Table of Contents

State/Territory Name: Maine

State Plan Amendment (SPA) #:12-007

This file contains the following documents in the order listed:

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

April 30, 2015

Mary C. Mayhew, Commissioner
Department of Health and Human Services
Commissioner's Office
11 State House Station
Augusta, Maine 04333-001

Dear Commissioner Mayhew:

We are pleased to enclose a copy of approved Maine State Plan Amendment (SPA) No. 12-007, which was submitted to my office on June 29, 2012. This SPA transmitted a proposed amendment to Maine's approved Title XIX State Plan to update and amend pharmacy coverage and reimbursement sections of the state plan. As requested by the State, the SPA has been approved effective April 1, 2012.

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

- Attachment to Attachment 3.1A Pages 5, 5b and 5c were amended and replaced with Attachment to Attachment 3.1A, pages 5, 5.1, 5.2 and a new page 5.3 was added
- Attachment 4.19B, pages 3, 3(a) were amended and a new page 3(b) was 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

cc: Stefanie Nadeau, Director, Office of MaineCare Services
John M. Coster, Director, CMS, Division of Pharmacy

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

April 30, 2015

Ms. Mary C. Mayhew
Commissioner
Maine Department of Health and Human Services
#11 State House Station
442 Civic Center Drive
Augusta, Maine 04333-0011

Attention: Ms. Stefanie Nadeau

Dear Ms. Mayhew:

We have reviewed Maine State Plan Amendment (SPA) 12-007 received in the Boston Regional Office on June 29, 2012. Under this SPA, the state proposes to restructure its state plan to specify reimbursement methodologies for Medicaid covered outpatient prescription drugs. Unless otherwise specified, the effective date for this SPA is April 1, 2012. In addition, the state proposes to reduce the reimbursement methodology for brand name drugs from Average Wholesale Price (AWP) minus 15 percent to AWP minus 16 percent. Effective July 1, 2012, the state proposes mandatory generic substitution with exceptions for certain target populations and conditions, except where the federal upper limit applies. Effective September 1, 2012, the state proposes to change its coverage for outpatient drugs for smoking cessation from all Medicaid beneficiaries to pregnant women only. In addition, the state increases the dispensing fee for mail order pharmacies for brand and generic drugs from $1.00 to $2.50, effective June 30, 2013.

Based on the information provided, we are pleased to inform you that the Maine SPA 12-007 is approved with an effective date of April 1, 2012. A copy of the signed CMS-179 form, as revised, as well as the pages approved for incorporation into the Maine state plan will be forwarded by the Boston Regional Office.

Please note that a companion letter is also forthcoming with the complete formal SPA approval package requiring a corrective action plan within a specified time frame.

If you have any questions regarding this amendment, please contact Bernadette Leeds at (410) 786-9463.

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

cc: Richard McGreal, ARA, Boston Regional Office
Aimee Campbell-O'Connor, Boston Regional Office
Pascale Desir, MaineCare Services

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
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Division of Medicaid and Children's Health Operations / Boston Regional Office

April 30, 2015

Mary C. Mayhew, Commissioner
Department of Health and Human Services
Commissioner's Office
11 State House Station
Augusta, Maine 04333-001

Dear Commissioner Mayhew:

This letter is being sent as a companion to our approval of Maine State Plan Amendment (SPA) 12-007, which clarifies and amends pharmacy coverage and reimbursement provisions in the Medicaid state plan. This SPA was received in the Boston Regional Office under the Centers for Medicare & Medicaid Services (CMS) on June 29, 2012, with an effective date of April 1, 2012. We are noting one area within the SPA that requires additional follow-up from the state.

Section 1902(a) of the Social Security Act (the Act) requires that states have a state plan for medical assistance that meets certain federal requirements that set out a framework for the state program. Implementing regulations at 42 CFR 430.10 require that the state plan be a comprehensive written statement describing the nature and scope of the state's Medicaid Program and that it contain all information necessary for CMS to determine whether the plan can be approved to serve as the basis for Federal financial participation (FFP) in the state program. While the SPA is approvable, CMS' analysis determined that additional review related to the state's reimbursement methodology for Medicaid covered outpatient generic drugs for retail independent and chain pharmacies are needed in the Maine Medicaid state plan.

Section 1902(a)(30)(A) of the Social Security Act requires, in part, that states have methods and procedures to assure that payment rates are "consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan." Under that authority, the Secretary has issued regulations prescribing state rate setting procedures and requirements. States establish their reimbursement methodologies for the ingredient cost of a drug by establishing an estimated acquisition cost (EAC). The definition of EAC under 42 CFR 447.502 is "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of the drug most frequently purchased by providers."

During CMS' review of the state's responses to the request for additional information, the state was requested to provide support that the average wholesale price (AWP) minus 13 percent is the best estimate for what retail independent and chain pharmacies are currently paying for generic drugs. The state provided the following response:

> The state will review and adjust this rate to assure that the rate paid is the best estimate for what retail independent and chain pharmacies are currently paying for generic drugs and that the rates are economic, efficient and sufficient. The state's goal is to have a competitive rate that will more closely align with approved rates in other states.

The state will have 90 days from the date of this letter to address this issue. Within that period, the state may submit a SPA to reflect this change in policy or the state may submit a corrective action plan describing in detail how the state will resolve this issue in a timely manner. Failure to respond will result in the initiation of a formal compliance process. During the 90-day period, CMS will provide you with any required technical assistance to assist you in resolving this issue.

If there are any questions, please contact Aimee Campbell-O'Connor at 617/565-1642 or Aimee.Campbell-Oconnor@cms.hhs.gov. We look forward to working with you on this issue.

Sincerely,

/s/

Richard R. McGreal
Associate Regional Administrator

cc: Stefanie Nadeau, Director, Office of MaineCare Services
John M. Coster, Director, CMS, Division of Pharmacy

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 12-007

2. STATE: MAINE

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE AND MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE(S): 4/1/12

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:
42 CFR §§ 440.120(A), 441.25, 447.331-447.334

7. FEDERAL BUDGET IMPACT:
~~SFY12-$768,516.08~~ FFY 12- ($1,382,873.75)
~~SFY13-$1,438,366.18~~ FFY 13- ($1,438,049.13)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
~~4.19B PAGES 3-3(B) AND 3.1A PAGE 5~~ Attachment to Attachment 3.1A Pages 5, 5.1, 5.2 and 5.3. AND Attachment 4.19B Pages 3, 3a and 3b

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: ATTACHMENT 4.19B, PAGE 3, 3(A), ~~4 AND 3.1A PAGES PAGE 5~~ AND See Remarks Below for 3.1A

SUBJECT OF AMENDMENT: PHARMACY COVERAGE AND REIMBURSEMENT

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
COMMISSIONER, DEPT. OF HUMAN SERVICES

12. SIGNATURE OF STATE AGENCY OFFICIAL:
/s/

13. TYPED NAME:
MARY C. MAYHEW

14. TITLE:
Commissioner, Maine Department of Health and Human Services

15. DATE SUBMITTED: 06/29/12

16. RETURN TO:

STEFANIE NADEAU

Director, MaineCare Services
#11 State House Station

242 STATE STREET
Augusta, ME 04333-0011

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 6/29/2012

18. DATE APPROVED: 4/30/2015

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 4/1/2012

20. SIGNATURE OF REGIONAL OFFICIAL:
/s/

21. TYPED NAME: Richard McGreal

22. TITLE: Associate Regional Administrator

23. REMARKS: Box 9 Superceded pages continued: Attachment to Attachment 3.1A Pages 5, 5b and 5c
On 4/17/15, the state submitted an unsigned revised CMS 179 form giving CMS authorization to make pen and ink changes to Boxes 7, 8 and 9 to be consistent with the final submitted Fiscal Impact, submitted existing pages and new pages for this SPA.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

ATTACHMENT TO
ATTACHMENT 3.1-A PAGE 5

State/Territory: Maine

AMOUNT, DURATION, AND SCOPE OF MEDICAL
AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

Item 12a Prescribed Drugs

Limited to prescribed medications, including certain prescribed over-the-counter drugs.

