

Table of Contents

State/Territory Name: Montana

State Plan Amendment (SPA) #: 22-0037

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 3) Approved SPA Pages

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 and Elderly Health Programs Group

March 08 2022

Mike Randol
State Medicaid Director
Montana Department of Public Health and Human Services
P.O. Box 4210
Helena, MT 59620

Dear Mike Randol:

The CMS Division of Pharmacy has reviewed Montana's State Plan Amendment (SPA) 22-0037 received in the CMS Medicaid & CHIP Operations Group on December 23, 2022. This SPA proposes to do the following:

- Remove the reference to Average Sales Price (ASP) + 6% on the Pharmacy reimbursement State Plan page.
- Modify language on Pharmacy coverage pages to reflect coverage of select over-the-counter (OTC) medications.
- Remove the reference of vaccines and agents used for cosmetic purposes from Pharmacy coverage pages.

In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. We believe that there is evidence regarding the sufficiency of Montana's pharmacy provider network at this time to approve SPA 22-0037. Specifically, Montana has reported to CMS that 286 of the state's 356 licensed in-state retail pharmacies are enrolled in Montana's Medicaid program. With an 80 percent participation rate, we can infer that Montana's beneficiaries will have access to pharmacy services at least to the extent available to the general population since Medicaid requires that beneficiaries be provided access to all covered outpatient drugs of participating drug manufacturers with a rebate agreement through a broad pharmacy network. In contrast, commercial insurers often have more limited drug formularies and a more limited pharmacy network.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 22-0037 is approved with an effective date of November 2, 2022.

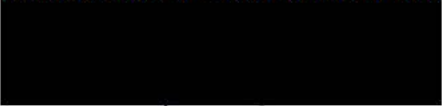

We are attaching a copy of the signed, revised CMS-179 form, as well as the page approved for incorporation into Montana's state plan. If you have any questions regarding this amendment, please contact Charlotte Hammond at (410) 786-1092 or charlotte.hammond@cms.hhs.gov.

Sincerely,



Cynthia R. Denemark, R.Ph.
Acting Director
Division of Pharmacy

cc: Mary Eve Kulawik, SPA Coordinator, State of Montana
Barbara Prehmus, CMS Division of Program Operations - West Branch

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		1. TRANSMITTAL NUMBER 22 - 0037	2. STATE Montana
		3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="checkbox"/> XIX <input type="checkbox"/> XXI	
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE 11/02/2022	
5. FEDERAL STATUTE/REGULATION CITATION Section 1902(a)(30)(A)		6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY 2023 \$40,416 b. FFY 2024 \$44,532	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 4.19B Methods and Standards for Establishing Payment Rates, Service 12 a, Outpatient Drug Services, Pages 1-3 of 3 Supplement to Attachment 3.1A and 3.1B Service 12a Prescribed Drugs, Pages 1-4 of 4		8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Attachment 4.19B Methods and Standards for Establishing Payment Rates, Service 12 a, Outpatient Drug Services, Pages 1-3 of 3 Supplement to Attachment 3.1A and 3.1B Service 12a Prescribed Drugs, Pages 1-4 of 4	
9. SUBJECT OF AMENDMENT			
<ul style="list-style-type: none"> Remove the reference of vaccines being covered in an outpatient pharmacy setting, as vaccines are referenced in the 13.c Preventative Services pages. Remove the reference to Average Sales Price (ASP) + 6% in the prescribed Drug State Plan. This allows the state to implement reimbursement of ASP plus 8% for certain biosimilar biological products. Modifying the language to reflect coverage of select over-the-counter (OTC) medications, instead of listing out each individual OTC in the State Plan. This change allows the state to cover over-the-counter medications that may move from prescription to OTC, without having to do a state plan amendment every time this occurs. Also, per State Release 179, the state is removing all references to agents used for cosmetic purposes. The changes to Attachments 3.1A and 3.1B are budget neutral. 			
10. 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: <input checked="" type="checkbox"/> Single Agency Review	
11. SIGNATURE OF STATE AGENCY OFFICIAL 		15. RETURN TO: Montana Department of Public Health and Human Services Mike Randol Attn: Mary Eve Kulawik PO Box 4210 Helena MT 59620	
12. TYPED NAME: Mike Randol			
13. TITLE Medicaid & Health Services Executive Director/ Medicaid Director			
14. DATE SUBMITTED 12/23/2022			
FOR CMS USE ONLY			
16. DATE RECEIVED December 23, 2023		17. DATE APPROVED March 08, 2023	
PLAN APPROVED - ONE COPY ATTACHED			
18. EFFECTIVE DATE OF APPROVED MATERIAL November 2, 2022		1 	
20. TYPED NAME OF APPROVING OFFICIAL CYNTHIA R. DENEMARK		21. TITLE OF APPROVING OFFICIAL ACTING DIRECTOR, DIVISION OF PHARMACY	
22. REMARKS			

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. Opioid prescriptions dispensed to opioid naïve members must not exceed a 7-day supply. The department posts a list of current drug classes which are 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 Food and Drug Administration (FDA). (Drug Efficacy Study Implementation (DESI) drugs); or
 - 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. The Department will reimburse for compounded nonrebutable Active Pharmaceutical Ingredient (API) bulk powders and excipients on the Department’s maintained drug formulary.
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. Weight gain agents are covered when medically necessary. Agents when used for anorexia and weight loss continue as excluded drugs.
- (b) agents when used to promote fertility
- (c) agents when used for the symptomatic relief cough and colds
- (d) prescription vitamins and mineral products, except prenatal vitamins and fluoride

MONTANA

- (e) Selective non-prescription (over-the-counter) medications will be covered as listed on the state's website
- (f) 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 Drug Utilization Review (DUR) 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 in 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 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.

