Table of Contents

State/Territory Name: Montana

State Plan Amendment (SPA) #: 16-0006

This file contains the following documents in the order listed:

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

Disabled & Elderly Health Programs Group

April 5, 2017

Mary E. Dalton
State Medicaid Director
Montana Department of Public Health and Human Services
P. O. BOX 4210
Helena, MT, 59620

Dear Ms. Dalton,

We have reviewed Montana's State Plan Amendment (SPA) 16-006 received in the Denver Regional Office on August 5, 2016. This SPA proposes changes to reimbursement methodologies to comply with requirements of the Covered Outpatient Drug Final Rule with comment (CMS-2345-FC) (81 FR 5170).

Specifically, Montana proposes shifting from Estimated Acquisition Cost (EAC) to Actual Acquisition Cost (AAC) plus a volume-based professional dispensing fee. Any pharmacy non-responsive to Montana's annual cost of dispensing survey will be assigned the lowest observed rate from the most recent survey response, until such time as the pharmacy responds to the survey. When AAC is not available, reimbursement shall be the lesser of the Wholesale Acquisition Cost (WAC), the Federal Upper Limit, or the pharmacies submitted ingredient cost.

For physician administered drugs the SPA proposes paying the Medicare Average Sale Price (ASP) plus 6 percent and no professional dispensing fee. For clotting factors not purchased through the 340B program, the SPA proposes paying the lesser of the WAC plus the volume-based professional dispensing fee, the submitted ingredient cost plus the volume-based professional dispensing fee, or the usual and customary (U&C) charge. For 340B-puchased clotting factor, it proposes paying the lesser of the U&C charge, or WAC plus the professional dispensing fee. Additionally, drugs purchased through the 340B pricing program, or the Federal Supply Schedule (FSS), will be reimbursed no more than the 340B ceiling price or FSS price accordingly. The SPA's proposed effective date is July 1, 2016.

We are pleased to inform you that MT SPA 16-006 is approved with an effective date of July 1, 2016.

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

Sincerely

[redacted]

Meagan Khau
Deputy Director
Division of Pharmacy

cc: Mary Eve Kulawik, Suzanne Bierman, Medicaid Analyst, Montana
Dan Peterson, Bureau Chief, Montana
Dave Campana, RPh, Medicaid Pharmacist, Montana
Katie Hawkins, Supervisor, Montana Medicaid
Dani Feist, Pharmacy Program Officer, Montana
Richard C. Allen, Associate Regional Administrator, Denver Regional Office
Barbara Prehmus, Denver Regional Office

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: 16-0006	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 07/01/2016	

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: Section 1902(a)(30)(A)	7. FEDERAL BUDGET IMPACT: a. FFY 16: ($693,599) b. FFY 17: ($2,760,379) c. FFY 18: ($2,088,442)
8. 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 1-2 of 2, **New Pages**: Supplement to Attachment 3.1A, Service 6(d), Other Practioners' Services-Pharmacist Services, page 1 of 1. Supplement to Attachment 3.1B, Service 6(d), Other Practioners' Services-Pharmacist Services, page 1 of 1. Attachment 4.19B Methods and Standards for Establishing Payment Rate, Service 6(d), Other Practioners' Services-Pharmacist Services, page 1 of 1.	9. 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 1-2 of 2

10. SUBJECT OF AMENDMENT:
Change the dispensing fee structure to a three tier prescription volume based dispensing fee structure. Change the fee for each additional vaccine administration to $13.00. Remove EAC pricing as the pricing methodology utilized and replace with Average Acquisition Cost. Require 340B providers to disclose when a claim is for a 340B product. Reimbursement for pharmacist administered vaccines has been moved to Service 6(d), Other Practitioners' Services-Pharmacist Services.

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: Single Agency Director Review

12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]	16. RETURN TO: Montana Department of Public Health and Human Services Mary E. Dalton Attn: Mary Eve Kulawik PO Box 4210 Helena MT 59620
13. TYPED NAME: Mary E. Dalton	
14. TITLE: State Medicaid Director	
15. DATE SUBMITTED: original submittal 8/5/16 Resubmittal 3/24/17	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: August 5, 2016	18. DATE APPROVED: April 5, 2017
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: July 1, 2016	[redacted] L OFFICIAL:
21. TYPED NAME: Richard C. Allen	ARA, DMCHO

23. REMARKS:

FORM HCFA-179 (07-92)

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:
        i. The AAC; or
        ii. Submitted ingredient cost.
            1. 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 (of ASP+6%) 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

1. The professional dispensing fees assigned will be the calculated cost to dispense not to exceed the specified tier amount:
   a. $15.00 for pharmacies with an annual prescription volume between 0 and 39,999 prescriptions;
   b. $13.00 for pharmacies with an annual prescription volume between 40,000 and 69,999; or
   c. $11.00 for pharmacies with an annual prescription volume greater than 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.

MONTANA

Montana Medicaid covers vaccine administration by licensed pharmacists in an outpatient pharmacy setting.

Services considered experimental are not a benefit of the Montana Medicaid Program. Experimental services include all procedures, items and prescribed drugs:

1. Considered experimental by the U.S. Department of Health and Human Services (HHS) or any other appropriate federal agency.

2. Provided as part of a control study, approved by HHS 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; and,

3. Which may be subject to question but not covered in #1 and #2 above. These services will be evaluated by the Department's designated medical review organization.

MONTANA

Montana Medicaid covers vaccine administration by licensed pharmacists in an outpatient pharmacy setting.

Services considered experimental are not a benefit of the Montana Medicaid Program. Experimental services include all procedures, items and prescribed drugs:

1. Considered experimental by the U.S. Department of Health and Human Services (HHS) or any other appropriate federal agency.

2. Provided as part of a control study, approved by HHS 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; and,

3. Which may be subject to question but not covered in #1 and #2 above. These services will be evaluated by the Department's designated medical review organization.

MONTANA

Reimbursement for pharmacist administered vaccines shall be paid to the Montana Medicaid enrolled pharmacy. This administration fee will be provided in lieu of the professional dispensing fee for any covered vaccine. Reimbursement for vaccine administration shall be the lower of:

A. The provider's usual and customary charge for the service; or

B. Reimbursed under the Attachment 4.19B, Methods and Standards for Establishing Payment Rates for Services 5(a), Physicians' Services.