

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 13-039	2. STATE Montana
FOR: HEALTH CARE FINANCING ADMINISTRATION		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE October 1, 2013	
5. TYPE OF PLAN MATERIAL (Check One): <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT			
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR 430.10		7. FEDERAL BUDGET IMPACT: N/A	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Supplement to Attachment 3.1A and 3.1B Service 12a Supplement to Attachment 3.1A and 3.1B, Attachment A (4 of 4) Supplement to Attachment 3.1A and 3.1B Attachment A-1 Supplement to Attachment 3.1A and 3.1B Attachment A-2 Supplement to Attachment 3.1A and 3.1B Attachment B		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Supplement to Attachment 3.1A and 3.1B Service 12a Supplement to Attachment 3.1A and 3.1B, Attachment A (2 of 2) Supplement to Attachment 3.1A and 3.1B Attachment A-1	
10. SUBJECT OF AMENDMENT: Amending the State Plan to the update the NMPI Supplemental Drug Rebate Agreement, to add ketotifer ophthalmic solution as a covered over-the-counter medication and to remove mention to barbiturates, benzodiazepines and smoking cessation products as potentially excludable medications.			
11. GOVERNOR'S REVIEW (Check One): <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input checked="" type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL: <i>Mary E. Dalton</i>		16. RETURN TO: Montana Dept. of Public Health and Human Services Mary E. Dalton, State Medicaid Director Attn: Jo Thompson PO Box 4210 Helena MT 59604	
13. TYPED NAME: Mary E. Dalton			
14. TITLE: State Medicaid Director			
15. DATE SUBMITTED: 9/29/13			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: 9/29/13		18. DATE APPROVED: 11/29/13	
PLAN APPROVED - ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 10/1/13		20. SIGNATURE OF REGIONAL OFFICIAL: <i>[Signature]</i>	
21. TYPED NAME: RICHARD C. ALLEN		22. TITLE: ARA, DMCHS	
23. REMARKS:			

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



**Center for Medicaid and CHIP Services
Disabled & Elderly Health Programs Group**

November 26, 2013

Mary E. Dalton
State Medicaid Director
Montana Department of Public Health and Human Services
P.O. BOX 4210
Helena, MT, 59604

Attn: Jo Thompson

Dear Ms. Dalton,

We reviewed the Montana State Plan Amendment (SPA) TN 13-039 received on September 29, 2013. This amendment proposed a revision of the National Medicaid Pooling Initiative (NMPI) Supplemental Rebate Agreement (SRA) previously submitted to CMS on September 22, 2010 to include definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates. In addition, the SPA adds Ketitofen ophthalmic solution as a covered over-the-counter medication and removes benzodiazepines, barbiturates and smoking cessation drugs from the list of excludable drugs in the plan.

We are pleased to inform you that the amendment is approved, effective October 1, 2013. We believe that the state plan continues to be consistent with the objectives of the Medicaid program. Please note that this authorization extends only to the revised SRA and attachments and schedules included in this approval packet which will replace the current SRA packet submitted to CMS on September 22, 2010. Inclusion of the managed care organization (MCO) utilization under the NMPI SRA is optional and at the sole discretion of each member state. If revisions are subsequently made to include MCO utilization for supplemental rebate collection or any other changes to the supplemental drug rebate agreement, attachments or schedules, all such documents should be submitted to CMS for review and approval.