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- 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 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

DEFINITIONS

Average Acquisition Cost (AAC) is defined as the calculated average drug ingredient cost per drug determined by direct pharmacy survey, wholesale survey, and other relevant cost information.

Submitted ingredient cost is defined as a pharmacy's actual ingredient cost. For drugs purchased under the 340B Drug Pricing Program, submitted ingredient cost means the actual 340B purchase price. For drugs purchased under the Federal Supply Schedule (FSS) submitted ingredient cost means the FSS purchase price.

REIMBURSEMENT METHODOLOGY

- A. Reimbursement for brand and generic prescribed drugs shall not exceed the lowest of:
 - a. The provider's usual and customary charge of the drug to the general public; or
 - b. The allowed ingredient cost plus a professional dispensing fee. Where allowed ingredient cost is defined as the lower of:
 - 1. The AAC; or
 - 2. Submitted ingredient cost.
 - i. If AAC is not available, drug reimbursement will be determined at the lower of:
 - a. Wholesale Acquisition Cost (WAC);
 - b. Affordable Care Act Federal Upper Limit (ACA FUL); or
 - c. Submitted Ingredient Cost.
- B. For 340B purchased drugs, specialty or non-specialty, will be reimbursed utilizing the logic outlined in subsection A. 340B providers are required to bill no more than their acquisition cost as their submitted ingredient amount, and will be reimbursed no more than the 340B ceiling price.
- C. All Indian Health Service, tribal, and urban Indian pharmacies are paid under the methodology outlined in subsection A.
- D. For drug purchased under the FSS, providers will be required to bill their actual acquisition cost as their submitted ingredient amount, and will be reimbursed no more than the FSS price.
- E. Clotting factors from Specialty Pharmacies, Hemophilia Treatment Centers (HTC), or Centers of Excellence:
 - a. not purchased through the 340B program will be reimbursed the lesser of the Usual and Customary (U&C), Submitted Ingredient Cost or WAC plus the professional dispensing fee; and
 - b. when purchased through the 340B program, will be reimbursed the lesser of the U & C or WAC plus the professional dispensing fee.
- F. Drugs acquired at a Nominal Price (outside of 340B or FSS) will be reimbursed at no more than the actual acquisition cost plus the professional dispensing fee, through use of the methodology outlined in Subsection A.
- G. Montana Medicaid does not pay for investigational drugs.

MONTANA

H. For specialty and non-specialty, physician administered drugs reimbursement is as follows:

- a. The Department requires that National Drug Codes (NDC) must be submitted for all physician administered drugs. Montana Medicaid will cover only those physician administered drugs manufactured by companies that have a signed rebate agreement with CMS. Reimbursement for physician-administered drugs is made according to the department's fee schedule or the provider's usual and customary charge, whichever is lower. The physician administered drug fee schedule is updated effective the 1st day of each quarter as determined by:
 1. The Medicare Average Sales Price (ASP) methodology if there is an ASP fee; or
 2. The logic outlined in Subsection A, with the exception of the professional dispensing fee. No professional dispensing fee will be paid for physician administered drugs.
- b. Providers participating in the 340B Drug Pricing Program are required to bill Montana Medicaid their actual acquisition cost, and these drugs will be reimbursed at no more than the 340B ceiling price.

EXCEPTION:

For outpatient drugs provided to Medicaid participants in state institutions, reimbursement will conform to the state contract for pharmacy services; or for institutions not participating in the state contract for pharmacy services, reimbursement will be the actual cost of the drug and professional dispensing fee. In either case, reimbursement will not exceed, in the aggregate, the AAC plus the professional dispensing fee.

PROFESSIONAL DISPENSING FEE

- a. The professional dispensing fees assigned will be the calculated cost to dispense not to exceed the specified tier amount:
 1. \$15.73 for pharmacies with an annual prescription volume between 0 and 39,999 prescriptions;
 2. \$13.62 for pharmacies with an annual prescription volume between 40,000 and 69,999; or
 3. \$11.52 for pharmacies with an annual prescription volume greater than or equal to 70,000.

Pharmacy providers that are new to the Montana Medicaid program will be assigned the maximum dispensing fee in (1)(a) until a dispensing fee questionnaire can be completed for six months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated for the pharmacy or the maximum allowed dispensing fee provided in (1).

If a pharmacy does not return the annual dispensing fee questionnaire, they will be assigned a dispensing fee based on the lowest calculated cost to dispense from the annual dispensing fee questionnaire. Once returned, the pharmacy's calculated cost to dispense will be updated. This assignment will not be retroactive.

An additional professional dispensing fee of \$0.75 will be paid for "unit dose" prescriptions. This "unit dose" professional dispensing fee will offset the additional cost of packaging supplies and materials which are directly related to filling "unit dose" prescriptions by the individual pharmacy and is in addition to the regular professional dispensing fee allowed. Only one unit dose professional dispensing fee will be allowed each month for each prescribed medication. A professional dispensing fee will not be paid for a unit dose prescription packaged by the drug manufacturer.

MONTANA

A compounding fee based on level of effort will be paid for compounded prescriptions in lieu of a professional dispensing fee. Montana Medicaid shall reimburse pharmacies for compounding drugs only if the client's drug therapy needs cannot be met by commercially available dosage strengths and/or forms of the therapy. Reimbursement for each drug component shall be determined in accordance with "lower of" pricing methodology. The compounding fee for each compounded drug shall be based on the level of effort required by the pharmacist. The levels of effort compounding fees payable are level 1: \$12.50, level 2: \$17.50, and level 3: \$22.50.