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

January 30, 2014

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's State Plan Amendment (SPA) 12-014, received in the San Francisco Regional Office on March 30, 2012. This proposed SPA would increase the payment rate for specific drugs, categories of drugs and certain pharmacies, effective March 31, 2012. In effect, SPA 12-014 would reverse, in certain circumstances, the ten percent payment reduction that was approved through SPA 11-009, which became effective on June 1, 2011, for specific drug products and/or categories of drugs and pharmacies. Subsequent to our approval of SPA 11-009, the state received additional information from pharmacy providers identifying specific drugs and drug categories for which the ten percent rate reduction would result in reimbursement below their cost to acquire those drugs. Specifically, providers expressed concern that they might not be able to continue to furnish specific drugs and/or categories to Medi-Cal beneficiaries. In response to this new information, the state submitted SPA 12-014. Under the proposed SPA, the state would exempt specific drug products and/or categories of drugs from the ten percent reduction if the state determines that such a reduction would result in reimbursement less than actual acquisition costs or if beneficiary access issues arise, based on clinical conditions, provider invoice information, or wholesaler cost information. The state would also monitor pharmacy provider participation rates, by geographic area, based on Medi-Cal utilization and increase rates if the state determines that an increase is appropriate.

While we review proposed SPAs to ensure their consistency with the relevant provisions of the Social Security Act (the Act), we conducted our review of your submittal with particular attention to the statutory requirements at section 1902(a)(30)(A) of the Act ("Section 30(A)"). Section 30(A) of the Medicaid Act requires that state plans contain "methods and procedures . . . to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A). As we explain in greater detail below, we find that the state's proposed SPA is consistent with the requirements of the Act, including those set forth in Section (30)(A).

States must submit information sufficient to allow CMS to determine whether a proposed amendment to a state plan is consistent with the requirements of section 1902 of the Act. However, consistent with the statutory text, CMS does not require a state to submit any particular type of data, such as provider cost studies, to demonstrate compliance. *See* Proposed Rule, Dep't of Health & Human Servs., Ctrs. For Medicare & Medicaid Servs., 76 Fed. Reg. 26342, 26344 (May 6, 2011). Rather, as explained in more detail in the May 6, 2011 proposed rule, CMS believes that the appropriate focus of Section(30)(A) is on beneficiary access to quality care and services. CMS has followed this interpretation for many years when reviewing proposed SPAs.[1]

This interpretation---which declines to adopt a bright line rule requiring the submission of provider cost studies---is consistent with the text of Section 30(A) for several reasons. First, Section 30(A) does not mention the submission of any particular type of data or provider costs; the focus of the Section is instead on the availability of services generally. Second, the Medicaid Act defines the "medical assistance" provided under the Act to mean "payment of *part* or all of the cost" of the covered service. *See* 42 U.S.C. § 1396d(a) (emphasis added). Third, when Congress has intended to require states to base Medicaid payment rates on the costs incurred in providing a particular service, it has said so expressly in the text of the Act. For example, the now-repealed Boren Amendment to the Medicaid Act required states to make payments based on rates that "are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities." 42 U.S.C. § 1396a(a)(13)(A). By contrast, Section 30(A) does not set forth any requirement that a state consider costs in making payments. Finally, CMS observes that several federal courts of appeals have interpreted Section 30(A) to give states flexibility in demonstrating compliance with the provision's access requirement and have held that provider costs need not always be considered when evaluating a proposed SPA. *See Managed Pharmacy Care v. Sebelius, 716 F.3d 1235 (9th Cir. 2013); Rite Aid of Pa., Inc. v. Houstoun*, 171 F.3d 842, 853 (3d Cir. 1999); *Methodist Hosps., Inc. v. Sullivan*, 91 F.3d 1026, 1030 (7th Cir. 1996); *Minn. Homecare Ass'n v. Gomez*, 108 F.3d 917, 918 (8th Cir. 1997) (per curiam). These decisions suggest that CMS's interpretation of Section 30(A) is a reasonable one. CMS's interpretation does not, of course, *prevent* states or CMS from considering provider costs.[2]

