



TOBY DOUGLAS
DIRECTOR

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



EDMUND G. BROWN JR.
GOVERNOR

November 1, 2013

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

Dear Ms. Nagle:

Subsequent to our original submission of SPA 09-021, the state requested SPA 09-021 be divided into two separate SPAs, 09-021A and 09-021B. The purpose of this letter is to officially respond to the questions contained in CMS's Dec. 8, 2009, RAI related to the content of proposed SPA 09-021B. For the sake of completeness, we have included all of the questions included in the original RAI, but have only provided substantive responses to the questions that apply to SPA 09-021B.

Our responses are as follows:

- 1. Please explain how the notice you published in the California Regulatory Notice Register complies with the Federal regulations at 42 CFR 447.205. Also, please verify the date the notice was published.**

42 CFR 447.205 declares that the State "must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services" and that the notice must appear as a public announcement in one of the following publications: (i) A State register similar to the Federal Register, (ii) The newspaper of widest circulation in each city with a population of 50,000 or more, or (iii) The newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more.

The State of California complied with 42 CFR 447.205(d)(2)(i) and published a notice in the State register on August 28, 2009, describing the proposed changes to reimbursement in methods and standards, explaining why the changes were occurring, as well as providing an estimate of 2009-2010 cost savings to the Medi-Cal Program. A local agency and address were identified where copies of the

proposed changes are available for public review and comments from the public could be forwarded. Please see pages 1470 & 1471 of the California Regulatory Notice Register, Register 2009, 35-Z, dated August 28, 2009 (enclosed).

- 2. On the CMS-179 form, you indicated “no impact” under block 7. However, in the notice published in the California Regulatory Notice Register, you indicated the reimbursement changes in this SPA are expected to generate a total General Fund savings of \$20.9 million in budget year 2009-2010. Please provide a revised estimate of the impact of this amendment for Federal fiscal years 2010 and 2011 under block 7 of the CMS-179 form.**

On January 20, 2012, DHCS provided CMS with pen and ink changes to the CMS-179 to reflect 09-021B and provided revised fiscal estimates related only to that portion of the original SPA (enclosed). Additionally, during the technical assistance process, DHCS moved the content of SPA 09-021B from page 5 to page 10 and added this as a pen and ink change to the enclosed CMS-179.

- 3. We note that several pages of this SPA overlap with your SPA 08-009B, which is pending approval by CMS. Until the issues regarding 08-009B are resolved, we will be unable to take the favorable action on this SPA.**

This question is no longer relevant. CMS denied California SPA 08-009B2 on November 18, 2010.

- 4. On page 1, paragraph A.1., you define estimated acquisition cost (EAC) as the lowest of average wholesale price (AWP) – 17%, the MAIC, the federal upper limit (FUL) of reimbursement for listed multiple source drugs, or the provider’s usual and customary charge to the public. However, on page 5, paragraphs 1 and 2, you define EAC as the lowest of AWP – 17%, the selling price, the FUL, or the MAIC. Please specify which formula is being adopted and submit revised plan pages(s) as appropriate.**

This question does not directly relate to the content of SPA 09-021B.

- 5. On page 3, you define AWP as the AWP in the department’s primary price reference source. What is the department’s primary price reference source?**

This question does not directly relate to the content of SPA 09-021B.

6. On page 4, in the definition of usual and customary charge, please revise “third-arty” to “third party”.

This question does not directly relate to the content of SPA 09-021B.

7. Also on page 4, you added a definition of “wholesaler acquisition cost.” We note that wholesale acquisition cost (WAC) is a term used in the pharmacy industry to represent the manufacturer’s list price. Please clarify which terms you intend to use.

This question does not directly relate to the content of SPA 09-021B.

8. On page 5, you indicated that the EAC will be the lowest of the several prices, one of which is “the selling price.” Since this term is not defined elsewhere in your plan, please provide a definition of this term or, if it was used inadvertently, please revise the page accordingly.

This question does not directly relate to the content of SPA 09-021B.

9. On page 6, you indicated that the MAIC will be based on the mean of AMPs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by the Department to represent the average purchase price paid by retail pharmacies in California. Since we cannot currently provide these AMPs to you, please explain how you intend to obtain AMPs for this purpose and clarify how you will determine the current markup. Also, please explain how the department will determine the average purchase price paid by retail pharmacies in California.

This question does not directly relate to the content of SPA 09-021B.

10. Also on page 6, you indicate that if AMPs are unavailable, the department will establish the MAIC as either 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. Please explain how California will decide which methodology to use to calculate the MAIC and provide further documentation as to these methodologies.

This question does not directly relate to the content of SPA 09-021B.

