DHCS
TOBY DOUGLAS
DIRECTOR

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

EDMUND G. BROWN JR.
GOVERNOR

MAR 3 0 2012

Gloria Nagle, Ph.D., MPA
Associate Regional Administrator
Division of Medicaid and Children's Health Operations
Centers for Medicare and Medicaid Services, Region IX
90 Seventh Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

Dear Ms. Nagle:

The Department of Health Care Services' (DHCS) proposed State Plan Amendment (SPA) 12-014, "Implementing drug product payment reductions" with a requested effective date of March 31, 2012, is enclosed for your review and approval.

Assembly Bill (AB) 97, Section 93.5 of the Statutes of 2011, authorized DHCS to implement payment reductions for Medi-Cal outpatient services up to 10 percent, in the aggregate, for dates of service on or after June 1, 2011. The statute authorizes DHCS to implement the reductions only to the extent DHCS determines the reduced payments, which result from the reductions, comply with applicable federal Medicaid requirements, including 42 United States Code Section 1396a(a)(30)(A) and that federal financial participation will be available.

On October 27, 2011, the Centers for Medicare and Medicaid Services (CMS) approved SPA 11-009, which provides for 10 percent provider payment reductions, effective June 1, 2011. SPA 11-009 also states DHCS will monitor the effect of the payment reductions in accordance with its monitoring plan entitled, "Monitoring Access to Medi-Cal Covered Healthcare Services."

Based on preliminary information, as well as input from pharmacy providers received subsequent to CMS's approval of the 10 percent payment reduction, DHCS believes that for selected specific drug products, or for specific types of providers, or in specific geographic areas, such a reduction may impede access to selected Medi-Cal drug benefits and possibly result in a violation of federal Medicaid requirements.

Proposed SPA 12-014 incorporates language that will provide DHCS the flexibility to adjust drug product payments in a manner that will result in an aggregate savings of no more than 10 percent while providing access consistent with federal Medicaid requirements. Public notice of DHCS' intent to implement this change will appear in the March 30, 2012, issue of the California Regulatory Notice Register.

Indian Health Programs and Urban Indian Organizations were provided notification by way of a Tribal Organizational Summary detailing the provisions of proposed SPA 12-014 on February 14, 2012, and were given the opportunity to comment on this proposal. In addition, a teleconference was held for Tribal Organizations on February 29, 2012, during which the proposal was reviewed and an opportunity for comment was provided.

If you have questions or need additional information, please contact Harry Hendrix, Acting Chief, Pharmacy Benefits Division, at (916) 552-9500 or by email at harry.hendrix@dhcs.ca.gov.

Sincerely,

Toby Douglas
Director

Enclosures

cc: Carolyn Kenline
California State Representative
Division of Medicaid and Children's Health Operations
Centers for Medicare and Medicaid Services, Region IX
90 Seventh Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

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: 12-014

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
March 31, 2012

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 **11-12** **$29 million (6 months)**
b. FFY **12-13** **$58 million**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Supplement 2 to Attachment 4.19-B, page 8, 9

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Supplement 2 to Attachment 4.19-B, page 9

10. SUBJECT OF AMENDMENT:
Implementing drug product payment reductions. (Note: The figures in box #7, "Federal Budget Impact" are the amounts by which drug product payment savings previously assumed as a result of the 10% payment reductions will be reduced.)

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:

13. TYPED NAME:
Toby Douglas

14. TITLE:
Director

15. DATE SUBMITTED: MAR 3 0 2012

16. RETURN TO:

Department of Health Care Services
Attn: State Plan Coordinator
1501 Capitol Avenue, Suite 71.3.26
P.O. Box 997417
Sacramento, CA 95899-7417

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

18. DATE APPROVED:

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

22. TITLE:

23. REMARKS:

FORM HCFA-179 (07-92)

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: CALIFORNIA

METHODS AND STANDARDS FOR ESTABLISINGPAYMENT RATES–PRESCRIBED DRUGS

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 will be reduced by an amount that does not exceed ten percent. The Department may adjust the payments with respect to one or more drug products to impose a reduction of less than 10 percent to assure that such reductions result in payments consistent with applicable federal Medicaid requirements. The Department shall base any decision to adjust a drug product or provider payment reduction on either of the following factors:

1. For drugs within the following categories, a 10 percent payment reduction will result in reimbursement less than actual acquisition cost and as a result, may negatively impact beneficiary access:

