Property Damage: Minimum of $1,000,000.00 per occurrence

☑ Professional Liability: Minimum of $1,000,000.00 per occurrence

☐

☐

☐

The apparent successful Vendor shall also furnish proof of any additional insurance requirements contained in the specifications prior to Contract award regardless of whether or not that insurance requirement is listed above.

☐ **LICENSE(S) / CERTIFICATIONS / PERMITS:** In addition to anything required under the Section entitled Licensing, of the General Terms and Conditions, the apparent successful Vendor shall furnish proof of the following licenses, certifications, and/or permits prior to Contract award, in a form acceptable to the Purchasing Division.

☐

☐

☐

☐

The apparent successful Vendor shall also furnish proof of any additional licenses or certifications contained in the specifications prior to Contract award regardless of whether or not that requirement is listed above.

9. **LITIGATION BOND:** The Director reserves the right to require any Vendor that files a protest of an award to submit a litigation bond in the amount equal to one percent of the lowest bid submitted or $5,000, whichever is greater. The entire amount of the bond shall be forfeited if the hearing officer determines that the protest was filed for frivolous or improper purpose, including but not limited to, the purpose of harassing, causing unnecessary delay, or needless expense for the Agency. All litigation bonds shall be made payable to the Purchasing Division. In lieu of a bond, the protester may submit a cashier's check or certified check payable to the Purchasing Division. Cashier's or certified checks will be deposited with and held by the State Treasurer's office. If it is determined that the protest has not been filed for frivolous or improper purpose, the bond or deposit shall be returned in its entirety.

10. **ALTERNATES:** Any model, brand, or specification listed herein establishes the acceptable level of quality only and is not intended to reflect a preference for, or in any way favor, a particular brand or vendor. Vendors may bid alternates to a listed model or brand provided that the alternate is at least equal to the model or brand and complies with the required specifications. The equality of any alternate being bid shall be determined by the State at its sole discretion. Any Vendor bidding an alternate model or brand should clearly identify the alternate items in its bid and should include manufacturer's specifications, industry literature, and/or any other relevant documentation demonstrating the equality of the alternate items. Failure to provide information for alternate items may be grounds for rejection of a Vendor's bid.

11. **EXCEPTIONS AND CLARIFICATIONS:** The Solicitation contains the specifications that shall form the basis of a contractual agreement. Vendor shall clearly mark any exceptions, clarifications, or

other proposed modifications in its bid. Exceptions to, clarifications of, or modifications of a requirement or term and condition of the Solicitation may result in bid disqualification.

12. **LIQUIDATED DAMAGES:** Vendor shall pay liquidated damages in the amount NA for NA

This clause shall in no way be considered exclusive and shall not limit the State or Agency's right to pursue any other available remedy.

13. **ACCEPTANCE/REJECTION:** The State may accept or reject any bid in whole, or in part. Vendor's signature on its bid signifies acceptance of the terms and conditions contained in the Solicitation and Vendor agrees to be bound by the terms of the Contract, as reflected in the Purchase Order, upon receipt.

14. **REGISTRATION:** Prior to Contract award, the apparent successful Vendor must be properly registered with the West Virginia Purchasing Division and must have paid the $125 fee if applicable.

15. **COMMUNICATION LIMITATIONS:** In accordance with West Virginia Code of State Rules §148-1-6.6, communication with the State of West Virginia or any of its employees regarding this Solicitation during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited without prior Purchasing Division approval. Purchasing Division approval for such communication is implied for all agency delegated and exempt purchases.

16. **FUNDING:** This Contract shall continue for the term stated herein, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise made available, this Contract becomes void and of no effect beginning on July 1 of the fiscal year for which funding has not been appropriated or otherwise made available.

17. **PAYMENT:** Payment in advance is prohibited under this Contract. Payment may only be made after the delivery and acceptance of goods or services. The Vendor shall submit invoices, in arrears, to the Agency at the address on the face of the purchase order labeled "Invoice To."

18. **UNIT PRICE:** Unit prices shall prevail in cases of a discrepancy in the Vendor's bid.

19. **DELIVERY:** All quotations are considered freight on board destination ("F.O.B. destination") unless alternate shipping terms are clearly identified in the bid. Vendor's listing of shipping terms that contradict the shipping terms expressly required by this Solicitation may result in bid disqualification.

20. **INTEREST:** Interest attributable to late payment will only be permitted if authorized by the West Virginia Code. Presently, there is no provision in the law for interest on late payments.

21. **PREFERENCE:** Vendor Preference may only be granted upon written request and only in accordance with the West Virginia Code § 5A-3-37 and the West Virginia Code of State Rules. A Resident Vendor Certification form has been attached hereto to allow Vendor to apply for the preference. Vendor's

failure to submit the Resident Vendor Certification form with its bid will result in denial of Vendor Preference. Vendor Preference does not apply to construction projects.

22. **SMALL, WOMEN-OWNED, OR MINORITY-OWNED BUSINESSES:** For any solicitations publicly advertised for bid on or after July 1, 2012, in accordance with West Virginia Code §5A-3-37(a)(7) and W. Va. CSR § 148-22-9, any non-resident vendor certified as a small, women-owned, or minority-owned business under W. Va. CSR § 148-22-9 shall be provided the same preference made available to any resident vendor. Any non-resident small, women-owned, or minority-owned business must identify itself as such in writing, must submit that writing to the Purchasing Division with its bid, and must be properly certified under W. Va. CSR § 148-22-9 prior to submission of its bid to receive the preferences made available to resident vendors. Preference for a non-resident small, women-owned, or minority owned business shall be applied in accordance with W. Va. CSR § 148-22-9.

23. **TAXES:** The Vendor shall pay any applicable sales, use, personal property or any other taxes arising out of this Contract and the transactions contemplated thereby. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.

24. **CANCELLATION:** The Purchasing Division Director reserves the right to cancel this Contract immediately upon written notice to the vendor if the materials or workmanship supplied do not conform to the specifications contained in the Contract. The Purchasing Division Director may cancel any purchase or Contract upon 30 days written notice to the Vendor in accordance with West Virginia Code of State Rules § 148-1-7.16.2.

25. **WAIVER OF MINOR IRREGULARITIES:** The Director reserves the right to waive minor irregularities in bids or specifications in accordance with West Virginia Code of State Rules § 148-1-4.6.

26. **TIME:** Time is of the essence with regard to all matters of time and performance in this Contract.

27. **APPLICABLE LAW**: This Contract is governed by and interpreted under West Virginia law without giving effect to its choice of law principles. Any information provided in specification manuals, or any other source, verbal or written, which contradicts or violates the West Virginia Constitution, West Virginia Code or West Virginia Code of State Rules is void and of no effect.

28. **COMPLIANCE**: Vendor shall comply with all applicable federal, state, and local laws, regulations and ordinances. By submitting a bid, Vendors acknowledge that they have reviewed, understand, and will comply with all applicable law.

29. **PREVAILING WAGE:** On any contract for the construction of a public improvement, Vendor and any subcontractors utilized by Vendor shall pay a rate or rates of wages which shall not be less than the fair minimum rate or rates of wages (prevailing wage), as established by the West Virginia Division of Labor under West Virginia Code §§ 21-5A-1 et seq. and available at http://www.sos.wv.gov/administrative-law/wagerates/Pages/default.aspx. Vendor shall be responsible for ensuring compliance with prevailing wage requirements and determining when prevailing wage

requirements are applicable. The required contract provisions contained in West Virginia Code of State Rules § 42-7-3 are specifically incorporated herein by reference.

30. **ARBITRATION:** Any references made to arbitration contained in this Contract, Vendor's bid, or in any American Institute of Architects documents pertaining to this Contract are hereby deleted, void, and of no effect.

31. **MODIFICATIONS**: This writing is the parties' final expression of intent. Notwithstanding anything contained in this Contract to the contrary, no modification of this Contract shall be binding without mutual written consent of the Agency, and the Vendor, with approval of the Purchasing Division and the Attorney General's office (Attorney General approval is as to form only). **No Change shall be implemented by the Vendor until such time as the Vendor receives an approved written change order from the Purchasing Division.**

32. **WAIVER:** The failure of either party to insist upon a strict performance of any of the terms or provision of this Contract, or to exercise any option, right, or remedy herein contained, shall not be construed as a waiver or a relinquishment for the future of such term, provision, option, right, or remedy, but the same shall continue in full force and effect. Any waiver must be expressly stated in writing and signed by the waiving party.

33. **SUBSEQUENT FORMS:** The terms and conditions contained in this Contract shall supersede any and all subsequent terms and conditions which may appear on any form documents submitted by Vendor to the Agency or Purchasing Division such as price lists, order forms, invoices, sales agreements, or maintenance agreements, and includes internet websites or other electronic documents. Acceptance or use of Vendor's forms does not constitute acceptance of the terms and conditions contained thereon.

34. **ASSIGNMENT**: Neither this Contract nor any monies due, or to become due hereunder, may be assigned by the Vendor without the express written consent of the Agency, the Purchasing Division, the Attorney General's office (as to form only), and any other government agency or office that may be required to approve such assignments. Notwithstanding the foregoing, Purchasing Division approval may or may not be required on certain agency delegated or exempt purchases.

35. **WARRANTY**: The Vendor expressly warrants that the goods and/or services covered by this Contract will: (a) conform to the specifications, drawings, samples, or other description furnished or specified by the Agency; (b) be merchantable and fit for the purpose intended; and (c) be free from defect in material and workmanship.

36. **STATE EMPLOYEES:** State employees are not permitted to utilize this Contract for personal use and the Vendor is prohibited from permitting or facilitating the same.

37. **BANKRUPTCY**: In the event the Vendor files for bankruptcy protection, the State of West Virginia may deem this Contract null and void, and terminate this Contract without notice.

38. [RESERVED]

39. CONFIDENTIALITY: The Vendor agrees that it will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the Agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the Agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/default.html.

40. DISCLOSURE: Vendor's response to the Solicitation and the resulting Contract are considered public documents and will be disclosed to the public in accordance with the laws, rules, and policies governing the West Virginia Purchasing Division. Those laws include, but are not limited to, the Freedom of Information Act found in West Virginia Code § 29B-1-1 et seq.

If a Vendor considers any part of its bid to be exempt from public disclosure, Vendor must so indicate by specifically identifying the exempt information, identifying the exemption that applies, providing a detailed justification for the exemption, segregating the exempt information from the general bid information, and submitting the exempt information as part of its bid but in a segregated and clearly identifiable format. Failure to comply with the foregoing requirements will result in public disclosure of the Vendor's bid without further notice. A Vendor's act of marking all or nearly all of its bid as exempt is not sufficient to avoid disclosure and WILL NOT BE HONORED. Vendor's act of marking a bid or any part thereof as "confidential" or "proprietary" is not sufficient to avoid disclosure and WILL NOT BE HONORED. In addition, a legend or other statement indicating that all or substantially all of the bid is exempt from disclosure is not sufficient to avoid disclosure and WILL NOT BE HONORED. Vendor will be required to defend any claimed exemption for nondisclosure in the event of an administrative or judicial challenge to the State's nondisclosure. Vendor must indemnify the State for any costs incurred related to any exemptions claimed by Vendor. Any questions regarding the applicability of the various public records laws should be addressed to your own legal counsel prior to bid submission.

41. LICENSING: In accordance with West Virginia Code of State Rules §148-1-6.1.7, Vendor must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agency or political subdivision. Upon request, the Vendor must provide all necessary releases to obtain information to enable the Purchasing Division Director or the Agency to verify that the Vendor is licensed and in good standing with the above entities.

42. ANTITRUST: In submitting a bid to, signing a contract with, or accepting a Purchase Order from any agency of the State of West Virginia, the Vendor agrees to convey, sell, assign, or transfer to the State of West Virginia all rights, title, and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired

by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to Vendor.

43. **VENDOR CERTIFICATIONS:** By signing its bid or entering into this Contract, Vendor certifies (1) that its bid was made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, person or entity submitting a bid for the same material, supplies, equipment or services; (2) that its bid is in all respects fair and without collusion or fraud; (3) that this Contract is accepted or entered into without any prior understanding, agreement, or connection to any other entity that could be considered a violation of law; and (4) that it has reviewed this RFQ in its entirety; understands the requirements, terms and conditions, and other information contained herein. Vendor's signature on its bid also affirms that neither it nor its representatives have any interest, nor shall acquire any interest, direct or indirect, which would compromise the performance of its services hereunder. Any such interests shall be promptly presented in detail to the Agency.

    The individual signing this bid on behalf of Vendor certifies that he or she is authorized by the Vendor to execute this bid or any documents related thereto on Vendor's behalf; that he or she is authorized to bind the Vendor in a contractual relationship; and that, to the best of his or her knowledge, the Vendor has properly registered with any State agency that may require registration.

44. **PURCHASING CARD ACCEPTANCE:** The State of West Virginia currently utilizes a Purchasing Card program, administered under contract by a banking institution, to process payment for goods and services. The Vendor must accept the State of West Virginia's Purchasing Card for payment of all orders under this Contract unless the box below is checked.

    ☐ Vendor is not required to accept the State of West Virginia's Purchasing Card as payment for all goods and services.

45. **VENDOR RELATIONSHIP:** The relationship of the Vendor to the State shall be that of an independent contractor and no principal-agent relationship or employer-employee relationship is contemplated or created by this Contract. The Vendor as an independent contractor is solely liable for the acts and omissions of its employees and agents. Vendor shall be responsible for selecting, supervising, and compensating any and all individuals employed pursuant to the terms of this Solicitation and resulting contract. Neither the Vendor, nor any employees or subcontractors of the Vendor, shall be deemed to be employees of the State for any purpose whatsoever. Vendor shall be exclusively responsible for payment of employees and contractors for all wages and salaries, taxes, withholding payments, penalties, fees, fringe benefits, professional liability insurance premiums, contributions to insurance and pension, or other deferred compensation plans, including but not limited to, Workers' Compensation and Social Security obligations, licensing fees, *etc.* and the filing of all necessary documents, forms and returns pertinent to all of the foregoing. Vendor shall hold harmless the State, and shall provide the State and Agency with a defense against any and all claims including, but not limited to, the foregoing payments, withholdings, contributions, taxes, Social Security taxes, and employer income tax returns.

46. **INDEMNIFICATION:** The Vendor agrees to indemnify, defend, and hold harmless the State and the Agency, their officers, and employees from and against: (1) Any claims or losses for services rendered

by any subcontractor, person, or firm performing or supplying services, materials, or supplies in connection with the performance of the Contract; (2) Any claims or losses resulting to any person or entity injured or damaged by the Vendor, its officers, employees, or subcontractors by the publication, translation, reproduction, delivery, performance, use, or disposition of any data used under the Contract in a manner not authorized by the Contract, or by Federal or State statutes or regulations; and (3) Any failure of the Vendor, its officers, employees, or subcontractors to observe State and Federal laws including, but not limited to, labor and wage and hour laws.

47. **PURCHASING AFFIDAVIT:** In accordance with West Virginia Code § 5A-3-10a, all Vendors are required to sign, notarize, and submit the Purchasing Affidavit stating that neither the Vendor nor a related party owe a debt to the State in excess of $1,000. The affidavit must be submitted prior to award, but should be submitted with the Vendor's bid. A copy of the Purchasing Affidavit is included herewith.

48. **ADDITIONAL AGENCY AND LOCAL GOVERNMENT USE:** This Contract may be utilized by and extends to other agencies, spending units, and political subdivisions of the State of West Virginia; county, municipal, and other local government bodies; and school districts ("Other Government Entities"). This Contract shall be extended to the aforementioned Other Government Entities on the same prices, terms, and conditions as those offered and agreed to in this Contract. If the Vendor does not wish to extend the prices, terms, and conditions of its bid and subsequent contract to the Other Government Entities, the Vendor must clearly indicate such refusal in its bid. A refusal to extend this Contract to the Other Government Entities shall not impact or influence the award of this Contract in any manner.

49. **CONFLICT OF INTEREST:** Vendor, its officers or members or employees, shall not presently have or acquire any interest, direct or indirect, which would conflict with or compromise the performance of its obligations hereunder. Vendor shall periodically inquire of its officers, members and employees to ensure that a conflict of interest does not arise. Any conflict of interest discovered shall be promptly presented in detail to the Agency.

50. **REPORTS:** Vendor shall provide the Agency and/or the Purchasing Division with the following reports identified by a checked box below:

☑ Such reports as the Agency and/or the Purchasing Division may request. Requested reports may include, but are not limited to, quantities purchased, agencies utilizing the contract, total contract expenditures by agency, etc.

☐ Quarterly reports detailing the total quantity of purchases in units and dollars, along with a listing of purchases by agency. Quarterly reports should be delivered to the Purchasing Division via email at purchasing.requisitions@wv.gov.

51. **BACKGROUND CHECK:** In accordance with W. Va. Code § 15-2D-3, the Director of the Division of Protective Services shall require any service provider whose employees are regularly employed on the grounds or in the buildings of the Capitol complex or who have access to sensitive or critical information

to submit to a fingerprint-based state and federal background inquiry through the state repository. The service provider is responsible for any costs associated with the fingerprint-based state and federal background inquiry.

After the contract for such services has been approved, but before any such employees are permitted to be on the grounds or in the buildings of the Capitol complex or have access to sensitive or critical information, the service provider shall submit a list of all persons who will be physically present and working at the Capitol complex to the Director of the Division of Protective Services for purposes of verifying compliance with this provision.

The State reserves the right to prohibit a service provider's employees from accessing sensitive or critical information or to be present at the Capitol complex based upon results addressed from a criminal background check.

Service providers should contact the West Virginia Division of Protective Services by phone at (304)558-9911 for more information.

52. **PREFERENCE FOR USE OF DOMESTIC STEEL PRODUCTS:** Except when authorized by the Director of the Purchasing Division pursuant to W. Va. Code § 5A-3-56, no contractor may use or supply steel products for a State Contract Project other than those steel products made in the United States. A contractor who uses steel products in violation of this section may be subject to civil penalties pursuant to W. Va. Code § 5A-3-56. As used in this section:

    a. "State Contract Project" means any erection or construction of, or any addition to, alteration of or other improvement to any building or structure, including, but not limited to, roads or highways, or the installation of any heating or cooling or ventilating plants or other equipment, or the supply of and materials for such projects, pursuant to a contract with the State of West Virginia for which bids were solicited on or after June 6, 2001.

    b. "Steel Products" means products rolled, formed, shaped, drawn, extruded, forged, cast, fabricated or otherwise similarly processed, or processed by a combination of two or more or such operations, from steel made by the open heath, basic oxygen, electric furnace, Bessemer or other steel making process.

The Purchasing Division Director may, in writing, authorize the use of foreign steel products if:

    a. The cost for each contract item used does not exceed one tenth of one percent (.1%) of the total contract cost or two thousand five hundred dollars ($2,500.00), whichever is greater. For the purposes of this section, the cost is the value of the steel product as delivered to the project; or

    b. The Director of the Purchasing Division determines that specified steel materials are not produced in the United States in sufficient quantity or otherwise are not reasonably available to meet contract requirements.

53. PREFERENCE FOR USE OF DOMESTIC ALUMINUM, GLASS, AND STEEL: In Accordance with W. Va. Code § 5-19-1 et seq., and W. Va. CSR § 148-10-1 et seq., for every contract or subcontract, subject to the limitations contained herein, for the construction, reconstruction, alteration, repair, improvement or maintenance of public works or for the purchase of any item of machinery or equipment to be used at sites of public works, only domestic aluminum, glass or steel products shall be supplied unless the spending officer determines, in writing, after the receipt of offers or bids, (1) that the cost of domestic aluminum, glass or steel products is unreasonable or inconsistent with the public interest of the State of West Virginia, (2) that domestic aluminum, glass or steel products are not produced in sufficient quantities to meet the contract requirements, or (3) the available domestic aluminum, glass, or steel do not meet the contract specifications. This provision only applies to public works contracts awarded in an amount more than fifty thousand dollars ($50,000) or public works contracts that require more than ten thousand pounds of steel products.

The cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than twenty percent (20%) of the bid or offered price for foreign made aluminum, glass, or steel products. If the domestic aluminum, glass or steel products to be supplied or produced in a "substantial labor surplus area", as defined by the United States Department of Labor, the cost of domestic aluminum, glass, or steel products may be unreasonable if the cost is more than thirty percent (30%) of the bid or offered price for foreign made aluminum, glass, or steel products.

This preference shall be applied to an item of machinery or equipment, as indicated above, when the item is a single unit of equipment or machinery manufactured primarily of aluminum, glass or steel, is part of a public works contract and has the sole purpose or of being a permanent part of a single public works project. This provision does not apply to equipment or machinery purchased by a spending unit for use by that spending unit and not as part of a single public works project.

All bids and offers including domestic aluminum, glass or steel products that exceed bid or offer prices including foreign aluminum, glass or steel products after application of the preferences provided in this provision may be reduced to a price equal to or lower than the lowest bid or offer price for foreign aluminum, glass or steel products plus the applicable preference. If the reduced bid or offer prices are made in writing and supersede the prior bid or offer prices, all bids or offers, including the reduced bid or offer prices, will be reevaluated in accordance with this rule.

REQUEST FOR PROPOSAL

West Virginia Bureau for Medical Services
RFP # BMS14028

SECTION FOUR: PROJECT SPECIFICATIONS

1. **Location:** The Bureau for Medical Services (BMS) is located at 350 Capitol Street, Room 251, Charleston, WV 25301.

2. **Background and Current Operating Environment:** Mountain Health Trust (MHT) is the Medicaid managed care program that has operated in the State of West Virginia since 1996. The program emphasizes the effective organization, financing, and delivery of primary health care services as a means to improve Medicaid enrollee access to care and enhance quality through the provision of coordinated services. MHT includes a primary care case management program known as the Physician Assured Access System (PAAS) and a capitated managed care organization (MCO) program. MHT is overseen by the Office of Managed Care within the Bureau for Medical Services. It is the goal of the Agency to procure an enrollment broker that will assist the State in its efforts to improve access to Medicaid managed care and PAAS services in a manner that assures the highest level of quality, accuracy and efficiency.

   As used throughout this solicitation, the following terms shall have the meanings set forth below:

   Enrollee - a Medicaid recipient enrolled in an MCO under the MHT program or in the PAAS program.

   Potential Enrollee - 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 enrolled with a specific MCO or PAAS provider.

   Eligibility Categories for Enrollment

   The program currently enrolls mandatory Temporary Assistance for Needy Families (TANF) and Aid to Families with Dependent Children (AFDC)-related populations under Section 1937 benchmark authority and Section 1915(b) waiver authority of the Social Security Act.

   Beginning October 1, 2014, or a later date to be determined, the program may enroll individuals with incomes below 138% of the federal poverty level (FPL) based on the new eligibility categories defined under the Affordable Care Act of 2010 and/or Supplemental Security Income (SSI) enrollees may also be enrolled in the managed care program at a later date.

   The Department of Health and Human Resources (DHHR or the Department) county offices determine whether an individual or family is eligible for Medicaid. Information regarding the location of county offices is available at:

   http://www.dhhr.wv.gov/bms/Pages/LocateACountyOffice.aspx and is included in Exhibit A – State Documents of this RFP.

   Managed Care Program Expansion

   Additional populations and/or services will be considered for future managed care enrollment and/or benefit expansions. The eligible SSI population may become mandatory for the managed

care program at a date yet to be determined. Enrollment of SSI eligibles may be phased-in over a period of at least one (1) year. The following beneficiaries are currently excluded from the Medicaid managed care program: beneficiaries that are medically needy with incomes at or above the spend-down threshold, are dually eligible for Medicare and Medicaid, participate in a Home and Community Based waiver, or reside in nursing facilities or Intermediate Care Facilities for Persons with Intellectual Disabilities.

Currently, BMS is in the process of transitioning Medicaid behavioral health, children's dental, and personal care services into the capitated model for the population participating in the managed care program.

MCO Services

BMS has developed comprehensive capitated risk contracts with qualified MCOs for serving Medicaid managed care program enrollees. Currently, there are three (3) such contractors, each of which is a licensed Health Maintenance Organization (HMO) under the West Virginia Offices of the Insurance Commissioner. Two (2) MCOs, CoventryCares of West Virginia (formerly Carelink) and The Health Plan of the Upper Ohio Valley, have participated in the MHT program since its inception. UniCare of West Virginia began enrolling beneficiaries in November 2003.

MCOs provide enrollees with most acute and preventive physical health care services. MCOs also provide and manage a wide range of additional services related to the Medicaid benefit delivery, including prescription drugs, health service coordination, case management, health education and outreach to their members to ensure the quality of provided health care services.

As of February 2014, there were approximately 197,000 enrollees in managed care plans, which operate in all fifty-five (55) counties, and 4,400 enrollees in the PAAS program.

TANF beneficiaries in counties with two (2) or more contracted MCOs must choose between one (1) of the MCOs. TANF beneficiaries in certain counties with only one (1) contracted MCO can choose between the MCO and the PAAS program; non-choosers are assigned to the MCO in their county. Information regarding county configuration may be found at:

http://www.dhhr.wv.gov/bms/mco/Pages/ExpansionMap.aspx and is included Exhibit A of this RFP.

Non-MCO Covered Services

Services, such as behavioral health, nursing facilities, and non-emergency transportation, are currently available through fee-for-service (FFS) Medicaid. However, behavioral health is in the process of being transitioned into the managed care delivery system.

3. **Qualifications and Experience:** Vendors should provide in **Attachment A: Vendor Response Sheet** *a response regarding the following: firm and staff qualifications and experience in completing similar projects; references; copies of any staff certifications or degrees applicable to this project; proposed staffing plan; descriptions of past projects completed entailing the location*

of the project, project manager name and contact information, type of project, and what the project goals and objectives were and how they were met.

A. Vendor should supply the following information regarding their firm:

a. Firm History
b. Principle staff qualifications, experience and education
c. Seven (7) years of direct experience with enrollment brokering functions in other states with a minimum of three (3) references of state work (excluding West Virginia) performed within the last five (5) years that validate the scope of work.

B. Vendor should provide proof of the firm's financial ability to undertake this project including:

a. Balance sheet for past three (3) years
b. Income statement for past three (3) years
c. Statements of Cash Flows for the past three (3) years
d. Credit Report (Dunn & Bradstreet)
e. Most recent quarterly financial statement
f. Litigations and Claims for the past three (3) years

4. **Project and Goals:** The project goals and objectives are for the BMS to obtain the services of an experienced Vendor to provide timely and adequate information and education about managed care delivery systems, and to perform all functions directly related to the enrollment of the recipients into the program of their choice in which they are eligible to participate. The Vendor should develop written policies and procedures in consultation with BMS for the functions outlined in this RFP:

4.1 The Vendor should propose a plan to provide choice counseling to and enroll eligible participants into an approved Medicaid MCO or primary care provider (PCP) that is enrolled in the PAAS Program, according to the counties outlined in Exhibit A. All enrollment tasks detailed in this section apply to both new enrollments and changes in MCOs/PCPs and should comply with 42 CFR 438.6 which can be found in Exhibit B – Code of Federal Regulations.

4.1.1 The Vendor should include in its plan a process for assisting the State with enrollment in each of the fifty-five (55) counties, including addressing the unique enrollment needs of each county. Such circumstances may include the participating MCOs and PAAS in the county, rural/urban location, the number of Medicaid enrollees, and the number of providers. The plan for choice counseling and enrollment services should be in accordance with counties served by each MCO or PAAS Provider (which can be found at: http://www.dhhr.wv.gov/bms/mco/Pages/ExpansionMap.aspx and are included in Exhibit A), including objectively informing enrollees regarding the choices available, their rights and responsibilities regarding both the enrollment process and the ensuing

enrollment, processing the forms and calls to perform enrollment, and acting as an educator on the MHT program.

The plan should indicate how the Vendor may remain impartial in assisting Medicaid enrollees with the managed care system and primary care provider (PCP) of their choice and not discriminate against individuals eligible to be covered under contract on the basis of health status or need for health services.

The plan should ensure that all enrollment tasks comply with all Federal and State laws and regulations, including Title 42, Section 438.6 of the Code of Federal Regulations (42 CFR §438.6) found in Exhibit B.

4.1.2 The plan should include how the Vendor, working with BMS, may identify the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State in accordance with 42 CFR §438.10 found in Exhibit B. The plan should indicate how the Vendor might make all information available in each prevalent non-English language (if BMS and the Vendor determine a prevalent language other than English is present) to the same extent as the information available in English. Provider and other stakeholder communications may not require prevalent language translation.

The plan should ensure that all information for enrollees or potential enrollees complies with the requirements of 42 CFR §438.10, found in Exhibit B, and is at or below a sixth grade reading level.

4.1.3 The Vendor should develop sample enrollment forms and phone scripts for potential enrollees that comply with the requirements of 42 CFR §438 Subparts A-J found in Exhibit B. A sample enrollment form should be provided to BMS. The enrollment form and scripts should ask potential enrollees to indicate: his or her choice of MCO or PAAS provider; the name of his or her existing provider(s); and his or her race, ethnicity, primary language spoken and health status. The form should specify that information on race, ethnicity, primary language and health status is not mandatory for enrollment.

The plan should include a process for mailing the enrollment form and accompanying enrollment materials, as described in section 4.1.4, to potential enrollees within two (2) business days of receiving the eligibility file from the fiscal agent.

BMS anticipates approving the enrollment form and enrollment phone script at least thirty (30) calendar days prior to use. BMS reserves the right to alter the enrollment form and the script at any time. In the event that BMS alters the enrollment form, the Vendor has thirty (30) calendar days' to implement BMS requested changes. The Vendor may not make changes to the enrollment form or script without prior approval from BMS.

The Vendor should attach a draft copy of the enrollment form and scripts in its response to this RFP.

4.1.4 The plan should include the development of materials to notify members of the expectation to select an MCO or PAAS provider within forty-five (45) calendar days or be assigned to one (1) by the State. The Vendor should also recommend a process for accommodating passive enrollment as needed. The plan should also propose a process to develop additional materials that meet the requirements of 42 CFR §438.10 (found in Exhibit B) to help members in making their choice (e.g., member handbooks, network provider listings, letters related to MHT and PAAS programs). Such information may include:

4.1.4.1 MCO/PAAS availability in the service area (county);

4.1.4.2 Information specific to each MCO or PAAS program operating in the county, such as benefits covered, service area, and names, locations, telephone numbers, and non-English languages spoken for current contracted providers and identification of providers not accepting new patients (including information on primary care physicians, specialists and hospitals for current contracted providers);

4.1.4.3 How to obtain services that are accessed through the FFS system and any value-added services the MCO provides;

4.1.4.4 The role of the primary care provider in MCO/PAAS;

4.1.4.5 Processes for enrollment, disenrollment, exemptions and grievances;

4.1.4.6 Availability of oral translation services free of charge for persons who do not understand English materials; and

4.1.4.7 Information on the benefits available under the State plan but not covered under the contract, including how and where the enrollee may obtain those benefits.

Written materials could include, but are not limited to:

4.1.4.8 A general informational pamphlet that can be used in any of the enrolled counties;

4.1.4.9 Specific pamphlets that describe in detail the choices available to enrollees depending on their place of residence; and

4.1.4.10 Letters or other materials that advertise changes in delivery systems and promote preventive care.

The plan should also include a process to mail additional materials, including those created by BMS and/or the MCOs, to help enrollees in making their choice (e.g., network provider listings, any BMS-approved marketing materials, question and answer sheets, letters related to the managed care programs).

In its response to this RFP, the Vendor should submit sample educational materials, including a general informational pamphlet, a specific pamphlet and a letter to enrollees.

4.1.5 The Vendor should describe its approach for reviewing MCO and PAAS member materials and other information in any medium. BMS may request the Vendor to assist in the review and approval of marketing materials and proposed marketing/outreach efforts. Any review of marketing materials should ensure that they comply with the requirements of 42 CFR §438 Subpart C found in Exhibit B.

4.1.6 The Vendor should offer multiple approaches for members to enroll, including by mail, telephone, text, web-based applications and other innovative and unique vehicles. The Vendor should address its approach for receiving enrollment forms via mail, telephone and internet. The Vendor should also propose timeframes not to exceed 24 hours for processing enrollment forms and for returning forms received from eligible participants that cannot be processed due to incomplete or illegible information.

4.1.7 The Vendor should describe a process for following up on returned mail, including MHT and PAAS.

4.1.8 The Vendor should describe the process for educating members at the time of their MCO enrollment on how to access services that are accessed through the FFS system and carved out of the managed care program.

4.1.9 The Vendor should propose an approach for collecting and submitting third party liability information to BMS regarding discrepancies between the eligibility system information and the information the Vendor collected.

4.1.10 The Vendor should propose a comprehensive outreach and education strategy, which includes the development of materials and an approach for engaging stakeholders. The Vendor should submit to BMS its proposed outreach, education and enrollment plan for review and approval. The Vendor should request BMS approval for any subsequent adjustments.

4.1.11 The Vendor should develop written and visual materials for use in outreach and educational efforts to educate Medicaid members, advocates, providers, community agencies, caseworkers and DHHR staff about any changes in Medicaid delivery systems. These materials should include, but not be limited to, enrollment forms, notices, letters, pamphlets, presentations, videos, internet websites and other information.

The Vendor should obtain BMS approval for outreach and educational materials in any medium prior to production and distribution. Production, reproduction, updates and distribution of materials should be at the Vendor's expense.

Each material submitted for approval should be accompanied by a concise memo indicating the material's purpose, expected use, target audience and printing specifications. BMS reserves the right to edit all or portions of materials prior to distribution. Upon BMS approval, the Vendor should print all written materials, maintaining a sufficient stock of materials and distributing materials as needed at the Vendor's expense. The Vendor is responsible for supplying and distributing any pamphlets and other mailing material in addition to DHHR approved materials supplied by the MCOs/PAAS and DHHR.

4.1.12 The Vendor should include in its strategy a plan for engaging stakeholders. The Vendor should address how it plans to schedule educational presentations with these stakeholders on an ongoing basis and serve as a resource on the managed care and PAAS programs for stakeholders in the community. The Vendor's strategy should include participation in statewide annual provider workshops, where the written material for each session should be provided by the Vendor. Historically, BMS has conducted seven (7) provider workshops at various locations throughout the state.

4.1.13 The Vendor should describe its approach for sorting enrollment forms for processing, identifying enrollees for outreach, researching issues in State systems and identifying enrollment forms that cannot be processed. The Vendor should also propose a process for identifying address discrepancies in State systems.

4.1.14 The Vendor should include in its strategy an approach for informing all county offices of any changes in the managed care and PAAS programs or processes for enrollment.

4.1.15 The Vendor should describe a process for providing additional, highly mobile benefits managers to travel to all fifty-five (55) counties to educate enrollees, providers, agencies, and organizations.

4.1.16 The Vendor should propose a plan for performing outreach to members that, because of housing circumstance, cultural differences, inability or unwillingness to access information through the county office or community hosted information program or other circumstances, makes enrollment a challenge.

4.1.17 The Vendor should propose a plan for mailings and electronic communications to MCO/PAAS members. The Vendor should be responsible for all member mailings for the managed care and PAAS programs and for coordinating all member mailings with BMS. The cost of the materials, printing and postage for these mailings should be the responsibility of the Vendor. The Vendor should also be responsible for the cost of re-mailings of returned mail, other notices sent on an individual basis and any mailings not done through the system process. The Vendor should advise BMS on the style and content of the mailings and notices.

4.1.18 The Vendor should include its approach for designing and maintaining an enrollment assistance website available to West Virginia Medicaid beneficiaries for the managed care and PAAS programs. The Vendor should address the type of web accessibility software, the types of information available to beneficiaries, languages supported on the website, frequency of updates to the website, search capabilities, user-friendly provider directories and interactive functionality to facilitate the secure submission of member plan and PCP changes.

4.1.19 The Vendor should design all educational materials and member content so that they clearly inform members about the programs and possible choices in their area. The Vendor should propose specific content to be included in the educational materials and member content.

4.1.20 The Vendor should make recommendations for educating and engaging enrollees in high quality health homes and patient centered medical homes.

4.2 The Vendor should propose a plan for creating and operating a telephone unit. Such responsibilities of the telephone unit should be to complete the enrollment of members into the MCO of their choice or PAAS; answer enrollment questions regarding the MHT and PAAS programs asked by Medicaid members, providers and the general community; settle complaints when possible; provide information on covered services; and complete research as requested by BMS. Types of calls could include but not necessarily be limited to:

4.2.1 Enrolling enrollees into the MCO or PAAS PCP of his or her choice;

4.2.2 Enrolling newborns into the mother's county-appropriate choice of MCO or PAAS provider;

4.2.3 Assisting enrollees in transferring from one (1) MCO to another, from an MCO to PAAS, from PAAS to an MCO and from one (1) PAAS PCP to another;

4.2.4 Processing exemption requests using BMS developed criteria;

4.2.5 Assessing any unique health care needs to ensure appropriate enrollment;

4.2.6 Identifying and, if possible, maintaining existing enrollee/provider relationships;

4.2.7 Explaining the options available to individuals depending upon their place of residence;

4.2.8 Explaining the health benefit coverage;

4.2.9 Providing specific information about each MCO and PAAS option such as the network of providers (e.g., physicians, hospitals) and the extent of new enrollees being accepted;

4.2.10 Documenting reasons for changes in MCO and/or PAAS enrollment and including change information in monthly reports to BMS;

4.2.11 Explaining Medicaid covered services and freedom of choice for access to family planning services;

4.2.12 Referring enrollees to the correct human service agency if calls are received that are outside the scope of the managed care programs;

4.2.13 "Triaging" enrollee calls to service representatives and medical hotlines when necessary, and resolving complaints and acting as troubleshooter and enrollee "ombudsman" for enrollees in the program.

The plan should include:

4.2.14 The development of operational procedures, manuals, forms and reports necessary for the operation of the telephone unit.

4.2.15 The Vendor's approach to staffing the telephone unit and training personnel on all relevant issues on an ongoing basis. The staff operating the telephone unit should be responsible for responding to a variety of phone calls from members (e.g., disenrollment, exemptions, choice counseling, covered services).

4.2.16 Procedures to ensure that telephone operators treat all callers with dignity and respect the callers' need for privacy.

4.2.17 Procedures for providing access to oral translation services that can be used to answer questions and provide information to enrollees who do not understand English.

4.2.18 The Vendor should address in its proposal how it plans to provide special services necessary to accommodate Medicaid members. Special services may include, but not be limited to teletypewriter (TTY) line translation services, assistance for the blind/literacy challenged, and program fact sheets in different languages for prevalent non-English members as defined in 42 CFR 438.10 (c).

4.2.19 The plan should include procedures for identifying individuals with special health needs through health assessments conducted as part of the enrollment process. In addition to identification strategies proposed by the Vendor, the Vendor should ask enrollees to indicate whether they have a special health care need. The Vendor should review health assessment forms and enter information on medical conditions, physician preferences or potential health problems within the Medicaid Management Information System (MMIS) and their own data system. It is anticipated that this data, along with a copy of the health assessment form, be forwarded to the MCOs by BMS's fiscal agent.