A copy of the CMS-179 form as well as the pages approved for incorporation into the Montana State plan will be forwarded to you by the Denver Regional Office. If you have any questions regarding this SPA approval, please contact Emeka Egwim at (410) 786-1092.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Richard D. Allen, ARA, Denver Regional Office
Sophia Hinojosa, Denver Regional Office
Trudy Turner, Denver Regional Office

MONTANA

Drugs covered by the Medicaid Program are subject to the following limitations:

1. Drugs must be prescribed by a physician or other licensed practitioner who is authorized by law to prescribe drugs and is recognized by the Medicaid program;
2. Maintenance medications may be dispensed in quantities sufficient for a 90-day supply or 100 units, whichever is greater. Other medications may not be dispensed in quantities greater than a 34-day supply except where manufacturer packaging cannot be reduced to a smaller quantity. The department will post a list of current drug classes which will be considered maintenance medications on the department's web site at <http://medicaidprovider.hhs.mt.gov>.
3. Drugs are not covered if they:
 - a. Have been classified as "less than effective" by the FDA (DESI drugs);
 - b. Are produced by manufacturers who have not signed a rebate agreement with CMS.
4. Nursing facilities are responsible for providing over-the-counter laxatives, antacids, and aspirin to their residents as these items are included in the facility per diem rate determined by the Department.
5. Montana Medicaid will cover vaccines administered in an outpatient pharmacy setting.
6. The Department may reimburse for compounded nonrebutable API bulk powders and excipients on the Department's maintained drug formulary.
7. Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
8. The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.
 - The following excluded drugs are covered:
 - (a) agents when used for anorexia, weight loss, weight gain
 - (b) agents when used to promote fertility
 - (c) agents when used for cosmetic purposes or hair growth
 - (d) agents when used for the symptomatic relief cough and colds
 - (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride

MONTANA

- (f) nonprescription drugs
Aspirin, Laxatives, Antacids, Head lice treatment, H2 antagonist GI products, Bronchosaline, Proton Pump Inhibitors, Non-sedating Antihistamines, Diphenhydramine, over-the-counter contraceptive drugs, ketotifen ophthalmic solution
- (g) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

Services considered experimental are not a benefit of the Montana Medicaid Program.

Experimental services include:

1. All procedures and items, including prescribed drugs, considered experimental by the U.S. Department of Health and Human Services or any other appropriate federal agency.
2. All procedures and items, including prescribed drugs, provided as part of a control study, approved by the Department of Health and Human Services or any other appropriate federal agency to demonstrate whether the item, prescribed drug or procedure is safe and effective in curing/preventing, correcting or alleviating the effects of certain medical conditions.
3. All procedures and items, including prescribed drugs, which may be subject to question but are not covered in #1 and #2 above, will be evaluated by the Department's designated medical review organization.

MONTANA

Product Restrictions:

The Medicaid program restricts coverage of certain drug products through the operation of an outpatient drug formulary. The state utilizes the University of Montana, School of Pharmacy and Allied Health Sciences for literature research and the state DUE CARE (Drug Utilization Review, Concurrent and Retrospective Evaluation) Board as the formulary committee. Criteria used to include/exclude drugs from the formulary is based upon safety, efficacy and clinical outcomes as provided by the product labeling of the drug. Montana's formulary committee meets the formulary requirements that are specified in section 1927(d)(4) of the Social Security Act.

Prior Authorization:

Drugs may require prior authorization for the reimbursement of any covered outpatient drugs. Prior authorization is under the provisions of Section 1927(d)(5) of the Social Security Act. For drugs requiring prior authorization, an automated voice response system is used to meet the requirements for providing a response within 24 hours. Up to a 72-hour supply of medication requiring prior authorization may be dispensed in an emergency.

Preferred Drug List:

Certain designated therapeutic classes will be reviewed periodically to consider which products are clinically appropriate and most cost-effective. Those products within the therapeutic class that are not determined to be clinically superior and/or are not cost-effective will require prior authorization. The Department may maintain a Preferred Drug List containing the names of pharmaceutical drugs for which prior authorization will not be required under the medical assistance program. All other pharmaceutical drugs not on the Preferred Drug List, and determined by the Department to be in the same drug class and used for the treatment of the same medical condition as drug(s) placed on the Preferred Drug List, will require prior authorization.

The Department will appoint a Formulary Committee or utilize the drug utilization review committee in accordance with Federal law.

