FACT SHEET

Issue Title: Implementation of Centers for Medicare and Medicaid Services’ (CMS) Covered Outpatient Drugs (COD) Final Rule - Update. On February 1, 2016, CMS issued its final rule on CODs. This final rule implements provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for CODs. The effective date of implementing these requirements is no later than April 1, 2017, and CMS will not provide for any extension beyond this effective date. Failure to meet this deadline will place significant federal matching funds at risk. The changes proposed in this trailer bill legislation update and specify the selected alternatives proposed for implementation to comply with the COD Final Rule in the Welfare and Institutions (W&I) Code that will provide California the authority to meet this federal mandate.

Background: The rule mandates state Medicaid agencies to implement certain provisions, including the transition to an acquisition cost based reimbursement methodology so payments are based on a more accurate estimate of the prices available in the marketplace, while maintaining sufficient beneficiary access. It also mandates that when a state changes its reimbursement methodology for the ingredient cost of drugs, it also examine, and if necessary revise, its professional dispensing fee to ensure that Medicaid pharmacy providers are adequately reimbursed in accordance with the requirements of Section 1902(a)(30)(A) of the Social Security Act. The term “professional dispensing fee” is defined in the rule to establish that the dispensing fee paid to pharmacies reflects the cost of the pharmacist’s professional services associated with dispensing the drug product to a Medicaid beneficiary. Lastly, states must comply by submitting a state plan amendment with an effective date of no later than April 1, 2017.

Pursuant to AB 102 (Committee on Budget and Fiscal Review, Chapter 29, Statutes of 2011), the Department of Health Care Services (DHCS) was authorized to transition to an acquisition cost based reimbursement methodology and to establish a new dispensing fee, if needed. It also required that, prior to the implementation of an acquisition cost based methodology, DHCS seek stakeholder input on and conduct a survey of providers’ average acquisition costs and dispensing fees, and that any change in the dispensing fee go through the budget process. SB 833 (Committee on Budget and Fiscal Review, Chapter 30, Statutes of 2016) gave DHCS general authority to implement a new dispensing fee or fees, if needed, effective April 1, 2017, as required by the COD Final Rule; however, it did not name specifics of what that dispensing fee or fees would be. This proposal adds that specificity.

To prepare for compliance with these state and federal requirements, DHCS engaged Mercer Government Human Services Consulting, LLC (Mercer) to conduct a study of outpatient pharmacy provider costs associated with purchasing and dispensing outpatient prescription drugs to Medi-Cal beneficiaries. DHCS also conducted a series of stakeholder meetings to provide ample opportunities for input on the survey and subsequent results. Mercer submitted
its study findings and implementation alternatives to DHCS in January 2017 (http://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP_Merc_Rpt_170127.pdf). DHCS performed an analysis on each of the alternatives, and for drug ingredient reimbursement, concluded to move forward with: Mercer Actual Acquisition Cost 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. With regard to the professional dispensing fee, DHCS concluded to move forward with Mercer’s Professional Dispensing Fee 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

Based on the conclusion, DHCS is now proposing to update existing law to codify California’s implementation of the final rule.

**Justification for the Change:** Legislation is needed to comply with the existing statutory requirement that changes made to the professional dispensing fee be subject to the state budget process, as well as update existing law to codify California’s implementation of the final rule.

DHCS’ proposed TBL would:

- Replace all references to “average acquisition cost” with “actual acquisition cost” throughout W&I Code Section 14105.45 to be consistent with the COD Final Rule.
- Link definitions, where possible, to existing state or federal statute and delete an incorrect reference (W&I Code Sections 14105.45(a) and 14105.456(a)).
- Replace references to “estimated acquisition cost” in the explanation of reimbursement to Medi-Cal pharmacy providers with “ingredient cost” since estimated acquisition cost is no longer a valid concept pursuant to the COD Final Rule (W&I Code Section 14105.45(b)).
- Describe the new professional dispensing fee methodology (W&I Code Section 14105.45(b)(2)(B)).
- Clarify that the current drug ingredient cost methodology that includes average wholesale price is effective through March 31, 2017, and that the new drug ingredient cost methodology commences April 1, 2017 (W&I Code Sections 14105.45(b)(3)(A & B)).
- Clarify that blood factor drug ingredient cost will be based on average sales price (W&I Code Section 14105.86), rather than actual acquisition cost (W&I Code Section 14105.45(b)(3)(C)).
- Provide DHCS flexibility on the implementation of the Maximum Allowable Ingredient Cost (MAIC) program (W&I Code Section 14105.45(b)(4)). DHCS requires flexibility to determine whether or not to implement a MAIC program based on the degree to which implementation of the National Average Drug Acquisition Cost benchmark mitigates the potential shifting of market share (purchasing) to higher priced generic products.
• Modify the MAIC update requirement from every three months to annually (W&I Code Section 14105.45(b)(4)(D)).
• For purposes of establishing a MAIC, remove “delivery” from the list of provider related costs that must be considered when determining an average purchase price, since the Final Rule includes delivery costs as a component of the professional dispensing fee, rather than as a component of average purchase price (W&I Code 14105.45(b)(4)(F)).
• Add April 1, 2017 as the specific date that pharmacy drug payment reductions mandated by W&I Code 14105.192 shall be discontinued (W&I Code Section 14105.45(i)).
• Clarify that blood factors provided as physician administered drugs (e.g. by non-pharmacy providers) are required to be reimbursed based on average sale price (W&I Code Section 14105.456(f)).

Summary of Arguments in Support: Compliance with the provisions of the COD Final Rule preserves federal matching funds. Addition of new dispensing fee and ingredient cost methodologies provide DHCS specific authority to modify reimbursement for covered outpatient drugs to comply with the COD Final Rule.

BCP or Estimate Issue # and Title: OA PC 45. Vendor for AAC Rate Study.