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State/Territory Name: Maine

State Plan Amendment (SPA) #:17-012

This file contains the following documents in the order listed:

- 1) Cover Letter
- 2) Approval Letter
- 3) Companion Letter
- 4) CMS 179 Form
- 4) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2275
Boston, Massachusetts 02203



Division of Medicaid and Children's Health Operations / Boston Regional Office

September 13, 2018

Bethany Hamm, Acting Commissioner
Department of Health and Human Services
Commissioner's Office
11 State House Station
Augusta, Maine 04333-001

Dear Commissioner Hamm:

We are pleased to enclose a copy of approved Maine State Plan Amendment (SPA) No. 17-012, which was submitted to my office on June 29, 2017. This SPA transmitted a proposed amendment to Maine's approved Title XIX State Plan to update and amend pharmacy reimbursement sections of the state plan. As requested by the State, the SPA has been approved effective September 1, 2017.

Changes are reflected in the following sections of your approved State Plan:

- Attachment 4.19-B Pages 3 and 3a were amended and replaced with Attachment 4.19-B Pages 3 and 3(a) and new pages 3(a)(1) and 3(a)(2) were added

If you have any questions you may contact Aimee Campbell-O'Connor at (617) 565-1642 or by email at Aimee.Campbell-Oconnor@cms.hhs.gov.

Sincerely,

/s/

Richard R. McGreal
Associate Regional Administrator



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

September 13, 2018

Ms. Stefanie Nadeau
Director, MaineCare Services
#11 State House Station
242 State Street
Augusta, ME 04333-0011

Dear Ms. Nadeau:

We have reviewed Maine's State Plan Amendment (SPA) 17-0012, Prescribed Drugs, received in the Boston Regional Office on June 29, 2017 and the response to our request for additional information (RAI) on June 28, 2018. This SPA proposes to bring Maine into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

Maine SPA 17-0012 includes reimbursement methods that use, among others, the National Average Drug Acquisition Cost (NADAC), plus the professional dispensing fee of \$11.89 for generic, brand-name and specialty drugs. This SPA also includes reimbursement rates for hemophilia treatment centers, mail order pharmacy providers, compounded drugs for retail providers, drugs purchased at a nominal price, drugs not distributed by a retail pharmacy and physician administered drugs.

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 Maine's pharmacy provider network at this time to approve SPA 17-0012. Specifically, Maine has reported to CMS that 537 of the state's 566 licensed in-state retail pharmacies are enrolled in Maine's Medicaid fee-for-service program. With over a 94 percent participation rate, we can infer that Maine'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 17-0012 is approved with an effective date of September 1, 2017. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Maine's state plan will be forwarded by the Boston Regional Office.

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If you have any questions regarding this request, please contact Lisa Shochet at 410-786-5445 or Lisa.Shochet@cms.hhs.gov.

Sincerely,

/s/

John M. Coster, Ph.D., R.Ph.
Director, Division of Pharmacy

cc: Richard McGreal, Associate Regional Administrator, Boston Regional Office
Aimee Campbell-O'Connor, Boston Regional Office
Samuel Senft, Policy Director, MaineCare Services



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

September 13, 2018

Ms. Stefanie Nadeau
Director, MaineCare Services
#11 State House Station
242 State Street
Augusta, ME 04333-0011

Dear Ms. Nadeau:

This letter is being sent as a companion to our approval of the Maine State Plan Transmittal Notice (TN) 17-0012, which amends the state plan to implement required changes from the Covered Outpatient Drug Rule. The changes in this state plan amendment are effective on September 1, 2017.

During the review process for SPA 17-0012, it was determined that Maine required additional time to adequately address its reimbursement for drugs purchased through the 340B program. Therefore, in consultation with CMS it was agreed that the state would remove reference to reimbursement for drugs purchased through the 340B program from SPA 17-0012 and submit a subsequent SPA to become fully compliant with the requirements of the Covered Outpatient Drug Rule.

When submitting the subsequent SPA to address reimbursement requirements for drugs purchased through the 340B program, please ensure that the state addresses the following items:

1. In Attachment 4.19-B, page 3(b)(6), please include how you will reimburse physician administered drugs purchased through the 340B program.
2. Please provide the reimbursement methodology for 340B purchased drugs. The state may consider the following language: "Payment for drugs purchased through the 340B program by 340B covered entities will be at the 340B actual acquisition cost, not to exceed the 340B ceiling price, plus the 340B professional dispensing fee."
3. Describe reimbursement for 340B covered entities purchasing drugs outside of the 340B program (i.e. payment for drugs purchased outside of the 340B program by 340B covered entities will be reimbursed using the lowest of logic plus the professional dispensing fee listed in Attachment 4.19-B.
4. Does the state allow for 340B entities or providers to carve out of the 340B drug pricing program? Please include the reimbursement methodology on the state plan page.
5. How were providers, advocates and beneficiaries engaged in the discussion of the use of 340B purchased medications? What were their concerns and how did the state address these concerns?