TN 13-039
Supersedes 13-010

Approved 11/29/13

Effective 10-01-13

MONTANA

Supplemental Drug Rebate Programs:

The State is in compliance with section 1927(d)(4) of the Social Security Act. The State has the following policies for the Supplemental Rebate Program for the Medicaid population:

- CMS has authorized the State of Montana to enter into the Michigan multi-state pooling agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on August 10, 2004 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on October 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- CMS has authorized Montana's collection of supplemental rebates through the NMPI.
- The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a turn-around response by either telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medication (except for those drugs that are excluded or restricted from coverage).
- Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal government on the same percentage basis as applied under the National Drug Rebate Agreement.
- All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization.
- All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the National Drug Rebate Agreement.
- The unit rebate amount is confidential and will not be disclosed except in accordance with §1927 (b)(3)(D) of the Act.

ATTACHMENT A-1

**Participating State's Non-Medicaid Programs Approved by CMS in the Medicaid
State Plan(s)**

Participating State: Montana

Non-Medicaid programs approved by CMS in the Medicaid State Plan(s) – Date of
Approval

- 1. None
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____

ATTACHMENT A-2

Attestation of Inclusion/Exclusion of Medicaid MCOs

The State of _____ acting by and through the _____ (hereinafter collectively referred to as "Participating State"), hereby represents and warrants the following with respect to Medicaid MCOs (must check one):

- Effective for utilization dispensed to Participating Medicaid MCO members on or after _____ [DATE*], the Participating State will include utilization of Participating Medicaid MCO(s) for Supplemental Rebates under this Agreement. I certify on behalf of the Participating State listed below that the State Medicaid Plan permits the inclusion of Medicaid MCO utilization in Supplemental Rebates, and that the State's contracts with Participating MCOs do not prohibit such inclusion. I further certify on behalf of the Participating State listed below that the State has reasonably determined that: (i) the utilization of any Participating Medicaid MCO submitted hereunder is eligible for CMS Rebates under 42 U.S.C. § 1396r-8 and (ii) each such Participating Medicaid MCO shall align their respective formulary(ies) and/or preferred drug list(s), as applicable, assuring access to preferred Supplemental Covered Product is no more restrictive than the applicable Participating State PDL requirements for any period with respect to which the Participating State will invoice for Supplemental Rebates for utilization under this Agreement. It is the intent and expectation of the Participating Medicaid Programs that Supplemental Rebates hereunder shall be excluded from Manufacturer's calculation of Best Price or AMP. *If this option is checked, the State must have documented the above determination via applicable regulation, law, contract, or other formal state agency issuance and the State must attach hereto: (1) a copy of such documentation, as well as (2) a copy of the applicable Participating State Medicaid Plan (and/or amendment thereto) permitting the election of this option.*
- The Participating State will exclude utilization from all of its Medicaid MCO(s) under this Agreement.
- The Participating State has no Medicaid MCOs.

MANUFACTURER CONSENT SHALL NOT BE REQUIRED FOR A STATE TO AMEND THIS ATTACHMENT A-2.

So Certified:

Participating State: _____

By: _____

Title: _____

Date: _____

**Effective date for including Participating MCO utilization shall not predate the date this Attachment A-2 is executed by the Participating State.*

ATTACHMENT B

CATALOGUE OF NMPI PARTICIPATING STATE MEDICAID PROGRAMS

The Participating State Medicaid Programs participating in NMPI are summarized in Table B-1 Catalogue of NMPI Participating Medicaid Programs.

Table B-1 Catalogue of NMPI Participating State Medicaid Programs
Alaska
District of Columbia
Kentucky
Michigan
Minnesota
Montana
New Hampshire
New York
North Carolina
Rhode Island
South Carolina

This Attachment will be updated in accordance with Section 3.13 and 8.4 of the Agreement.

