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State/Territory Name: California

State Plan Amendment (SPA) #: 14-034

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

Disabled & Elderly Health Programs Group

August 28, 2015

Mari Cantwell
Chief Deputy Director, Health Care Programs
California Department of Health Care Services
Director's Office, MS 0000
P.O. Box 997413
Sacramento, CA 95899-7413

Dear Ms. Cantwell:

We have reviewed California (CA) State Plan Amendment (SPA) 14-034 received in the San Francisco Regional Office on December 1, 2014. This amendment proposes to revise the CA single-state Medicaid Supplemental Drug Rebate Agreements, that is, the Medi-Cal Average Manufacturer Price Supplemental Drug Rebate Agreement and the Medi-Cal Net Cost Supplemental Drug Rebate Agreement, to give the state the ability to collect state supplemental drug rebates from manufacturers for managed care populations.

Because we believe that the state has demonstrated that this amendment complies with all applicable requirements, we are pleased to inform you that consistent with the regulations at 42 CFR 430.20, CA SPA 14-034 is approved, effective October 1, 2014. Please note that this authorization extends only to the supplemental drug rebate agreements named above, which were submitted to the Centers for Medicare & Medicaid Services (CMS) on December 1, 2014. If revisions are subsequently made to either or both of the state's single state supplemental drug rebate agreements, a new SPA and required documents should be submitted to CMS for review and authorization.

A copy of the CMS-179 form as well as the pages approved for incorporation into the CA state plan will be forwarded to you by the San Francisco Regional Office. If you have any questions regarding this SPA approval please contact Gail Sexton, at (410)-786-4583.

Sincerely,

/s/

John M. Coster, PhD, RPh
Director
Division of Pharmacy

cc: Henrietta Sam-Louie, Acting ARA, San Francisco Regional Office
Cheryl Young, San Francisco Regional Office

Enclosure 1 - CMS 179 form, pen & ink revision

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 14-034

2. STATE: CA

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

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE: 10/1/2014

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 U.S.C. 1396r–8

7. FEDERAL BUDGET IMPACT:
a. FFY ~~14-15~~ 2015 ~~$0~~ $ 3,000,000
b. FFY ~~15-16~~ 2016 ~~$0~~ $ 6,000,000

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Supplement 2 to Attachment 4.19-B, pages 6, 7, ~~12-37~~ 8, 9, 10, 11

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: 8, 9, 9a, 10, 11
Supplement 2 to Attachment 4.19-B, pages 6, 7, including the appended Medi-Cal Average Manufacturer Price Supplemental Drug Rebate Agreement, pages 1-6 and 9 and the Medi-Cal Net Cost Drug Rebate Agreement, pages 1-5, and 7 (Note: Existing rebate contract template pages are not numbered as part of the state plan.)

10. SUBJECT OF AMENDMENT:
Modify state supplemental drug rebate agreements to give the Department of Health Care Services the ability to collect supplemental drug rebates from Managed Care Organizations ~~in accordance with California Welfare and Institutions Code 14105.33~~.

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

12. SIGNATURE OF STATE AGENCY OFFICIAL:
[redacted]

13. TYPED NAME:
Toby Douglas

14. TITLE:
Director

15. DATE SUBMITTED:
December 1, 2014

DEC 0 1 2014

16. RETURN TO:
Department of Health Care Services
Attn: State Plan Coordinator
1501 Capitol Avenue, MS 4506
P.O. Box 997419
Sacramento, CA 95899-7419

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:
December 1, 2014

18. DATE APPROVED:
August 28, 2015

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
October 1, 2014

20. SIGNATURE OF REGIONAL OFFICIAL:
/s/

21. TYPED NAME:
Henrietta Sam-Louie

22. TITLE:
Acting Associate Regional Administrator, Division of Medicaid & Children's Health Operations

23. REMARKS:

FORM HCFA-179 (07-92)

I. The State Agency believes reimbursement to long-term pharmacy providers to be consistent and reasonable with costs reimbursed to other providers. The State Agency maintains an advisory committee known as the Medi-Cal Contract Drug Advisory Committee in accordance with Federal law.

J. The payment for drug products, including the drug product payment and the dispensing fee, as described in paragraph A and paragraph B, for drug products dispensed on or after March 1, 2011, through and including May 31, 2011, will be reduced by five percent.

K. The payment for drug products, including the drug product payment and the dispensing fee, as described in paragraph A and paragraph B, for drug products dispensed on or after June 1, 2011 and through March 30, 2012 will be reduced by ten percent.

