



DAVID MAXWELL-JOLLY
Director

State of California—Health and Human Services Agency
Department of Health Care Services



ARNOLD SCHWARZENEGGER
Governor

October 5, 2009

Ms. Gloria Nagle
Associate Regional Administrator
Centers for Medicare and Medicaid Services
Division of Medicaid and Children's Health
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

Dear Ms. Nagle,

STATE PLAN AMENDMENT 09-021

Enclosed is the State Plan Amendment (SPA) 09-021, Supplement 2, Attachment 4.19B, (Page 1-11), CMS Form 179, Transmittal and Notice of Approval of State Plan Material, and SPA Impact form for your review and approval. Also included are copies of the California Regulatory Notice Register and provider bulletins announcing the changes to the program.

Pursuant to Medicaid Program Memorandum 93-1, California is required to complete and return to the Centers for Medicare & Medicaid Services (CMS) the enclosed State Plan Preprint.

The preprint incorporates modifications in the methodology utilized by the State Agency in compliance with Title 42 Code of Federal Regulations, C.F.R. Sections 447.331 AND 447.332, in establishing payment rates for Pharmaceutical Services (pharmacy dispensing fees) and Prescribed Drugs (dispensed drug products).

In accordance with 42 C.F.R. Section 447.333, the state makes the following findings and assurances:

1. Finding: To the best of our knowledge at this time, in the aggregate, Medicaid expenditures for multiple source drugs, identified and listed in accordance with 42 C.F.R. Section 447.332(a) are in accordance with the upper limits specified in 42 C.F.R. Section 447.332(b).

2. Finding: Medicaid expenditures for all "other drugs" are in accordance with the respective requirements of 42 C.F.R. § 447.331.
3. Assurances: The State acknowledges, and hereby provides assurance to CMS that:
 - a. For multiple source drugs, the State will annually assure that the requirements set forth in 42 C.F.R. Sections 447.331(a) and 447.332 concerning upper limits and in Section 447.333(b)(1) concerning agency findings are met; and
 - b. For "other drugs," the State will assure triennially that the requirements set forth in 42 C.F.R. § 447.331(b) concerning upper limits and in Section 447.333(b)(1) concerning agency findings are met.

If you have questions or need additional information, please contact Ms. Pilar Williams, Chief, Pharmacy Benefits Division, at (916) 552-9500.

Sincerely,



Toby Douglas
Chief Deputy Director
Health Care Programs

Enclosures

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

1. TRANSMITTAL NUMBER <u>09 — 02 1</u>	2. STATE CA
3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	

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

4. PROPOSED EFFECTIVE DATE
October 1, 2009

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

7. FEDERAL BUDGET IMPACT

a. FFY No Impact \$ _____

b. FFY _____ \$ _____

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Supplement 2, Attachment 4.19B Pages 1-11

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (*If Applicable*)

Replace pp 1-11 of TN 08-009B2

10. SUBJECT OF AMENDMENT

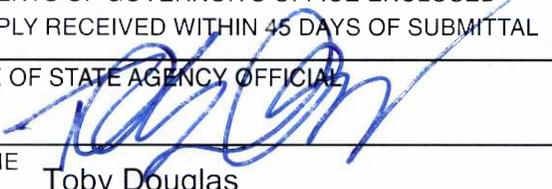
2009 Budget Act Changes to Billing Requirements and Reimbursement of Drugs

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 review state plan amendments

NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL


13. TYPED NAME
Toby Douglas

14. TITLE
Chief Deputy Director, Health Care Program

15. DATE SUBMITTED

16. RETURN TO

Department of Health Care Services
ATTN: State Plan Coordinator
1501 Capitol Ave, Ste 71-4083
P. O. Box 997413, MS 4600
Sacramento, CA 95899-7413

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED

18. DATE APPROVED

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

21. TYPED NAME

23. REMARKS

20. SIGNATURE OF REGIONAL OFFICIAL

22. TITLE

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

PAYMENT METHODOLOGY FOR PRESCRIPTION DRUGS

The policy of the State Agency is that reimbursement for Pharmaceutical Services and Prescribed Drugs, as one category of health care or service from among those listed in Section 1905(a) of the Social Security Act that are included in the program under the plan, will be at the provider pharmacy's current charges to the general public, up to the State Agency's limits. The price providers charge to the program shall not exceed that charged to the general public. The pharmacist, to the extent permitted by law, shall dispense the lowest cost, therapeutically equivalent drug product that the pharmacy has in stock, which meets the medical needs of the beneficiary.

The methodology utilized by the State Agency, in compliance with 42 C.F.R. §§ 447.331 and 447.332, in establishing payment rates for Pharmaceutical Services (pharmacy dispensing fees) and Prescribed Drugs (dispensed drug products) to implement the policy is as follows:

- A.1. The method used to establish maximum drug product payments is that payments for drugs dispensed by pharmacists shall consist of the state's Estimated Acquisition Cost (EAC) of the drug product dispensed plus a dispensing fee that is added to the drug product payment (see paragraph B below). The EAC is the lowest of the Average Wholesale Price (AWP) minus 17 percent, the Maximum Allowable Ingredient Cost (MAIC); the federal upper limit of reimbursement for listed multiple source drugs (called "Federal Upper Limit," or FUL), or the provider's usual and customary charge to the public.
2. The amount of payment for dispensed drug products as described in paragraph A.1 above will be reduced by ten percent effective July 1, 2008,

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through and including February 28, 2009.