MONTANA

Drugs covered by the Medicaid Program are subject to the following limitations:

1. Drugs must be prescribed by a physician or other licensed practitioner who is authorized by law to prescribe drugs and is recognized by the medicaid program;
2. Maintenance medications may be dispensed in quantities sufficient for a 90-day supply or 100 units, whichever is greater. Other medications may not be dispensed in quantities greater than a 34-day supply except where manufacturer packaging cannot be reduced to a smaller quantity. The department will post a list of current drug classes which will be considered maintenance medications on the department's web site at <http://medicaidprovider.hhs.mt.gov>.
3. Drugs are not covered if they:
 - a. Have been classified as "less than effective" by the FDA (DESI drugs);
 - b. Are produced by manufacturers who have not signed a rebate agreement with CMS.
4. Nursing facilities are responsible for providing over-the-counter laxatives, antacids, and aspirin to their residents as these items are included in the facility per diem rate determined by the Department.
5. Montana Medicaid will cover vaccines administered in an outpatient pharmacy setting.
6. The Department may reimburse for compounded nonrebtable API bulk powders and excipients on the department's maintained drug formulary.
7. Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.
8. The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.
 - The following excluded drugs are covered:
 - (a) agents when used for anorexia, weight loss, weight gain
 - (b) agents when used to promote fertility
 - (c) agents when used for cosmetic purposes or hair growth
 - (d) agents when used for the symptomatic relief cough and colds
 - (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride

MONTANA

- (f) nonprescription drugs
Aspirin, Laxatives, Antacids, Head lice treatment, H2 antagonist GI products, Bronchosaline, Proton Pump Inhibitors, Non-sedating Antihistamines, Diphenhydramine, over-the-counter contraceptive drugs, ketotifen ophthalmic solution
- (g) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

Services considered experimental are not a benefit of the Montana Medicaid Program.

Experimental services include:

1. All procedures and items, including prescribed drugs, considered experimental by the U.S. Department of Health and Human Services or any other appropriate federal agency.
2. All procedures and items, including prescribed drugs, provided as part of a control study, approved by the Department of Health and Human Services or any other appropriate federal agency to demonstrate whether the item, prescribed drug or procedure is safe and effective in curing/preventing, correcting or alleviating the effects of certain medical conditions.
3. All procedures and items, including prescribed drugs, which may be subject to question but are not covered in #1 and #2 above, will be evaluated by the Department's designated medical review organization.

MONTANA

Product Restrictions:

The Medicaid program restricts coverage of certain drug products through the operation of an outpatient drug formulary. The state utilizes the University of Montana, School of Pharmacy and Allied Health Sciences for literature research and the state DUE CARE (Drug Utilization Review, Concurrent and Retrospective Evaluation) Board as the formulary committee. Criteria used to include/exclude drugs from the formulary is based upon safety, efficacy and clinical outcomes as provided by the product labeling of the drug. Montana's formulary committee meets the formulary requirements that are specified in section 1927(d)(4) of the Social Security Act.

Prior Authorization:

Drugs may require prior authorization for the reimbursement of any covered outpatient drugs. Prior authorization is under the provisions of Section 1927(d)(5) of the Social Security Act. For drugs requiring prior authorization, an automated voice response system is used to meet the requirements for providing a response within 24 hours. Up to a 72-hour supply of medication requiring prior authorization may be dispensed in an emergency.

Preferred Drug List:

Certain designated therapeutic classes will be reviewed periodically to consider which products are clinically appropriate and most cost-effective. Those products within the therapeutic class that are not determined to be clinically superior and/or are not cost-effective will require prior authorization. The Department may maintain a Preferred Drug List containing the names of pharmaceutical drugs for which prior authorization will not be required under the medical assistance program. All other pharmaceutical drugs not on the Preferred Drug List, and determined by the Department to be in the same drug class and used for the treatment of the same medical condition as drug(s) placed on the Preferred Drug List, will require prior authorization.

The Department will appoint a Formulary Committee or utilize the drug utilization review committee in accordance with Federal law.

