Issue Title: Proposal to Restrict use of Contract Pharmacies in 340B Program for Medi-Cal. In 2016, the Centers for Medicare and Medicaid Services (CMS) issued two final rules, one covering Medicaid and Children’s Health Insurance Program (CHIP) Managed Care and the other related to Covered Outpatient Drugs (COD). Both final rules contained directives pertaining to the 340B program. Under the managed care final rule, CMS requires that managed care plans have procedures to exclude utilization data for drugs subject to the 340B program. The COD final rule requires states to describe what processes are in place so that 340B contract pharmacies are properly identifying 340B claims in order to prevent duplicate discounts. DHCS has determined that given the federal requirements regarding the 340B Drug Pricing Program, changes are necessary to how the program is administered within Medi-Cal in order to maintain program integrity, alleviate overpayments, and promote administrative efficiency and effectiveness.

Background: The 340B Drug Pricing Program is a federal program created in 1992 after the adoption of the Medicaid Drug Rebate Program. The Health Resources and Services Administration (HRSA), an agency under the U.S. Department of Health and Human Services, administers and manages the program through its Office of Pharmacy Affairs.

Section 340B of the Public Health Services Act (42 U.S.C. 256b) requires drug manufacturers to offer drugs to certain hospitals and other health care providers (covered entities) at a greatly reduced price. In selling drugs at a low price, participating drug manufacturers are not required to pay a Medicaid drug rebate on drugs purchased through the program and provided to a Medicaid beneficiary (better known as the provision against “duplicate discounts”). A covered entity may choose to not dispense 340B purchased drugs to Medicaid beneficiaries (“carve out”) or to dispense 340B purchased drugs to Medicaid beneficiaries (“carve in”). The entity must declare to HRSA the option they choose when registering as a covered entity. To assist Medicaid programs in the prevention of duplicate discounts, HRSA maintains a file of covered entities that indicates whether the covered entity carves in Medicaid patients.

HRSA permits covered entities to dispense drugs purchased through the 340B program via multiple, off-site, contract pharmacies, most of which are community retail pharmacies and unaware they are processing a claim for a 340B drug. Contract pharmacies may submit a claim to DHCS based on their non-340B acquisition cost and not identify it as a 340B claim (making it eligible for Medicaid rebate). As reported to DHCS by 340B covered entities, reconciliation of claims between the covered entity and the contract pharmacy is done on a regular basis to ensure 340B claims are submitted with the proper identifier. While resubmission of claims will reflect the proper 340B
identifier (making it ineligible for Medicaid rebate), it may not reflect the actual acquisition cost of the drug and the pharmacy is reimbursed Medi-Cal’s lowest rate on file, which is typically higher than the 340B ceiling price. This reconciliation results in a profit that is retained by the covered entity.

In 2014, the Office of Inspector General (OIG) for the Department of Health and Human Services conducted a nationwide study of the 340B Drug Pricing Program. The findings of this study, published in February 2014\(^1\), showed an inconsistency in identification of 340B eligible prescriptions resulting in duplicative discounts without any process in place that would identify improper multiple discounts. The report described an unwillingness or inability (by states) to implement, maintain, and conduct all oversight activities recommended by HRSA. The report was unable to offer recommendations for improving the problems involved with 340B drug utilization in Medicaid programs but implied 340B entities will be subject to increased regulation and scrutiny.

In a March 2016 article in the Journal of Managed Care & Specialty Pharmacy\(^2\), problems were identified in the management of 340B programs within Managed Care systems nationwide relating to formulary rebates, profits from managed care paid prescriptions, and oversight of managed care 340B pharmacy networks. One conclusion that stands out in the article states, “There is also an urgent need for objective, transparent research on the 340B program’s costs, benefits, and implications for managed care pharmacy and practice.”

During a series of meetings with 340B entities and associations since January, DHCS received confirmation that the issues identified in the OIG report, and further described in the aforementioned journal article, not only continue to exist but are complex and significantly institutionalized throughout all delivery systems. Resolution, which would address all the areas of concern, has not been identified by federal or state oversight entities. Without a viable resolution of identified problems, combined with challenges in accessing ceiling prices in order to implement prospective safeguards to circumvent inappropriate billing from covered entities and their contract pharmacy networks, it is in the State’s best interest to prohibit or restrict 340B contract pharmacy arrangements within the Medi-Cal program. Restricting 340B contract pharmacies within the Medi-Cal program would maintain the State’s compliance with Federal requirements, maintain program integrity, and decrease the risk of duplicate discounts and overpayments.

Per CMS, three states have already received State Plan Amendment (SPA) approval to not cover drugs acquired through the federal 340B program and dispensed by contract pharmacies; they are currently reviewing similar SPAs from approximately 20 more.

**Justification for the change:** Legislation is needed to authorize DHCS to restrict the use of 340B contract pharmacies within the Medi-Cal program to comply with existing Federal statutory requirements. Such restrictions would help protect program integrity, decrease unnecessary overpayments, may result in additional drug rebate savings, as

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\(^2\) *J Manag Care Spec Pharm.* 2016;22(3):197-203
well as mitigate the amount of time and resources expended to resolve drug rebate disputes related to 340B claims.

DHCS’ proposed TBL would:

- Require DHCS to seek federal approval to prohibit or otherwise limit the use of contract pharmacies by a covered entity participating in the Medi-Cal program, including but not limited to, the fee-for-service and Medi-Cal managed care delivery systems (W&I Code Section 14105.46 (g)(1)).
- Require DHCS, upon federal approval, to implement on a prospective basis at least 90 days from the date federal approval is obtained but no sooner than January 1, 2018 (W&I Code Section 14105.46 (g)(2)).
- Implement only to the extent that any necessary federal approvals are obtained and federal financial participation is available and is not otherwise jeopardized (W&I Code Section 14105.46 (g)(3)).

Summary of Arguments in Support:
Compliance with the provisions of the COD Final Rule, and Medicaid and CHIP Final Rule preserves federal matching funds by reducing the risk of duplicate discounts, maintaining program integrity and reducing overpayments. Furthermore, when covered entities, without in-house pharmacies to fill and bill 340B prescriptions, cease retroactive submission of 340B claim identification of drugs billed by contract pharmacies, Medi-Cal program savings may be achieved through the collection of rebates for previously excluded 340B drug utilization.

BCP or Estimate Issue # and Title: None