340B Drug Pricing Program Policy

In 2009, California's Welfare and Institutions (W&I) Code 14105.46 was added to require covered entities that purchase drugs under the federal 340B Drug Pricing Program (340B Program) shall dispense only 340B Program-purchased drugs to Medi-Cal recipients. For clarification purposes, the Department of Health Care Services (DHCS) incorporated these requirements into the California Medicaid State Plan for the Medi-Cal program (Fee-For-Service (FFS) and managed care delivery systems) via State Plan Amendment 17-002.

Pursuant to the Centers for Medicare and Medicaid Services (CMS) guidance, states must have a mechanism in place to exclude utilization data for covered outpatient drugs subject to discounts under the 340B Program. CMS clarified that State Medicaid programs have the flexibility to determine how to identify 340B claims.

This bulletin provides further clarification on how these policies apply to various situations within FFS and managed care.

Fee-For Service:
Medi-Cal providers that are covered entities and purchase drugs through the 340B 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 or the beneficiary is ineligible to receive a 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal beneficiary.

- 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 pursuant to W&I Code, Section 14105.45(b)(2)(B).
    - In determining actual acquisition cost, DHCS considers any reasonable method utilized by the covered entity to determine the acquisition cost. Acquisition cost can include shipping and handling charges actually incurred by the covered entity in connection with the purchase of 340B program drugs. The covered entity shall reduce its incurred cost by any discounts, rebates, refunds, price reductions or credits actually received by the covered entity, and that are directly attributable 340B program drugs. Costs of the covered entity that are incurred during the dispensing of a drug shall not be used to determine the acquisition cost of a drug.
- A covered entity that dispenses a drug purchased at regular drug wholesale rates because it is unable to purchase it pursuant to the 340B Program, shall bill the

department at the Usual and Customary charge. The covered entity is required to maintain documentation of their inability to obtain the 340B drug and payment will be made pursuant to W&I Code, Section 14105.45.

- On March 5, 2010, Health Resources & Services Administration (HRSA) released the final rulemaking Notice regarding 340B Contract Pharmacy Services. Unless a covered entity, its contracted pharmacies, and the state Medicaid agency have established an arrangement to prevent duplicate discounts, the Notice prohibits the covered entity and its 340B contracted pharmacies from using drugs purchased under the 340B Program to be dispensed to Medicaid members. Under the Medi-Cal program, a pharmacy under contract with a 340B covered entity may only use 340B drugs to dispense Medi-Cal prescriptions if the covered entity, the contract pharmacy, and the DHCS have established such an arrangement. A 340B contract pharmacy properly identifying 340B claims does not, in and of itself, constitute an "established arrangement" as referenced above. (Please note: DHCS will be providing separate, specific guidance regarding this arrangement.)

- Pursuant to W&I Code, Section 14105.46 and to prevent duplicate discounts, covered entities must identify a 340B drug on the claim submitted to the Medi-Cal FFS program. DHCS requires a "08" be placed in the "Basis of Cost Determination" field (NCPDP Data Element: 423-DN) to identify a 340B drug, which prevents the duplicate discount.

- Physician Administered Drugs:
  Billing and reimbursement for 340B Program drugs dispensed or administered by physicians, clinics, outpatient hospitals, or other provider types, classified as physician administered drug (PAD) claims must also comply with W&I Code, Section 14105.46. However, pursuant to Business and Professions Code, Section 4183, these claim types are not eligible for the pharmacy dispensing fee. Providers billing PAD claims should bill at the actual acquisition cost of the drug plus the administration fee outlined in California Code of Regulations (CCR) Section 51503(e) or the dispensing fee in W&I Code 14132.01 for qualifying entities.

  In February 2009, DHCS notified providers that all PAD claims must include a National Drug Code (NDC). That same update notified providers of the requirement to include a modifier of "UD" whenever a 340B drug was used.

Managed Care:
In (month), 2018 DHCS published All Plan Letter 18-XXX notifying all Medi-Cal managed care health plans (MCPs) of DHCS' requirements and responsibilities associated with encounter data involving 340B purchased drugs.

Covered entities should contact their respective MCP for clarification on billing, reimbursement, and claim identification requirements for both the covered entity and their contract pharmacies.

Medicare Crossover Claims and Other Health Coverage (OHC):
CMS State Release #64 outlined Other Health Coverage rebate requirements for Medicaid programs. OHC claims, including Medicare claims, are rebate eligible when Medi-Cal pays any portion of the claim. For purposes of the rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug. As such, 340B claims billed to other payers must include the claim line indicators ("08" for pharmacy claims and "UD" for PAD claims) when transmitted to Medi-Cal programs, to prevent the duplicate discount. For claim line identifiers required by Medi-Cal managed care plans, please seek guidance from the managed care entity which you have a contract.

When the OHC carrier pays a portion of the claim the "bill at acquisition cost" requirements of W& I Code, Section 14105.46 do not apply. However, where the claim is denied, or the OHC carrier pays zero, Medi-Cal becomes the primary payer and the "bill at acquisition cost" components of W&I Code, Section 14105.46 apply.