TN 13-039
Supersedes 13-010

Approved 11/29/13

Effective 10-01-13

MONTANA

Supplemental Drug Rebate Programs:

The State is in compliance with section 1927(d)(4) of the Social Security Act. The State has the following policies for the Supplemental Rebate Program for the Medicaid population:

- CMS has authorized the State of Montana to enter into the Michigan multi-state pooling agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the Amendment to the SRA submitted to CMS on August 10, 2004 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to CMS on October 2013 has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
- CMS has authorized Montana's collection of supplemental rebates through the NMPI.
- The prior authorization process complies with the requirements of Section 1927 of the Social Security Act and provides for a turn-around response by either telephone or other telecommunications device within 24 hours of receipt of a prior authorization request. In emergency situations, providers may dispense a 72-hour supply of medication (except for those drugs that are excluded or restricted from coverage).
- Supplemental rebates received by the State in excess of those required under the National Drug Rebate Program will be shared with the Federal government on the same percentage basis as applied under the National Drug Rebate Agreement.
- All drugs covered by the National Drug Rebate Agreements remain available to Medicaid beneficiaries, although some may require prior authorization.
- All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the National Drug Rebate Agreement.
- The unit rebate amount is confidential and will not be disclosed except in accordance with §1927 (b)(3)(D) of the Act.

ATTACHMENT A
National Medicaid Pooling Initiative ("NMPI") Medicaid Program Participation Agreement
For
_____ **[STATE AGENCY]**

WHEREAS, the State of _____ [STATE] acting by and through the _____ [STATE AGENCY], _____ [ADDRESS] (hereinafter collectively referred to as "**Participating State**"), hereby enters into this NMPI Medicaid Program Participation Agreement ("**Participation Agreement**") effective as of _____ [DATE], with Magellan Medicaid Administration, Inc. ("**Magellan Medicaid**").

WHEREAS, the Participating State administers Participating State's Medicaid Program pursuant to the Social Security Act (42 U.S.C. 1396 *et seq.*); and

WHEREAS, Magellan Medicaid has negotiated and, along with the State of Michigan, entered into Supplemental Rebate Agreements ("**NMPI Agreement(s)**") with prescription drug manufacturers ("**Manufacturers**") to provide discounts and rebates ("**State Supplemental Rebate(s)**") on certain of such Manufacturers' drug products that are covered by the Participating State's Medicaid Program; and

WHEREAS, the Participating State represents and warrants that it has determined any Medicaid MCO for which State Supplemental Rebates will be invoiced hereunder (a "**Participating Medicaid MCO**") is eligible for such Supplemental Rebates and has documented such determination via applicable regulation, law, contract, or other formal state agency issuance.

WHEREAS, the Participating State desires to access State Supplemental Rebates; and

WHEREAS, the Participating State has contracted with Magellan Medicaid for the provision of State Supplemental Rebate contracting and preferred drug list ("**PDL**") administration and invoicing services; and

WHEREAS, "**Controlling Agreement**" shall mean the contract between Magellan Medicaid, as either a prime contractor or a subcontractor, and a Participating State pursuant to which Magellan Medicaid is obligated to provide one or more of the following services to the Participating State: State Supplemental Rebate negotiation, contracting services, PDL design and maintenance, and pharmacy and therapeutics committee administration services.

WHEREAS, the states named in the NMPI Catalogue of Participating State Medicaid Programs (Attachment B to the NMPI Agreement) have signed a Participation Agreement; and

NOW, THEREFORE, in consideration of the mutual covenants, promises, and conditions contained herein and in the NMPI Agreement, the parties agree as follows:

1. **Obligations of Parties:** Participating State hereby agrees to participate in the multi-state State

TN 13-039
Supersedes TN 10-031

Approved 11/29/13

Effective October 1, 2013

Supplemental Rebate pooling program known as the National Medicaid Pooling Initiative ("NMPI") and understands and agrees to be bound by the terms of the NMPI Agreement. Magellan Medicaid agrees to negotiate and enter into State Supplemental Rebate Agreements on behalf of Participating State and other state Medicaid agencies who agree to participate in NMPI.

