DEPARTMENT OF HEALTH CARE SERVICES
NOTICE OF GENERAL PUBLIC INTEREST

PROPOSED CHANGES TO PHARMACY REIMBURSEMENT FOR COVERED OUTPATIENT DRUGS

This notice serves to provide information of public interest that the Department of Health Care Services (DHCS) is seeking federal authority to modify the reimbursement methodology for covered outpatient drugs and to make other related changes to the California Medicaid State Plan.

The Centers for Medicare and Medicaid Services (CMS) published its Final Rule on Covered Outpatient Drugs (CODs) on February 1, 2016 (81 Fed.Reg. 5170). This rule implements provisions of the 2010 Patient Protection and Affordable Care Act, pertaining to Medicaid reimbursement for CODs. States are required to submit State Plan Amendments (SPAs) implementing the new requirements no later than June 30, 2017, with an effective date of no later than April 1, 2017.

In preparation for these requirements, DHCS engaged Mercer Government Human Services Consulting (Mercer) to conduct a study of outpatient pharmacy provider costs associated with purchasing and dispensing outpatient prescription drugs to Medi-Cal beneficiaries. Mercer submitted its study findings and implementation alternatives to DHCS. DHCS analyzed these alternatives and—in compliance with the final rule—plans to submit SPA 17-002 by June 30, 2017, with the following proposed changes and a proposed effective date of April 1, 2017.

1. Replace the current professional dispensing fee structure ($7.25 for retail and $8.00 for Long Term Care pharmacies) with the implementation of a two-tiered professional dispensing fee based upon a pharmacy's total (both Medicaid and non-Medicaid) annual claim volume, as follows:
   - Less than 90,000 claims per year = $13.20 (requires annual provider self-attestation)
   - 90,000 or more claims per year = $10.05

2. Adopt CMS's National Average Drug Acquisition Cost (NADAC) as the basis for ingredient cost reimbursement. Wholesale Acquisition Cost (WAC) + 0% will be used as the basis for reimbursement when a NADAC is not available. The NADAC and WAC benchmarks will replace Average Wholesale Price (AWP) minus 17% in the existing drug ingredient cost reimbursement methodology, which currently reimburses the lowest of AWP minus 17%, the Federal Upper Limit (FUL), Maximum Allowable Ingredient Cost (MAIC), or the pharmacy's usual and customary (U&C) charge.

3. Update the methodology for how MAICs may be calculated to reflect current California law as follows:

    a. State that a MAIC may only be established when three or more generically equivalent drugs are available for purchase and dispensing by retail pharmacies in California.
    b. Require that DHCS base MAICs on the mean of the Average Manufacturers Price (AMP) of drugs generically equivalent to the particular innovator drug plus a percent markup determined by DHCS to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California. If AMPs are not available, DHCS may establish MAICs in one of the following ways:
        i. Based on the volume weighted average of wholesaler acquisition costs of drugs generically equivalent to the particular innovator drug plus a percent markup determined by DHCS to be necessary for the MAIC to represent the average purchase price paid by retail pharmacies in California, or
        ii. Pursuant to a contract with a vendor for the purpose of surveying drug price information, collecting data, and calculating a proposed MAIC.
        iii. Based on the volume weighted actual acquisition cost of drugs generically equivalent to the particular innovator drug adjusted by the department to represent the average purchase price paid by Medi-Cal pharmacy providers.
    c. Change the frequency with which MAICs must be updated from every three months to annually.
    d. Require that DHCS establish a process for providers to seek a change to a specific MAIC when providers believe a MAIC does not reflect current available market prices.
    e. Require that, when determining average purchase price, DHCS shall consider the provider-related costs of the products that include, but are not limited to, shipping and handling, but does not include costs that are included in the costs of dispensing.

4. Clarify that 340B contract pharmacies are prohibited from dispensing 340B drugs to Medicaid beneficiaries unless the covered entity (as defined in Section 256b of Title 42 of the United States Code), the contract pharmacy and the state Medicaid agency have established an arrangement to prevent duplicate (rebate) discounts consistent with federal guidelines. Also, clarify that covered entities that use contract pharmacies are expected to ensure compliance with federal rules.

5. Clarify that drugs acquired via the Federal Supply Schedule (FSS) or at Nominal Price (outside of 340B or FSS) are to be billed at those prices (the FSS or Nominal Price).

6. Add a description of the State's current policy on reimbursement for investigational drugs.

Additionally, the definitions section of the State Plan will be updated to remove outdated and/or unnecessary language.

The overall budgetary impact of adopting these proposed changes is projected to be an aggregate annual expenditures decrease of $72 million (in total funds, including $36 million general fund).

These proposed changes are subject to CMS approval.

Public Review and Comments

Once available and prior to submission to CMS, a draft copy of proposed SPA 17-002 will be made available for public input at:
http://www.dhcs.ca.gov/formsandpubs/laws/Pages/Pro_SPA.aspx

Once the proposed SPA is made available, the public will have 30-days to submit comments related to SPA 17-002 that DHCS will consider prior to the initial submission of SPA 17-002 to CMS. Please note that comments will continue to be accepted after the 30-day period, but that DHCS may be unable to consider those comments prior to the initial submission of SPA 17-002 to CMS.

Upon submission to CMS, a copy of the proposed SPA #17-002 will be published at:
http://www.dhcs.ca.gov/formsandpubs/laws/Pages/Pending_2017.aspx

If you would like to view the SPA in person once it becomes available, please visit your local county welfare department. You may also request a copy of the SPA from the mailing address or e-mail address below.

Any written comments, including those with respect to the SPA's impact to beneficiary access to care, may be sent to: Department of Health Care Services, Pharmacy Benefits Division, 1501 Capitol Avenue, MS 4604, Sacramento, California 95899-7413, or may be emailed to Publicinput@dhcs.ca.gov. Please indicate SPA 17-002 in the subject line or message.

A copy of submitted public comments related to SPA 17-002 may be requested in writing to the same address and e-mail inbox identified above.

Release date: March 30, 2017