Issue Paper – Proposed Pharmacy Reimbursement Changes to Comply with CMS' Covered Outpatient Drug Final Rule (42CFR Part 447 Part II)

Background

The current California Medicaid Fee for Service (FFS) pharmacy reimbursement methodology is principally based on Average Wholesale Price (AWP). In recent years, the Office of Inspector General reports have found that the AWP may not be the most reasonable method of reimbursement, even suggesting that Medicaid may have overpaid for some types of drugs.

On February 1, 2016, a Final Rule (42CFR Part 447 Part II) for Covered Outpatient Drugs (CODs) was released by the Centers for Medicare and Medicaid Services (CMS). This rule implements provisions of the Patient Protection and Affordable Care Act of 2010, pertaining to Medicaid reimbursement for CODs. Under the final rule, each state is responsible for establishing a Medicaid FFS payment methodology that reimburses outpatient pharmacy providers based on an actual acquisition cost (AAC), plus a professional dispensing fee (PDF). The effective date of implementing these requirements is no later than April 1, 2017.

To prepare for compliance with these requirements, the California Department of Health Care Services (DHCS) engaged Mercer Government Human Services Consulting (Mercer) to conduct a study on outpatient pharmacy provider costs associated with purchasing and dispensing outpatient prescription drugs to Medi-Cal beneficiaries. DHCS and Mercer performed extensive stakeholder outreach before and during the study providing awareness of the final rule requirements, soliciting feedback on the survey development, encouraging survey participation, and responding to questions regarding survey completion.

Mercer has recently submitted its study findings and implementation alternatives to DHCS ("Mercer report"), which is attached to this issue paper. Subsequently, DHCS performed an analysis on each of the alternatives, examining the implementation considerations relative to the following categories: projected fiscal impact, provider impact, DHCS initial startup and ongoing operational impact, and system impact. After careful review of the alternatives and their implementation considerations, DHCS is proposing the adoption of two of the alternatives as outlined in the Mercer report and summarized below to comply with the requirements of the final rule.

Professional Dispensing Fee

DHCS is recommending the adoption of Mercer's PDF Alternative 2, which is to implement a two-tiered dispensing fee based upon a pharmacy's total claim volume (both Medicaid and non-Medicaid), as follows:

- \$13.20 < 90,000 claims yearly
- \$10.05 ≥ 90,000 claims yearly

DHCS selected this option in consultation with Mercer because it accurately reflects the disparity in the actual costs of dispensing a medication as it applies to smaller, independent pharmacy owners and the larger multi-store or chain pharmacies. In addition, from an administrative perspective this option can be operationalized through

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the customary system change processes, allowing a timely implementation. Further, this option seemed to be the most acceptable to CMS during informal communications with them.

Implementation Considerations

The Mercer fiscal impact analysis indicates this increase to providers from the current dispensing fee structure (\$7.25 for retail and \$8.00 for Long Term Care pharmacies) will result in a projected cost of \$60 million (total fund)/\$30 million (general fund) annually to DHCS. This alternative requires annual self-attestation by pharmacies to their total claim volume, with the need for DHCS validation procedures. DHCS will establish financial and/or other administrative penalties for pharmacies that intentionally provide fraudulent self-attested information. Moderate claims payment system changes will be required to implement this alternative.

Actual Acquisition Cost

DHCS is recommending Mercer's AAC Alternative 1, which is the adoption of the National Average Drug Acquisition Cost (NADAC) pricing file, and Wholesale Acquisition Cost (WAC) + 0% as a backup benchmark when a NADAC price is not available.

The NADAC and WAC benchmarks will replace AWP minus 17% in the existing 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 charge (U&C). The report analysis demonstrated that the NADAC rates were not significantly different from the survey's invoiced acquisition costs for single-source, brand name drugs. Informal discussions with CMS have indicated that this option would best meet the intentions of the provisions in the Final Rule.

Implementation Considerations

The Mercer fiscal impact analysis indicates that the projected savings to DHCS in adopting this methodology is \$132 million (total fund)/\$66 million (general fund) annually (\$126 million from NADAC adoption, and \$6 million annually with secondary benchmark of WAC + 0% when NADAC does not exist). Although this method decreases reimbursement to providers, there is no ongoing state survey burden on DHCS or Medi-Cal providers. System changes required to implement this alternative are anticipated to be of moderate to high complexity, and historical claim adjustments will be required between the CMS effective date of April 1, 2017 and the implementation date of the claims payment changes, which will occur after the effective date of April 1, 2017.

Blood Factors

The Mercer Report presented what was believed to be two viable reimbursement alternatives for Blood Factor reimbursement for Medi-Cal; one of which was Medi-Cal's current payment methodology, which is defined as the lesser of the Average Selling Price (ASP) + 20%, or Usual and Customary Fee. None of the study findings presented in the report steered DHCS to believe that a change in reimbursement was necessary

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for Blood Factors. However, in a subsequent phone conversation between CMS and DHCS on December 22, 2016 on this topic, CMS indicated to DHCS that ASP + 20% is no longer an acceptable reimbursement alternative. CMS further elaborated that the expectation is that Medicaid Agencies will break out their reimbursement for Blood Factors into three components: ingredient cost, professional dispensing fee, and associated services. This CMS feedback was verbal, and DHCS is waiting official written guidance from CMS before proceeding with further action at this time.

Net Impact

The overall budgetary impact of adopting the two-tier Professional Dispensing Fee, in combination with the NADAC pricing and WAC + 0% when NADAC does not exist, is projected to be an annual total fund savings of \$72 million (\$36 million general fund).