3. The amount of payment for dispensed drug products as described in paragraph A.1 and provided on or after March 1, 2009, will be reduced by five percent.

- B.1. The professional fee for dispensing is seven dollars and 25 cents (\$7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility is eight dollars (\$8.00) per dispensed prescription. For the purposes of this paragraph B, "skilled nursing facility" and "intermediate care facility" mean as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

2. The amount of payment for the professional fee as described in paragraph B.1 above will be reduced by ten percent effective July 1, 2008, through and including February 28, 2009.

3. The amount of payment for the professional fee as described in paragraph B.1 and provided on or after March 1, 2009, will be reduced by five percent.

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- C. For purposes of this Supplement 2, the following definitions apply:
- "Average wholesale price" means the price for a drug product listed as the average wholesale price in the department's primary price reference source.
 - "Direct price" means the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source.
 - "Federal upper limit" means the maximum per unit reimbursement when established by the Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.
 - "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.
 - "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

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- "Maximum Allowable Ingredient Cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

- "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code, the National Rebate Agreement, and other Federal instructions.

- "Nonlegend drug" means any drug whose labeling does not contain one or more of the statements required to be a "legend drug".

- "Usual and customary charge" means the lower of the following:
 1. The lowest price reimbursed to the pharmacy by other third-arty payers in California, excluding Medi-Cal managed care plans and Medicare Part D prescription drug plans.
 2. The lowest price routinely offered to any segment of the general public
 3. Donations or discounts provided to a charitable organization are not considered usual and customary

- "Wholesaler Acquisition Cost" (WAC) means the price for a drug product listed as the wholesaler acquisition cost in the department's primary price reference source.

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- D. For purposes of paragraph A, the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in Medi-Cal pharmacy provider bulletins and manuals. The department will update the list of MAICs and establish additional MAICs in accordance with the following:
- The department shall establish the estimated acquisition cost of legend and nonlegend drugs as follows:
 1. For single source and innovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, the federal upper limit, or the MAIC.
 2. For noninnovator multiple source drugs, the estimated acquisition cost shall be equal to the lowest of the average wholesale price minus 17 percent, the selling price, the federal upper limit, or the MAIC.
 - For purposes of paragraph (2), the department shall establish:
 1. a list of MAICs for generically equivalent drugs, which shall be published in pharmacy provider bulletins and manuals. The department shall establish a MAIC only when three or more generically equivalent drugs are available for purchase and dispensing by retail pharmacies in California. The department

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expedited process for contracts under this section is necessary. Therefore, contracts entered into on a nonbid basis shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

- The department will update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.
- The department will base the MAIC on the mean of the average manufacturer's price of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California. If average manufacturer prices are unavailable, the department shall establish the MAIC in either of the following ways:
 - Based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the department to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California.
 - Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.

E. The federal upper limits of reimbursement, FUL, are initiated by CMS and provided to the State Agency for implementation in the State Medicaid

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Manual of Instructions. Periodic revisions to Addendum A of Section 6305.3 of the Manual, which is the list of multiple source drugs and the FUL prices, are implemented by the State Agency following notice by CMS of new FUL prices. New FUL prices are implemented within the timeframe required by the CMS notice and as required by applicable California statutes and regulations.

- F. Overrides to both the state and federal price ceilings are available only through a state prior approval mechanism. Prior approval is limited to those cases where the medical necessity of a specific manufacturer's brand of a drug, priced above the ceiling, is adequately demonstrated to a state consultant. The documentation of the approval is linked to the claims payment system assuring correct reimbursement for the brand dispensed. The same system is used for approval and payment for drugs not on the state Medicaid Drug Formulary, known as the Medi-Cal List of Contract Drugs.
- G. 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. A covered entity is also required to bill an amount not to exceed the entity's actual acquisition cost for the drug plus the professional fee or dispensing fee set by the Medi-Cal program. A covered entity can include shipping and handling charges actually incurred by the covered entity in connection with the purchase of 340B drugs. The covered entity shall exclude from its incurred cost any

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discounts, rebates, refunds, price reductions or credits actually received by the covered entity, and that are directly attributable 340B drugs.

- H. The Medi-Cal List of Contract Drugs (List), a preferred drug list, is established pursuant to Section 1927 of the Social Security Act with prior authorization required for drugs not included on the List. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations. Prior authorization is applied to certain drug classes, particular drugs, or medically accepted indications for use and doses. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.
- I. The Medicaid program restricts coverage of certain covered outpatient drugs through the operation of a prior authorization program. The prior authorization process provides for a turn-around response by telephone, fax, or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a 72-hour supply of medications in accordance with the provisions of Section 1927(d)(5) of the Social Security Act.
- J. 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.

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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 30, 2005 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 30, 2005 and has been authorized by CMS.

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

TN No. 09-021
Supersedes
TN No. 08-009B2

Approval Date _____

Effective Date: October 1, 2009