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State/Territory Name: California

State Plan Amendment (SPA) #: 17-002

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 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



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

Mari Cantwell
State Medicaid Director
1501 Capitol Avenue, Suite 71.326
Sacramento, CA 95899-7417

August 25, 2017

Dear Ms. Cantwell:

We have reviewed California's State Plan Amendment (SPA) 17-0002, Prescribed Drugs, received in the San Francisco Regional Office on May 30, 2017. This SPA proposes to bring California into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

SPA 17-0002 establishes reimbursement for covered outpatient drugs using an actual acquisition cost methodology and implements a professional dispensing fee of \$13.20 for pharmacies with a total of fewer than 90,000 prescription claims annually and \$10.05 for pharmacies with 90,000 or more annual prescription claims. The state provided data and studies to demonstrate that the acquisition cost methodology and pharmacy dispensing fees being paid are sufficient to assure that Medi-Cal beneficiaries will have access to pharmacy services at least to the extent as the general population. This SPA also includes reimbursement methods for 340B drugs and physician-administered drugs. California has yet to formally submit their blood clotting reimbursement methodology, but will do so no later than third quarter 2018.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 17-0002 is approved with an effective date of April 1, 2017. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into California's state plan will be forwarded by the San Francisco Regional Office.

Addendum: This approval letter superseded the SPA approval letter dated August 25, 2017 to account for a typo on Supplement 2 to Attachment 4.19-B, Page 1. Supplement 2 to Attachment 4.19-B, Page 1, section 5(b) on previously submitted SPA page stated "90,000 or more claims= \$10." The corrected version now states "90,000 or more claims= \$10.05"

The correction are of a technical nature only and the effective date and approval date of the SPA remain unchanged.

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

Sincerely,

A large black rectangular redaction box covers the signature of Meagan T. Kato. A handwritten flourish is visible to the right of the redaction.

Meagan T. Kato
Deputy Director
Division of Pharmacy

Cc : Harry Hendrix, Chief, Pharmacy Benefits Division
Henrietta Sam-Louie, CMS Associate Regional IX Administrator
Trudi Balestreri, Project Manager Pharmacy Benefits Division
Cheryl Young, CMS San Francisco Regional Office
Kitaho Kato, CMS San Francisco Regional Office

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

1. TRANSMITTAL NUMBER 17-002	2. STATE CA
3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
4. PROPOSED EFFECTIVE DATE 04/01/2017	

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*)

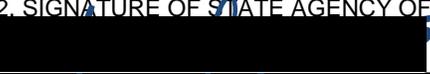
6. FEDERAL STATUTE/REGULATION CITATION 42 CFR Part 447 Subpart I – Payment for Drugs	7. FEDERAL BUDGET IMPACT FFY 2016/17: (\$18 million) savings FFY 2017/18: (\$36 million) savings
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Supplement 2 to ATTACHMENT 4.19-B, pages 1-10	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>) Supplement 2 to ATTACHMENT 4.19-B, pages 1-10

10. SUBJECT OF AMENDMENT

Proposed Changes to Pharmacy Reimbursement for Covered Outpatient Drugs

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

- GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED The Governor's Office does not wish to
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL review the State Plan Amendment

12. SIGNATURE OF STATE AGENCY OFFICIAL 	16. RETURN TO Department of Health Care Services Attn: State Plan Coordinator 1501 Capitol Avenue, Suite 71.326 P.O. Box 997417 Sacramento, CA 95899-7417
13. TYPED NAME Mari Cantwell	
14. TITLE State Medicaid Director	
15. DATE SUBMITTED May 30, 2017	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED May 30, 2017	18. DATE APPROVED August 25, 2017
PLAN APPROVED - ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL April 1, 2017	20. SIGNATURE OF REGIONAL OFFICIAL /s/
21. TYPED NAME Henrietta Sam Louie	22. TITLE Associate Regional Administrator

23. REMARKS

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).

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

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

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.

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

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METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

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:

- If based on a National Drug Code (NDC), the NDC rate of reimbursement shall be equal to the drug's ingredient cost, as described in Paragraph 4 of this supplement, or
- 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 drug's ingredient cost for generically equivalent drugs as described in Paragraph 4 of this supplement.

For physician administered 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.