4.2.20 The Vendor should propose a Quality Assurance Plan to assure that all telephone functions meet their own internal standards, subject to BMS approval. As part of this plan, the Vendor should propose promptness and quality standards (e.g., percent of

telephone calls answered within four (4) rings, maximum number of calls per operator in a queue, wait time in the queue, rate of abandoned/dropped calls).

4.2.21 The Vendor should establish, maintain and operate an office within fifteen (15) miles of the city limits of Charleston, West Virginia (Charleston). The Vendor should administer telephone support (as described in Section 4.3) from that location or an additional location within fifteen (15) miles of the city limits of Charleston.

4.3 The Vendor should propose a plan for systems development and ongoing communication with BMS and the MCOs. This plan should address the Vendor's process for:

4.3.1 Maintaining direct, ongoing communication with BMS regarding the Vendor's activities and working closely to assure accomplishment of the enrollment goals and objectives.

4.3.2 Meeting with the MCOs after contract award and on an ongoing basis, as necessary to obtain detailed information about each individual operation.

4.3.3 Providing training and technical assistance to all designated DHHR and BMS staff and their contractors participating in this project during the duration of the contract.

4.3.4 Forwarding any complaints concerning its staff to BMS with an explanation. Serious or repeated complaints about any staff person may result in a recommendation for removal of the staff member.

4.3.5 Notifying BMS, on a case-by-case basis, of any discrepancies found on the enrollment form such as, but not limited to, name spelling, date of birth, number of family members in the home, returned mail which indicates the Medicaid eligible has moved, etc., for resolution. Any discrepancy found on the enrollment form should be tracked and reported to BMS monthly via electronic file.

For discrepancies identified, the Vendor should work with BMS to reconcile the monthly list of enrollees for each MCO, which may require extensive research. The Vendor should monitor reports from the fiscal agent and alert BMS regarding any discrepancies.

The Vendor should be alert to possible discrepancies between approved materials and actual practices as may be reported by members. Any discrepancies discovered should be documented and forwarded to BMS for disposition.

4.3.6 The Vendor's proposal should specify its approach for implementing and performing the systems development tasks listed below:

4.3.6.1 Establish and maintain databases and systems to support the enrollment operation.

4.3.6.2 Work with BMS to learn the data entry screens within the MMIS which allows members to be enrolled in a managed care plan or PCP and develop linkage to Recipient Automated Payment and Information Data System (RAPIDS), to facilitate research.

4.3.6.3 Work with BMS and the fiscal agent to identify any modifications needed.

4.3.6.4 Work with BMS staff in refining the default auto-assignment algorithm and responding to county-specific algorithm needs as appropriate (e.g., mandatory MCO enrollment, voluntary MCO enrollment).

4.3.6.5 Work with BMS staff in supporting any additional auto-assignment strategies which could include passive enrollment and pay-for-performance (P4P) approaches. BMS reserves the right to modify the methodology for assigning enrollees at any time.

4.3.7 The Vendor should provide BMS with a monthly snapshot of key activities, which includes a comparison of the current month's report with previous periods, as appropriate. The Vendor should also identify trends in enrollment, any issues encountered and recommendations for improvements, policy changes or procedural improvements. Reports should include charts and graphs to illustrate program performance. The Vendor should propose indicators to include in the monthly report; final format and indicators are subject to BMS approval. A sample report should be provided to BMS that may include some or all of the following elements:

4.3.7.1 Number and type of enrollee mailings related to the MHT program sent by the Vendor;

4.3.7.2 Per outreach effort, the number of enrollees mailed to or contacted through electronic methods along with the reason for the mailing or contact and the date of the mailing or contact;

4.3.7.3 The number of total newborn enrollments;

4.3.7.4 The total number of enrollments per month;

4.3.7.5 The auto-assignment rate per month;

4.3.7.6 The number of defaulted enrollments per month;

4.3.7.7 The number of choice enrollments per month;

4.3.7.8 The number of changes in existing enrollment and reason for change per month;

4.3.7.9 The number and percentage of choice enrollments that are processed accurately within two (2) business days of receipt of completed application;

4.3.7.10 Problems reported by counties or providers and the number and types of questions asked;

4.3.7.11 Number and type of complaints about marketing methods or discrepancies in enrollment materials;

4.3.7.12 Number and type of complaints about the Vendor, including the number of complaints that were resolved, how the complaints were resolved, and the average length of time it took to resolve the complaints;

4.3.7.13 Number of enrollees in the various benefit packages by eligibility groups;

4.3.7.14 Enrollment activities by county, program (i.e., managed care and PAAS), and by MCO, including the number of enrollment forms and enrollment phone calls received per day and, of those, the number processed, the number of contacts made, the number of forms returned and the reason the forms were returned; and

4.3.7.15 Telephone activities, including:

4.3.7.16 Number of days the telephone unit was operational;

4.3.7.17 Number of telephone calls received by all operators and by each operator per day, per week and per month;

4.3.7.18 Total number of telephone calls answered regarding enrollment into the managed care programs by all operators and by each operator per day, per week, and per month;

4.3.7.19 Number of calls abandoned and abandonment rate by all operators and by each operator per day, per week, and per month;

4.3.7.19 Average length of call by all operators and by each operator per day, per week, and per month;

4.3.7.20 Number of calls in the queue at peak times, as determined by the Vendor;

4.3.7.21 Average wait time for calls in queue per operator per day, per week, and per month;

4.3.7.22 Number of calls resulting in information generated to BMS's Third Party Liability (TPL) unit and whether previously unknown resources were referred or if TPL resources were coded on the system that are no longer valid;

4.3.7.23 Active time and inactive time for each operator's line; and

4.3.7.24 Log of requests for presentations for stakeholders, including meeting details and content presented.

The Vendor should respond to BMS requests for additional detail on activities within ten (10) business days.

4.4 The Vendor should provide the names and contact information for key staff assigned to this project, including resumes. Key staff should include the account lead (primary liaison) and direct or indirect reports that manage functional units. All key staff should demonstrate past experience specifically related to this project. For any key staff not currently employed, the Vendor should submit qualifications, job descriptions and plans for recruiting proposed key staff.

4.4.1 The Vendor should provide a functional organizational chart indicating the proposed project structure. The Vendor should indicate on the chart, or separately, the name of each proposed staff member and the percentage of time each proposed staff member will be dedicated to this project, expressed in a full-time equivalent (FTE) percent.

4.4.2 If the Vendor proposes to subcontract with organizations or individuals, it should provide a copy of the subcontract/agreement and a summary of the subcontractor's size, resources, location and responsibilities under the contract. The primary contractor should assume responsibility for all subcontracted work.

4.5 The Vendor should propose a solution that may be extended to other State Agencies, United States Territory or political subdivision upon mutual consent by Vendor and entity.

5. **Mandatory Requirements**

Vendor must agree to the following mandatory requirements as a part of the submitted proposal. Failure on the part of the Vendor to meet any of the mandatory specifications shall result in the disqualification of the proposal. The terms "must", "will", "shall", "minimum", "maximum" or "is/are required" identify a mandatory item or factor. Decisions regarding compliance with any mandatory requirements shall be at the sole discretion the Purchasing Division.

5.1 The Vendor must agree to, no later than upon award of the Contract, provide a single lead point of contact that will serve as project manager and be immediately available by telephone and email, at a minimum, during business hours of Monday through Friday, 8:00 am – 5:00 pm Eastern Standard Time. This person will be responsible for overseeing Vendor performance and act as a liaison between the Vendor, BMS, and the MCOs/PAAS. BMS reserves the right to reject any staff proposed or later assigned to the project and require the successful Vendor to remove them from the project. The Vendor will notify BMS two (2) weeks in advance of replacing any key staff. Any changes or addition in key staff once the contract has begun must be reported to BMS accompanied by resumes.

5.2 The Vendor must agree to prepare and submit a draft implementation plan as part of its response. The Vendor must further agree to submit any revisions to its implementation plan for review and approval by DHHR/BMS within fifteen (15) calendar days from the date of contract award. In addition, the vendor must agree to complete implementation activities within the timeframe allotted in the implementation plan and no more than (90) calendar days following the award.

5.3 In accordance with 42 CFR §438.810(f) found in Exhibit B, enrollment brokering activities, the Vendor must attest in writing that it has no corporate connections or financial interest in any of West Virginia's MCOs.

5.4 The vendor must agree to provide telephone, toll free numbers, faxing, paper supplies, postage machines, furniture, etc. for its work force. This involves purchasing capital

equipment including equipment that will be necessary to carry out the responsibilities of the contract.

5.5 The Vendor must agree to provide only hardware, software and communications components which are compatible with the most current West Virginia Office of Technology (WVOT) supported versions of the Microsoft™ Operating System, Microsoft Office™ Suite and Internet Explorer™, and current technologies for data interchange.

5.6 The Vendor must agree to continue outreach activities in each county and initiate intensive outreach activities at least forty-five (45) calendar days prior to any change of choice or process in that county.

5.7 The Vendor must agree to process enrollment forms to effect the member's enrollment or change in enrollment for the following month by the cutoff date, which falls in the third week of the month. MCO/PAAS enrollments are effective from the first day of the month to the last day of the month.

5.8 The Vendor must agree to develop enrollment materials that comply with the requirements of 42 CFR §438.10(e) found in Exhibit B and that are at or below a sixth grade reading level.

5.9 The Vendor must agree to work with BMS to develop the algorithm that will be used to assign members who do not make a selection to an MCO or PAAS. The algorithm must assign members based on their current PCP affiliation and their geographic access to providers in accordance with relevant Federal regulations. In addition, the Vendor must work with BMS to assure compliance with new and innovative enrollment strategies that may include passive enrollment and auto assignment based on P4P.

5.10 The Vendor must agree to all relevant requirements under 42 CFR 438.100 and 42 CFR 438.10 found in Exhibit B including furnishing the following information to all managed care and PAAS program enrollees:

- 5.10.1 Notify all enrollees of their disenrollment rights, at a minimum annually;
- 5.10.2 Notify all enrollees, at the time of enrollment, of the enrollee's rights to change providers or disenrollment for cause;
- 5.10.3 Notify all enrollees of their right to request and obtain the information listed under 42 CFR §438.10 found in Exhibit B, at least once a year; and
- 5.10.4 Furnish to each of its enrollees the information specified under 42 CFR §438.10(g) found in Exhibit B within a reasonable time after enrollment.

5.11 In accordance with 42 CFR §438.810 found in Exhibit B, the Vendor must affirm that it and its officers, members, employees, and/or subcontractors shall be free from any conflict of interest. Specifically, the Vendor affirms that neither it, nor any employee, subcontractor, or consultant:

5.11.1 Has any direct or indirect interest financial interest in any health care entity or health care provider that furnishes services in West Virginia;

5.11.2 Has been excluded from participation under title XVII or XIX of the Act;

5.11.3 Has been debarred by any Federal agency; or

5.11.4 Has been, or is now subject to, civil penalties under the Act.

The Vendor must covenant that in the performance of the contract, the Vendor shall periodically inquire of its officers, members and employees concerning such interests. Any such interests discovered shall be promptly presented in detail to BMS.

The Vendor must certify that it is independent from any MCO or health care provider that provides coverage in the State of West Virginia.

5.12 The Vendor must agree to put safeguards in place at least equal to Federal safeguards per Section 1932(d)(3) of the Social Security Act addressing the default enrollment process under the managed care and PAAS programs.

5.13 The Vendor must agree that the contract shall be governed by the laws of the State of West Virginia. The Vendor further agrees to comply with the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972 (regarding education programs and activities), The Age Discrimination Act of 1975, The Rehabilitation Act of 1973, The Americans with Disabilities Act, and all other applicable laws (Federal, State or Local Government) regulations.

REQUEST FOR PROPOSAL

West Virginia Bureau for Medical Services
RFP # BMS14028

SECTION FIVE: VENDOR PROPOSAL

1. **Economy of Preparation:** Proposals should be prepared simply and economically providing a straightforward, concise description of the Vendor's abilities to satisfy the requirements of the RFP. Emphasis should be placed on completeness and clarity of the content.

2. **Incurring Cost:** Neither the State nor any of its employees or officers shall be held liable for any expenses incurred by any Vendor responding to this RFP, including but not limited to preparation, delivery, or travel.

3. **Proposal Format:** Vendors should provide responses in the format listed below:

   Title Page: State the RFP subject, number, Vendor's name, business address, telephone number, fax number, name of contact person, e-mail address, and Vendor signature and date.

   Table of Contents: Clearly identify the material by section and page number.

   Attachment A: Within the attached response sheet (**Attachment A: Vendor Response Sheet**), provide the following: firm and staff qualifications and experience in completing similar projects; references; copies of any staff certifications or degrees applicable to this project; proposed staffing plan; descriptions of past projects completed entailing the location of the project, project manager name and contact information, type of project, and what the project goals and objectives were and how they were met.

   Also, describe the approach and methodology proposed for this project. This should include how each of the goals and objectives listed is to be met.

   Attachment B: Complete **Attachment B: Mandatory Specification Checklist**. By signing and dating this attachment, the Vendor acknowledges that they meet or exceed each of these specifications as outlined in 4.5 of Section Four: Project Specifications. The State reserves the right to require documentation detailing how each is met at its discretion.

   Attachment C: Complete **Attachment C: Cost Sheet** included in this RFP and submit in a separate sealed envelope. Cost should be clearly marked.

   Oral Presentations: If established by the Agency in the Schedule of Events (Section 1.3), all Vendors participating in this RFP will be required to provide an oral presentation. During oral presentations, Vendors may not alter or add to their submitted proposal, but only to clarify information.

4. **Proposal Submission:** Proposals must be received in **two distinct parts**: technical and cost.

- **Technical proposals** must not contain any cost information relating to the project.
- **Cost proposal** shall be sealed in a separate envelope and will not be opened initially.

All proposals must be submitted to the Purchasing Division **prior** to the date and time stipulated in the RFP as the opening date. All bids will be dated and time stamped to verify official time and date of receipt. All submissions must be in accordance with the provisions listed below and in Section Two: Instructions to Bidders Submitting Bids above.

5. **Technical Bid Opening**: The Purchasing Division will open and announce only the technical proposals received prior to the date and time specified in the Request for Proposal. The technical proposals shall then be provided to the Agency evaluation committee.

6. **Cost Bid Opening**: The Purchasing Division shall schedule a date and time to publicly open and announce cost proposals when the Purchasing Division has approved the technical recommendation of the evaluation committee. All cost bids for qualifying proposals will be opened. Cost bids for non-qualifying proposals will also be opened but shall not be considered. A proposal may be deemed non-qualifying for a number of reasons including, but not limited to, the bidder's technical proposal failing to meet the minimum acceptable score and the bidder's technical proposal failing to meet a mandatory requirement of the contract. Certain information, such as technical scores and reasons for disqualification, will not be available until after the contract award, pursuant to ***West Virginia Code*** §5A-3-11(h) and ***West Virginia Code of State Rules*** §148-1-6.2.5..

REQUEST FOR PROPOSAL

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SECTION SIX: EVALUATION AND AWARD

1. **Evaluation Process**: Proposals will be evaluated by a committee of three (3) or more individuals against the established criteria with points deducted for deficiencies. The Vendor who demonstrates that they meet all of the mandatory specifications required; and has appropriately presented within their written response and/or during the oral demonstration (if applicable) their understanding in meeting the goals and objectives of the project; and attains the highest overall point score of all Vendors shall be awarded the contract. The selection of the successful Vendor will be made by a consensus of the evaluation committee.

2. **Evaluation Criteria**: All evaluation criteria is defined in the specifications section and based on a 100 point total score. Cost shall represent a minimum of 30 of the 100 total points.

   The following are the evaluation factors and maximum points possible for technical point scores:

• Qualifications and experience	35 Points Possible
• Approach and methodology	35 Points Possible
• Cost	30 Points Possible
Total	100 Points Possible

Each cost proposal cost will be scored by use of the following formula for all Vendors who attained the minimum acceptable score:

Lowest price of all proposals

_____ **X 30 = Price Score**

Price of Proposal being evaluated

2.1 **Technical Evaluation:** The Agency evaluation committee will review the technical proposals, deduct points where appropriate, and make a final written recommendation to the Purchasing Division.

2.2 **Minimum Acceptable Score:** Vendors must score a minimum of 70% (49 points) of the total technical points possible. All Vendors not attaining the minimum acceptable score (MAS) shall be considered as non-qualifying. A proposal may be deemed non-qualifying for a number of reasons including, but not limited to, the bidder's technical proposal failing to meet the minimum acceptable score and the bidder's technical proposal failing to meet a mandatory requirement of the contract. Cost bids for non-qualifying proposals will also be opened but shall not be considered. Certain information, such as technical scores and reasons for disqualification, will not be available until after the contract award, pursuant to ***West Virginia Code*** §5A-3-11(h) and ***West Virginia Code of State Rules*** §148-1-6.2.5.

2.3 **Cost Evaluation:** The Agency evaluation committee will review the cost proposals, assign appropriate points, and make a final recommendation to the Purchasing Division.

REQUEST FOR PROPOSAL

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ATTACHMENT A: Vendor Response Sheet

Provide a response regarding the following: firm and staff qualifications and experience in completing similar projects; references; copies of any staff certifications or degrees applicable to this project; proposed staffing plan; descriptions of past projects completed entailing the location of the project, project manager name and contact information, type of project, and what the project goals and objectives were and how they were met.

List project goals and objectives contained in Section 4, Subsection 4:

Section 4, Subsection 4.1:

4.1 The Vendor should propose a plan to provide choice counseling to and enroll eligible participants into an approved Medicaid MCO or primary care provider (PCP) that is enrolled in the PAAS Program, according to the counties outlined in Exhibit A. All enrollment tasks detailed in this section apply to both new enrollments and changes in MCOs/PCPs and should comply with 42 CFR 438.6 which can be found in Exhibit B – Code of Federal Regulations.

4.1.1 The Vendor should include in its plan a process for assisting the State with enrollment in each of the fifty-five (55) counties, including addressing the unique enrollment needs of each county. Such circumstances may include the participating MCOs and PAAS in the county, rural/urban location, the number of Medicaid enrollees, and the number of providers. The plan for choice counseling and enrollment services should be in accordance with counties served by each MCO or PAAS Provider (which can be found at: http://www.dhhr.wv.gov/bms/mco/Pages/ExpansionMap.aspx and are included in Exhibit A), including objectively informing enrollees regarding the choices available, their rights and responsibilities regarding both the enrollment process and the ensuing enrollment, processing the forms and calls to perform enrollment, and acting as an educator on the MHT program.

The plan should indicate how the Vendor may remain impartial in assisting Medicaid enrollees with the managed care system and primary care provider (PCP) of their choice and not discriminate against individuals eligible to be covered under contract on the basis of health status or need for health services.

The plan should ensure that all enrollment tasks comply with all Federal and State laws and regulations, including Title 42, Section 438.6 of the Code of Federal Regulations (42 CFR §438.6) found in Exhibit B.

4.1.2 The plan should include how the Vendor, working with BMS, may identify the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State in accordance with 42 CFR §438.10 found in Exhibit B. The plan should indicate how the Vendor might make all information available in each

prevalent non-English language (if BMS and the Vendor determine a prevalent language other than English is present) to the same extent as the information available in English. Provider and other stakeholder communications may not require prevalent language translation.

The plan should ensure that all information for enrollees or potential enrollees complies with the requirements of 42 CFR §438.10, found in Exhibit B, and is at or below a sixth grade reading level.