- 11. On page 7, you include three paragraphs that duplicate language already appearing on page 6. Please review this language and delete as necessary.**

This question does not directly relate to the content of SPA 09-021B.

- 12. On page 8, you indicate that the State prior approval mechanism is used for approval and payment for drugs not on the state Medicaid Drug Formulary, known as the Medi-Cal List of Contract Drugs. Please explain how this mechanism works.**

This question does not directly relate to the content of SPA 09-021B.

- 13. On page 8, you specify that 340B covered entities will be allowed to bill no more than the actual acquisition cost for a 340B drug plus the professional fee or dispensing fee set by the State. Please explain the basis for making the determination that the current dispensing fee is a reasonable dispensing fee for these providers. Also, please explain the difference between a “professional fee” and a “dispensing fee”. Finally, while we understand your authority to set payment rates for these providers, please clarify your authority to require those providers bill at their actual acquisition cost.**

This proposal does not change the dispensing fee for 340B entities. 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. Any additional changes in dispensing fees would require legislative action. In the document, the terms “professional fee” and “dispensing fee” are used synonymously.

California’s Welfare and Institutions (W&I) Code and federal guidance both provide DHCS with the authority to require that 340B providers bill at their actual acquisition cost. More specifically, California’s W&I Code Section 14105.46(b) states, “A covered entity shall dispense only 340B drugs to Medi-Cal beneficiaries.” California’s W&I Code 14105.46 (d) states: “A covered entity shall bill an amount not to exceed the entity’s actual acquisition cost for the drug...”

Federal guidance (Federal Register Vol. 65 No. 51, pg.13984) instructed covered entities to “refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits.”

14. Please explain what impact each of the proposed changes will have on beneficiary access to prescription drugs. What reaction have you received from pharmacy providers regarding each of these changes?

DHCS believes the proposed changes in SPA 09-021B will not negatively impact beneficiaries’ access to necessary medications. In fact, the number of providers billing 340B claims increased from 405 in fiscal year 2008-09, to 440 in fiscal year 09-10, and to 531 in fiscal year 10-11. Only two providers have expressed displeasure over the change, and neither of those have threatened withdrawal from the program.

15. Do pharmacy providers retain all of the State and Federal Medicaid payments (including dispensing fees, ingredient costs, benefit management costs, etc.) or are the providers obligated to return any portion of the Medicaid payment to the State or local government entity, or any other intermediary organization or entity?

Pharmacy providers do not return any portion of the Medicaid payments to the State or local government entities (unless an overpayment has occurred), or are otherwise required by the State to return any of those payments to other organizations or entities.

16. If pharmacy providers are obligated to return any portion of the payment, the State must provide a full description of the repayment methodology including: a complete list of pharmacy providers that return their payments; the amount or percentage of the payment; and the disposition and use of the funds once they are returned to the State (i.e., general revenue fund, medical services account, etc.)

Not applicable.

17. Describe whether the State share is from appropriation from the legislature, through intergovernmental transfer agreements (IGT), certified public expenditures (CPE), provider taxes, or any other mechanism used by the State to provide the State share.

The State share is funded through an appropriation from the Legislature.

18. Please provide the estimate of total expenditures and the State share amounts for each type of Medicaid payment.

The State share is funded 100 percent through an appropriation from the Legislature.

19. If any of the State share is being funded by IGTs or CPEs, please fully describe the matching arrangement. If CPEs are used, please describe how the State verifies that the expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b).

Not applicable.

20. The total amount for each enhanced or supplemental payment provided to pharmacy providers and the precise service cost this payment is covering.

No enhanced or supplemental payments are being provided.

Please find with this letter the State's resubmission of the latest draft of SPA 09-021B. The State requests that CMS disregard previously submitted versions of SPA 09-021B.

If you have any questions, or if we can provide further information, please contact Mr. Harry Hendrix Jr., Chief, Pharmacy Benefits Division. at (916) 552-9500.

Sincerely,



Toby Douglas
Director

Enclosures

cc: Tyler Sadwith
Centers for Medicare and Medicaid Services
Division of Medicaid and Children's Health
90th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

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

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED
DRUGS

- N. 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.

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

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED
DRUGS

- N. 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.
-

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

Approval Date _____ Effective Date: October 1, 2009

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 09 – 021 B	2. STATE CA
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	

FOR: HEALTH CARE FINANCING ADMINISTRATION	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 \$ 10 million (savings) b. FFY 10-11 \$ 10 million (savings)
---	--

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Supplement 2, Attachment 4.19-B, page 10	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): 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
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL wish to review the State Plan Amendment.

12. SIGNATURE OF STATE AGENCY OFFICIAL: Original document signed by:	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
13. TYPED NAME: Toby Douglas	
14. TITLE: Director	
15. DATE SUBMITTED:	

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: