

Table of Contents

State/Territory Name: California

State Plan Amendment (SPA)#: 24-0009

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



Medicaid Benefits and Health Programs Group

May 22, 2024

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

Dear Director Bass:

We have reviewed California's State Plan Amendment (SPA) 24-0009 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on March 14, 2024. This amendment authorizes the state to enter into value based supplemental drug rebate agreements.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that CA-24-0009 is approved with an effective date of April 1, 2024.

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

Sincerely,

A solid black rectangular box redacting the signature of Cynthia R. Denemark.

Cynthia R. Denemark, R.Ph.
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

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER 2 4 — 0 0 0 9 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
April 1, 2024

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR Part 447 Subpart I – Payment for Drugs

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, page 11

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
Supplement 2 to Attachment 4.19-B, page 11

9. SUBJECT OF AMENDMENT
Approval of Medi-Cal's Value Based Supplemental Drug Rebate Agreement Template

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


12. TYPED NAME
Michelle Baass

13. TITLE
Interim State Medicaid Director

14. DATE SUBMITTED
March 14, 2024

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
March 14, 2024

17. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
April 1, 2024

19. SIGNATURE OF APPROVING OFFICIAL

Date: 2024.05.22 15:52:33 -04'00'

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia Denmark, R.Ph

21. TITLE OF APPROVING OFFICIAL
Director, Division of Pharmacy

22. REMARKS

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California
METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

DRUG REBATE PROGRAM

The State Agency is in compliance with Section 1927 of the Social Security Act. The State Agency reimburses providers of drugs of manufacturers participating in the drug rebate program and is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data to the extent allowed under the Health Insurance Portability and Accountability Act (HIPAA) in order to ensure that the Department is protecting information in accordance with HIPAA. The unit rebate amount is confidential and is not disclosed to anyone not entitled to the information for purposes of rebate contracting, invoicing and verification.

SUPPLEMENTAL REBATE PROGRAM

The State Agency negotiates supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer are separately identified from the federal rebates.

Supplemental rebates received by the State Agency in excess of those required under the national drug rebate agreement are shared with the Federal government on the same percentage basis as applied under the national rebate agreement. CMS has authorized the State of California to enter into the Medi-Cal Supplemental Drug Rebate Average Manufacturer Price (AMP) Agreement. This supplemental drug rebate agreement was submitted to CMS on December 1, 2014 and has been authorized by CMS. CMS has also authorized the State of California to enter into the Medi-Cal Net Cost Supplemental Drug Rebate Agreements. This supplemental drug rebate agreement was submitted to CMS on February 13, 2019 and has been authorized by CMS. CMS has also authorized the State of California to enter into value-based supplemental drug rebate agreements. The Medi-Cal Value-Based Supplemental Drug Rebate Agreement template was submitted to CMS on March 14, 2024 and has been authorized by CMS. All drugs covered by the program, notwithstanding a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.