4.1.3 The Vendor should develop sample enrollment forms and phone scripts for potential enrollees that comply with the requirements of 42 CFR §438 Subparts A-J found in Exhibit B. A sample enrollment form should be provided to BMS. The enrollment form and scripts should ask potential enrollees to indicate: his or her choice of MCO or PAAS provider; the name of his or her existing provider(s); and his or her race, ethnicity, primary language spoken and health status. The form should specify that information on race, ethnicity, primary language and health status is not mandatory for enrollment.

The plan should include a process for mailing the enrollment form and accompanying enrollment materials, as described in section 4.1.4, to potential enrollees within two (2) business days of receiving the eligibility file from the fiscal agent.

BMS anticipates approving the enrollment form and enrollment phone script at least thirty (30) calendar days prior to use. BMS reserves the right to alter the enrollment form and the script at any time. In the event that BMS alters the enrollment form, the Vendor has thirty (30) calendar days' to implement BMS requested changes. The Vendor may not make changes to the enrollment form or script without prior approval from BMS.

The Vendor should attach a draft copy of the enrollment form and scripts in its response to this RFP.

4.1.4 The plan should include the development of materials to notify members of the expectation to select an MCO or PAAS provider within forty-five (45) calendar days or be assigned to one (1) by the State. The Vendor should also recommend a process for accommodating passive enrollment as needed. The plan should also propose a process to develop additional materials that meet the requirements of 42 CFR §438.10 found in Exhibit B to help members in making their choice (e.g., member handbooks, network provider listings, letters related to MHT and PAAS programs). Such information may include:

4.1.4.8 MCO/PAAS availability in the service area (county);

4.1.4.9 Information specific to each MCO or PAAS program operating in the county, such as benefits covered, service area, and names, locations, telephone numbers, and non-English languages spoken for current

contracted providers and identification of providers not accepting new patients (including information on primary care physicians, specialists and hospitals for current contracted providers);

4.1.4.10 How to obtain services that are accessed through the FFS system and any value-added services the MCO provides;

4.1.4.11 The role of the primary care provider in MCO/PAAS;

4.1.4.12 Processes for enrollment, disenrollment, exemptions and grievances;

4.1.4.13 Availability of oral translation services free of charge for persons who do not understand English materials; and

4.1.4.14 Information on the benefits available under the State plan but not covered under the contract, including how and where the enrollee may obtain those benefits.

Written materials could include, but are not limited to:

4.1.4.8 A general informational pamphlet that can be used in any of the enrolled counties;

4.1.4.9 Specific pamphlets that describe in detail the choices available to enrollees depending on their place of residence; and

4.1.4.11 Letters or other materials that advertise changes in delivery systems and promote preventive care.

The plan should also include a process to mail additional materials, including those created by BMS and/or the MCOs, to help enrollees in making their choice (e.g., network provider listings, any BMS-approved marketing materials, question and answer sheets, letters related to the managed care programs).

In its response to this RFP, the Vendor should submit sample educational materials, including a general informational pamphlet, a specific pamphlet and a letter to enrollees.

4.1.5 The Vendor should describe its approach for reviewing MCO and PAAS member materials and other information in any medium. BMS may request the Vendor to assist in the review and approval of marketing materials and proposed marketing/outreach efforts. Any review of marketing materials should ensure that they comply with the requirements of 42 CFR §438 Subpart C found in Exhibit B.

4.1.6 The Vendor should offer multiple approaches for members to enroll, including by mail, telephone, text, web-based applications and other innovative and unique vehicles. The Vendor should address its approach for receiving enrollment forms via mail, telephone and internet. The Vendor should also propose timeframes not to exceed 24 hours for processing enrollment forms and for returning forms received

from eligible participants that cannot be processed due to incomplete or illegible information.

4.1.7 The Vendor should describe a process for following up on returned mail, including MHT and PAAS.

4.1.8 The Vendor should describe the process for educating members at the time of their MCO enrollment on how to access services that are accessed through the FFS system and carved out of the managed care program.

4.1.9 The Vendor should propose an approach for collecting and submitting third party liability information to BMS regarding discrepancies between the eligibility system information and the information the Vendor collected.

4.1.10 The Vendor should propose a comprehensive outreach and education strategy, which includes the development of materials and an approach for engaging stakeholders. The Vendor should submit to BMS its proposed outreach, education and enrollment plan for review and approval. The Vendor should request BMS approval for any subsequent adjustments.

4.1.11 The Vendor should develop written and visual materials for use in outreach and educational efforts to educate Medicaid members, advocates, providers, community agencies, caseworkers and DHHR staff about any changes in Medicaid delivery systems. These materials should include, but not be limited to, enrollment forms, notices, letters, pamphlets, presentations, videos, internet websites and other information.

The Vendor should obtain BMS approval for outreach and educational materials in any medium prior to production and distribution. Production, reproduction, updates and distribution of materials should be at the Vendor's expense.

Each material submitted for approval should be accompanied by a concise memo indicating the material's purpose, expected use, target audience and printing specifications. BMS reserves the right to edit all or portions of materials prior to distribution. Upon BMS approval, the Vendor should print all written materials, maintaining a sufficient stock of materials and distributing materials as needed at the Vendor's expense. The Vendor is responsible for supplying and distributing any pamphlets and other mailing material in addition to DHHR approved materials supplied by the MCOs/PAAS and DHHR.

4.1.12 The Vendor should include in its strategy a plan for engaging stakeholders. The Vendor should address how it plans to schedule educational presentations with these stakeholders on an ongoing basis and serve as a resource on the managed care and PAAS programs for stakeholders in the community. The Vendor's strategy should include participation in statewide annual provider workshops, where the written

material for each session should be provided by the Vendor. Historically, BMS has conducted seven (7) provider workshops at various locations throughout the state.

4.1.13 The Vendor should describe its approach for sorting enrollment forms for processing, identifying enrollees for outreach, researching issues in State systems and identifying enrollment forms that cannot be processed. The Vendor should also propose a process for identifying address discrepancies in State systems.

4.1.14 The Vendor should include in its strategy an approach for informing all county offices of any changes in the managed care and PAAS programs or processes for enrollment.

4.1.15 The Vendor should describe a process for providing additional, highly mobile benefits managers to travel to all fifty-five (55) counties to educate enrollees, providers, agencies, and organizations.

4.1.16 The Vendor should propose a plan for performing outreach to members that, because of housing circumstance, cultural differences, inability or unwillingness to access information through the county office or community hosted information program or other circumstances, makes enrollment a challenge.

4.1.17 The Vendor should propose a plan for mailings and electronic communications to MCO/PAAS members. The Vendor should be responsible for all member mailings for the managed care and PAAS programs and for coordinating all member mailings with BMS. The cost of the materials, printing and postage for these mailings should be the responsibility of the Vendor. The Vendor should also be responsible for the cost of re-mailings of returned mail, other notices sent on an individual basis and any mailings not done through the system process. The Vendor should advise BMS on the style and content of the mailings and notices.

4.1.18 The Vendor should include its approach for designing and maintaining an enrollment assistance website available to West Virginia Medicaid beneficiaries for the managed care and PAAS programs. The Vendor should address the type of web accessibility software, the types of information available to beneficiaries, languages supported on the website, frequency of updates to the website, search capabilities, user-friendly provider directories and interactive functionality to facilitate the secure submission of member plan and PCP changes.

4.1.19 The Vendor should design all educational materials and member content so that they clearly inform members about the programs and possible choices in their area. The Vendor should propose specific content to be included in the educational materials and member content.

4.1.20 The Vendor should make recommendations for educating and engaging enrollees in high quality health homes and patient centered medical homes.

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Vendor Response:

Section 4, Subsection 4.2:

4.2 The Vendor should propose a plan for creating and operating a telephone unit. Such responsibilities of the telephone unit should be to complete the enrollment of members into the MCO of their choice or PAAS; answer enrollment questions regarding the MHT and PAAS programs asked by Medicaid members, providers and the general community; settle complaints when possible; provide information on covered services; and complete research as requested by BMS. Types of calls could include but not necessarily be limited to:

4.2.1 Enrolling enrollees into the MCO or PAAS PCP of his or her choice;

4.2.2 Enrolling newborns into the mother's county-appropriate choice of MCO or PAAS provider;

4.2.3 Assisting enrollees in transferring from one (1) MCO to another, from an MCO to PAAS, from PAAS to an MCO and from one (1) PAAS PCP to another;

4.2.4 Processing exemption requests using BMS developed criteria;

4.2.5 Assessing any unique health care needs to ensure appropriate enrollment;

4.2.6 Identifying and, if possible, maintaining existing enrollee/provider relationships;

4.2.7 Explaining the options available to individuals depending upon their place of residence;

4.2.8 Explaining the health benefit coverage;

4.2.9 Providing specific information about each MCO and PAAS option such as the network of providers (e.g., physicians, hospitals) and the extent of new enrollees being accepted;

4.2.10 Documenting reasons for changes in MCO and/or PAAS enrollment and including change information in monthly reports to BMS;

4.2.11 Explaining Medicaid covered services and freedom of choice for access to family planning services;

4.2.12 Referring enrollees to the correct human service agency if calls are received that are outside the scope of the managed care programs;

4.2.13 "Triaging" enrollee calls to service representatives and medical hotlines when necessary, and resolving complaints and acting as troubleshooter and enrollee "ombudsman" for enrollees in the program.

The plan should include:

4.2.14 The development of operational procedures, manuals, forms and reports necessary for the operation of the telephone unit.

4.2.15 The Vendor's approach to staffing the telephone unit and training personnel on all relevant issues on an ongoing basis. The staff operating the telephone unit should be responsible for responding to a variety of phone calls from members (e.g., disenrollment, exemptions, choice counseling, covered services).

4.2.16 Procedures to ensure that telephone operators treat all callers with dignity and respect the callers' need for privacy.

4.2.17 Procedures for providing access to oral translation services that can be used to answer questions and provide information to enrollees who do not understand English.

4.2.18 The Vendor should address in its proposal how it plans to provide special services necessary to accommodate Medicaid members. Special services may include, but not be limited to teletypewriter (TTY) line translation services, assistance for the blind/literacy challenged, and program fact sheets in different languages for prevalent non-English members as defined in 42 CFR 438.10 (c).

4.2.19 The plan should include procedures for identifying individuals with special health needs through health assessments conducted as part of the enrollment process. In addition to identification strategies proposed by the Vendor, the Vendor should ask enrollees to indicate whether they have a special health care need. The Vendor should review health assessment forms and enter information on medical conditions, physician preferences or potential health problems within the Medicaid Management Information System (MMIS) and their own data system. It is anticipated that this data, along with a copy of the health assessment form, be forwarded to the MCOs by BMS's fiscal agent.

4.2.20 The Vendor should propose a Quality Assurance Plan to assure that all telephone functions meet their own internal standards, subject to BMS approval. As part of this plan, the Vendor should propose promptness and quality standards (e.g., percent of telephone calls answered within four (4) rings, maximum number of calls per operator in a queue, wait time in the queue, rate of abandoned/dropped calls).

4.2.21 The Vendor should establish, maintain and operate an office within fifteen (15) miles of the city limits of Charleston, West Virginia (Charleston). The Vendor should administer telephone support (as described in Section 4.3) from that location or an additional location within fifteen (15) miles of the city limits of Charleston.

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Vendor Response:

Section 4, Subsection 4.3:

4.3 The Vendor should propose a plan for systems development and ongoing communication with BMS and the MCOs. This plan should address the Vendor's process for:

4.3.1 Maintaining direct, ongoing communication with BMS regarding the Vendor's activities and working closely to assure accomplishment of the enrollment goals and objectives.

4.3.2 Meeting with the MCOs after contract award and on an ongoing basis, as necessary to obtain detailed information about each individual operation.

4.3.3 Providing training and technical assistance to all designated DHHR and BMS staff and their contractors participating in this project during the duration of the contract.

4.3.4 Forwarding any complaints concerning its staff to BMS with an explanation. Serious or repeated complaints about any staff person may result in a recommendation for removal of the staff member.

4.3.5 Notifying BMS, on a case-by-case basis, of any discrepancies found on the enrollment form such as, but not limited to, name spelling, date of birth, number of family members in the home, returned mail which indicates the Medicaid eligible has moved, etc., for resolution. Any discrepancy found on the enrollment form should be tracked and reported to BMS monthly via electronic file.

For discrepancies identified, the Vendor should work with BMS to reconcile the monthly list of enrollees for each MCO, which may require extensive research. The Vendor should monitor reports from the fiscal agent and alert BMS regarding any discrepancies.

The Vendor should be alert to possible discrepancies between approved materials and actual practices as may be reported by members. Any discrepancies discovered should be documented and forwarded to BMS for disposition.

4.3.6 The Vendor's proposal should specify its approach for implementing and performing the systems development tasks listed below:

4.3.6.1 Establish and maintain databases and systems to support the enrollment operation.

4.3.6.2 Work with BMS to learn the data entry screens within the MMIS which allows members to be enrolled in a managed care plan or PCP and develop

linkage to Recipient Automated Payment and Information Data System (RAPIDS), to facilitate research.

4.3.6.3 Work with BMS and the fiscal agent to identify any modifications needed.

4.3.6.4 Work with BMS staff in refining the default auto-assignment algorithm and responding to county-specific algorithm needs as appropriate (e.g., mandatory MCO enrollment, voluntary MCO enrollment).

4.3.6.5 Work with BMS staff in supporting any additional auto-assignment strategies which could include passive enrollment and pay-for-performance (P4P) approaches. BMS reserves the right to modify the methodology for assigning enrollees at any time.

4.3.7 The Vendor should provide BMS with a monthly snapshot of key activities, which includes a comparison of the current month's report with previous periods, as appropriate. The Vendor should also identify trends in enrollment, any issues encountered and recommendations for improvements, policy changes or procedural improvements. Reports should include charts and graphs to illustrate program performance. The Vendor should propose indicators to include in the monthly report; final format and indicators are subject to BMS approval. A sample report should be provided to BMS that may include some or all of the following elements:

4.3.7.1 Number and type of enrollee mailings related to the MHT program sent by the Vendor;

4.3.7.2 Per outreach effort, the number of enrollees mailed to or contacted through electronic methods along with the reason for the mailing or contact and the date of the mailing or contact;

4.3.7.3 The number of total newborn enrollments;

4.3.7.4 The total number of enrollments per month;

4.3.7.5 The auto-assignment rate per month;

4.3.7.6 The number of defaulted enrollments per month;

4.3.7.7 The number of choice enrollments per month;

4.3.7.8 The number of changes in existing enrollment and reason for change per month;

4.3.7.9 The number and percentage of choice enrollments that are processed accurately within two (2) business days of receipt of completed application;

4.3.7.10 Problems reported by counties or providers and the number and types of questions asked;

4.3.7.11 Number and type of complaints about marketing methods or discrepancies in enrollment materials;

4.3.7.12 Number and type of complaints about the Vendor, including the number of complaints that were resolved, how the complaints were resolved, and the average length of time it took to resolve the complaints;

4.3.7.13 Number of enrollees in the various benefit packages by eligibility groups;

4.3.7.14 Enrollment activities by county, program (i.e., managed care and PAAS), and by MCO, including the number of enrollment forms and enrollment phone calls received per day and, of those, the number processed, the number of contacts made, the number of forms returned and the reason the forms were returned; and

4.3.7.15 Telephone activities, including:

4.3.7.16 Number of days the telephone unit was operational;

4.3.7.17 Number of telephone calls received by all operators and by each operator per day, per week and per month;

4.3.7.18 Total number of telephone calls answered regarding enrollment into the managed care programs by all operators and by each operator per day, per week, and per month;

4.3.7.19 Number of calls abandoned and abandonment rate by all operators and by each operator per day, per week, and per month;

4.3.7.19 Average length of call by all operators and by each operator per day, per week, and per month;

4.3.7.20 Number of calls in the queue at peak times, as determined by the Vendor;

4.3.7.21 Average wait time for calls in queue per operator per day, per week, and per month;

4.3.7.22 Number of calls resulting in information generated to BMS's Third Party Liability (TPL) unit and whether previously unknown resources were referred or if TPL resources were coded on the system that are no longer valid;

4.3.7.23 Active time and inactive time for each operator's line; and

4.3.7.24 Log of requests for presentations for stakeholders, including meeting details and content presented.

The Vendor should respond to BMS requests for additional detail on activities within ten (10) business days.

Vendor Response:

Section 4, Subsection 4.4:

4.4 The Vendor should provide the names and contact information for key staff assigned to this project, including resumes. Key staff should include the account lead (primary liaison) and

direct or indirect reports that manage functional units. All key staff should demonstrate past experience specifically related to this project. For any key staff not currently employed, the Vendor should submit qualifications, job descriptions and plans for recruiting proposed key staff.

4.4.1 The Vendor should provide a functional organizational chart indicating the proposed project structure. The Vendor should indicate on the chart, or separately, the name of each proposed staff member and the percentage of time each proposed staff member will be dedicated to this project, expressed in a full-time equivalent (FTE) percent.

4.4.2 If the Vendor proposes to subcontract with organizations or individuals, it should provide a copy of the subcontract/agreement and a summary of the subcontractor's size, resources, location and responsibilities under the contract. The primary contractor should assume responsibility for all subcontracted work.

Vendor Response:

Section 4, Subsection 4.5

4.5 The Vendor should propose a solution that may be extended to other State Agencies, United States Territory or political subdivision upon mutual consent by Vendor and entity.

Vendor Response:

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ATTACHMENT B: Mandatory Specification Checklist

List mandatory specifications contained in Section 4, Subsection .5:

Section 4, Subsection 5.1:

5.1 The Vendor must agree to, no later than upon award of the Contract, provide a single lead point of contact that will serve as project manager and be immediately available by telephone and email, at a minimum, during business hours of Monday through Friday, 8:00 am – 5:00 pm Eastern Standard Time. This person will be responsible for overseeing Vendor performance and act as a liaison between the Vendor, BMS, and the MCOs/PAAS. BMS reserves the right to reject any staff proposed or later assigned to the project and require the successful Vendor to remove them from the project. The Vendor will notify BMS two (2) weeks in advance of replacing any key staff. Any changes or addition in key staff once the contract has begun must be reported to BMS accompanied by resumes.

Vendor Response:

Section 4, Subsection 5.2:

5.2 The Vendor must agree to prepare and submit a draft implementation plan as part of its response. The Vendor must further agree to submit any revisions to its implementation plan for review and approval by DHHR/BMS within fifteen (15) calendar days from the date of contract award. In addition, the vendor must agree to complete implementation activities within the timeframe allotted in the implementation plan and no more than (90) calendar days following the award.

Vendor Response:

Section 4, Subsection 5.3:

5.3 In accordance with 42 CFR §438.810(f) found in Exhibit B, enrollment brokering activities, the Vendor must attest in writing that it has no corporate connections or financial interest in any of West Virginia's MCOs.

Vendor Response:

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Section 4, Subsection 5.4:

5.4 The vendor must agree to provide telephone, toll free numbers, faxing, paper supplies, postage machines, furniture, etc. for its work force. This involves purchasing capital equipment including equipment that will be necessary to carry out the responsibilities of the contract.

Vendor Response:

Section 4, Subsection 5.5:

5.5 The Vendor must agree to provide only hardware, software and communications components which are compatible with the most current West Virginia Office of Technology (WVOT) supported versions of the Microsoft™ Operating System, Microsoft Office™ Suite and Internet Explorer™, and current technologies for data interchange.

Vendor Response:

Section 4, Subsection 5.6:

5.6 The Vendor must agree to continue outreach activities in each county and initiate intensive outreach activities at least forty-five (45) calendar days prior to any change of choice or process in that county.

Vendor Response:

Section 4, Subsection 5.7:

5.7 The Vendor must agree to process enrollment forms to effect the member's enrollment or change in enrollment for the following month by the cutoff date, which falls in the third week of the month. MCO/PAAS enrollments are effective from the first day of the month to the last day of the month.