Mandatory Generic Substitution:
Effective July 1, 2012 the Department shall require substitution for a brand-name drug of a generic and therapeutically equivalent drug, absent prior authorization from the Department. If the prescriber has indicated that the brand-name drug must be dispensed and that the brand-name drug is medically necessary, the Department may authorized based upon its review for medical necessity.

Exemptions from mandatory substitution:
The Department shall grant prior authorization, without determining the medical necessity of a brand-name drug, on the basis of these exemptions:

1. Brand-name drugs for children under the age of eighteen (18);
2. Pregnant women;
3. Brand-name drugs required by federal law;
4. Brand-name drugs for the treatment of cancer;
5. Brand-name drugs for treatment of HIV or AIDS;
6. Brand-name antipsychotic drugs;
7. Brand-name drugs that have been determined by the Department to be more cost-effective for the Department than a generic and therapeutically equivalent drug.

The Department shall grant prior authorization without determining the medical necessity of a brand-name drug on the basis of these exemptions, except where federal upper limits of payment apply.

If there is a FUL established, the prescriber must handwrite "brand medically necessary" on the actual script or use an electronic alternative in accordance to the guidelines established by the National Council for Prescription Drug Programs.

The Department will reimburse providers for active pharmaceutical ingredients (APIs) and excipients used in extemporaneously compounded drugs. The following website specifies the active pharmaceutical ingredients covered by the state: http://www.mainecarepdl.org/.

Effective September 1, 2012, smoking cessation products will only be covered for pregnant women, in accordance with Section 4107 of the Patient Protection and Affordable Care Act.

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.

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:

☐ Drugs when used for anorexia, weight loss, weight gain

(None)

☐ Drugs when used to promote fertility

(None)

☐ Drugs when used for cosmetic purposes or hair growth

(None)

☑ Drugs when used for the symptomatic relief of cough and colds

Systemic decongestants, topical decongestants, antitussive-expectorants

☑ Prescription vitamins and mineral products

Vitamin K, vitamins for dialysis services and quadriplegia and paraplegia, prenatal vitamins

☑ Non-prescription drugs (Over-the-Counter)

Analgesic; antiasthmatics; otic agents; gastro intestinal (GI) agents including GI-anti-flatulents, GI stimulants, GI-antidiarrheal/antacids, antiperistaltic agents, GI-digestive enzymes, GI-H2-Antagonists, GI,-misc. and GI-proton pump inhibitors; minerals; NSAIDS; Ophthalmic artificial tears and lubricants; other anitihistimines; topical antifungals; topical corticosteroids; topical anesthetics; and vitamins.

☑ Barbiturates (drugs used before surgery to relieve anxiety or tension, to help control seizures in certain disorders or diseases, sometimes used to relieve nervousness or restlessness during the daytime).

all

☑ Benzodiazepines (drugs used to relieve anxiety, treat insomnia (trouble in sleeping), or help relax muscles or relieve muscle spasms)

all

☑ Smoking Cessation (except dual eligible as Part D will cover)

Effective September 1, 2012, smoking cessation products will only be covered for pregnant women, in accordance with Section 4107 of the Patient Protection and Affordable Care Act.

The State is in compliance with Section 1927 of the Social Security Act. The state will cover drugs of manufacturers participating in the federal rebate program. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Based on the requirements of Section 1927 of the Act, the State has the following policies for the supplemental rebate program for the Medicaid population:

a. A July 1, 2010 version of the rebate entitled "Supplemental Rebate Agreement" between the State and a drug manufacturer for drugs provided to the Medicaid population and the Sovereign States Drug Consortium Addendum to Member States' Supplemental Rebate Agreements as submitted to CMS on November 22, 2010 have been authorized by CMS.
b. Funds received from supplemental rebate agreements will be reported to CMS. The State will remit the Federal portion of any supplemental rebates collected.
c. Manufacturers with supplemental rebate agreements are allowed to audit utilization data.
d. The unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act (the Act). No changes will be made to the agreement without CMS authorization.
e. The state will negotiate the supplemental rebates in addition to federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates. Supplemental rebates received by the state in excess of those required under the federal drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the federal rebate agreement.
f. The State may negotiate the Supplemental Rebate Agreement that would classify any covered drug as preferred for as long as the agreement is in effect.
g. The prior authorization process for covered outpatient drugs conforms to section 1927(d)(5) of the Act. Utilization of certain covered drug products may be restricted by means of the prior authorization process, in compliance with federal law. Prior authorization programs for covered outpatient drugs provide a response within 24 hours of a request for prior authorization and for the dispensing of a 96-hour supply of medications in emergency situations.
h. Drugs that do not require prior authorization are considered preferred. Pursuant to 42 USC 1396r-8, the state has established a preferred drug list (PDL) with prior authorization requirements for drugs not included on the preferred drug list to negotiate drug discounts, rebates, or benefits for the Medicaid program.

