Table of Contents

State/Territory Name: California

State Plan Amendment (SPA)#: 23-0043

This file contains the following documents in the order listed below:

1) Approval Letter
2) CMS 179 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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Center for Medicaid and CHIP Services
Medical Benefits and Health Programs Group

January 25, 2024

Michelle Baass
Director and Interim State Medicaid Director
Department of Health Care Services
Attn: Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Director Baass:

We have reviewed California's State Plan Amendment (SPA) 23-0043 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on December 14, 2023. This SPA proposes to reimburse providers based on a submitted invoice price for a drug's ingredient cost when other pricing benchmarks are unavailable.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that CA-23-0043 is approved with an effective date of January 1, 2024.

We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into the California state plan. If you have any questions regarding this amendment, please contact Whitney Swears at Whitney.Swears@cms.hhs.gov.

Sincerely,

Mickey D. Morgan -S
Digitally signed by Mickey D. Morgan -S
Date: 2024.01.25 15:13:33 -05'00'

Mickey Morgan
Deputy Director
Division of Pharmacy

cc: Lindy Harrington, Assistant SMD, Department of Health Care Services
Rene Mollow, Director of Benefits and Coverage, Department of Health Care Services
Lisa Ghotbi, Chief of Pharmacy Benefits, Department of Health Care Services
Angeli Lee, SPA Coordinator, Department of Health Care Services
Cheryl Young, CMS, Medicaid and CHIP Operations Group
Whitney Swears, CMS, Medical Benefits and Health Programs Group

DEPARTMENT OF HEALTH ANDHUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 23-0043

2. STATE: CA

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

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
January 1, 2024

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR Part 447

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2024 $ 0
b. FFY 2025 $ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Supplement 2 to Attachment 4.19-B, pages 1-3

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Supplement 2 to Attachment 4.19-B, pages 1-3

9. SUBJECT OF AMENDMENT
To reimburse providers an ingredient cost, based on a submitted invoice price, for a covered outpatient drug when other pricing benchmarks are unavailable.

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:
Please note: The Governor's Office does not wish to review the State Plan Amendment.

11. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted]

12. TYPED NAME
Michelle Baass

13. TITLE
Director & Interim State Medicaid Director

14. DATE SUBMITTED
December 14, 2023

15. RETURN TO
Department of Health Care Services
Attn: Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

FOR CMS USE ONLY

16. DATE RECEIVED
December 14, 2023

17. DATE APPROVED
January 25, 2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2024

19. SIGNATURE OF APPROVING OFFICIAL
Mickey D. Morgan -S
Digitally signed by Mickey D. Morgan -S
Date: 2024.01.25 15:14:31 -05'00'

20. TYPED NAME OF APPROVING OFFICIAL
Mickey Morgan

21. TITLE OF APPROVING OFFICIAL
Deputy Director

22. REMARKS

Instructions on Back

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: CALIFORNIA

Methods and Standards for Establishing Payment Rates – Prescribed Drugs

PAYMENT METHODOLOGY FOR COVERED OUTPATIENT DRUGS

Medi-Cal's payment methodology for covered outpatient drugs complies with the Centers for Medicare and Medicaid (CMS) Covered Outpatient Drug Final Rule in accordance with 42 C.F.R. Part 447.

1. Payment for legend and non-legend covered outpatient drugs dispensed by a retail community pharmacy shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

2. Payment for specialty drugs not dispensed by a retail community pharmacy but dispensed primarily through the mail shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

3. Payment for legend and non-legend covered outpatient drugs not dispensed by a retail community pharmacy (i.e. institutional or long-term care facility pharmacies) shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

4. For purposes of this supplement, the "drug's ingredient cost" means the lowest of:

    a. The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
    b. The Federal Upper Limit (FUL), or
    c. The Maximum Allowable Ingredient Cost (MAIC).

    When the lowest drug ingredient cost is not available based on NADAC, WAC + 0%, FUL or MAIC, reimbursement paid to the Medi-Cal Provider will be their invoice price.

    The FUL is the maximum allowable ingredient cost reimbursement established by the federal government for selected multiple source drugs. The aggregate cost of product payment for drugs with FULs will not exceed the aggregate established by the federal government.

5. The "professional dispensing fee" shall be based on a pharmacy's total (Medicaid and non-Medicaid) annual claim volume of the previous year, as follows:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: CALIFORNIA

Methods and Standards for Establishing Payment Rates – Prescribed Drugs

a. Less than 90,000 claims = $13.20, or
b. 90,000 or more claims = $10.05

6. The Department may establish a list of MAICs for generically equivalent drugs.

7. Medi-Cal providers that are covered entities (as defined in Section 256b of Title 42 of the United States Code) and purchase drugs through the 340B Drug Pricing Program are required to use only 340B purchased drugs when dispensing drugs to Medi-Cal beneficiaries. If a covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary.

   a. For drugs purchased pursuant to the 340B program, a covered entity is required to bill and will be reimbursed an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code, plus the professional dispensing fee described in Paragraph 5.

   b. If a covered entity dispenses a drug purchased at regular drug wholesale rates because it is unable to purchase it pursuant to the 340B program, the covered entity is required to maintain documentation of their inability to obtain the 340B drug and payment will be made as described in Paragraph 1 of this supplement.

   c. A contract pharmacy, under contract with a 340B covered entity described in Section 1927(a)(5)(B) of the Social Security Act may only use 340B drugs to dispense Medicaid prescriptions if the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts as outlined in the HRSA Final Notice regarding Contract Pharmacy Services published at 75 Fed. Reg. 10272 (Mar. 5, 2010) and the details of that arrangement have been shared with HRSA.

      i. If the covered entity provides medications through contracted pharmacies, payment will be made as described in either Paragraph 7a or 7b of this supplement.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: CALIFORNIA

Methods and Standards for Establishing Payment Rates – Prescribed Drugs

ii. Covered entities that utilize contract pharmacy arrangements are expected to ensure compliance with all the requirements in the HRSA Final Notice.

8. Pharmacy providers purchasing drugs through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826 will be reimbursed no more than the actual acquisition cost for the drug, plus a professional dispensing fee as described in Paragraph 5 of this supplement.

9. Pharmacy providers purchasing drugs at Nominal Price (outside of 340B or FSS) will be reimbursed no more than the actual acquisition cost for the drug, plus a professional dispensing fee as described in Paragraph 5 of this supplement.

10. Payment for legend and non-legend covered outpatient drugs dispensed by Indian Health Service, tribal, and urban Indian pharmacies shall be the drug's ingredient cost as defined in Paragraph 4, 7, 8 or 9 of this supplement, as applicable, plus a professional dispensing fee as described in Paragraph 5.

11. All investigational drugs require prior authorization, and shall be reimbursed as described in paragraph 1 of this supplement.