   - Drugs purchased through the 340B program
   - Physician Administered Drugs
   - Blood factors
   - Drugs to treat pulmonary hypertension
   - Drugs to treat immunodeficiency (HIV/AIDS)
     1. Nucleoside-Nucleotide Analog
     2. Protease Inhibitors
   - Drugs to treat errors of metabolism
   - Growth hormones
   - Anti-inflammatory tumor necrosis factor inhibitors
   - Hepatitis C drugs
   - Antineoplastic
   - Anti-rejection drugs
   - Drugs to treat multiple sclerosis
   - Antiviral Monoclonal antibodies
   - Mental health drugs

2) The Department may reduce payments to specific providers by less than 10 percent if providers submit verifiable pricing information sufficient to demonstrate that the 10 percent reduction will reduce beneficiary access to pharmacy services in a specific area as determined by the following threshold metrics ;

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

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –PRESCRIBED DRUGS

- 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.

M. For purposes of making adjustments to provider payment reductions as described in Paragraph L:

1. The Department may require pharmacy providers to submit timely, accurate, reliable, verifiable pricing information for drug products within any of the identified categories sufficient to demonstrate that the reduction will result in reimbursement below actual acquisition cost for that product and as a result, negatively impact beneficiary access; and

2. The Department shall establish a list of specific drug products, identified by National Drug Codes (NDCs) and/or providers subject to a modified payment reduction and the amount of modification.

   a. The Department shall update and maintain the NDC drug product list based on actual acquisition cost data received by the Department in the previous quarter prior to the last published NDC list.
   b. The Department shall notify providers at least 30 days prior to the effective date of any change in payment reduction.
   c. The Department shall update and publish the above list at least on a quarterly basis.

N. The Department will monitor the effect of the payment reductions specified in paragraphs K and L in accordance with the monitoring plan at Attachment 4.19-F, entitled “Monitoring Access to Medi-Cal Covered Healthcare Services.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: CALIFORNIA

METHODS AND STANDARDS FOR ESTABLISINGPAYMENT RATES–PRESCRIBED DRUGS

~~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.~~

Comment [tam (PBD)1]: We need to make sure that CMS knows that we ONLY wish to remove these paragraphs because they are duplicates of paragraphs H and I on pages 5 and 6 of the existing approved state plan.

~~K.~~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.

~~L.~~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 will be reduced by an amount that does not exceed ten percent. The Department may adjust the payments with respect to one or more drug products to impose a reduction of less than 10 percent to assure that such reductions result in payments consistent with applicable federal Medicaid requirements. The Department shall base any decision to adjust a drug product or provider payment reduction on either of the following factors:

1. For drugs within the following categories, a 10 percent payment reduction will result in reimbursement less than actual acquisition cost and as a result, may negatively impact beneficiary access:

   - Drugs purchased through the 340B program
   - Physician Administered Drugs
   - Blood factors
   - Drugs to treat pulmonary hypertension
   - Drugs to treat immunodeficiency (HIV/AIDS)
     1. Nucleoside-Nucleotide Analog
     2. Protease Inhibitors
   - Drugs to treat errors of metabolism
   - Growth hormones
   - Anti-inflammatory tumor necrosis factor inhibitors
   - Hepatitis C drugs
   - Antineoplastic
   - Anti-rejection drugs

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –PRESCRIBED DRUGS

- Drugs to treat multiple sclerosis
- Antiviral Monoclonal antibodies
- Mental health drugs

2) The Department may reduce payments to specific providers by less than 10 percent if providers submit verifiable pricing information sufficient to demonstrate that the 10 percent reduction will reduce beneficiary access to pharmacy services in a specific area as determined by the following threshold 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.

M. For purposes of making adjustments to provider payment reductions as described in Paragraph L:

1. The Department may require pharmacy providers to submit timely, accurate, reliable, verifiable pricing information for drug products within any of the identified categories sufficient to demonstrate that the reduction will result in reimbursement below actual acquisition cost for that product and as a result, negatively impact beneficiary access; and

2. The Department shall establish a list of specific drug products, identified by National Drug Codes (NDCs) and/or providers subject to a modified payment reduction and the amount of modification.

   a. The Department shall update and maintain the NDC drug product list based on actual acquisition cost data received by the Department in the previous quarter prior to the last published NDC list.
   b. The Department shall notify providers at least 30 days prior to the effective date of any change in payment reduction.
   c. The Department shall update and publish the above list at least on a quarterly basis.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and CHIP Services
Disabled and Elderly Health Programs Group

JUN 2 7 2012

RECEIVED
JUL 0 2 2012
By

Toby Douglas
Director, California Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Mr. Douglas:

We have reviewed California State Amendment (SPA) 12-014, Implementing drug product payment reductions, received in the Regional Office on March 30, 2012. This amendment proposes that the payment for drug products dispensed on or after June 1, 2011 will be reduced by an amount that does not exceed ten percent. The Department may adjust the payments with respect to one or more drug products to impose a reduction of less than ten percent to assure that such reductions result in payments consistent with applicable federal Medicaid requirements. The State has requested an effective date of March 31, 2012 for this amendment.