Vendor Response:

Section 4, Subsection 5.8:

5.8 The Vendor must agree to develop enrollment materials that comply with the requirements of 42 CFR §438.10(e) found in Exhibit B and that are at or below a sixth grade reading level.

Vendor Response:

Section 4, Subsection 5.9:

5.9 The Vendor must agree to work with BMS to develop the algorithm that will be used to assign members who do not make a selection to an MCO or PAAS. The algorithm must assign members based on their current PCP affiliation and their geographic access to providers in accordance with relevant Federal regulations. In addition, the Vendor must work with BMS to assure compliance with new and innovative enrollment strategies that may include passive enrollment and auto assignment based on P4P.

Vendor Response:

Section 4, Subsection 5.10:

5.10 The Vendor must agree to all relevant requirements under 42 CFR 438.100 and 42 CFR 438.10 found in Exhibit B including furnishing the following information to all managed care and PAAS program enrollees:

5.10.1 Notify all enrollees of their disenrollment rights, at a minimum annually;

5.10.2 Notify all enrollees, at the time of enrollment, of the enrollee's rights to change providers or disenrollment for cause;

5.10.3 Notify all enrollees of their right to request and obtain the information listed under 42 CFR §438.10 found in Exhibit B, at least once a year; and

5.10.4 Furnish to each of its enrollees the information specified under 42 CFR §438.10(g) found in Exhibit B within a reasonable time after enrollment.

Vendor Response:

Section 4, Subsection 5.11

5.11 In accordance with 42 CFR §438.810 found in Exhibit B, the Vendor must affirm that it and its officers, members, employees, and/or subcontractors shall be free from any conflict of interest. Specifically, the Vendor affirms that neither it, nor any employee, subcontractor, or consultant:

5.11.1 Has any direct or indirect interest financial interest in any health care entity or health care provider that furnishes services in West Virginia;

5.11.2 Has been excluded from participation under title XVII or XIX of the Act;

5.11.3 Has been debarred by any Federal agency; or

5.11.4 Has been, or is now subject to, civil penalties under the Act.

The Vendor must covenant that in the performance of the contract, the Vendor shall periodically inquire of its officers, members and employees concerning such interests. Any such interests discovered shall be promptly presented in detail to BMS.

The Vendor must certify that it is independent from any MCO or health care provider that provides coverage in the State of West Virginia.

Vendor Response:

Section 4, Subsection 5.12:

5.12 The Vendor must agree to put safeguards in place at least equal to Federal safeguards per Section 1932(d)(3) of the Social Security Act addressing the default enrollment process under the managed care and PAAS programs.

Vendor Response:

Section 4, Subsection 5.13:

5.13 The Vendor must agree that the contract shall be governed by the laws of the State of West Virginia. The Vendor further agrees to comply with the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972 (regarding education programs and activities), The Age Discrimination Act of 1975, The Rehabilitation Act of 1973, The Americans with Disabilities Act, and all other applicable laws (Federal, State or Local Government) regulations.

Vendor Response:

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By signing below, I certify that I have reviewed this Request for Proposal in its entirety; understand the requirements, terms and conditions, and other information contained herein; that I am submitting this proposal for review and consideration; that I am authorized by the bidder to execute this bid or any documents related thereto on bidder's behalf; that I am authorized to bind the bidder in a contractual relationship; and that, to the best of my knowledge, the bidder has properly registered with any State agency that may require registration.

_____
(Company)

_____
(Representative Name, Title)

_____
(Contact Phone/Fax Number)

_____
(Date)

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ATTACHMENT C: Cost Sheet

Cost information below as detailed in the Request for Proposal and submitted in a separate sealed envelope. Cost should be clearly marked.

Vendors are to use their business expertise in pricing the work described in this RFP, taking into consideration any intervening steps or activities that must be performed in order to complete the work and offer their rates accordingly, even if BMS does not explicitly identify those intervening steps or activities in this RFP.

Section 1 - Implementation Cost

Expense	Total Cost
1. Staffing	$
2. Computer including software	$
3. Staffing	$
4. Facilities	$
5. Consulting services	$
6. Other (detail on separate sheet)	$
Total Not To Exceed Cost	$

Section 2 – Operations Cost

Expense	A. Members	B. PMPM Rate	C. Total Annual Cost (A * B)*12 = C
YEAR 1			
0 to 100,000 members	100,000	$	$
100,001 to 200,000 members	100,000	$	$
200,001 to 300,000 members	100,000	$	$
≥ 300,001 members	100,000	$	$
Subtotal Year 1			$
YEAR 2			
0 to 100,000 members	100,000	$	$
100,001 to 200,000 members	100,000	$	$
200,001 to 300,000 members	100,000	$	$
≥ 300,001 members	100,000	$	$
Subtotal Year 2			$
YEAR 3			
0 to 100,000 members	100,000	$	$
100,001 to 200,000 members	100,000	$	$
200,001 to 300,000 members	100,000	$	$

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≥ 300,001 members	100,000	$	$
Subtotal Year 3			$

YEAR 4

0 to 100,000 members	100,000	$	$
100,001 to 200,000 members	100,000	$	$
200,001 to 300,000 members	100,000	$	$
≥ 300,001 members	100,000	$	$
Subtotal Year 4			$

YEAR 5

0 to 100,000 members	100,000	$	$
100,001 to 200,000 members	100,000	$	$
200,001 to 300,000 members	100,000	$	$
≥ 300,001 members	100,000	$	$
Subtotal Year 5			$

Total Section 2: Operation Cost	$

Grand Total Cost of Contract (Total Section 1 & Section 2)	$

Notes:

1. *The Vendor may bill monthly for implementation activities in equal installments over the implementation period as defined in mandatory contract section five; sub-section 5.2*
2. *Participant population ranges were developed based on the current managed care enrollment and any future expansion.*
3. *During the Operation Phase of the Contract, the Vendor will be paid on a monthly per member per month (PMPM) basis in accordance with the Vendor's bid price proposals as set forth in Attachment C which shall be firm and fixed for the period of the Contract. Payment will be based on the actual monthly Medicaid managed care population. The final operational payment will be made upon determination by BMS that all contractual requirements have been completed prior to the termination of the contract.*
4. *The cost proposal will be evaluated based on the Grand Total Cost of Contract (Section 1 & Section 2). The cost bid shall include all anticipated training, travel and related expenses, including supplies and general administrative expenses.*

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_____
(Company)

_____
(Representative Name, Title)

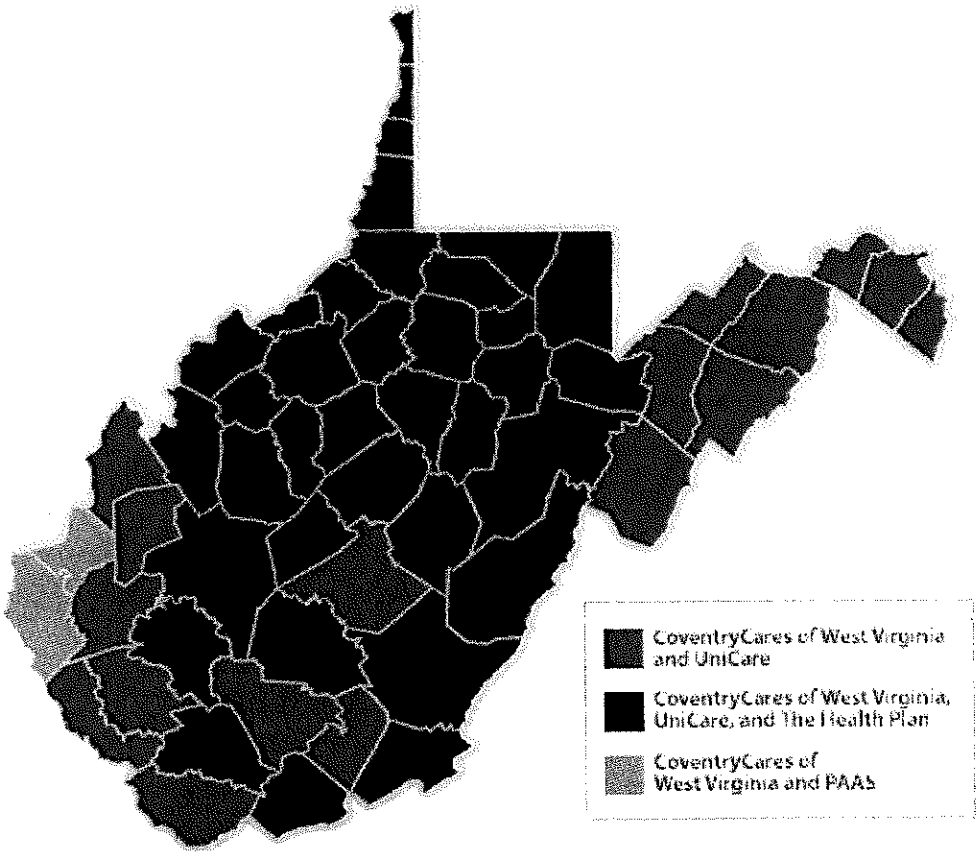
_____
(Contact Phone/Fax Number)

_____
(Date)

Exhibit A: State Documents

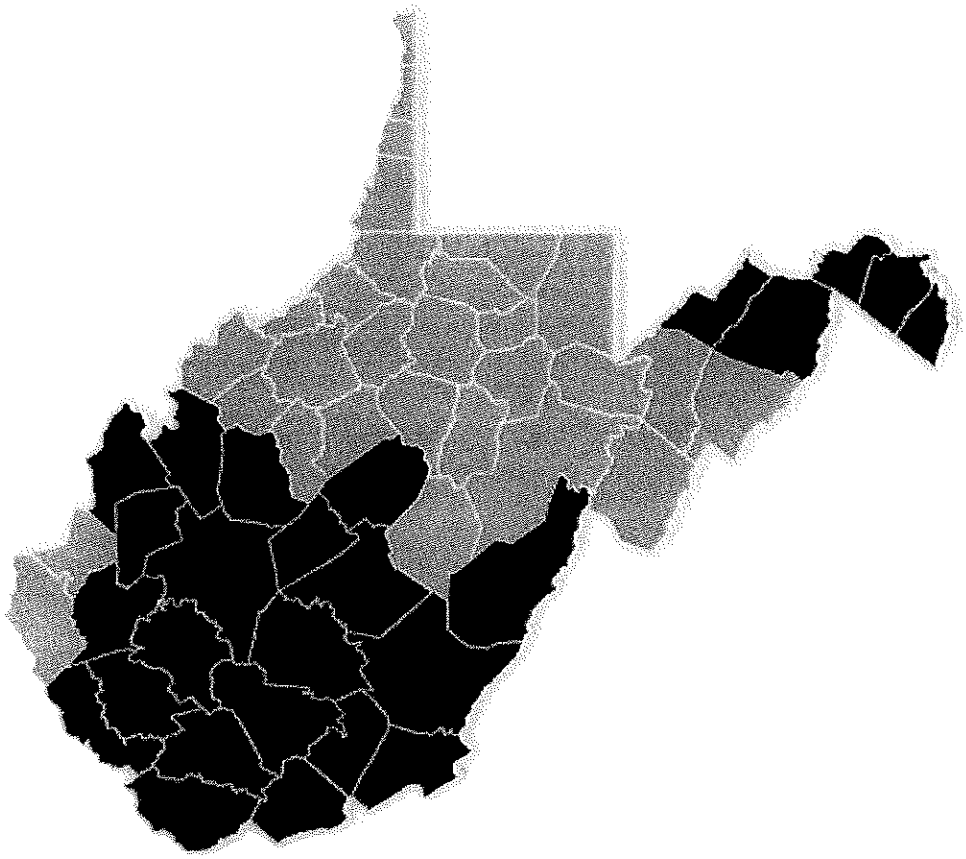
Locate a County Office or an MCO in your County

To view more information about each county, click on the map or county link below.



Managed Care Expansion Map

To view more information about each county, click on the map.



Unicare & Carelink

Unicare, Health Plan & Carelink

Carelink & PAAS

Unicare

WV Department of Health & Human Resources
Bureau for Children and Families
Local County Office Directory

The WV Department of Health and Human Resources (WV DHHR) comprises the central offices of Client Services; Family Support; and Social Services and the following county offices where clients may seek assistance.

COUNTY	PHONE	FAX	MAILING ADDRESS	PHYSICAL ADDRESS
Barbour	457-9030	457-4094	49 Mattaliano Drive Philippi, WV 26416	
Berkeley	267-0100	267-0123	P.O. Box 1247 Martinsburg, WV 25402	433 Mid-Atlantic Parkway Martinsburg, WV 25404
Boone	369-7802	369-7816	P.O. Box 970 Danville, WV 25053	156 Resource Lane Foster, WV 25081
Braxton	765-7344	765-3694	3708 Sutton Lane Sutton, WV	
Brooke (see Hancock)				
Cabell	528-5800	528-5523	2699 Park Avenue, Suite 100 Huntington, WV 25704	
Calhoun	354-6118	354-7076	P.O. Box 280 Grantsville, WV 26147	350 Main Street
Clay	587-4268	587-2567	P.O. Box 969 Clay, WV 25043	94 Main Street
Doddridge	873-2031	873-3078	22 Herbert Avenue Smithburg, WV 26436	PO Box 207 Smithburg, WV 26436
Fayette	465-9613	465-7288	1400 Virginia Street Oak Hill, WV 25901	
Gilmer	462-0412	462-0416	1493 WV Highway 5, East Glenville, WV 26351	
Grant	257-4211	257-1569	15 Grant St., Suite 1 Petersburg, WV 26847	
Greenbrier	647-7476	647-7486	150 Maplewood Ave. Lewisburg, WV 24901	
Hampshire	822-6900	822-7571	P.O. Box 1736 Romney, WV 26757	24954 Northwestern Pike
Hancock	794-3060	794-4169	100 Municipal Plaza, Suite 600 Weirton, WV 26062	
Hardy	538-2391	538-2476	149 Robert C. Byrd Industrial Park, Moorefield, WV 26836	
Harrison	627-2295	627-2171	P.O. Box 1877 Clarksburg, WV 26302	633 West Pike Street
Jackson	373-2560	372-7888	4285 Cedar Lakes Drive Ripley, WV 25271	
Jefferson	724-2600	728-0529	P.O. Box 984 Charles Town, WV 25414	239 Willow Spring Drive
Kanawha	746-2360	558-1801	4190 W. Washington Street Charleston, WV 25313	
Lewis	269-6820	269-0544	P.O. Box 1268 Weston, WV 26452	91 Arnold Avenue
Lincoln	824-5811	824-7811	P.O. Box 468 Hamlin, WV 25523	8209 Court Avenue
Logan	792-7095	792-7003	130 Stratton Street Logan, WV	
McDowell	436-8302	436-3248	840 Virginia Avenue Welch, WV 24801	
Marion	368-4420	368-4191	9083 Middletown Mall White Hall, WV 26554	
Marshall	843-4120	843-4127	400 Teletech Drive, Suite 2 Moundsville, WV 26041	
Mason	675-0880	675-0883	710 Viand Street Pt. Pleasant, WV 25550	
Mercer	425-8738	487-3589	200 Davis Street Princeton, WV 24739	

COUNTY	PHONE	FAX	MAILING ADDRESS	PHYSICAL ADDRESS
Mineral	788-4150	788-5363	18 N. Tornado Way Keyser, WV 26726	
Mingo	235-4680	235-4668	203 E. Third Avenue Williamson, WV 25661	
Monongalia	285-3175	285-3174	P.O. Box 800 Morgantown, WV 26507	114 S. High Street
Monroe	772-3013	772-4372	P.O. Box 678 Union, WV 24983	#174 Route 3, East Union, WV 24983
Morgan	258-1350	258-3794	P.O. Box 597 Berkeley Springs, WV 25411	62 Regal Court
Nicholas	872-0803	872-0832	1073 Arbuckle Road Summersville, WV 26651	
Ohio	232-4411	232-4773	P.O. Box 6165 Wheeling, WV 26003	69-16th Street
Pendleton	358-2305	358-7163	100 Thorn Creek Road Suite 200 Franklin, WV 26807	
Pleasants	684-9244	684-9245	201 Second Street St. Marys, WV 26170	
Pocahontas	799-2540	799-2560	211 Valhalla Lane Marlinton, WV 24954-5520	
Preston	329-4340	329-6082	P.O. Box 100 Kingwood, WV 26537	18351 Veteran's Mem Hgwy Kingwood, WV 26537
Putnam	586-1520	586-0300	3405 Winfield Road Winfield, WV 25213	
Raleigh	256-6930	256-6932	407 Neville St. Beckley, WV 25801	
Randolph	637-5560	637-0391	1027 N. Randolph Avenue Elkins, WV 26241	
Ritchie	643-2934	643-4098	220 W. Main Street Harrisville, WV 26362	
Roane	927-0956	927-0970	677 Ripley Road, Suite 3 Spencer, WV 25276	
Summers	466-2807	466-2814	320 Summers St., Suite A Hinton, WV 25951	
Taylor	265-6103	265-6107	P.O. Box 29 Grafton, WV 26354	235 Barrett Street
Tucker	478-3212	478-4514	9346 Seneca Trl Parsons, WV 26287-9575	
Tyler	758-2127	758-2587	P.O. Box 563 Middlebourne, WV 26149	210 Main Street
Upshur	473-4230	473-4207	P.O. Box 460 Buckhannon, WV 26201	Route 3, Box 376-A
Wayne	272-6311	272-5183	26452 East Lynn Road Wayne, WV 25570-5103	
Webster	847-2861	847-7244	110 N. Main St., Suite 201 Webster Springs, WV 26288	
Wetzel	455-0920	455-0928	1236 North State Route 2 New Martinsville, WV 26155	
Wirt	275-6551	275-3938	P.O. Box 310 Elizabeth, WV 26143	Court Street
Wood	420-2560	420-4884	P.O. Box 1547 Parkersburg, WV 26102	400 5th Street
Wyoming	732-6900	732-8223	HC 72, Box 300 Pineville, WV 24874	Route 97

Exhibit B: Code of Federal Regulations

day of the following month, the child's presumptive eligibility will end on that last day; and

(B) If a Medicaid application on behalf of the child is filed by the last day of the following month, the child's presumptive eligibility will end on the day that a decision is made on the Medicaid application; and

(v) For children determined not to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate—

(A) Of the reason for the determination; and

(B) That he or she may file an application for Medicaid on the child's behalf with the Medicaid agency; and

(3) Provide all services covered under the plan, including EPSDT.

(4) Allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

(c) The agency must adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child in a given time frame.

PART 438—MANAGED CARE

Subpart A—General Provisions

Sec.

Subpart B—State Responsibilities

Subpart C—Enrollee Rights and Protections

Subpart D—Quality Assessment and Performance Improvement

ACCESS STANDARDS

STRUCTURE AND OPERATION STANDARDS

MEASUREMENT AND IMPROVEMENT STANDARDS

Subpart E—External Quality Review

Subpart F—Grievance System

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 67 FR 41095, June 14, 2002, unless otherwise noted.

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State plan. The application of the requirements of this part to PIHPs and PAHPs that do not meet the statutory definition of an MCO or a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

(iv) Requires States to develop a quality assessment and performance improvement strategy;

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PIHPs, PAHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) FQHC services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

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

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

Health insuring organization (HIO) means a county operated entity, that in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers;

(2) Under a comprehensive risk contract with the State; and

(3) Meets the following criteria—

(i) First became operational prior to January 1, 1986; or

(ii) Is described in section 9517(e)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990).