The state has 90 days from the date of this letter to respond. Within that period, the state may submit SPAs to address the inconsistencies or submit a corrective action plan describing in detail

Page 2 – Ms Nadeau

how the state will resolve the issues identified above in a timely manner. Failure to respond may result in the initiation of a formal compliance process. During the 90 days, CMS will provide any required technical assistance.

If you have any questions regarding this letter, please contact Lisa Shochet at 410-786-5445 or Lisa.Shochet@cms.hhs.gov.

Sincerely,

/s/

John M. Coster, Ph.D., R.Ph.
Director, Division of Pharmacy

cc: Richard McGreal, Associate Regional Administrator, Boston Regional Office
Aimee Campbell-O'Connor, Boston Regional Office
Samuel Senft, Policy Director, MaineCare Services

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 17-0012	2. STATE Maine
FOR: HEALTH CARE FINANCING ADMINISTRATION		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
		4. PROPOSED EFFECTIVE DATE September 1, 2017	
TO: REGIONAL ADMINISTRATOR Centers for Medicare and Medicaid Services Department of Health and Human Services			
5. TYPE OF PLAN MATERIAL <i>(Check One)</i> : <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 <i>(Separate Transmittal for each amendment)</i>			
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR §447 (Subpart I)		7. FEDERAL BUDGET IMPACT: a. FFY 2017 increase: \$ 215,524 b. FFY 2018 increase: \$2,586,292	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 4.19-B Page 3, 3a , 3(a), 3(a)(1), 3(a)(2)		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT <i>(If Applicable)</i> : Attachment 4.19-B Page 3, 3a	
10. SUBJECT OF AMENDMENT: Covered Outpatient Drug Reimbursement			
11. GOVERNOR'S REVIEW <i>(Check One)</i> : <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 Stefanie Nadeau, Director, <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL MaineCare Services			
12. SIGNATURE OF STATE AGENCY OFFICIAL: /s/ _____		16. RETURN TO: Stefanie Nadeau Director, MaineCare Services #11 State House Station 242 State Street Augusta, Maine 04333-0011	
13. TYPED NAME: Stefanie Nadeau			
14. TITLE: Director, MaineCare Services			
15. DATE SUBMITTED: June 29, 2017			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: 6/29/17		18. DATE APPROVED: 9/13/18	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: 9/1/17		20. SIGNATURE OF REGIONAL OFFICIAL: /s/ _____	
21. TYPED NAME: Richard McGreal		22. TITLE: Associate Regional Administrator	
23. REMARKS: The state provided authority for pen and ink adjustments to the 179 on 8/23/18 in order to update the pagination consistent with the state's submission.			

PAYMENT RATES FOR CARE AND SERVICES OTHER THAN INPATIENT HOSPITAL

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

A. Prescribed drugs

The State of Maine pays for covered outpatient drugs as defined in Section 1927(k)(2) of the Act which are those that are prescribed for a medically accepted indications and produced by any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Act. Additionally, the State's prior authorization requirements comply with Section 1927(d)(5) of the Act.

Based on the requirements for Section 1927 of the Act, the State has the following policies for the supplemental rebate program for the Medicaid population:

- (1) A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid population, submitted to CMS on January 1, 2003 and entitled "State of Maine Supplemental Drug Rebate Agreement" has been approved by CMS.
- (2) Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement
- (3) All drugs covered by the program, irrespective of a prior authorization requirement, will comply with provisions of the national drug rebate agreement.

PAYMENT RATES FOR CARE AND SERVICES OTHER THAN INPATIENT HOSPITAL

B. Reimbursement**(1) Reimbursement for Retail Pharmacy Providers**

(a) **Generic Drugs:** The reimbursement rate for covered generic drugs shall be the lowest of the following:

1. National Average Drug Acquisition Cost (NADAC) plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
2. The Federal Upper Limit (FUL) plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
3. The Wholesale Acquisition Cost (WAC) plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
4. The Maine maximum allowable cost plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
5. The Submitted Ingredient Cost plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
6. The usual and customary charge; or
7. Gross Amount Due (GAD); or
8. The Average Wholesale Price (AWP) minus sixteen point six seven percent (16.67%) plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee.