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 indication 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 is made to retail pharmacies, for brand-name drugs at the lowest of the following:
a. The usual and customary charge; or
b. The Average Wholesale Price (AWP) – (minus) 16% plus $3.35 dispensing fee except as otherwise noted below, or
c. The Maine maximum allowable cost (MMAC) plus $3.35 dispensing fee except as otherwise noted below;

Payment is made to retail pharmacies for generic drugs at the lowest of the following:
a. The usual and customary charge; or
b. The Average Wholesale Price (AWP) – (minus) 13% plus $3.35 dispensing fee except; or
c. The Federal Upper Limit (FUL) unless the Department meets the FUL in aggregate; or
d. The Maine Maximum Allowable Cost (MMAC) + (plus) $3.35 dispensing fee.

Payment is made to specialty pharmacies at the lowest of the following:
a. The usual and customary charges; or
b. The Average Wholesale Price (AWP) – (minus) 17% plus $3.35 dispensing fee; or
c. The Federal Upper Limit (FUL) unless the Department meets FUL in aggregate; or
d. The Maine Maximum Allowable cost + (plus) $3.35 dispensing fee.

Payment is made to mail-order pharmacies for brand-name drugs at the lowest of the following:
a. The usual and customary charges; or
b. The Average Wholesale Price (AWP) – (minus) 20% + (plus) $2.50 dispensing fee (eff. 6/30/13); or
c. The Maine Maximum Allowable Cost (MMAC) + (plus) $2.50 dispensing fee.

Payment is made to mail order pharmacies for generic drugs at the lowest of the following:
a. The usual and customary charge; or
b. The Average Wholesale Price minus 60% plus $2.50 dispensing fee except as otherwise noted below (eff. 6/30/13); or
c. The Federal Upper Limit (FUL) unless the Department meets FUL in aggregate except as otherwise noted below; or
d. The Maine Maximum Allowable Cost (MMAC) plus $2.50 dispensing fee except as otherwise noted below.

Dispensing fees for compounded drugs are described below.

Dispensing Fees are as follows:

i. $3.35 for an amount dispensed from a stock supply, or for solutions or lotions involving no weighing.
ii. $4.35 for compound drugs except for filling insulin syringes.
iii. $5.35 for compounding handmade suppositories, powder papers, capsules and tablet triturates and for mixing home TPN hyper-alimentation.
iv. $12.50 for filling insulin syringes per 14-day supply.

There is no separate pricing for 340B providers. 340B providers receive reimbursement at the same level of Medicaid reimbursement specified above.

Pharmacy Rural Dispensing Fee Adjustment

The Department will pay a supplemental dispensing fee for prescriptions provided to members residing in rural areas in an attempt to assure continuing access to prescription services for these members. The rural dispensing fee will range from 55¢ to 65¢ per prescription dispensed to rural members, and will change on a quarterly basis to reflect the prior quarter's number of prescriptions filled. The Department will distribute the rural dispensing fee adjustment retrospectively on a quarterly basis. The Department will calculate the quarterly adjustment for each pharmacy by taking that quarter's total allotment ($500,000 per quarter) and dividing the total allotment for the quarter by the number of prescriptions filled for rural members in the quarter. The Department will then group these by pharmacy and distribute in the quarter following. Pharmacies will be notified on a quarterly basis on the Department's designated website the amount of the adjustment for the quarter.

Rural members will be defined using a standard and federally recognized definition of rural using Metropolitan Statistical Area (MSA) designations. The Department will determine MSA/Non-MSA designation based on the zip code of the member's residence.