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

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

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

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

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

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts*—(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to compensate for distortions in costs, utilization, or the number of eligibles.

(iii) *Cost neutral* means that the mechanism used to smooth data, share risk, or adjust for risk will recognize both higher and lower expected costs and is not intended to create a net aggregate gain or loss across all payments.

(iv) *Incentive arrangement* means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

(v) *Risk corridor* means a risk sharing mechanism in which States and contractors share in both profits and losses under the contract outside of predetermined threshold amount, so that after an initial corridor in which the contractor is responsible for all losses or retains all profits, the State

contributes a portion toward any additional losses, and receives a portion of any additional profits.

(2) *Basic requirements.* (i) All payments under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as medical trend inflation, incomplete data, MCO, PIHP, or PAHP administration (subject to the limits in paragraph (c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by—

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are—

(A) Based only upon services covered under the State plan (or costs directly related to providing these services, for example, MCO, PIHP, or PAHP administration).

(B) Provided under the contract to Medicaid-eligible individuals.

(iii) The State's projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies must be computed on an actuarially sound basis.

(ii) If risk corridor arrangements result in payments that exceed the approved capitation rates, these excess payments will not be considered actuarially sound to the extent that they result in total payments that exceed the amount Medicaid would have paid, on a fee-for-service basis, for the State plan services actually furnished to enrolled individuals, plus an amount for MCO, PIHP, or PAHP administrative costs directly related to the provision of these services.

(iii) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound.

(iv) For all incentive arrangements, the contract must provide that the arrangement is—

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Made available to both public and private contractors;

(D) Not conditioned on intergovernmental transfer agreements; and

(E) Necessary for the specified activities and targets.

(v) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State

plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, and PCCMs must provide as follows:

(1) The MCO, PIHP, PAHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO, PIHP, or PAHP contract may cover, for enrollees, services that are in addition to those covered under the State plan, although the cost of these services cannot be included when determining the payment rates under § 438.6(c).

(f) *Compliance with contracting rules.* All contracts must meet the following provisions:

(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act of 1990 as amended.

(2) Provide for the following:

(i) Compliance with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this subchapter.

(ii) Reporting all identified provider-preventable conditions in a form or frequency as may be specified by the State.

(3) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

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

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

(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 for advance directives.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

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

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

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

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

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

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

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with § 438.56(c).

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

[67 FR 41095, June 14, 2002, as amended at 76 FR 32837, June 6, 2011]

§ 438.8 Provisions that apply to PIHPs and PAHPs.

(a) The following requirements and options apply to PIHPs, PIHP contracts, and States with respect to PIHPs, to the same extent that they apply to MCOs, MCO contracts, and States for MCOs.

(1) The contract requirements of § 438.6, except for requirements that pertain to HIOs.

(2) The information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The enrollee rights and protection provisions in subpart C of this part.

(6) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PIHP.

(7) The grievance system provisions in subpart F of this part.

(8) The certification and program integrity protection provisions set forth in subpart H of this part.

(b) The following requirements and options for PAHPs apply to PAHPs, PAHP contracts, and States.

(1) The contract requirements of § 438.6, except requirements for—

(i) HIOs.

(ii) Advance directives (unless the PAHP includes any of the providers listed in § 489.102) of this chapter.

(2) All applicable portions of the information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The provisions on enrollee rights and protections in subpart C of this part.

(6) Designated portions of subpart D of this part.

(7) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(8) Prohibitions against affiliations with individuals debarred by Federal agencies in § 438.610.

[67 FR 41095, June 14, 2002, as amended at 67 FR 65505, Oct. 25, 2002]

§ 438.10 Information requirements.

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

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

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

(b) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, and

PCCM 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.

(2) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(3) Each MCO and PIHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(c) *Language.* The State must do the following:

(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) Make available written information in each prevalent non-English language.

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

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

(5) Notify enrollees and potential enrollees, and require each MCO, PIHP, PAHP, and PCCM 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; and

(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.* (1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary program, or is first required to enroll in a mandatory enrollment program.

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, or PCCMs.

(2) The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program; and

(C) MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO, PIHP, PAHP, or PCCM program operating in potential enrollee's service area. A summary of the following information is sufficient, but the State must provide more detailed information upon request:

(A) Benefits covered.

(B) Cost sharing, if any.

(C) Service area.

(D) Names, locations, telephone numbers of, and non-English language spoken by current contracted providers, and including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs, this includes at a minimum information on primary care physicians, specialists, and hospitals.

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover

because of moral or religious objections, the State must provide information about where and how to obtain the service.

(f) *General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs.* Information must be furnished to MCO, PIHP, PAHP, and PCCM enrollees as follows:

(1) The State must notify all enrollees of their disenrollment rights, at a minimum, annually. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 days before the start of each enrollment period.

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

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

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

(5) The MCO, PIHP, and, when appropriate, the PAHP or PCCM, 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 State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must provide the following information to all enrollees:

(i) Names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists, and hospitals.

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

(iii) Enrollee rights and protections, as specified in §438.100.

(iv) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in §438.10(g)(1), and for PAHP enrollees, the information specified in §438.10(h)(1).

(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 poststabilization services, with reference to the definitions in §438.114(a).

(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 poststabilization services covered under the contract.

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

(ix) The poststabilization care services rules set forth at § 422.113(c) of this chapter.

(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, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM need not furnish information on how and where to obtain the service. The State must provide information on 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(f), the State, its contracted representative, or the MCO and PIHP must provide the following information to their enrollees:

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

(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 timeframes 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).

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

(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.

(h) *Specific information for PAHPs.* The State, its contracted representative, or the PAHP must provide the following information to their enrollees:

(1) The right to a State fair hearing, including the following:

(i) The right to a hearing.

(ii) The method for obtaining a hearing.

(iii) The rules that govern representation.

(2) Advance directives, as set forth in § 438.6(i)(2), to the extent that the PAHP includes any of the providers listed in § 489.102(a) of this chapter.

(3) Upon request, physician incentive plans as set forth in § 438.6(h).

(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, within the timeframe specified in § 438.10(e)(1).

(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 or PCCM in the potential enrollees and enrollee's service area:

(i) The MCO's or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO or PCCM.

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

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP 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, or PAHP 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, or PAHP must comply with the requirements specified in § 438.214.

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

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

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

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

Subpart B—State Responsibilities

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

(1) Section 1903(m) of the Act, for MCOs and MCO contracts.

(2) Section 1905(t) of the Act, for PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, for MCOs and PCCMs.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.6(c), for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement

or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

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

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An "existing provider-recipient relationship" is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

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

§ 438.52 Choice of MCOs, PIHPs, PAHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PIHP, PAHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.* (1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, PAHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph (b)(1) of this section, must permit the recipient—

(i) To choose from at least two physicians or case managers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, PAHP, or PCCM 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, PAHP, or PCCM 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 recipient'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 treatment.

(3) As used in this paragraph, "rural area" is any area other than an "urban area" as defined in §412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The recipient who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PIHP, PAHP, or HIO under paragraph (b) or (c) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under §438.56(c).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§438.56 Disenrollment: Requirements and limitations.

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

(b) *Disenrollment requested by the MCO, PIHP, PAHP, or PCCM.* All MCO, PIHP, PAHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PIHP, PAHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PIHP, PAHP, or PCCM may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, or PCCM 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, PAHP, or PCCM assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, and PCCM 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 recipient's initial enrollment with the MCO, PIHP, PAHP, or PCCM, 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, PAHP, or PCCM, if the State permits MCOs, PIHP, PAHPs, and PCCMs to process disenrollment requests.

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

(i) The enrollee moves out of the MCO's, PIHP's, PAHP's, or PCCM'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, PAHP, or PCCM action on request.* (i) An MCO, PIHP, PAHP, or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, 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, PAHP, or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PIHP, PAHP, or PCCM at the agency's request.

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

(5) *Use of the MCO, PIHP, PAHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PIHP, PAHP, or PCCM'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, PAHP, or PCCM approves the 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, PAHP, or PCCM files the request.

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

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the default enrollment process specified in § 438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO, PIHP, or PAHP for services available under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are provided for in title XIX of the Act, in 42 CFR, or when the State agency has adjusted the capitation rates paid under the contract, in accordance with § 438.6(c)(5)(v), to make payments for graduate medical education.

§438.62 Continued services to recipients.

The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, or PCCM for any reason other than ineligibility for Medicaid.

§438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's, PIHP's, or PAHP's operations, including, at a minimum, operations related to the following:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

Subpart C—Enrollee Rights and Protections

§438.100 Enrollee rights.

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

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

(2) Each MCO, PIHP, PAHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account 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 paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, or PCCM has the following rights: The right to—

(i) Receive information in accordance with §438.10.

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

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

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

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

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR §164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§438.206 through 438.210.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, and PCCM complies with any other applicable Federal and State laws (such as: 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).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of 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, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1) An MCO, PIHP, or PAHP that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

(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, or PAHP to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(f)(4) requires the State, its contracted representative, or MCO, PIHP, or PAHP to furnish the information at least 30 days before the effective date of the policy.)

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

(c) *Information requirements: State responsibility.* For each service excluded by an MCO, PIHP, or PAHP under paragraph (a)(2) of this section, the State must provide information on how and where to obtain the service, as specified in § 438.10, paragraphs (e)(2)(ii)(E) and (f)(6)(xii).

(d) *Sanction.* An MCO that violates the prohibition of paragraph (a)(1) of this section is subject to intermediate sanctions under subpart I of this part.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.104 Marketing activities.

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

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

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

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to potential enrollees.

MCO, PIHP, PAHP, or PCCM include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements.* Each contract with an MCO, PIHP, PAHP, or

PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of §438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any private insurance; and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PIHP, PAHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PIHP, PAHP, or PCCM is endorsed by CMS, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under §431.12 of this chapter or an advisory committee with similar membership.

§438.106 Liability for payment.

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

(a) The MCO's, PIHP's, or PAHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO, PIHP, or PAHP; or

(2) The State, or the MCO, PIHP, or PAHP does not pay the individual or health care provider that 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, or PAHP 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.

§438.114 Emergency and poststabilization services.

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

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

(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 and outpatient services that are as follows:

(1) Furnished by a provider that is qualified to furnish these services under this title.

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

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized 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 poststabilization care services.

(1) The MCO, PIHP, or PAHP.

(2) The PCCM that has a risk contract that covers these services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(c) *Coverage and payment: Emergency services*—(1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, or PCCM; and

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

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

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

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

(ii) Pay for the services if the manager's contract is a risk contract that covers those services.

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

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

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

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

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at §422.113(c) of this chapter. In applying those provisions, reference to "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 and PAHPs.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP or PAHP is responsible, the rules under this section apply.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.116 Solvency standards.

(a) *Requirement for assurances* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO or PIHP, must meet the solvency standards established by the State for private health maintenance organizations, or

be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PIHP, that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs, PIHPs, and PAHPs. It also establishes standards that States, MCOs, PIHPs, and PAHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PIHP must do the following:

(a) Have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs.

(b) Obtain the input of recipients and other stakeholders in the development of the strategy and make the strategy available for public comment before adopting it in final.

(c) Ensure that MCOs, PIHPs, and PAHPs comply with standards established by the State, consistent with this subpart.

(d) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy periodically, as needed.

(e) Submit to CMS the following:

(1) A copy of the initial strategy, and a copy of the revised strategy whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following:

(a) The MCO and PIHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures that—

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

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

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

(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.

(d) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO and PIHP contract.

(e) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

ACCESS STANDARDS

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs.

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

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services, taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP.

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

(iv) The numbers 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 Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(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.

(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 services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP 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.

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

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

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

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

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

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by providers.

(v) Monitor providers regularly to determine compliance.

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

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

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of supporting documentation.* Each MCO, PIHP, and PAHP must submit documentation to the State, in

a format specified by the State to demonstrate that it complies with the following requirements:

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

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

(c) *Timing of documentation.* Each MCO, PIHP, and PAHP must submit the documentation described in paragraph (b) of this section as specified by the State, but no less frequently than the following:

(1) At the time it enters into a contract with the State.

(2) At any time there has been a significant change (as defined by the State) in the MCO's, PIHP's, or PAHP's operations that would affect adequate capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area or payments; or

(ii) Enrollment of a new population in the MCO, PIHP, or PAHP.

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP, the State must certify to CMS that the MCO, PIHP, or PAHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP.

§ 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, PIHP, and PAHP complies with the requirements of this section.

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

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

(ii) Implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For each MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare+Choice plan, the State determines to what extent the MCO must meet the primary care coordination, identification, assessment, and treatment planning provisions of paragraphs (b) and (c) of this section with respect to dually eligible individuals.

(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, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver primary care to and coordinate health care service for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:

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

(2) Coordinate the services the MCO, PIHP, or PAHP 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 that 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, PIHPs and PAHPs, as those persons are defined by the State. These identification mechanisms—

(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,

PIHPs and PAHPs.

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP by the State as 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, PIHPs, and PAHPs 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, 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, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP; and

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

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

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under fee-for-service Medicaid, as set forth in § 440.230.

(3) Provide that the MCO, PIHP, or PAHP—

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

(ii) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary;

(iii) May place appropriate limits on a service—

(A) On the basis of criteria applied under the State plan, such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(3)(i) of this section; and

(4) Specify what constitutes "medically necessary services" in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.

(B) The ability to achieve age-appropriate growth and development.

(C) The ability to attain, maintain, or regain functional capacity.

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

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

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; 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 enrollee's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs and PIHPs, 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, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) *Standard authorization decisions.* For standard authorization decisions, provide notice as expeditiously as the enrollee's 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, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

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

(ii) The MCO, PIHP, or PAHP 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, or PAHP 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.

STRUCTURE AND OPERATION STANDARDS

§438.214 Provider selection.

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

(b) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that each MCO, PIHP, and PAHP must follow.

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

(c) *Nondiscrimination.* MCO, PIHP, and PAHP provider selection policies and procedures, consistent with §438.12, must not discriminate against particular providers that serve high-risk

populations or specialize in conditions that require costly treatment.

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

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

[67 FR 41095, June 14, 2002; 67 FR 54532, Aug. 22, 2002]

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality.

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

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO, PIHP, and PAHP contract complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 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 or PIHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

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

(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, PIHP, and PAHP 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, PIHP, or PAHP 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 MCO laws and regulations.

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

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 and PAHP meets the requirements of this section.

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

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

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

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

(4) Are reviewed and updated periodically as appropriate.

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

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

§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) CMS, in consultation with States and other stakeholders, may specify performance measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs.

(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. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction.

(2) Submit performance measurement data as described in paragraph (c) of this section.

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

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

(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);

(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 activities described in paragraphs (c)(1) and (c)(2) of this section.

(d) *Performance improvement projects.* (1) MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and nonclinical 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.

(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.

§ 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 appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO 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 upon request to CMS, as required in this subpart.

Subpart E—External Quality Review

SOURCE: 68 FR 3635, Jan. 24, 2003, unless otherwise noted.

§ 438.310 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1932(c)(2), 1903(a)(3)(C)(ii), and 1902(a)(4) of the Act.

(b) *Scope.* This subpart sets forth requirements for annual external quality reviews of each contracting managed care organization (MCO) and prepaid inpatient health plan (PIHP), including—

(1) Criteria that States must use in selecting entities to perform the reviews;

(2) Specifications for the activities related to external quality review;

(3) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews; and

(4) Standards for making available the results of the reviews.

(c) *Applicability.* The provisions of this subpart apply to MCOs, PIHPs, and to health insuring organizations (HIOs) that began on or after January 1, 1986 that the statute does not explicitly exempt from requirements in section 1903(m) of the Act.

§ 438.320 Definitions.

As used in this subpart—

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO or PIHP, or their contractors furnish to Medicaid recipients.

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

Financial relationship means—

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

(2) A compensation arrangement with an entity.

Quality, as it pertains to external quality review, means the degree to which an MCO or PIHP increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge.

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

§438.350 State responsibilities.

Each State that contracts with MCOs or PIHPs must ensure that—

(a) Except as provided in §438.362, a qualified EQRO performs an annual EQR for each contracting MCO or PIHP;

(b) The EQRO has sufficient information to use in performing the review;

(c) The information used to carry out the review must be obtained from the EQR-related activities described in §438.358.

(d) For each EQR-related activity, the information must include the elements described in §438.364(a)(1)(i) through (a)(1)(iv);

(e) The information provided to the EQRO in accordance with paragraph (c) of this section is obtained through methods consistent with the protocols established under §438.352; and

(f) The results of the reviews are made available as specified in §438.364.

§438.352 External quality review protocols.

Each protocol must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

§438.354 Qualifications of external quality review organizations.

(a) *General rule.* The State must ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid recipients, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors are independent from the State Medicaid agency and from the MCOs or PIHPs that they review. To qualify as "independent"—

(1) A State agency, department, university, or other State entity may not have Medicaid purchasing or managed care licensing authority; and

(2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.

(3) An EQRO may not—

(i) Review a particular MCO or PIHP if either the EQRO or the MCO or PIHP exerts control over the other (as used in this paragraph, "control" has the meaning given the term in 48 CFR 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and

(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid recipients;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO or PIHP services, except for the related activities specified in §438.358; or

(iv) Have a present, or known future, direct or indirect financial relationship with an MCO or PIHP that it will review as an EQRO.

§438.356 State contract options.

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities; and

(2) May contract with additional EQROs to conduct EQR-related activities as set forth in § 438.358.

(b) Each EQRO must meet the competence requirements as specified in § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in § 438.354(c).

(e) For each contract, the State must follow an open, competitive procurement process that is in accordance with State law and regulations and consistent with 45 CFR part 74 as it applies to State procurement of Medicaid services.

§ 438.358 Activities related to external quality review.

(a) *General rule.* The State, its agent that is not an MCO or PIHP, or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(b) *Mandatory activities.* For each MCO and PIHP, the EQR must use information from the following activities:

(1) Validation of performance improvement projects required by the State to comply with requirements set forth in § 438.240(b)(1) and that were underway during the preceding 12 months.

(2) Validation of MCO or PIHP performance measures reported (as required by the State) or MCO or PIHP performance measure calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.240(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO's or PIHP's compliance with standards (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) established by the State to comply with the requirements of § 438.204(g).

(c) *Optional activities.* The EQR may also use information derived during the preceding 12 months from the following optional activities:

(1) Validation of encounter data reported by an MCO or PIHP.

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO or PIHP and validated by an EQRO.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO or PIHP and validated by an EQRO.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs or PIHPs to assist them in conducting activities related to the mandatory and optional activities that provide information for the EQR.

§ 438.360 Nonduplication of mandatory activities.

(a) *General rule.* To avoid duplication, the State may use, in place of a Medicaid review by the State, its agent, or EQRO, information about the MCO or PIHP obtained from a Medicare or private accreditation review to provide information otherwise obtained from the mandatory activities specified in § 438.358 if the conditions of paragraph (b) or paragraph (c) of this section are met.

(b) *MCOs or PIHPs reviewed by Medicare or private accrediting organizations.* For information about an MCO's or PIHP's compliance with one or more standards required under § 438.204(g), (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) the following conditions must be met:

(1) The MCO or PIHP is in compliance with standards established by CMS for Medicare+Choice or a national accrediting organization. The CMS or national accreditation standards are comparable to standards established by the State to comply with § 438.204(g)

and the EQR-related activity under § 438.358(b)(3).

(2) Compliance with the standards is determined either by—

(i) CMS or its contractor for Medicare; or

(ii) A private national accrediting organization that CMS has approved as applying standards at least as stringent as Medicare under the procedures in § 422.158.

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review applicable to the standards provided for in § 438.204(g); and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the standards for which the EQR will use information from Medicare or private accreditation reviews, and explains its rationale for why the standards are duplicative.

