



TOBY DOUGLAS
DIRECTOR

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



EDMUND G. BROWN JR.
GOVERNOR

NOV 23 2011

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

RE: California SPA 09-021

Dear Ms. Nagle:

The purposes of this letter are to:

- (1) Request that SPA 09-021 be split into two parts; 09-021-A, covering our revised definition of usual and customary and our new methodology for determining maximum allowable ingredient cost (MAIC) and 09-021-B, which states that 340B covered entities are allowed to bill no more than the actual acquisition cost for a 340B drug plus the dispensing fee set by the state. We have enclosed revised SPA pages, indicating how we would like them divided by the designation on each affected page of Supplement 2 to Attachment 4.19-B (as divided, SPA 09-021-A will affect pages 1-6 and SPA 09-021-B will only affect page 8). On these revised pages:
 - a. Changes previously proposed by SPA 08-009B2, which was denied, have been removed and are not shown at all.
 - b. Redlining on the pages denotes the original changes proposed by SPA 09-021.
 - c. Additional revisions made in response to the RAI are denoted in blue.
- (2) Inform you that our implementation of the provisions of SPA 09-021-A (revised definition of usual and customary and our new methodology for determining maximum allowable ingredient costs (MAICs)) have been put on hold pursuant to a preliminary injunction filed against the Department on May 5, 2010, and to
- (3) Officially respond to the December 18, 2009, Request for Additional Information (RAI).

Our responses to your questions from December 2009 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 may be forwarded. Please see pages 1470 & 1471 of the California Regulatory Notice Register, Register 2009, 35-Z, dated August 28, 2009 (pages 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.**

Our revised estimates (prior to when the preliminary injunction delaying full implementation was filed on May 5th, 2010) were \$33.6 million for FFY 2009-10, \$49.7 million for FFY 2010-11 and \$47 million for FFY 2011-12.

- 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.**

The Centers for Medicare and Medicaid Services (CMS) denied California SPA 08-009B2 on November 18, 2010, and California requested reconsideration of that SPA on November 19, 2010. That request for reconsideration has since been dropped.

4. On page 1, paragraph A.1., you define estimated acquisition cost (EAC) as the lowest of average wholesale price (AWP) – 17 percent, 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 percent, the selling price, the FUL, or the MAIC. Please specify which formula is being adopted and submit revised plan pages(s) as appropriate.

The definition of estimated acquisition cost (EAC) which will be adopted is the one described on page 1, paragraph A. The term "selling price" was inadvertently included in the EAC definition on page 5. It has been removed from the definitions of EAC on Page 5.

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?

The Department's current primary price reference source is First Data Bank.

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

The words "third-party" have been corrected in the definition of usual and customary charge.

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.

We recognize that "wholesale acquisition cost" is defined in federal statute, however, California Welfare and Institutions (W & I) Code Section 14105.45 (a)(13)* specifically refers to "wholesaler acquisition cost, therefore, our use of the term "wholesaler" in the SPA is consistent with state statute.

- *14105.45(a)(13) "Wholesaler acquisition cost" means the price for a drug product listed as the wholesaler acquisition cost in the department's primary price reference source.

Our objective was simply to acknowledge that the Department's source for WAC, if used, would be the Department's primary price reference source, currently First Data Bank.

- 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.**

As discussed in #4, above, the term “selling price” has been removed.

- 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 provision is only relevant if CMS provides AMPs. Please note that the section that immediately follows the paragraph in question on page 6 describes what will happen if AMPs are unavailable. The methodology for determining the average purchase price paid by pharmacies is described in our response to item #10. If AMPs are available from CMS the percent markup would be determined using average drug purchase information gathered from surveys of California wholesalers and/or pharmacy providers and the mean of the AMPs of drugs generically equivalent to the particular innovator drug. The Department or a vendor would conduct the wholesaler or provider surveys.

- 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.**

Given the uncertainty of the availability of certain types of data needed to establish reasonable MAICs, California statute specifically gives the Department the flexibility to select from a variety of approaches. The deciding factors specifically will be the availability of AMP data from CMS, whether wholesalers are willing to provide

average purchase price data to the Department (since there is no current mandate for them to do so) or whether funds are available to execute a vendor contract to survey prices and propose MAICs.

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

The duplicate language on page 7 has been deleted.

- 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.**

In California, prior approval is linked to medical necessity. A request for prior approval is known as a Treatment Authorization Request (TAR). Such requests must include the patient's information, diagnosis, and medical justification for receiving the medication. A state consultant (pharmacists review drug TARS) at a central location reviews the TAR, makes a decision based on the information provided and responds to the dispensing pharmacy. A TAR can either be: 1) *approved*, in which the dispensing pharmacy submits the claim, the claim is approved, and the drug is given to the patient, 2) *deferred*, whereby the state consultant requests more information for further review before approving or denying the request, or 3) *denied*. If the pharmacy receives a denial, the patient has the option to pay out-of-pocket for the drug, request a different drug from the doctor, or not receive the drug. It should be noted that Section F of the Plan was already part of the existing State Plan and not subject to revision under this request.

