DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 10-031

2. STATE: Montana

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
July 01, 2010

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:

7. FEDERAL BUDGET IMPACT: n/a

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment(s) 3.1A and 3.1B Service 12a Prescribed Drugs

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

Attachment(s) 3.1A and 3.1B Service 12a Prescribed Drugs

10. SUBJECT OF AMENDMENT: Amending the State Plan to reflect the updated NMPI Supplemental Drug Rebate Agreement

11. GOVERNOR'S REVIEW *(Check One)*:
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: Mary E. Dalton

14. TITLE: State Medicaid Director

15. DATE SUBMITTED: 9-20-2010

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

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 9/20/10

18. DATE APPROVED: 3/16/11

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 7/1/10

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME: Richard C. Allen

22. TITLE: ARA, DMCHO

23. REMARKS:

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid, CHIP and Survey & Certification

Disabled and Elderly Health Programs Group

March 16, 2011

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

Dear Ms. Dalton:

We have reviewed Montana State Plan Amendment (SPA) 10-031, Reimbursement for Drugs received in the Regional Office on September 20, 2010. This amendment proposes to revise the National Medicaid Pooling Initiative Supplemental Drug Rebate Agreement to change the supplemental rebate vendor's name from First Health Services Corporation to Magellan Medicaid Administration, Inc. We are pleased to inform you that the amendment is approved, effective July 1, 2010.

A copy of the CMS-179 form, as well as the pages approved for incorporation into the Montana's state plan will be forwarded by the Denver Regional Office. If you have any questions regarding this request, please contact Steven Johnson at (410) 786-3332.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Richard Allen, ARA, Denver Regional Office
Diane Dunstan, 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. 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.

7. 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

☐ (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

☑ (h) barbiturates

☑ (i) benzodiazepines

☑ (j) smoking cessation for non-dual eligibles as Part D will cover

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.

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 July, 2010 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.

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;

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   a. Have been classified as "less than effective" by the FDA (DESI drugs);
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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.

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- 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.

Participating State Amendment to Supplemental Drug-Rebate Agreement
Between
Magellan Medicaid Administration, Inc.
And
_____ ("Manufacturer")

WHEREAS, the State of Michigan, Magellan Medicaid Administration, Inc. ("Magellan Medicaid"), and Manufacturer have entered into a Supplemental Drug-Rebate Agreement (the "Agreement"), effective as of _____; and

WHEREAS, the states named in Section 8 below have become parties to the Agreement as Participating States by previous amendment or addenda; and

Now, therefore, in consideration of the mutual covenants, promises, and conditions contained herein and in the Agreement, the parties agree as follows:

1. The State of Montana is hereby added as a party to the Agreement as a Participating State, as defined in Section 3.14 of the Agreement.

2. This Amendment shall become effective upon the date determined in accordance with Section 3.16 of the Agreement.

3. An executed copy of this Amendment shall be sent via certified mail, return receipt requested to Manufacturer's address of record as set forth in the Agreement within five (5) business days of its execution by the parties. Any notice to Participating State shall be sent to:

   Medicaid Pharmacy Program Officer
   Montana DPHHS
   1400 Broadway
   P.O. Box 202951
   Helena, MT 59620-2951

4. This Amendment adds Participating State to the Agreement and does not otherwise change or alter the Agreement. Participating State understands and agrees to be bound by the terms of the Agreement.

5. The undersigned State acknowledges that manufacturer rebate pricing information is confidential information under applicable Federal law and shall be exempt from public disclosure pursuant to subsection 1 of MONT. CODE ANN. §2-6-102 (2004).

6. The undersigned State represents that it has not requested authorization from CMS to include any state pharmaceutical assistance program within the rebate provisions of the Agreement [or CMS has authorized the inclusion of Not Applicable within the Agreement]. The above representation shall not prohibit the undersigned State from requesting CMS authorization to include (other) pharmaceutical assistance programs within the Agreement at a later date. Upon receipt of CMS authorization, 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 State's non-Medicaid programs approved by CMS in the Medicaid state plan(s) by completing the attached Exhibit A1.

7. The approximate enrollment in the undersigned State's Medicaid program at the time of execution of this Amendment is **82,269.**

8. As of the effective date of this Amendment, the following are all of the Participating States under the Agreement:

a. Alaska
b. Kentucky
c. Michigan
d. Minnesota
e. Montana
f. Nevada
g. New Hampshire
h. District of Columbia
i. New York
j. South Carolina
k. Rhode Island
l. North Carolina

State of Montana
Department of Public Health &
Human Services

Magellan Medicaid Administration, Inc.

By: _____

Name: _____

Title: _____

Date: _____

By: _____

Name: _____

Title: _____

Date: _____

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e. Montana
f. Nevada
g. New Hampshire
h. District of Columbia
i. New York
j. South Carolina
k. Rhode Island
l. North Carolina

State of Montana
Department of Public Health &
Human Services

By: _____

Name: _____

Title: _____

Date: _____

Magellan Medicaid Administration, Inc.

By: _____

Name: _____

Title: _____

Date: _____