(c) *Additional provisions for MCOs or PIHPs serving only dually eligibles.* The State may use information obtained from the Medicare program in place of information produced by the State, its agent, or EQRO with respect to the mandatory activities specified in § 438.358 (b)(1) and (b)(2) if the following conditions are met:

(1) The MCO or PIHP serves only individuals who receive both Medicare and Medicaid benefits.

(2) The Medicare review activities are substantially comparable to the State-specified mandatory activities in § 438.358(b)(1) and (b)(2).

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare review from the activities specified under § 438.358(b)(1) and (b)(2) and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the mandatory activities for which it has exercised this option and explains its rationale for why these activities are duplicative.

§ 438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO or PIHP from EQR if the following conditions are met:

(1) The MCO or PIHP has a current Medicare contract under part C of title XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO or PIHP has been subject to EQR under this part, and found to be performing acceptably with respect to the quality, timeliness, and access to health care services it provides to Medicaid recipients.

(b) *Information on exempted MCOs or PIHPs.* When the State exercises this option, the State must obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO or PIHP that it exempts from EQR the most recent Medicare review findings reported on the MCO or PIHP including—

(i) All data, correspondence, information, and findings pertaining to the MCO's or PIHP's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities;

(ii) All measures of the MCO's or PIHP's performance; and

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for Medicare+Choice deeming.* (i) If an exempted MCO or PIHP has been reviewed by a private accrediting organization, the State must require the MCO or PIHP to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(B) To deem compliance with Medicare requirements, as provided in § 422.156 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation

review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

§ 438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR produces at least the following information:

(1) A detailed technical report that describes the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO or PIHP. The report must also include the following for each activity conducted in accordance with § 438.358:

(i) Objectives.

(ii) Technical methods of data collection and analysis.

(iii) Description of data obtained.

(iv) Conclusions drawn from the data.

(2) An assessment of each MCO's or PIHP's strengths and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid recipients.

(3) Recommendations for improving the quality of health care services furnished by each MCO or PIHP.

(4) As the State determines, methodologically appropriate, comparative information about all MCOs and PIHPs.

(5) An assessment of the degree to which each MCO or PIHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Availability of information.* The State must provide copies of the information specified in paragraph (a) of this section, upon request, through print or electronic media, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO or PIHP, recipient advocacy groups, and members of the general public. The State must make this information available in alternative formats for persons with sensory impairments, when requested.

(c) *Safeguarding patient identity.* The information released under paragraph (b) of this section may not disclose the identity of any patient.

§ 438.370 Federal financial participation.

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and EQR-related activities set forth in § 438.358 conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO.

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act.

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

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

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

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

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 an MCO or PIHP to act within the timeframes provided in § 438.408(b); or

(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, under § 438.52(b)(2)(ii), to obtain services outside the network.

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.)

§ 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.

§ 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) to ensure ease of understanding.

(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 services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

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

(4) If the MCO or PIHP extends the timeframe in accordance with § 438.210(d)(1), 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).

§ 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 the 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.

§ 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 timeframes that may not exceed the timeframes 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 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 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 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 an 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.

§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) Make reasonable efforts to give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice.

§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.

§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.

§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 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, unless 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.

§ 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.

Subpart G [Reserved]

Subpart H—Certifications and Program Integrity

§ 438.600 Statutory basis.

This subpart is based on sections 1902(a)(4), 1902(a)(19), 1903(m), and 1932(d)(1) of the Act.

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

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

(c) Section 1903(m) establishes conditions for payments to the State with respect to contracts with MCOs.

(d) Section 1932(d)(1) prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals excluded under Federal regulations from participating in specified activities, or with affiliates of those individuals.

§ 438.602 Basic rule.

As a condition for receiving payment under the Medicaid managed care program, an MCO, PCCM, PIHP, or PAHP must comply with the applicable certification, program integrity and prohibited affiliation requirements of this subpart.

§438.604 Data that must be certified.

(a) *Data certifications.* When State payments to an MCO or PIHP are based on data submitted by the MCO or PIHP, the State must require certification of the data as provided in §438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Additional certifications.* Certification is required, as provided in §438.606, for all documents specified by the State.

§438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data specified in §438.604, the data the MCO or PIHP submits to the State must be certified by one of the following:

(1) The MCO's or PIHP's Chief Executive Officer.

(2) The MCO's or PIHP's Chief Financial Officer.

(3) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PIHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of the data.

(2) To the accuracy, completeness and truthfulness of the documents specified by the State.

(c) *Timing of certification.* The MCO or PIHP must submit the certification concurrently with the certified data.

§438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PIHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

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

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision for internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PIHP's contract.

§438.610 Prohibited affiliations with individuals debarred by Federal agencies.

(a) *General requirement.* An MCO, PCCM, PIHP, or PAHP may not knowingly have a relationship of the type described in paragraph (b) of this section with the following:

(1) An individual who is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

(b) *Specific requirements.* The relationships described in this paragraph are as follow:

(1) A director, officer, or partner of the MCO, PCCM, PIHP, or PAHP.

(2) A person with beneficial ownership of five percent or more of the MCO's, PCCM's, PIHP's, or PAHP's equity.

(3) A person with an employment, consulting or other arrangement with the MCO, PCCM, PIHP, or PAHP for the provision of items and services that are significant and material to the

MCO's, PCCM's, PIHP's, or PAHP's obligations under its contract with the State.

(c) *Effect of Noncompliance.* If a State finds that an MCO, PCCM, PIHP, or PAHP is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

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

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines whether an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) A State determines whether an MCO, PIHP, PAHP or PCCM has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines whether—

(1) An MCO has violated any of the other requirements of sections 1903(m) or 1932 of the Act, and any implementing regulations;

(2) A PCCM has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act and any implementing regulations;

(3) For any of the violations under paragraphs (d)(1) and (d)(2) of this section, only the sanctions specified in § 438.702, paragraphs (a)(3), (a)(4), and (a)(5) may be imposed.

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management for an MCO as provided in § 438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until CMS or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties.

(a) *General rule.* The limit on, or the maximum civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under the following paragraphs of § 438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (Failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is $100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to CMS or the State) of § 438.700.

(3) The limit is $15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of § 438.700. (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the maximum amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary management only if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that—

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act; or

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or section 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3), and must notify the affected enrollees of their right to terminate enrollment.

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM has failed to do either of the following:

(a) Carry out the substantive terms of its contract; or

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Due process: Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Except as provided in § 438.706(c), before imposing any of the intermediate sanctions specified in this subpart, the State must give the affected entity timely written notice that explains the following:

(1) The basis and nature of the sanction.

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing*—(1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures.* The State must do the following:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may do the following:

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract.

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give the CMS Regional Office written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must—

(1) Be given no later than 30 days after the State imposes or lifts a sanction; and

(2) Specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

§ 438.726 State plan requirement.

(a) The State plan must include a plan to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

(b) A contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by CMS under section 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs

(a) *Basis for sanction.* (1) A State agency may recommend that CMS impose the denial of payment sanction specified in paragraph (e) of this section on an MCO with a contract under this part if the agency determines that the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(b) *Effect of an Agency Determination.* (1) The State agency's determination becomes CMS's determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the agency decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless CMS rejects this recommendation within 15 days.

(c) *Notice of sanction.* If the State agency's determination becomes CMS's determination under section (b)(2), the State agency takes the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction;

(2) Allows the MCO 15 days from the date it receives the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

(3) May extend the initial 15-day period for an additional 15 days if—

(i) the MCO submits a written request that includes a credible explanation of why it needs additional time;

(ii) the request is received by CMS before the end of the initial period; and

(iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation;

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision; and

(iii) Forwards the decision to CMS.

(2) The agency decision under paragraph (d)(1)(ii) of this section becomes CMS's decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State agency decision, the agency sends the MCO a copy of CMS's decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (b)(6) of §438.700, is affirmed on review under paragraph (d) of this section.

(ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under §438.726(b), CMS's denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (b) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in CMS's reconsideration notice.

(ii) If CMS, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (c)(1)(ii) of this section.

(g) *CMS's role.* (1) CMS retains the right to independently perform the functions assigned to the State agency under paragraphs (a) through (d) of this section.

(2) At the same time that the agency sends notice to the MCO under paragraph (c)(1)(i) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

§438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

(a) Meets the requirements of this part; and

(b) Is in effect.

§438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of §438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of

section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PIHP, PAHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person;

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both, and;

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered "independent" if it—

(i) Is an MCO, PIHP, PAHP, PCCM or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(3) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

Sec.

Subpart B—Requirements and Limits Applicable to All Services

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

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

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

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

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

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts*—(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to compensate for distortions in costs, utilization, or the number of eligibles.

(iii) *Cost neutral* means that the mechanism used to smooth data, share risk, or adjust for risk will recognize both higher and lower expected costs and is not intended to create a net aggregate gain or loss across all payments.

(iv) *Incentive arrangement* means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

(v) *Risk corridor* means a risk sharing mechanism in which States and contractors share in both profits and losses under the contract outside of predetermined threshold amount, so that after an initial corridor in which the contractor is responsible for all losses or retains all profits, the State

contributes a portion toward any additional losses, and receives a portion of any additional profits.

(2) *Basic requirements.* (i) All payments under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as medical trend inflation, incomplete data, MCO, PIHP, or PAHP administration (subject to the limits in paragraph (c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by—

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are—

(A) Based only upon services covered under the State plan (or costs directly related to providing these services, for example, MCO, PIHP, or PAHP administration).

(B) Provided under the contract to Medicaid-eligible individuals.

(iii) The State's projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies must be computed on an actuarially sound basis.

(ii) If risk corridor arrangements result in payments that exceed the approved capitation rates, these excess payments will not be considered actuarially sound to the extent that they result in total payments that exceed the amount Medicaid would have paid, on a fee-for-service basis, for the State plan services actually furnished to enrolled individuals, plus an amount for MCO, PIHP, or PAHP administrative costs directly related to the provision of these services.

(iii) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound.

(iv) For all incentive arrangements, the contract must provide that the arrangement is—

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Made available to both public and private contractors;

(D) Not conditioned on intergovernmental transfer agreements; and

(E) Necessary for the specified activities and targets.

(v) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State

plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, and PCCMs must provide as follows:

(1) The MCO, PIHP, PAHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO, PIHP, or PAHP contract may cover, for enrollees, services that are in addition to those covered under the State plan, although the cost of these services cannot be included when determining the payment rates under § 438.6(c).

(f) *Compliance with contracting rules.* All contracts must meet the following provisions:

(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act of 1990 as amended.

(2) Provide for the following:

(i) Compliance with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this subchapter.

(ii) Reporting all identified provider-preventable conditions in a form or frequency as may be specified by the State.

(3) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

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

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

(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 for advance directives.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

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

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

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

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

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

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

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with §438.56(c).

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

[67 FR 41095, June 14, 2002, as amended at 76 FR 32837, June 6, 2011]

§438.8 Provisions that apply to PIHPs and PAHPs.

(a) The following requirements and options apply to PIHPs, PIHP contracts, and States with respect to PIHPs, to the same extent that they apply to MCOs, MCO contracts, and States for MCOs.

(1) The contract requirements of §438.6, except for requirements that pertain to HIOs.

(2) The information requirements in §438.10.

(3) The provision against provider discrimination in §438.12.

(4) The State responsibility provisions of subpart B of this part except §438.50.

(5) The enrollee rights and protection provisions in subpart C of this part.

(6) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PIHP.

(7) The grievance system provisions in subpart F of this part.

(8) The certification and program integrity protection provisions set forth in subpart H of this part.

(b) The following requirements and options for PAHPs apply to PAHPs, PAHP contracts, and States.

(1) The contract requirements of §438.6, except requirements for—

(i) HIOs.

(ii) Advance directives (unless the PAHP includes any of the providers listed in §489.102) of this chapter.

(2) All applicable portions of the information requirements in §438.10.

(3) The provision against provider discrimination in §438.12.

(4) The State responsibility provisions of subpart B of this part except §438.50.

(5) The provisions on enrollee rights and protections in subpart C of this part.

(6) Designated portions of subpart D of this part.

(7) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(8) Prohibitions against affiliations with individuals debarred by Federal agencies in §438.610.

[67 FR 41095, June 14, 2002, as amended at 67 FR 65505, Oct. 25, 2002]

§438.10 Information requirements.

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

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

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

(b) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, and

(1) The contract requirements of § 438.6, except requirements for—

(i) HIOs.

(ii) Advance directives (unless the PAHP includes any of the providers listed in § 489.102) of this chapter.

(2) All applicable portions of the information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The provisions on enrollee rights and protections in subpart C of this part.

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

(b) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, and PCCM 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.

(2) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(3) Each MCO and PIHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(c) *Language.* The State must do the following:

(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) Make available written information in each prevalent non-English language.

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

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

(5) Notify enrollees and potential enrollees, and require each MCO, PIHP, PAHP, and PCCM 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; and

(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.* (1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary program, or is first required to enroll in a mandatory enrollment program.

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, or PCCMs.

(2) The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program; and

(C) MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO, PIHP, PAHP, or PCCM program operating in potential enrollee's service area. A summary of the following information is sufficient, but the State must provide more detailed information upon request:

(A) Benefits covered.

(B) Cost sharing, if any.

(C) Service area.

(D) Names, locations, telephone numbers of, and non-English language spoken by current contracted providers, and including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs, this includes at a minimum information on primary care physicians, specialists, and hospitals.

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service.

(f) *General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs.* Information must be furnished to MCO, PIHP, PAHP, and PCCM enrollees as follows:

(1) The State must notify all enrollees of their disenrollment rights, at a minimum, annually. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 days before the start of each enrollment period.

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

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

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

(5) The MCO, PIHP, and, when appropriate, the PAHP or PCCM, 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 State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must provide the following information to all enrollees:

(i) Names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists, and hospitals.

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

(iii) Enrollee rights and protections, as specified in § 438.100.

(iv) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in § 438.10(g)(1), and for PAHP enrollees, the information specified in § 438.10(h)(1).

(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 poststabilization services, with reference to the definitions in § 438.114(a).

(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 poststabilization services covered under the contract.

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

(ix) The poststabilization care services rules set forth at § 422.113(c) of this chapter.

(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, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM need not furnish information on how and where to obtain the service. The State must provide information on 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(f), the State, its contracted representative, or the MCO and PIHP must provide the following information to their enrollees:

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

(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 timeframes 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).

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

(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.

(h) *Specific information for PAHPs.* The State, its contracted representative, or

the PAHP must provide the following information to their enrollees:

(i) The right to a State fair hearing, including the following:

(i) The right to a hearing.

(ii) The method for obtaining a hearing.

(iii) The rules that govern representation.

(2) Advance directives, as set forth in §438.6(i)(2), to the extent that the PAHP includes any of the providers listed in §489.102(a) of this chapter.

(3) Upon request, physician incentive plans as set forth in §438.6(h).

(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, within the timeframe specified in §438.10(e)(1).

(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 or PCCM in the potential enrollees and enrollee's service area:

(i) The MCO's or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO or PCCM.

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

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP 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, or PAHP 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, or PAHP must comply with the requirements specified in §438.214.

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

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

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

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

Subpart B—State Responsibilities

§438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's, PIHP's, or PAHP's operations, including, at a minimum, operations related to the following:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

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

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

(2) Each MCO, PIHP, PAHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account 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 paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, or PCCM has the following rights: The right to—

(i) Receive information in accordance with § 438.10.

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

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

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

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

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR § 164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, and PCCM complies with any other applicable Federal and State laws (such as: 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).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.102 Provider-enrollee communications.

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

Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

(a) Meets the requirements of this part; and

(b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PIHP, PAHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person;

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both, and;

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, or other

health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered "independent" if it—

(i) Is an MCO, PIHP, PAHP, PCCM or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(3) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible beneficiaries is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

Sec.

Subpart B—Requirements and Limits Applicable to All Services

WV STATE GOVERNMENT

HIPAA BUSINESS ASSOCIATE ADDENDUM

This Health Insurance Portability and Accountability Act of 1996 (hereafter, HIPAA) Business Associate Addendum ("Addendum") is made a part of the Agreement ("Agreement") by and between the State of West Virginia ("Agency"), and Business Associate ("Associate"), and is effective as of the date of execution of the Addendum.

The Associate performs certain services on behalf of or for the Agency pursuant to the underlying Agreement that requires the exchange of information including protected health information protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5) (the "HITECH Act"), any associated regulations and the federal regulations published at 45 CFR parts 160 and 164 (sometimes collectively referred to as "HIPAA"). The Agency is a "Covered Entity" as that term is defined in HIPAA, and the parties to the underlying Agreement are entering into this Addendum to establish the responsibilities of both parties regarding HIPAA-covered information and to bring the underlying Agreement into compliance with HIPAA.

Whereas it is desirable, in order to further the continued efficient operations of Agency to disclose to its Associate certain information which may contain confidential individually identifiable health information (hereafter, Protected Health Information or PHI); and

Whereas, it is the desire of both parties that the confidentiality of the PHI disclosed hereunder be maintained and treated in accordance with all applicable laws relating to confidentiality, including the Privacy and Security Rules, the HITECH Act and its associated regulations, and the parties do agree to at all times treat the PHI and interpret this Addendum consistent with that desire.

NOW THEREFORE: the parties agree that in consideration of the mutual promises herein, in the Agreement, and of the exchange of PHI hereunder that:

1. **Definitions.** Terms used, but not otherwise defined, in this Addendum shall have the same meaning as those terms in the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

    a. **Agency Procurement Officer** shall mean the appropriate Agency individual listed at: http://www.state.wv.us/admin/purchase/vrc/agencyli.html.

    b. **Agent** shall mean those person(s) who are agent(s) of the Business Associate, in accordance with the Federal common law of agency, as referenced in 45 CFR § 160.402(c).

    c. **Breach** shall mean the acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information, except as excluded in the definition of Breach in 45 CFR § 164.402.

    d. **Business Associate** shall have the meaning given to such term in 45 CFR § 160.103.

    e. **HITECH Act** shall mean the Health Information Technology for Economic and Clinical Health Act. Public Law No. 111-05. 111th Congress (2009).

f. **Privacy Rule** means the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR Parts 160 and 164.

g. **Protected Health Information or PHI** shall have the meaning given to such term in 45 CFR § 160.103, limited to the information created or received by Associate from or on behalf of Agency.

h. **Security Incident** means any known successful or unsuccessful attempt by an authorized or unauthorized individual to inappropriately use, disclose, modify, access, or destroy any information or interference with system operations in an information system.

i. **Security Rule** means the Security Standards for the Protection of Electronic Protected Health Information found at 45 CFR Parts 160 and 164.

j. **Subcontractor** means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

2. **Permitted Uses and Disclosures.**

a. **PHI Described.** This means PHI created, received, maintained or transmitted on behalf of the Agency by the Associate. This PHI is governed by this Addendum and is limited to the minimum necessary, to complete the tasks or to provide the services associated with the terms of the original Agreement, and is described in Appendix A.

b. **Purposes.** Except as otherwise limited in this Addendum, Associate may use or disclose the PHI on behalf of, or to provide services to, Agency for the purposes necessary to complete the tasks, or provide the services, associated with, and required by the terms of the original Agreement, or as required by law, if such use or disclosure of the PHI would not violate the Privacy or Security Rules or applicable state law if done by Agency or Associate, or violate the minimum necessary and related Privacy and Security policies and procedures of the Agency. The Associate is directly liable under HIPAA for impermissible uses and disclosures of the PHI it handles on behalf of Agency.

c. **Further Uses and Disclosures**. Except as otherwise limited in this Addendum, the Associate may disclose PHI to third parties for the purpose of its own proper management and administration, or as required by law, provided that (i) the disclosure is required by law, or (ii) the Associate has obtained from the third party reasonable assurances that the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party by the Associate; and, (iii) an agreement to notify the Associate and Agency of any instances of which it (the third party) is aware in which the confidentiality of the information has been breached. To the extent practical, the information should be in a limited data set or the minimum necessary information pursuant to 45 CFR § 164.502, or take other measures as necessary to satisfy the Agency's obligations under 45 CFR § 164.502.