The state furnished documentation and new information which CMS evaluated in the course of its SPA review. In particular, CMS relied on the following factors identified by the state as justification for the proposed SPA's compliance with Section (30)(A)'s access requirement:

- The state collaborated with providers and issued a Public Notice and Consultation Meeting with Tribes.
- The state identified specific criteria that it will use when determining whether to exempt either a drug product, a therapeutic category of drugs, or a pharmacy provider from the ten percent pharmacy provider payment reduction. The state indicated that a single pharmacy provider submission could serve as a trigger for evaluation to determine whether a drug or provider should be exempt from the ten percent reduction. The state informed CMS that they will also monitor the effect of the payment reductions as specified in the monitoring plan, entitled "Monitoring Access to Medi-Cal Covered Healthcare Services".

[1] *See, e.g.*, Br. of the United States as Amicus Curiae, *Douglas v. Independent Living Ctr.*, No. 09-958, at 9-10 (2010); Br. of United States as Amicus Curiae, *Belshe v. Orthopaedic Hosp.*, 1997 WL 33561790, at *6-*12 (1997).

[2] CMS also reserves the right to insist on cost studies to show compliance with Section 30(A) in certain limited circumstances – particularly when considering a SPA that involves reimbursement rates that are substantially higher than the cost of providing services, thus implicating concerns about efficiency and economy.

- The state delineated that they will re-evaluate the list of exempted drugs or categories of drugs for additions or deletions from the list. The state also specified that it will notify the pharmacy providers of any changes to the list via the monthly pharmacy provider bulletin and providers could find information regarding the current exemptions in the provider manual on the state's website. The state indicated that the methodology used by the state to identify exempted drugs was developed in collaboration with pharmacy providers and stakeholders and that the process for considering exemption request would be based on provider invoices, as well as, Medi-Cal claims data, to determine if the ten percent reduction would result in reimbursement below the actual acquisition cost. The state indicated that a drug or categories of drugs meeting the following criteria would be considered for exemption: 1) Drugs for which documentation exists that the ten percent reduction will result in reimbursement below the acquisition cost generally available to the Medi-Cal pharmacy provider community, 2) Drugs that are only dispensed through limited or specialized networks of pharmacy providers, 3) Drugs that are used to treat unique clinical conditions with relatively low prevalence in the Medi-Cal population, and 4) 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.). The state also indicated that it would re-evaluate and modify the exempted drug list as needed, in response to a provider request, in order to preserve beneficiary access.
- The state provided rationale for the use of measures of beneficiary access by geographic distribution and participation. The geographic measures, which were developed based on Medi-Cal claims data and Department of Consumer Affairs Board of Pharmacy Licensing data, serve as a trigger for the state to further investigate whether the Medi-Cal pharmacy networks are sufficient to assure beneficiary access consistent with the following geographic metrics: 1) In urban areas, at least 90 percent of Medi-Cal beneficiaries, on average, live within 2 miles of a participating retail pharmacy; 2) In suburban areas, at least 90 percent of Medi-Cal beneficiaries, on average, live within 5 miles of a participating retail pharmacy; and 3) In rural areas, at least 70 percent of Medi-Cal beneficiaries, on average, live within 15 miles of a participating retail pharmacy. The state indicated that it will review provider exemptions at least annually in order to determine if access has been restored and it will monitor the effect of the payment reduction in accordance with the "Monitoring Access to Medi-Cal Covered Healthcare Services" plan.

Applying our interpretation of Section (30)(A) to this proposed SPA, we believe that the information that the state has provided, as described above, is sufficient to support its proposed payment change. Although Section (30)(A) of the Act does not require states to base payment rates on the costs incurred by providers, the payment proposal is designed to provide payment based on information concerning acquisition cost of the drugs subject to this proposed SPA. We believe that the criteria are reasonable because the state has identified specific drug categories and drugs which pharmacy providers might not be able to acquire at the reduced rate. Accordingly, we believe the state plan, as modified by the proposed SPA, will ensure access consistent with Section (30)(A).

