California Department of Health Care Services
Proposed Trailer Bill Legislation

Restricting 340B Drug Reimbursement within the Medi-Cal Program

FACT SHEET

Issue Title: Proposal to Restrict 340B Drug Reimbursement within the Medi-Cal Program. In 2016, the Centers for Medicare and Medicaid Services (CMS) issued the Medicaid and Children's Health Insurance Program (CHIP) Managed Care and Covered Outpatient Drugs (COD) final rules, which contained directives pertaining to the 340B Drug Pricing 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. Under the COD Final Rule, CMS requires the reimbursement of drugs purchased through the 340B program not exceed the 340B ceiling price. If the drug is purchased outside the 340B program, the reimbursement is not to exceed the provider's acquisition cost. 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 comply with federal requirements, 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.

The 340B Program, authorized in 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. If the entity chooses to serve Medicaid beneficiaries, HRSA prohibits using a contract pharmacy, absent an arrangement between the contract pharmacy, covered entity, and state Medicaid agency to prevent duplicate discounts. Any such arrangement is required to be reported to the HRSA Office of Pharmacy Affairs by the covered entity. HRSA maintains a file of covered entities that indicates whether the covered entity carves in Medicaid patients. Although covered entities can purchase 340B drugs for all eligible patients, state Medicaid programs may collect rebates only on drugs purchased outside of the 340B program.

HRSA also provides 340B entities with a ceiling price for each 340B drug, reflecting the maximum price a manufacturer can charge for that drug. 340B entities often purchase

at less than the ceiling price. The list of ceiling prices is not available to anyone other than 340B entities, including state Medicaid programs. Furthermore, a covered entity's actual acquisition cost can only be obtained upon review of the entity's invoice. Given this, DHCS cannot load 340B ceiling prices into the claims processing system for purposes of appropriate claim adjudication prospectively.

As mentioned above, 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 are 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 the state being out of compliance with the new COD Final Rule given that the reimbursement has exceeded the maximum allowable ceiling price for a 340B drug. Furthermore, there have been no arrangements (with the exception of one) among the contract pharmacy, covered entity, and DHCS to prevent issues related to the ceiling price or duplicate discounts.

In October 2009, California codified a pre-existing policy that requires 340B entities to dispense only 340B inventory to Medi-Cal beneficiaries, and bill at actual acquisition cost (AAC) for those drugs (Welfare and Institutions (W&I) Code Section 14105.46). This policy was then made effective through a change in California's Medicaid State Plan.

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 did not 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 relating to formulary rebates, profits from managed care paid prescriptions, and oversight of managed care 340B pharmacy networks.

In response to the COD Final Rule requirement on states to describe how they regulate the use of 340B contract pharmacies, CMS informed DHCS that more than ten states

[1] https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp

[2] *J Manag Care Spec Pharm.* 2016;22(3):197-203

have approved State Plan Amendments disallowing the use of contract pharmacies and additional states are seeking to do the same.

During a series of meetings with 340B entities and associations since January 2017, DHCS has confirmed 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 DHCS' inability to access 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 otherwise limit 340B claims within the Medi-Cal program.

Justification for the change: Legislation is needed to provide DHCS the authority to restrict the scope of the use of the 340B program within the Medi-Cal program in order to comply with existing federal statutory requirements. Such restrictions would help protect program integrity, prevent unnecessary overpayments, result in additional drug rebate savings, as well as serve to mitigate the amount of time and resources expended to resolve drug rebate disputes related to 340B claims.

DHCS' proposed TBL would:

- Make W&I Code Section 14105.46 inoperative upon the effective date specified in a written notification by the Director to the applicable fiscal and policy committees of the Legislature that all applicable federal approvals have been obtained to implement section 14105.465. Also, repeals W&I Code Section 14105.46 90 days following the effective date specified in the notification (W&I Code Section 14105.46 (g)).
- Require DHCS to seek federal approval to prohibit covered entities from dispensing or administering a 340B drug to a Medi-Cal beneficiary (W&I Code 14105.456 (b)).
- Require DHCS, in the event federal approval is not obtained to prohibit dispensing or administering a 340B drug to a Medi-Cal beneficiary, to seek federal approval to limit the use of contract pharmacies by a covered entity; and/or, to prohibit or limit which covered entities, and which specified drugs, can be dispensed or administered to a Medi-Cal beneficiary (W&I Code 14105.456 (c)).
- Allow DHCS to apply the prohibitions and limitations within W&I Code Section 14105.456(c)(2) to the entirety of the Medi-Cal program, or a segment thereof, including but not limited to the Medi-Cal fee-for-service and managed care delivery systems, and any other program eligible for federal drug rebates pursuant to Title 42 of the United States Code Section 1396r-8.
- Require a covered entity subject to the limitations proposed, to bill DHCS or a managed care plan their usual and customary charge (W&I Code Section 14105.456 (d)).

- Require that covered entities bill the Medi-Cal program at their acquisition cost, plus the appropriate dispensing fee for the applicable delivery system (fee-for-service or managed care) in which they operate (W&I Code Section 14105.456 (e)).
- Allow that if a covered entity required to use 340B drugs 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. The covered entity is required to maintain documentation of their inability to obtain the 340B drug, in the form and manner specified by DHCS (W&I Code Section 14105.456 (f)).
- Require a covered entity to identify a 340B drug on the claim submitted to the Medi-Cal program or to a managed care plan for reimbursement, in the form and manner specified by DHCS (W&I Code Section 14105.456 (g)).
- 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, 2019 (W&I Code Section 14105.456 (h)(2)).
- Allows DHCS to implement changes without taking regulatory action (W&I Code Section 14105.456 (i)), and commits DHCS to adopting regulations within five years.

Summary of Arguments in Support:
Compliance with the provisions of the COD Final Rule and Managed Care Final Rule preserves federal matching funds by reducing or eliminating the risk of duplicate discounts, maintaining program integrity and alleviate overpayments. Furthermore, Medi-Cal program savings will be achieved through the collection of rebates for previously excluded drug utilization.