3. **Obligations of Associate.**

a. **Stated Purposes Only.** The PHI may not be used by the Associate for any purpose other than as stated in this Addendum or as required or permitted by law.

b. **Limited Disclosure.** The PHI is confidential and will not be disclosed by the Associate other than as stated in this Addendum or as required or permitted by law. Associate is prohibited from directly or indirectly receiving any remuneration in exchange for an individual's PHI unless Agency gives written approval and the individual provides a valid authorization. Associate will refrain from marketing activities that would violate HIPAA, including specifically Section 13406 of the HITECH Act. Associate will report to Agency any use or disclosure of the PHI, including any Security Incident not provided for by this Agreement of which it becomes aware.

c. **Safeguards.** The Associate will use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of the PHI, except as provided for in this Addendum. This shall include, but not be limited to:

i. Limitation of the groups of its workforce and agents, to whom the PHI is disclosed to those reasonably required to accomplish the purposes stated in this Addendum, and the use and disclosure of the minimum PHI necessary or a Limited Data Set;

ii. Appropriate notification and training of its workforce and agents in order to protect the PHI from unauthorized use and disclosure;

iii. Maintenance of a comprehensive, reasonable and appropriate written PHI privacy and security program that includes administrative, technical and physical safeguards appropriate to the size, nature, scope and complexity of the Associate's operations, in compliance with the Security Rule;

iv. In accordance with 45 CFR §§ 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information.

d. **Compliance With Law.** The Associate will not use or disclose the PHI in a manner in violation of existing law and specifically not in violation of laws relating to confidentiality of PHI, including but not limited to, the Privacy and Security Rules.

e. **Mitigation.** Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Associate of a use or disclosure of the PHI by Associate in violation of the requirements of this Addendum, and report its mitigation activity back to the Agency.

f. **Support of Individual Rights.**

i. **Access to PHI.** Associate shall make the PHI maintained by Associate or its agents or subcontractors in Designated Record Sets available to Agency for inspection and copying, and in electronic format, if requested, within ten (10) days of a request by Agency to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.524 and consistent with Section 13405 of the HITECH Act.

ii. **Amendment of PHI.** Within ten (10) days of receipt of a request from Agency for an amendment of the PHI or a record about an individual contained in a Designated Record Set, Associate or its agents or subcontractors shall make such PHI available to Agency for amendment and incorporate any such amendment to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR § 164.526.

iii. **Accounting Rights.** Within ten (10) days of notice of a request for an accounting of disclosures of the PHI, Associate and its agents or subcontractors shall make available to Agency the documentation required to provide an accounting of disclosures to enable Agency to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 CFR §164.528 and consistent with Section 13405 of the HITECH Act. Associate agrees to document disclosures of the PHI and information related to such disclosures as would be required for Agency to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. This should include a process that allows for an accounting to be collected and maintained by Associate and its agents or subcontractors for at least six (6) years from the date of disclosure, or longer if required by state law. At a minimum, such documentation shall include:

- the date of disclosure;
- the name of the entity or person who received the PHI, and if known, the address of the entity or person;
- a brief description of the PHI disclosed; and
- a brief statement of purposes of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization, or a copy of the written request for disclosure.

iv. **Request for Restriction**. Under the direction of the Agency, abide by any individual's request to restrict the disclosure of PHI, consistent with the requirements of Section 13405 of the HITECH Act and 45 CFR § 164.522, when the Agency determines to do so (except as required by law) and if the disclosure is to a health plan for payment or health care operations and it pertains to a health care item or service for which the health care provider was paid in full "out-of-pocket."

v. **Immediate Discontinuance of Use or Disclosure.** The Associate will immediately discontinue use or disclosure of Agency PHI pertaining to any individual when so requested by Agency. This includes, but is not limited to, cases in which an individual has withdrawn or modified an authorization to use or disclose PHI.

g. **Retention of PHI.** Notwithstanding section 4.a. of this Addendum, Associate and its subcontractors or agents shall retain all PHI pursuant to state and federal law and shall continue to maintain the PHI required under Section 3.f. of this Addendum for a period of six (6) years after termination of the Agreement, or longer if required under state law.

h. **Agent's, Subcontractor's Compliance.** The Associate shall notify the Agency of all subcontracts and agreements relating to the Agreement, where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum. Such notification shall occur within 30 (thirty) calendar days of the execution of the subcontract and shall be delivered to the Agency Procurement Officer. The Associate will ensure that any of its subcontractors, to whom it provides any of the PHI it receives hereunder, or to whom it provides any PHI which the Associate creates or receives on behalf of the Agency, agree to the restrictions and conditions which apply to the Associate hereunder. The Agency may request copies of downstream subcontracts and agreements to determine whether all restrictions, terms and conditions have been flowed down. Failure to ensure that downstream contracts, subcontracts and agreements contain the required restrictions, terms and conditions may result in termination of the Agreement.

j. **Federal and Agency Access.** The Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI, as well as the PHI, received from, or created or received by the Associate on behalf of the Agency available to the U.S. Secretary of Health and Human Services consistent with 45 CFR § 164.504. The Associate shall also make these records available to Agency, or Agency's contractor, for periodic audit of Associate's compliance with the Privacy and Security Rules. Upon Agency's request, the Associate shall provide proof of compliance with HIPAA and HITECH data privacy/protection guidelines, certification of a secure network and other assurance relative to compliance with the Privacy and Security Rules. This section shall also apply to Associate's subcontractors, if any.

k. **Security.** The Associate shall take all steps necessary to ensure the continuous security of all PHI and data systems containing PHI. In addition, compliance with 74 FR 19006 Guidance Specifying the Technologies and Methodologies That Render PHI Unusable, Unreadable, or Indecipherable to Unauthorized Individuals for Purposes of the Breach Notification Requirements under Section 13402 of Title XIII is required, to the extent practicable. If Associate chooses not to adopt such methodologies as defined in 74 FR 19006 to secure the PHI governed by this Addendum, it must submit such written rationale, including its Security Risk Analysis, to the Agency Procurement Officer for review prior to the execution of the Addendum. This review may take up to ten (10) days.

l. **Notification of Breach.** During the term of this Addendum, the Associate shall notify the Agency and, unless otherwise directed by the Agency in writing, the WV Office of Technology immediately by e-mail or web form upon the discovery of any Breach of unsecured PHI; or within 24 hours by e-mail or web form of any suspected Security Incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the Agency Procurement Officer at www.state.wv.us/admin/purchase/vrc/agencyli.htm and,

unless otherwise directed by the Agency in writing, the Office of Technology at incident@wv.gov or https://apps.wv.gov/ot/ir/Default.aspx.

The Associate shall immediately investigate such Security Incident, Breach, or unauthorized use or disclosure of PHI or confidential data. Within 72 hours of the discovery, the Associate shall notify the Agency Procurement Officer, and, unless otherwise directed by the Agency in writing, the Office of Technology of: (a) Date of discovery; (b) What data elements were involved and the extent of the data involved in the Breach; (c) A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data; (d) A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized; (e) A description of the probable causes of the improper use or disclosure; and (f) Whether any federal or state laws requiring individual notifications of Breaches are triggered.

Agency will coordinate with Associate to determine additional specific actions that will be required of the Associate for mitigation of the Breach, which may include notification to the individual or other authorities.

All associated costs shall be borne by the Associate. This may include, but not be limited to costs associated with notifying affected individuals.

If the Associate enters into a subcontract relating to the Agreement where the subcontractor or agent receives PHI as described in section 2.a. of this Addendum, all such subcontracts or downstream agreements shall contain the same incident notification requirements as contained herein, with reporting directly to the Agency Procurement Officer. Failure to include such requirement in any subcontract or agreement may result in the Agency's termination of the Agreement.

m. **Assistance in Litigation or Administrative Proceedings.** The Associate shall make itself and any subcontractors, workforce or agents assisting Associate in the performance of its obligations under this Agreement, available to the Agency at no cost to the Agency to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against the Agency, its officers or employees based upon claimed violations of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inaction or actions by the Associate, except where Associate or its subcontractor, workforce or agent is a named as an adverse party.

4. **Addendum Administration.**

a. **Term.** This Addendum shall terminate on termination of the underlying Agreement or on the date the Agency terminates for cause as authorized in paragraph (c) of this Section, whichever is sooner.

b. **Duties at Termination.** Upon any termination of the underlying Agreement, the Associate shall return or destroy, at the Agency's option, all PHI received from, or created or received by the Associate on behalf of the Agency that the Associate still maintains in any form and retain no copies of such PHI or, if such return or destruction is not feasible, the Associate shall extend the protections of this Addendum to the PHI and limit further uses and disclosures to the purposes that make the return or destruction of the PHI infeasible. This shall also apply to all agents and subcontractors of Associate. The duty of the Associate and its agents

and subcontractors to assist the Agency with any HIPAA required accounting of disclosures survives the termination of the underlying Agreement.

c. **Termination for Cause.** Associate authorizes termination of this Agreement by Agency, if Agency determines Associate has violated a material term of the Agreement. Agency may, at its sole discretion, allow Associate a reasonable period of time to cure the material breach before termination.

d. **Judicial or Administrative Proceedings.** The Agency may terminate this Agreement if the Associate is found guilty of a criminal violation of HIPAA. The Agency may terminate this Agreement if a finding or stipulation that the Associate has violated any standard or requirement of HIPAA/HITECH, or other security or privacy laws is made in any administrative or civil proceeding in which the Associate is a party or has been joined. Associate shall be subject to prosecution by the Department of Justice for violations of HIPAA/HITECH and shall be responsible for any and all costs associated with prosecution.

e. **Survival.** The respective rights and obligations of Associate under this Addendum shall survive the termination of the underlying Agreement.

5. **General Provisions/Ownership of PHI.**

a. **Retention of Ownership.** Ownership of the PHI resides with the Agency and is to be returned on demand or destroyed at the Agency's option, at any time, and subject to the restrictions found within section 4.b. above.

b. **Secondary PHI.** Any data or PHI generated from the PHI disclosed hereunder which would permit identification of an individual must be held confidential and is also the property of Agency.

c. **Electronic Transmission.** Except as permitted by law or this Addendum, the PHI or any data generated from the PHI which would permit identification of an individual must not be transmitted to another party by electronic or other means for additional uses or disclosures not authorized by this Addendum or to another contractor, or allied agency, or affiliate without prior written approval of Agency.

d. **No Sales.** Reports or data containing the PHI may not be sold without Agency's or the affected individual's written consent.

e. **No Third-Party Beneficiaries.** Nothing express or implied in this Addendum is intended to confer, nor shall anything herein confer, upon any person other than Agency, Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

f. **Interpretation.** The provisions of this Addendum shall prevail over any provisions in the Agreement that may conflict or appear inconsistent with any provisions in this Addendum. The interpretation of this Addendum shall be made under the laws of the state of West Virginia.

g. **Amendment.** The parties agree that to the extent necessary to comply with applicable law they will agree to further amend this Addendum.

h. **Additional Terms and Conditions.** Additional discretionary terms may be included in the release order or change order process.

AGREED: West Virginia Department of Health and Human Resources, Bureau for Medical Services

Name of Agency:_____ Name of Associate:_____

Signature:_____ Signature:_____

Title:_____ Title:_____

Date:_____ Date:_____

Form - WVBAA-012004
Amended 06.26.2013

APPROVED AS TO FORM THIS 26th
DAY Of January 20 13
Patrick Morrisey
Attorney General
BY _____

Appendix A

(To be completed by the Agency's Procurement Officer prior to the execution of the Addendum, and shall be made a part of the Addendum. PHI not identified prior to execution of the Addendum may only be added by amending Appendix A and the Addendum, via Change Order.)

Name of Associate: _____

Name of Agency: West Virginia Department of Health and Human Resources
Bureau for Medical Services

Describe the PHI (do not include any actual PHI). If not applicable, please indicate the same.

All [types of PHI listed on App. A] in paper, electronic, verbal or any other form.
Including, but not limited to:
Member Eligibility Verfication Extract File
Member Name
Member Address
Member ID Number

BID BOND PREPARATION INSTRUCTIONS

AGENCY (A)
RFQ/RFP# (B)

(A)	WV State Agency (Stated on Page 1 "Spending Unit")
(B)	Request for Quotation Number (upper right corner of page #1)
(C)	Your Business Entity Name (or Individual Name if Sole Proprietor)
(D)	City, Location of your Company
(E)	State, Location of your Company
(F)	Surety Corporate Name
(G)	City, Location of Surety
(H)	State, Location of Surety
(I)	State of Surety Incorporation
(J)	City of Surety's Principal Office
(K)	Minimum amount of acceptable bid bond is 5% of total bid. You may state "5% of bid" or a specific amount on this line in words.
(L)	Amount of bond in numbers
(M)	Brief Description of scope of work
(N)	Day of the month
(O)	Month
(P)	Year
(Q)	Name of Business Entity (or Individual Name if Sole Proprietor)
(R)	Seal of Principal
(S)	Signature of President, Vice President, or Authorized Agent
(T)	Title of Person Signing for Principal
(U)	Seal of Surety
(V)	Name of Surety
(W)	Signature of Attorney in Fact of the Surety

NOTE 1: **Dated Power of Attorney with Surety Seal must accompany this bid bond.**

Bid Bond

KNOW ALL MEN BY THESE PRESENTS, That we, the undersigned, (C) of (D), (E), as Principal, and (F) of (G), (H), a corporation organized and existing under the laws of the State of (I) with its principal office in the City of (J), as Surety, are held and firmly bound unto The State of West Virginia, as Obligee, in the penal sum of (K) ($ (L)) for the payment of which, well and truly to be made, we jointly and severally bind ourselves, our heirs, administrators, executors, successors and assigns.

The Condition of the above obligation is such that whereas the Principal has submitted to the Purchasing Section of the Department of Administration a certain bid or proposal, attached hereto and made a part hereof to enter into a contract in writing for

(M)

NOW THEREFORE

(a) If said bid shall be rejected, or

(b) If said bid shall be accepted and the Principal shall enter into a contract in accordance with the bid or proposal attached hereto and shall furnish any other bonds and insurance required by the bid or proposal, and shall in all other respects perform the agreement created by the acceptance of said bid then this obligation shall be null and void, otherwise this obligation shall remain in full force and effect. It is expressly understood and agreed that the liability of the Surety for any and all claims hereunder shall, in no event, exceed the penal amount of this obligation as herein stated

The Surety for value received, hereby stipulates and agrees that the obligations of said Surety and its bond shall be in no way impaired or affected by any extension of time within which the Obligee may accept such bid: and said Surety does hereby waive notice of any such extension.

WITNESS, the following signatures and seals of Principal and Surety, executed and sealed by a proper officer of Principal and Surety, or by Principal individually if Principal is an individual, the (N) day of (O), 20 (P).

Principal Seal (R)

(Q)
(Name of Principal)

By (S)
(Must be President, Vice President, or Duly Authorized Agent)

(T)
Title

Surety Seal (U)

(V)
(Name of Surety)

(W)
Attorney-in-Fact

IMPORTANT – Surety executing bonds must be licensed in West Virginia to transact surety insurance, must affix its seal, and must attach a power of attorney with its seal affixed.

Agency_____
REQ.P.O#_____

BID BOND

KNOW ALL MEN BY THESE PRESENTS, That we, the undersigned, _____ _____ of _____, _____, as Principal, and _____ _____of _____, _____, a corporation organized and existing under the laws of the State of ____ _____ with its principal office in the City of _____, as Surety, are held and firmly bound unto the State of West Virginia, as Obligee, in the penal sum of _____ ($_____) for the payment of which, well and truly to be made, we jointly and severally bind ourselves, our heirs, administrators, executors, successors and assigns.

The Condition of the above obligation is such that whereas the Principal has submitted to the Purchasing Section of the Department of Administration a certain bid or proposal, attached hereto and made a part hereof, to enter into a contract in writing for

_____

_____

_____

NOW THEREFORE,

(a) If said bid shall be rejected, or

(b) If said bid shall be accepted and the Principal shall enter into a contract in accordance with the bid or proposal attached hereto and shall furnish any other bonds and insurance required by the bid or proposal, and shall in all other respects perform the agreement created by the acceptance of said bid, then this obligation shall be null and void, otherwise this obligation shall remain in full force and effect. It is expressly understood and agreed that the liability of the Surety for any and all claims hereunder shall, in no event, exceed the penal amount of this obligation as herein stated.

The Surety, for the value received, hereby stipulates and agrees that the obligations of said Surety and its bond shall be in no way impaired or affected by any extension of the time within which the Obligee may accept such bid, and said Surety does hereby waive notice of any such extension.

WITNESS, the following signatures and seals of Principal and Surety, executed and sealed by a proper officer of Principal and Surety, or by Principal individually if Principal is an individual, this_____day of _____, 20____.

Principal Seal

_____
(Name of Principal)

By_____
(Must be President, Vice President, or
Duly Authorized Agent)

_____
(Title)

Surety Seal

_____
(Name of Surety)

_____
Attorney-in-Fact

IMPORTANT – Surety executing bonds must be licensed in West Virginia to transact surety insurance, must affix its seal, and must attach a power of attorney with its seal affixed.

RFQ No. BMS14028

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code* §61-5-3) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: _____

Authorized Signature: _____ Date: _____

State of _____

County of _____, to-wit:

Taken, subscribed, and sworn to before me this ___ day of _____, 20___.

My Commission expires _____, 20___.

AFFIX SEAL HERE

NOTARY PUBLIC _____

REQUEST FOR PROPOSAL

West Virginia Bureau for Medical Services
RFP # BMS14028

If applicable, sign and submit the attached Resident Vendor Preference Certificate with the proposal.

Rev. 04/14

State of West Virginia

VENDOR PREFERENCE CERTIFICATE

Certification and application* is hereby made for Preference in accordance with ***West Virginia Code***, §5A-3-37. (Does not apply to construction contracts). ***West Virginia Code***, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the ***West Virginia Code***. This certificate for application is to be used to request such preference. The Purchasing Division will make the determination of the Vendor Preference, if applicable.

1. **Application is made for 2.5% vendor preference for the reason checked:**

____ Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

____ Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; **or,**

____ Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; **or,**

2. **Application is made for 2.5% vendor preference for the reason checked:**

____ Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

3. **Application is made for 2.5% vendor preference for the reason checked:**

____ Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; **or,**

4. **Application is made for 5% vendor preference for the reason checked:**

____ Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; **or,**

5. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**

____ Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; **or,**

6. **Application is made for 3.5% vendor preference who is a veteran for the reason checked:**

____ Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.

7. **Application is made for preference as a non-resident small, women- and minority-owned business, in accordance with *West Virginia Code* §5A-3-59 and *West Virginia Code of State Rules.***

____ Bidder has been or expects to be approved prior to contract award by the Purchasing Division as a certified small, women- and minority-owned business.

Bidder understands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the requirements for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty against such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency or deducted from any unpaid balance on the contract or purchase order.

By submission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and authorizes the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid the required business taxes, provided that such information does not contain the amounts of taxes paid nor any other information deemed by the Tax Commissioner to be confidential.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true and accurate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate changes during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Bidder:_____ **Signed:**_____

Date:_____ **Title:**_____