- 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 to 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 CMS at

the time. A change in dispensing fee would require a legislative change. In the document, the terms "professional fee" and "dispensing fee" are used synonymously.

W&I Code and federal guidance both provide the Department 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?

The Department believes that the proposed changes in SPA 09-021A & B will not negatively impact beneficiaries' access to necessary medications. The revised definition of usual and customary was implemented effective October 1, 2009 through May 5, 2010, and during that time, pharmacy providers continued to dispense medications to beneficiaries and the Department did not see a statistically significant decrease in the number of Medi-Cal claims or providers.

As indicated above, and as of May 5, 2010, the usual and customary and MAIC components of this SPA are subject to a preliminary injunction, and will not be implemented until the injunction is lifted or otherwise resolved.

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.

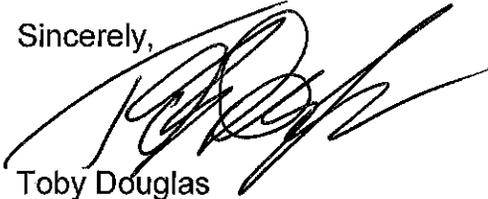
20. The total amount for each enhanced or supplemental payment provided to pharmacy providers and the precise service cost this payment is covering.

No enhanced or supplemental payments are being provided.

Ms. Nagle
Page 8

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

Sincerely,



Toby Douglas
Director

Enclosures

cc: Beverly Binkier
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Center for Medicaid & State Operations

Disabled and Elderly Health Programs Group

December 18, 2009

Toby Douglas
Chief Deputy Director
Health Care Programs
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Dear Mr. Douglas:

We have reviewed California's State plan amendment (SPA) 09-021, which would make several changes to the State's reimbursement methodology for prescribed drugs. The SPA would revise the definition of average wholesale price, add definitions of usual and customary charge and wholesaler acquisition cost, and delete the definition of wholesale selling cost. It would revise how the maximum allowable ingredient cost is calculated. It would also require 340B covered entities to only dispense 340B drugs to Medi-Cal beneficiaries, and require that the entities bill an amount not to exceed the actual acquisition cost of the drugs plus a professional fee or dispensing fee. You have requested an effective date of October 1, 2009 for this SPA.

Before we can continue processing the SPA, we need clarifying information as indicated below. Therefore, we are requesting this additional information pursuant to section 1915(f) of the Social Security Act (the Act).

1. Please explain how the notice you published in the California Regulatory Notice Register complies with Federal regulations at 42 CFR 447.205. Also, please verify the date the notice was published.
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.
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 favorable action on this SPA.
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 page(s) as appropriate.

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?
6. On page 4, in the definition of usual and customary charge, please revise "third-arty" to "third-party".
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 term you intend to use.
8. On page 5, you indicated that the EAC will be the lowest of 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.
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 percent markup. Also, please explain how the department will determine the average purchase price paid by retail pharmacies in California.
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 or 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.
11. On page 7, you include three paragraphs that duplicate language already appearing on page 6. Please review this language and delete as necessary.
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.
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 these providers bill at their actual acquisition cost.
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?

Funding Questions

The State did not provide responses to the standard funding questions with this SPA. We ask that you provide the following information pursuant to a methodology described in Attachment 4.19B of the State plan or indicate that there has been no change since the last pharmacy reimbursement SPA.

Section 1903(a)(1) of the Social Security Act (the Act) provides that Federal financial participation (FFP) is only available for expenditures made by States for services under the approved State Plan. To ensure that program dollars are used only to pay for Medicaid services, we are asking States to confirm to CMS that pharmacies retain 100 percent of the payments provided to them as indicated in Attachment 4.19B. Specifically, please answer the following questions regarding the proposed amendment and current reimbursement made under the Medicaid State plan for pharmacy providers:

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

Section 1902(a)(2) of the Act provides that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the State share of each type of Medicaid payment in attachment 4.19B is funded, including the payments made under the proposed amendment. Specifically:

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

Section 1902(a)(30) of the Act requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a)(1) of the Act provides for FFP to States for expenditures for services under an approved State plan. If you are providing, or propose to provide under this amendment, an enhanced or supplemental payment to pharmacy providers under section 4.19B of the State plan, please provide the following information:

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

Indicate whether there are public pharmacy providers and if they are receiving payments in accordance with attachment 4.19B that in the aggregate exceed its reasonable costs of providing services. If the payment exceeds the reasonable costs of services (for pharmacy that would be a reasonable dispensing fee and ingredient cost) please indicate whether the State recoups the excess and returns the Federal share of the excess to CMS on the quarterly expenditure report.

This request for additional information is made pursuant to section 1915(f) of the 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 will 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 Federal financial participation (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 request for additional information via the San Francisco Regional Office SPA/Waiver mailbox at [CMS SPA Waivers SanFrancisco R09@cms.hhs.gov](mailto:CMS_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 Marge Watchorn at (410) 786-4361.

Sincerely,

/s/

Larry Reed
Director
Pharmacy Division

cc: Gloria Nagle, Associate Regional Administrator, San Francisco Regional Office
Michelle Baldi, San Francisco Regional Office