

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 and Elderly Health Programs Group

March 21, 2019

Mari Cantwell, State Medicaid Director
Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Ms. Cantwell:

We have reviewed California State Plan Amendment (SPA) 19-0008, received in the San Francisco Regional Office on February 13, 2019. This amendment proposes to revise the state's Supplemental Drug Rebate Agreement template. The template updates the term Estimated Acquisition Cost (EAC) with Actual Acquisition Cost (AAC).

Based on the information provided, we are pleased to inform you that, consistent with the regulations at 42 CFR 430.20, SPA 19-0008 is approved with an effective date of January 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into the California state plan will be forwarded by the San Francisco Regional Office.

If you have any questions regarding this amendment, please contact Mickey Morgan at (410) 786-4048 or mickey.morgan@cms.hhs.gov.

Sincerely,

/s/

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

CC:

Harry Hendrix, Chief, Pharmacy Benefits Division
Richard C. Allen, Director, Western Regional Operations Group
Trudi Balestreri, Project Manager Pharmacy Benefits Division
Cheryl Young, CMS San Francisco Regional Office

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

1. TRANSMITTAL NUMBER <u>19</u> — <u>0008</u>	2. STATE California
3. PROGRAM IDENTIFICATION: Title XIX of the Social Security Act (Medicaid)	
4. PROPOSED EFFECTIVE DATE January 1, 2019	

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

5. TYPE OF PLAN MATERIAL (*Check One*)

NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

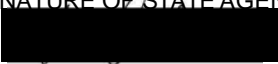
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION 42 CFR Part 447 Subpart I – Payment for Drugs	7. FEDERAL BUDGET IMPACT a. FFY <u>2018/2019</u> \$ <u>0</u> b. FFY <u>2019/2020</u> \$ <u>0</u>
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Supplement 2 to Attachment 4.19-B, page 11	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>) Supplement 2 to Attachment 4.19-B, page 11

10. SUBJECT OF AMENDMENT
Modify the Net Cost Supplemental Drug Rebate Contract template to replace the term Estimated Acquisition Cost (EAC) with Actual Acquisition Cost (AAC)

11. GOVERNOR'S REVIEW (*Check One*)

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL 	16. RETURN TO Department of Health Care Services Attn: Director's Office P.O. Box 997413, MS 0000 Sacramento, CA 95899-7413
13. TYPED NAME Mari Cantwell	
14. TITLE State Medicaid Director	
15. DATE SUBMITTED February 13, 2019	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED	18. DATE APPROVED March 21, 2019
-------------------	-------------------------------------

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2019	20. SIGNATURE OF REGIONAL OFFICIAL 
21. TYPED NAME Richard C. Allen	22. TITLE Director, Regional Operations Group

23. REMARKS
For Box 11 "Other, As Specified," Please note: The Governor's Office does not wish to review the State Plan Amendment.

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. All drugs covered by the program, notwithstanding a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.