



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

RE: State Plan Amendment (SPA) 12-014 – DHCS Responses to CMS Request for Additional Information (RAI)

Dear Ms. Nagle:

This letter provides responses to your June 27, 2012, request for additional information on SPA 12-014, including revised SPA language subsequent to substantial technical assistance provided by CMS.

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.**

The effective date of this SPA is March 31, 2012. As requested, we have revised the SPA language to more clearly delineate the effective date of the changes made by this SPA (see paragraphs L & M on page 8).

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

The most recent draft of this SPA language has been significantly revised and this question is no longer relevant.

- 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.**

The most recently proposed SPA language identifies the specific criteria that the Department of Health Care Services (DHCS) will use in determining whether to exempt a drug product, therapeutic category of drugs, or a provider from the ten percent pharmacy provider payment reduction. It also delineates how often the exemptions will be reviewed, how providers will be notified of any changes, and where providers can find information online regarding the current exemptions.

- 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 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.

When SPA 12-014 was originally submitted, it was the state’s intent to adjust different exempted drugs by different amounts so that the ten percent payment reduction would not result in reimbursement below acquisition cost. This approach proved to be administratively unworkable, and the currently proposed SPA provides for exempted drugs/category of drugs to be completely exempt, e.g., no reduction in payment if exempted.

- 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”.**

With the revised state plan language, this is no longer necessary.

- 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.**

The revised SPA language uses the word "will" in relation to the geographic exemption of providers (see paragraph M (2)).

- 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".**

This language has been removed from the SPA.

- 8. 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.**

The rationale for the use of each of these two measures and how they will measure beneficiary access are described in the monitoring plan entitled, "Monitoring Access to Medi-Cal Covered Healthcare Services," as approved by CMS in SPA CA-11-009. They are excerpted below for easy reference.

Measure #7: Pharmacy Participation Rates

(located on page 42 of "Monitoring Access to Medi-Cal Covered Healthcare Services")

Description: Number of pharmacy providers, who submitted a claim for services during the period of measurement, divided by the number of pharmacy providers state-wide, stratified by county group.

Rationale: This measure will allow DHCS to monitor pharmacy participation rates by geographic distribution. Decreases in pharmacy participation rates will serve as a trigger for DHCS to further investigate whether the Medi-Cal pharmacy network is sufficient to meet enrollees' needs. Data can be compared quarterly to identify trends in pharmacy participation using administrative data readily available through Medi-Cal.

Data Source: Medi-Cal claims data, and Department of Consumer Affairs, Board of Pharmacy Licensing Data.

Frequency of Reporting: Annually

Measure # 16: Service Rates per 1,000 Member Months

Description: The number of units of service utilized during the measurement period, divided by the number of Medi-Cal beneficiary member months (multiplied by 1,000), stratified by provider types, beneficiary age grouping, and aid category. Broad service categories will be constructed for all Medi-Cal services being evaluated under this measure as follows:

- Physician/Clinic
- Non-emergency medical transportation
- Emergency medical transportation
- Home Health
- Hospital Inpatient
- Hospital Outpatient
- Nursing Facility
- Pharmacy
- Other

Rationale: Appropriate use of health care services is the end result of effective health care access. This measure will allow DHCS to monitor service utilization for all services types offered under Medi-Cal, by beneficiary age and aid categories. As noted in Measure # 3, the Medi-Cal data set does not currently include information necessary to conduct an analysis specifically for physician extenders. Periodic review of these Medi-Cal service types can be achieved using administrative data readily available through Medi-Cal.

Data Source: Medi-Cal claims data and Medi-Cal Eligibility System Monthly Extract File.

Frequency of Reporting: Quarterly

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Please find with this letter the State's resubmission of the latest (October 25, 2013) draft of SPA 12-014. The State requests that CMS disregard previously submitted versions of SPA 12-014.

Sincerely,

ORIGINAL DOCUMENT SIGNED BY:

Toby Douglas
Director

Enclosure

cc: Tyler Sadwith
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90th Street, Suite 5-300 (5W)
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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.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.
- ~~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.~~
- 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.)

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- 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:
 - 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.

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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 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, ~~and L and M will be monitored~~ 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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- 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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- 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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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.”

TN No. 12-014

Supersedes

TN No. _____

Approved: _____

Effective Date: March 31, 2012