DEPARTMENT OF HEALTH CARE SERVICES

REQUEST FOR STAKEHOLDER INPUT ON PROPOSED CHANGES TO PHARMACY REIMBURSEMENT FOR COVERED OUTPATIENT DRUGS

POSTED – April 14, 2017

The Department of Health Care Services (DHCS) requests input from beneficiaries, providers, and other interested stakeholders concerning the below State Plan Amendment (SPA) 17-002 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. Under the Final Rule, each state is responsible for establishing a Medicaid Fee-For-Service payment methodology that reimburses outpatient pharmacy providers based on an actual acquisition cost (AAC), plus a professional dispensing fee (PDF). States are required to submit SPAs implementing the new requirements no later than June 30, 2017, with an effective date of no later than April 1, 2017.

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 in general funds).

These proposed changes are subject to CMS approval.

DHCS is requesting stakeholder input, questions and concerns regarding this proposed action's impact, if any, on continued service access.

To be assured of consideration prior to SPA submission to CMS, comments must be received no later than 5 p.m. on May 15, 2017. Written comments may be sent to: Department of Health Care Services, Pharmacy Benefits Division, 1501 Capitol Avenue, MS 4604, Sacramento, California 95899-7413. Comments may also be emailed to publicinput@dhcs.ca.gov. Please indicate SPA 17-002 in the subject line or message.

Please note that comments will continue to be accepted after May 15, 2017, but DHCS may not be able to consider those comments prior to the initial submission of SPA 17-002 to CMS.

PAYMENT METHODOLOGY FOR COVERED OUTPATIENT DRUGS

1. Payment for legend and non-legend covered outpatient drugs dispensed by a retail community pharmacy shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

2. Payment for specialty drugs not dispensed by a retail community pharmacy but dispensed primarily through the mail shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

3. Payment for legend and non-legend covered outpatient drugs not dispensed by a retail community pharmacy (i.e. institutional or long-term care facility pharmacies) shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

4. Payment for legend and non-legend covered outpatient drugs dispensed by Indian Health Service, tribal, and urban Indian pharmacies shall be the lower of the drug's ingredient cost plus a professional dispensing fee, or the pharmacy's usual and customary charge to the public.

5. For purposes of this supplement, the "drug's ingredient cost" means the lowest of:

    a. The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
    b. The Federal Upper Limit (FUL), or
    c. The Maximum Allowable Ingredient Cost (MAIC).

6. The "professional dispensing fee" shall be based on a pharmacy's total (Medicaid and non-Medicaid) annual claim volume of the previous year, as follows:

    a. Less than 90,000 claims = $13.20, or
    b. 90,000 or more claims = $10.05

    Pharmacies seeking the higher professional dispensing fee shall submit an annual attestation of their total claims volume and shall include supporting documentation.

7. The department may establish a list of MAICs for generically equivalent drugs in accordance with the following:

   a. The department may establish a MAIC only when three or more generically equivalent drugs are available for purchase and dispensing by retail community pharmacies in California.

   b. The department shall 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 the department to be necessary for the MAIC to represent the average purchase price paid by retail community pharmacies in California.

   c. If AMPs are not available, the department 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 the department to be necessary for the MAIC to represent the average purchase price paid by retail community 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, or
      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.

   d. The department shall publish the list of MAICs in pharmacy provider bulletins and manuals, update MAICs at least annually and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

   e. The department shall establish a process for pharmacy providers to seek a change to a specific MAIC when the pharmacy providers believe the MAIC does not reflect current available market prices. If the department determines a MAIC change is warranted, the department may update a specific MAIC prior to notifying pharmacy providers.

f. In determining the average purchase price, the department shall consider the pharmacy provider-related costs of the products that include, but are not limited to, shipping, handling and storage. Costs of the provider that are included in the costs of the dispensing shall not be used to determine the average purchase price.

8. Medi-Cal restricts coverage of certain covered outpatient drugs through the operation of a prior authorization program in accordance with the provisions of Section 1927(d)(5) of the Social Security Act.

9. 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.

a. 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 dispensing fee described in Paragraph 6.

b. 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 Paragraph 1 of this supplement.

c. A contract pharmacy, under contract with a 340B covered entity described in Section 1927(a)(5)(B) of the Social Security Act may only use 340B drugs to dispense Medicaid prescriptions if the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts as outlined in the HRSA Final Notice regarding Contract Pharmacy Services published at 75 Fed. Reg. 10272 (Mar. 5, 2010). Covered entities that utilize contract pharmacy arrangements are expected to ensure compliance with all the requirements in the Final Notice. If the covered entity provides

medications through contracted pharmacies, the contract pharmacy must bill using the NPI of the covered entity for fee-for-service claims and payment will be made as described in either Paragraph 9a or 9b of this supplement.

10. Pharmacy providers purchasing drugs through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826 will be reimbursed no more than the actual acquisition cost for the drug, plus a professional dispensing fee as described in Paragraph 6 of this supplement.

11. Pharmacy providers purchasing drugs at Nominal Price (outside of 340B or FSS) will be reimbursed no more than the actual acquisition cost for the drug, plus a professional dispensing fee as described in Paragraph 6 of this supplement.

12. Investigational drugs are not covered except when it is clearly documented that all of the following apply:

    a. Conventional therapy will not adequately treat the intended patient's condition;

    b. Conventional therapy will not prevent progressive disability or premature death;

    c. The provider of the proposed drug has a record of safety and success with it equivalent or superior to that of other providers of the investigational drug;

d. The investigational drug is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives;

e. The drug is not being provided as a part of a research study protocol; and

f. There is a reasonable expectation that the investigational drug will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living.

All investigational drugs require prior authorization. Payment will not be authorized for investigational drugs that do not meet the above criteria. If an investigational drug meets all of the above criteria, it shall be reimbursed as described in paragraph 1 of this supplement.

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

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

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PAYMENT METHODOLOGY FOR PHYSICIAN ADMINISTERED DRUGS

The reimbursement rate for physician administered drugs shall be equal to the Medicare Part B reimbursement rate for drugs and biologicals, when available for a particular product and published by CMS, as described in Section 1847A of the Social Security Act and currently defined as Average Sales Price (ASP) plus 6%. When a Medicare Part B reimbursement rate is not available or published by CMS for a physician administered drug, the reimbursement rate will be determined as follows:

i. If based on a National Drug Code (NDC), the NDC rate of reimbursement shall be equal to the pharmacy rate of reimbursement, as described in Paragraph 5a of this supplement, or

ii. If based on a Healthcare Common Procedure Coding system (HCPCS) code, the HCPCS code rate of reimbursement shall be equal to the volume-weighted average of the pharmacy rate of reimbursement, as described in Paragraph 5a of this supplement for generically equivalent drugs.