While we appreciate the State's responses to informal questions, before we can continue processing the SPA, we need clarifying information regarding the State's documentation to support the proposed changes. We have reviewed your proposal and are unable to approve it as submitted. Therefore, we are requesting additional information pursuant to Section 1915(f) of the Social Security Act.

Supplement 2 to Attachment 4.19-B- Methods and Standards for Establishing Payment Rates-Prescribed Drugs

1. On the CMS 179 Form, the State requested an effective date of March 31, 2012. It appears that the State plans to implement payment reductions for Medi-Cal outpatient services up to 10 percent, in the aggregate, for dates of service on or after June 1, 2011. Please confirm that the effective date of this SPA is March 31, 2012 and provide the corrected SPA pages.

2. Under K.1, please explain the difference between adjusting a drug product and a provider payment and when each would be applied.

3. Under K.1, the SPA lists several categories of drugs to be exempt from the ten percent rate reduction. Please discuss how the State will make changes to the specific drug categories when changes are made.

4. In the informal responses, the State indicated that, "For cases in which the 10 percent reduction would result in reimbursement levels below the average acquisition cost for individual drugs within one of these categories, the State intends to adjust the reduction so that the reimbursement level provided shall be no lower than the average acquisition

so that the reimbursement level provided shall be no lower than the average acquisition cost, as validated and verified by the DHCS using provider submitted pricing information (e.g. invoices) and additional available pricing benchmark information (e.g. NADAC, NARP, AMP, wAMP)."

The above statement appears that it may be used to describe the State's pharmacy reimbursement methodology for these specific categories of drugs. We recommend that the State document this methodology in the State plan.

5. On page 9, under M, the new proposed language states, "For purposes of making adjustments to provider payment reductions as described in Paragraph L:" Please change the letter "L" to "K".

6. On page 9, the State indicates that the Department may reduce payments to specific providers by less than 10 percent. In the State's response to informal questions, it was indicated that the State would modify the SPA language to use the word "will." Please provide a revised SPA page that documents the change.

7. On page 9, the State indicates that the Department may require pharmacy providers to submit timely, accurate, reliable, verifiable pricing information for drug products within any of the identified categories sufficient to demonstrate that the reduction will result in reimbursement below actual acquisition cost for that product and as a result negatively impact beneficiary access. Please provide a revised SPA page that changes the word "may" to "will".

   In the informal responses, the State indicated that it is not considering changing the pharmacy Measure #7: Pharmacy Participation rates and Measure #16: Service Rates per 1,000 Member Months as listed in the monitoring plan entitled, "Monitoring Access to Medi-Cal Covered Healthcare Services" as approved by CMS in SPA CA-11-009. Please discuss how these two specific measures will monitor beneficiary access.

This request for additional information (RAI) is made pursuant to Section 1915(f) of the Social Security Act and will stop the 90-day period for CMS' review and approval of a SPA. Upon receipt of your additional information, a new 90-day period will begin. In accordance with our guidelines to all State Medicaid Directors, dated January 2, 2001, we request that you provide a formal response to this RAI no later than 90 days from the date of this letter. If you do not provide us with a formal response by that date, we will conclude that the State has not established that the proposed SPA is consistent with all statutory and regulatory requirements and may initiate disapproval action on the amendment.

Because this amendment was submitted after January 2, 2001 and is effective on or after January 1, 2001, please be advised that we will defer FFP for State payments made in accordance with this amendment until it is approved. Upon approval, FFP will be available for the period beginning with the effective date through the date of actual approval.

We ask that you respond to this RAI via the San Francisco Regional Office SPA/Waiver mail box at SPA_Waivers_SanFrancisco_R09@cms.hhs.gov. In addition, please send hard copies to the San Francisco Regional Office and to me at the address above.

If you have any questions regarding this request, please contact Angel Davis at (410) 786-4693.

Sincerely,

Larry Reed
Director
Division of Pharmacy

cc: Harry Hendrix, California Department of Health Care Services
Teresa Miller, California Department of Health Care Services
Gloria Nagle, ARA, DMCHO, San Francisco Regional Office
Kristin Dillon, San Francisco Regional Office