(b) **Brand-name Drugs:** The reimbursement rate for covered brand-name drugs shall be the lowest of the following:

1. NADAC plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
2. The WAC plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
3. The Maine maximum allowable cost plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
4. The Submitted Ingredient Cost plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
5. The usual and customary charge; or
6. GAD; or
7. The AWP minus sixteen percent (16%) plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee.

(2) Reimbursement for Specialty Pharmacy Providers: The reimbursement rate for Specialty Pharmacy Providers shall be the lowest of the following:

- (a) NADAC plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
- (b) The FUL plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
- (c) The Maine maximum allowable cost plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
- (d) The WAC plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
- (e) The Maine maximum allowable cost plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
- (f) The Submitted Ingredient Cost plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee; or
- (g) The usual and customary charge; or
- (h) GAD; or
- (i) The AWP minus sixteen point six seven (16.67%) plus eleven dollars and eighty-nine cents (\$11.89) professional dispensing fee.

PAYMENT RATES FOR CARE AND SERVICES OTHER THAN INPATIENT HOSPITAL

- (3) **Hemophilia Treatment Centers:** Hemophilia Treatment Centers are reimbursed the Average Sale Price (ASP) minus the Furnishing Fee plus dispensing fee of \$120.45.
- (4) **Reimbursement for Mail Order Pharmacy Providers**
- (a) **Generic Drugs:** The reimbursement rate for covered generic drugs obtained through mail order pharmacy providers shall be the lowest of the following:
1. The FUL plus a two-dollar and fifty cent (\$2.50) professional dispensing fee; or
 2. The Maine maximum allowable cost plus a two-dollar and fifty cent (\$2.50) professional dispensing fee; or
 3. The usual and customary charge; or
 4. The AWP minus sixty percent (60%) plus a two-dollar and fifty cent (\$2.50) professional dispensing fee.
- (b) **Brand Name Drugs:** The reimbursement rate for covered brand name drugs obtained through mail order pharmacy providers shall be the lowest of the following:
1. The usual and customary charge; or
 2. The AWP minus twenty percent (20%) plus a two-dollar and fifty cent (\$2.50) professional dispensing fee.
- (5) **Reimbursement for Compounded Drugs for Retail Pharmacy Providers**
- The ingredient cost is the sum of the cost of the defined ingredients contained in the compounded drug. Professional dispensing fees for compound drugs are as follows:
- (a) Eleven dollars and eighty-nine cents (\$11.89) except for filling insulin syringes.
- (b) Twelve dollars and fifty cents (\$12.50) for filling insulin syringes per fourteen (14) day supply.
- (6) **Reimbursement for Physician Administered Drugs**
- MaineCare determines drug fee schedules for these drugs as Average Sales Price (ASP) plus six percent (6%) as set by Medicare Part B for Maine area "99." MaineCare will reimburse the lower of:
- (a) The fee schedule rate (when the ASP is available), or
- (b) The provider's acquisition cost only, excluding shipping and handling.
- (7) Drugs not distributed by a retail community pharmacy, such as in a long-term care facility, will be paid utilizing generic (see Section 12 (B)(1)(a)), brand (see Section 12 (B)(1)(b)), or specialty pricing (see Section 12 (B)(2)), as appropriate;
- (8) Drugs not distributed by a retail community pharmacy, such as in a long-term care facility, will be paid utilizing generic (see Section 12 (B)(1)(a)), brand (see Section 12 (B)(1)(b)), or specialty pricing (see Section 12 (B)(2)), as appropriate;
- (9) Drugs acquired at nominal price are reimbursed at no more than AAC plus the professional dispensing fee as described in Section 12 (B), as appropriate;
- (10) Drugs acquired at the Federal Supply Schedule (FSS) are reimbursed at no more than AAC plus the professional dispensing fee as described in Section 12 (B), as appropriate;
- (11) MaineCare does not cover investigational drugs.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: MAINE

Attachment 4.19-B

Page 3(a)(2)

PAYMENT RATES FOR CARE AND SERVICES OTHER THAN INPATIENT HOSPITAL

MaineCare reimburses 340 drugs off the fee schedule or through Ambulatory Payment Classifications (APC), and does not collect rebates on the 340B drugs.

TN No. 17-0012

Supersedes

New

Approval Date 9/13/18

Effective Date 9/1/2017