We also conclude that the proposed SPA is consistent with the efficiency and economy requirements in Section (30)(A) of the Act. We have generally considered a proposed payment rate as being inefficient or uneconomical if it was substantially above the cost of providing covered services. *See Pa. Pharmacists Ass'n v. Houstoun*, 283 F.3d 531, 537 (3d Cir. 2002) ("What sort of payments would make a program inefficient and uneconomical? Payments that are *too high*."). For this reason we do not believe that it is appropriate for states to address potential access concerns by setting rates unreasonably high in relation to costs—such rates would necessarily be neither efficient nor economical. Consistent with this view, HHS

has promulgated Upper Payment Limit ("UPL") regulations that "place an upper limit on overall aggregate payments" for certain types of services. 65 Fed. Reg. 60151-01. Applying our interpretation of the statute to the proposed SPA at issue here, we believe payment under the state plan, as increased in this SPA, will be both economical and efficient, as doing so ensures that providers are not paid substantially in excess of their costs.

Furthermore, we conclude that that the proposed payment methodology is consistent with the quality of care requirement in Section (30)(A) of the Act. CMS does not interpret Section (30)(A) of the Act as requiring a state plan by itself to ensure quality of care. As the text of the statute reflects, payments must be "consistent" with quality of care, but they do not need to directly assure quality of care by themselves. CMS therefore believes that Section 30(A) leaves room to rely on factors external to a state plan to ensure quality of care. In this particular instance, for example, CMS relies on applicable statutes and regulations, including those promulgated by the Food and Drug Administration, to ensure the quality of covered outpatient drugs provided through the Medicaid program. CMS believes that it is reasonable to assume that covered outpatient drugs provided to Medicaid patients by pharmacy providers will continue to meet FDA quality standards.

Finally, the state plan's proposed effective date is permissible under the Medicare regulations. Consistent with 42 C.F.R. § 430.20 and 42 C.F.R. § 447.256, a SPA that is approved may become effective as early as the first day of the quarter in which the amendment is submitted; however, Federal Financial Participation is not available until the SPA is approved (we note that annual appropriations statutes make Federal Financial Participation available as of the first day of the quarter in which a SPA is submitted.).

Based on the foregoing, we believe the state has demonstrated that proposed payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and service are available to the general population in the geographic area.

Because we find that this amendment complies with all applicable requirements, we are pleased to inform you that the California SPA 12-014 is approved, effective March 31, 2012. A copy of the 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 approval, please contact Delaine Deardorff-Beck at (410)-786-2991.

Sincerely,

/s/

Kim Howell
Acting Director
Division of Pharmacy

cc: Gloria Nagle, ARA, DMCHO, San Francisco Regional Office
Harry Hendrix, California Department of Health Care Services
Kathryn Waje, California Department of Health Care Services
Tyler Sadwith, San Francisco Regional Office

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
03/31/2012

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) $36 million**
b. FFY **12-13** ~~**$58 million**~~ **$72 million**

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

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Supplement 2 to Attachment 4.19-B, page 9 **(superseded)**
Pages 8 and 9a (new)

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:
Original Copy Signed by Toby Douglas

13. TYPED NAME:
Toby Douglas

14. TITLE:
Director

15. DATE SUBMITTED:
March 30, 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:
3/30/3012

18. DATE APPROVED:
1/30/2014 January 30, 2014

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
1/31/2012 March 31, 2012

20. SIGNATURE OF REGIONAL OFFICIAL:
Original Copy Signed By:

21. TYPED NAME:
Gloria Nagle, PH.D., MPA Gloria Nagle, Ph. D, MPA

22. TITLE:
Associate Regional Administrator Associate Regional Administrator

23. REMARKS:

FORM HCFA-179 (07-92)

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES–PRESCRIBED DRUGS

J. 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.

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 March 1, 2011, through and including May 31, 2011, will be reduced by five 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 June 1, 2011 and through March 30, 2012 will be reduced by ten percent.

M. 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 M 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 M 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:

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES–PRESCRIBED DRUGS

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 M, 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 M (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 M (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 M (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

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES–PRESCRIBED DRUGS

the Pharmacy section of the Medi-Cal Provider Manual, by going to www.medi-cal.ca.gov, then selecting Publications>Provider Manuals>Pharmacy>Reimbursement.

N. The Department will monitor the effect of the payment reductions specified in paragraphs K, L and M 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."

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