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State/Territory Name: California

State Plan Amendment (SPA) #: 09-021B

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved SPA Pages



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:

I am responding to your request to approve California's SPA (SPA) 09-21B, originally received in the San Francisco Regional Office on October 12, 2009 as SPA 09-21. On December 18, 2009, CMS issued a formal request for additional information for SPA 09-21. On November 23, 2011, the state requested that SPA 09-021 be divided into two separate SPAs; 09-021A and 09-021B. We have reviewed the formal response you submitted to the San Francisco Regional Office on November 1, 2013 regarding the questions that pertain to SPA 09-21B. This SPA would provide Medi-Cal providers that are qualifying 340B eligible covered entities and purchase drugs through the 340B drug pricing program to bill an amount not to exceed the entity's actual acquisition cost for the drug plus a professional fee for dispensing of \$7.25. The SPA would also require covered entities to dispense only 340B-purchased drugs to Medi-Cal beneficiaries who are eligible to receive 340B drugs, unless the covered entity is unable to purchase a specific drug through the 340B program (e.g., for certain covered entities, orphan drugs are excluded from the 340B program when used for the indicated orphan designation). In that case, the covered entity can dispense the non-340B drug and be reimbursed at the state plan rate.

Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara County*, 131 S. Ct. 1342, 1345 (2011). The 340B program requires manufacturers to enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services. Under the 340B program and in accordance with the PPA, pharmaceutical manufacturers agree to charge at or below statutorily defined prices, known as the 340B ceiling prices, for sales to qualified 340B entities. The Health Resources and Services Administration (HRSA) oversees the 340B Program, which includes monitoring the PPA. Participation in the 340B program is voluntary; eligible entities must notify HRSA of their intention to participate by completing appropriate registration forms. Upon receipt and approval of the forms, HRSA adds the entity to its covered entity database, which is available on HRSA's web site. The 340B entity is responsible for alerting wholesalers and manufacturers of its participation and referring them to the database for confirmation so it can purchase covered outpatient drugs at or below the ceiling prices.

California's Welfare and Institutions (W&I) Code provided the Department of Health Care Services (DHCS) with the authority to require that 340B providers bill at their acquisition cost. More specifically,

California's W&I Code Section 14105.46(b) states, "A covered entity shall bill 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 pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01."

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 submission 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 Pharm. 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).²

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.

CMS's interpretation does not, of course, *prevent* states or CMS from considering provider costs. For example, CMS believes that costs are relevant here to the statutory factors of efficiency and economy, as the proposed SPA ensures that 340B providers are not paid substantially in excess of their costs. Because we recognize the substantial discounts that these providers receive as a result of their participation in the 340B program and the limits of what drug manufacturers may charge 340B entities, there is little reason for us to conclude that the proposed SPA would diminish access or quality of care.

The state furnished documentation and supplemental 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 met with 340B providers, issued a Public Notice and Consultation Meeting with Tribes, and obtained assurances that pharmacy providers will continue to provide services to the Medicaid enrollees.
- The state provided information demonstrating that they have assessed the impact of the proposed SPA on the 340B provider network. The state provided CMS with a list of providers who had a paid claim in a given year with the drug identified as 340B. The state contends that the data validates the overall impact to the 340B provider network, as a result of the legislation the state is attempting to have incorporated into the state plan, and that it has not resulted in fewer providers billing 340B products, but an increase each year in the number of providers billing 340B. Although the state has not yet implemented the payment rate proposed in this SPA, the state indicated that most 340B providers have voluntarily complied by reducing their amount billed to the state for 340B products to an amount that does not exceed the entity's actual acquisition cost for the drug plus a professional fee for dispensing of \$7.25. Consequently, the state believes that beneficiary access will not be negatively impacted by this proposed change in reimbursement because providers have reduced the amount they bill the state for 340B products, and the number of providers billing 340B products has increased.
- The state's payment methodology is based on the actual acquisition costs for 340B drugs in accordance with section 340B of the Public Health Service Act. The calculation for the 340B ceiling price for Medicaid-covered outpatient drugs is determined by subtracting the Unit Rebate Amount (URA) from the Average Manufacturer Price (AMP), consistent with the statutory pricing formula for the 340B Drug Pricing Program. The maximum amount paid for the ingredient cost of the Medicaid-covered outpatient drug would be the 340B ceiling price. Since drug manufacturers participating in the Medicaid Drug Rebate Program are required under the 340B Program to provide covered outpatient drugs to qualifying 340B eligible covered entities at or below 340B ceiling prices, the state's proposed payment is reasonable given that it is consistent with the payment methodology under the 340B Program.
- By reimbursing at the lesser of actual acquisition costs or the 340B ceiling price, the possibility of duplicate discounts for drugs dispensed through the 340B program would be reduced. In accordance with section 1927(a)(5) of the Act and section 340B of the Public Health Service Act, states may not seek Medicaid rebates for discounted drugs provided to covered entities under the 340B program. This proposal would ensure compliance with these provisions and with the recommendations in the June 2011 Office of Inspector General report, "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs" (OEI-05-09-003621) that states develop methods to identify 340B claims.