2. **Notices:** All written notices, requests and communications, unless specifically required to be given by a specific method, may be: (i) delivered in person, obtaining a signature indicating successful delivery; (ii) sent by a recognized overnight delivery service, obtaining a signature indicating successful delivery; (iii) sent by certified mail, obtaining a signature indicating successful delivery; or (iv) transmitted by telefacsimile, producing a document indicating the date and time of successful transmission, to the address or telefacsimile number set forth below. A party may at any time give notice in writing to the other parties of a change of name, address, telephone, or telefacsimile number.

To Participating State:

Telephone _____
Telefacsimile _____

To Magellan Medicaid:

Magellan Medicaid Administration, Inc.
Attn: Chief Financial Officer
With a copy to: Legal Department
11013 W. Broad St.
Suite 500
Glen Allen, Virginia 23060-5937

3. **Term.** This Participation Agreement shall be effective as to Participating State as of the date herein stated above in this Participation Agreement, subject to CMS authorization, and shall continue in effect until _____ [DATE]. Thereafter, this Participation Agreement shall automatically renew for successive one (1)-year terms, unless this Participation Agreement is otherwise terminated as provided for in this Participation Agreement or until such time as the Controlling Agreement between the Participating State and Magellan Medicaid is terminated. Notwithstanding the forgoing, no rebates shall accrue hereunder with respect to any drug product until the latter of the date: (i) such drug product is effective upon public dissemination of Participating State's Preferred Drug List via website for providers and prescribers, (ii) the applicable Participation Agreement is fully executed and a copy provided to the Manufacturer,

- or (iii) the effective date of CMS approval of the Participating State's applicable state plan amendment.
4. **Termination by Participating State.** Participating State may terminate its participation in the NMPI Agreements by giving Manufacturer and Magellan Medicaid Administration written notice at least (90) days prior to the anniversary date of the NMPI Agreement, in which case termination shall become effective as to the terminating Participating State on the anniversary date of the NMPI Agreement and as further defined in Sections 8.3 of the NMPI Agreement.
 5. **Addition of Participating Medicaid MCOs.** To the extent permitted by: (i) CMS, (ii) applicable law, and (iii) the Participating State Medicaid Plan, any Participating State added hereunder may elect, but shall not be required, to include Medicaid Utilization from all Participating Medicaid MCOs in their Supplemental Rebate invoices, provided that the Participating State provide to Magellan Medicaid an executed and complete copy of Attachment A-2 indicating such election, along with any required attachments thereto. Supplemental Rebates shall begin to accrue to Participating Medicaid MCO(s) pursuant to this Participation Agreement for a Covered Product upon the later of: (i) Magellan Medicaid receiving the applicable State's complete and executed Attachment A-2 (along with any required attachments) electing to include Participating Medicaid MCO utilization hereunder, or (ii) effective date for such Participating Medicaid MCO utilization, as set forth on Attachment A-2. The Participating State shall be solely responsible for ensuring that all Participating Medicaid MCOs for which utilization is invoiced for Supplemental Rebates comply with all applicable terms and conditions of this Participation Agreement, applicable law, the State Medicaid Plan, and the Participating State's contracts with its Medicaid MCOs.
 6. The undersigned Participating State acknowledges that manufacturer rebate pricing information is confidential information under applicable Federal law and shall be exempt from public disclosure pursuant to _____.
 7. The undersigned Participating State represents that it has not requested authorization from CMS to include any state pharmaceutical assistance program within the rebate provisions of the NMPI Agreement [or CMS has authorized the inclusion of Not Applicable within the NMPI Agreement]. The above representation shall not prohibit the undersigned Participating State from requesting CMS authorization to include (other) pharmaceutical assistance programs within the NMPI Agreement at a later date. Upon receipt of CMS authorization, Participating State shall give written notice to Manufacturer of the date Manufacturer's Supplemental Covered Product is effectively placed on the preferred drug list of the undersigned Participating State's non-Medicaid programs approved by CMS in the Medicaid state plan(s) by completing the attached Exhibit A-1.
 8. Any state which has the necessary state and CMS authorizations to operate a PDL and State Supplemental Rebate program and which is contracted to utilize Magellan Medicaid Administration to administer its PDL and Supplemental Rebate program is eligible to join NMPI as a Participating State subject to CMS authorization. Upon the expansion or contraction of NMPI, to either include a state Medicaid agency as a Participating State Medicaid Program or exclude a Participating State Medicaid Program, Magellan Medicaid Administration shall