L. The payment for drug products, including the drug product payment and the dispensing fee, as described in paragraph A and paragraph B, for drug products dispensed on or after March 31, 2012 will be reduced by ten percent, unless exempted pursuant to Paragraphs 1 or 2 below:

1. The Department will exempt specific drug products and/or categories of drugs from the reductions specified in paragraph L if the Department determines that such a reduction will result in reimbursement less than actual acquisition cost or will otherwise negatively impact beneficiary access.

    a. Individual drugs, or therapeutic categories of drugs meeting one or more of the following criteria will be considered for exemption:

        i. Drugs for which documentation exists that the reduction specified in paragraph L will result in reimbursement below the acquisition cost generally available to the Medi-Cal pharmacy provider community.
        ii. Drugs that are only dispensed through limited or specialized networks of pharmacy providers.
        iii. Drugs that are used to treat unique clinical conditions with relatively low prevalence in the Medi-Cal population.
        iv. Drugs for which immediate or rapid negative clinical impact(s) will occur if consistent and ongoing access is impeded (e.g. drugs

used to treat cancer, life-threatening infections, end stage renal disease, hemophilia, etc.)

b. The Department shall establish a list of the specific drug products and/or categories that are exempt from the ten percent payment reductions and shall:

i. Publish the list online in the Pharmacy section of the Medi-Cal Provider Manual, which can be found by going to www.medi-cal.ca.gov, then selecting Publications>Provider Manuals>Pharmacy>Reimbursement.

ii. Re-evaluate the list of exempted drugs or categories of drugs for additions or deletions as needed, but not less than annually. Whenever a change is made to the list, pharmacy providers will be notified via the next monthly pharmacy provider bulletin and an updated list will be published online.

iii. Establish and publish in its provider manual a process for providers to seek a change to the list of exempted drugs and/or categories of drugs.

2. If a pharmacy provider notifies the Department that they intend to withdraw as a Medi-Cal provider as a result of the ten percent payment reduction for drugs dispensed on or after March 31, 2012 described in Paragraph L, the Department will exempt that provider from the ten percent reduction in payments if the Department determines that doing so is necessary in order to assure beneficiary access consistent with the following geographic metrics:

- In urban areas, at least 90 percent of Medi-Cal beneficiaries, on average, live within 2 miles of a participating retail pharmacy.

- In suburban areas, at least 90 percent of Medi-Cal beneficiaries, on average, live within 5 miles of a participating retail pharmacy.

- In rural areas, at least 70 percent of Medi-Cal beneficiaries, on average, live within 15 miles of a participating retail pharmacy.

a. The start date of exemptions granted pursuant to Paragraph L (2) will be the date the provider requests to be withdrawn as a provider, subject to the Department's determination that such a withdrawal would result in an access issue, per the above stated geographic criteria.

b. At least annually, the Department will review exemptions granted pursuant to Paragraph L (2). If the Department determines that access has been restored consistent with the geographic criteria, (e.g. as a result of new pharmacies being built, or fewer beneficiaries residing in the area), the Department will notify exempted providers that their exemption no longer applies.

3. A complete description of the policies and procedures regarding the Medi-Cal reduction and exemptions described in paragraphs L (1) and (2), including the specific criteria the Department uses to determine the drug products and/or categories of drugs that are exempt from the payment reduction, can be located in the Pharmacy section of the Medi-Cal Provider Manual, by going to www.medi-cal.ca.gov, then selecting Publications>Provider Manuals>Pharmacy>Reimbursement.

M. The Department will monitor the effect of the payment reductions specified in paragraphs J, K and L in accordance with measures #7 and #16 of the monitoring plan at Attachment 4.19-F, entitled "Monitoring Access to Medi-Cal Covered Healthcare Services."

N. 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.

1. 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 fee described in Paragraph B.

a. When determining actual acquisition cost, a covered entity can include shipping and handling charges actually incurred by the covered entity in connection with the purchase of 340B drugs.

b. The covered entity shall reduce from its incurred cost any discounts, rebates, refunds, price reductions or credits actually received by the covered entity, and that are directly attributable to 340B drugs. Costs of the covered entity that are incurred during the dispensing of a drug shall not be used to determine the acquisition cost of a drug.

2. 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 Paragraphs A and B.

3. Drugs billed to Medi-Cal programs by covered entities at an amount not to exceed the actual acquisition cost, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee described in Paragraph B are exempt from legislatively mandated provider payment reductions.

PAYMENT METHODOLOGY FOR PHYSICIAN ADMINISTERED DRUGS

The reimbursement rate for physician administered drugs shall be equal to the Medicare Part B reimbursement rate for drugs and biologicals, when available for a particular product and published by CMS, as described in Section 1847A of the Social Security Act and currently defined as Average Sales Price (ASP) plus 6%.

When a Medicare Part B reimbursement rate is not available or published by CMS for a physician administered drug, the reimbursement rate will be determined as follows:

i. If based on a National Drug Code (NDC), the NDC rate of reimbursement shall be equal to the pharmacy rate of reimbursement, or

ii. If based on a Healthcare Common Procedure Coding System (HCPCS) code, the HCPCS code rate of reimbursement shall be equal to the volume-weighted average of the pharmacy rate of reimbursement for generically equivalent drugs.

Reimbursement for physician administered drugs shall be exempt from legislatively mandated provider payment reductions.

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 authorized the State of California to enter into the Medi-Cal Net Cost Supplemental Drug Rebate Agreement. This supplemental drug rebate agreement was submitted to CMS on December 1, 2014 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.