- In this proposed SPA, the state did not propose changing the dispensing fee paid to 340B providers. The state indicated that the current dispensing fee for Medi-Cal and 340B providers was established in 2004 subsequent to a rate study and negotiations with pharmacy provider advocacy groups. The dispensing fee was approved by the California legislature and subsequently by CMS via SPA 04-010. Further, in light of the fact that the number of providers billing for 340B products has increased, the state believes that maintaining the current dispensing fee has not reduced beneficiary access to covered outpatient drugs.

Applying our interpretation of Section (30)(A) to your proposed SPA, we believe that the data the state has provided 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, this payment proposal is designed to provide payment based on the actual acquisition costs of the drugs subject to this proposed plan amendment. In accordance with section 1927 of the Act and section 340B of the Public Health Service Act, entities that participate in the 340B program are entitled to receive drugs at the 340B ceiling price – the ceiling rate at which such drugs would be paid under this proposed plan amendment. Accordingly, we believe the state plan, as modified by the proposed SPA, will be consistent with the access requirement under Section (30)(A) of the Act. The state has provided adequate documentation that the modified rate, coupled with the professional fee for dispensing of \$7.25, should cover the costs of providing these drugs to Medicaid beneficiaries, as well as, resulting in an increased number of providers billing 340B and ensuring continued access. As noted above, the state indicated that many 340B providers elected to voluntarily comply with the state statute that requires them to bill at their actual acquisition cost.

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. As these provisions reflect, we believe that states must balance access concerns with efficiency and economy concerns. Applying our interpretation of the statute to the proposed SPA at issue here, we believe that paying actual acquisition cost for the ingredient cost of the drug, as charged by the manufacturer at a price consistent with Section 256b of the United States Code, plus a reasonable dispensing fee is 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 through pharmacies at 340B entities will

continue to meet FDA quality standards. *But see Orthopaedic*, 103 F.3d at 1497 (“The Department, itself, must satisfy the requirement that the payments themselves be consistent with quality care.”).

Finally, 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.).³

Based on the foregoing, we believe the state has demonstrated 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 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 09-21B is approved, effective October 1, 2009. 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

³ See, e.g., P.L. 110-161, Division G – Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008, Title II – Department of Health and Human Services (H.R. 2764, Consolidated Appropriations Act, 2008) (“Payment under title XIX may be made for any quarter with respect to a State plan or plan amendment in effect during such quarter, if submitted in or prior to such quarter and approved in that or any subsequent quarter.”).

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER <u>09-021B</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)

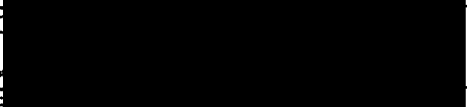
6. FEDERAL STATUTE/REGULATION CITATION	7. FEDERAL BUDGET IMPACT a. FFY No impact 09-10 \$ <u>10 million (savings)</u> b. FFY <u>10-11</u> \$ <u>10 million (savings)</u>
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Supplement 2, Attachment 4.19B Pages 1-14 10	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Replace pp 1-11 of TN 08-009B2 None

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 	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
13. TYPED NAME Toby Douglas	
14. TITLE Chief Deputy Director, Health Care Program	
15. DATE SUBMITTED	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED 11/23/2011	18. DATE APPROVED 1/30/2014
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PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL 2/23/2012	20. SIGNATURE OF REGIONAL OFFICIAL 
21. TYPED NAME Gloria Nagle, Ph.D, MPA	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

- O. 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.
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TN No. 09-021B
Supersedes
TN No. None

Approval Date January 30, 2014 Effective Date: October 1, 2009