expressly notify in writing all Participating States as to the identity of the newly included state agency or the identity of newly excluded Participating State along with the effective date for such inclusion or exclusion.

IN WITNESS WHEREOF, the Participating State and Magellan Medicaid have caused this Participation Agreement to be executed on the dates shown below by representatives authorized to bind the respective parties.

[Participating State]

Magellan Medicaid Administration, Inc.

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

ATTACHMENT A-1

**Participating State's Non-Medicaid Programs Approved by CMS in the Medicaid
State Plan(s)**

Participating State: Montana

Non-Medicaid programs approved by CMS in the Medicaid State Plan(s) – Date of
Approval

1. None _____
2. _____
3. _____
4. _____
5. _____
6. _____

ATTACHMENT A-2

Attestation of Inclusion/Exclusion of Medicaid MCOs

The State of _____ acting by and through the _____ (hereinafter collectively referred to as "Participating State"), hereby represents and warrants the following with respect to Medicaid MCOs (must check one):

Effective for utilization dispensed to Participating Medicaid MCO members on or after _____ [DATE*], the Participating State will include utilization of Participating Medicaid MCO(s) for Supplemental Rebates under this Agreement. I certify on behalf of the Participating State listed below that the State Medicaid Plan permits the inclusion of Medicaid MCO utilization in Supplemental Rebates, and that the State's contracts with Participating MCOs do not prohibit such inclusion. I further certify on behalf of the Participating State listed below that the State has reasonably determined that: (i) the utilization of any Participating Medicaid MCO submitted hereunder is eligible for CMS Rebates under 42 U.S.C. § 1396r-8 and (ii) each such Participating Medicaid MCO shall align their respective formulary(ies) and/or preferred drug list(s), as applicable, assuring access to preferred Supplemental Covered Product is no more restrictive than the applicable Participating State PDL requirements for any period with respect to which the Participating State will invoice for Supplemental Rebates for utilization under this Agreement. It is the intent and expectation of the Participating Medicaid Programs that Supplemental Rebates hereunder shall be excluded from Manufacturer's calculation of Best Price or AMP. *If this option is checked, the State must have documented the above determination via applicable regulation, law, contract, or other formal state agency issuance and the State must attach hereto: (1) a copy of such documentation, as well as (2) a copy of the applicable Participating State Medicaid Plan (and/or amendment thereto) permitting the election of this option.*

The Participating State will exclude utilization from all of its Medicaid MCO(s) under this Agreement.

The Participating State has no Medicaid MCOs.

MANUFACTURER CONSENT SHALL NOT BE REQUIRED FOR A STATE TO AMEND THIS ATTACHMENT A-2.

So Certified:

Participating State: _____

By: _____

Title: _____

Date: _____

**Effective date for including Participating MCO utilization shall not predate the date this Attachment A-2 is executed by the Participating State.*

ATTACHMENT B

CATALOGUE OF NMPI PARTICIPATING STATE MEDICAID PROGRAMS

The Participating State Medicaid Programs participating in NMPI are summarized in Table B-1 Catalogue of NMPI Participating Medicaid Programs.

<u>Table B-1 Catalogue of NMPI Participating State Medicaid Programs</u>
Alaska
District of Columbia
Kentucky
Michigan
Minnesota
Montana
New Hampshire
New York
North Carolina
Rhode Island
South Carolina

This Attachment will be updated in accordance with Section 3.13 and 8.4 of the Agreement.