Physician-Administered Drugs (PADs) 340B Policy

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This section provides information about billing for physician-administered drugs (PADs) under the 340B Drug Pricing Program. For additional billing information, refer to the *Drugs: Onsite Dispensing Billing Instructions* or *Claim Completion: UB-04* sections in the Family Planning, Access, Care and Treatment (Family PACT) Program manual, or the following sections of this manual:

- *CMS-1500 Completion*
- *Physician-Administered Drugs – NDC: CMS-1500 Billing Instructions*
- *Physician-Administered Drugs – NDC: UB-04 Billing Instructions*
- *CMS-1500 Tips for Billing*

340B Drug Pricing Program

The 340B Drug Pricing Program, established under Section 340B of the Public Health Service Act (*United States Code*, Title 42, Section 256b), is a federal program overseen and administered by the Health Resources and Services Administration (HRSA). The program allows eligible covered entities to purchase covered outpatient drugs from participating manufacturers at discounted prices.

Covered entities must be registered and active in the 340B Office of Pharmacy Affairs Information System (OPAIS) before dispensing 340B drugs. A covered entity must ensure full compliance with all 340B program requirements, including compliance with any contract pharmacy arrangements.

Note: Under federal requirements, a “covered entity” meets all of the following: the entity is listed in Section 340B(a)(4) of the Public Health Service Act (PHSA), meets the 340B Drug Pricing Program’s eligibility requirements outlined in Section 340B(a)(5) of the PHSA and is registered and listed in HRSA’s Office of Pharmacy Affairs 340B OPAIS database. According to HRSA, “covered entities” may include Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, certain types of hospitals (children’s hospitals, critical access hospitals, disproportionate share hospitals, freestanding cancer hospitals, sole community hospitals, rural referral centers), and some specialized clinics (black lung clinics, comprehensive hemophilia diagnostic treatment centers, Title X family planning clinics, sexually transmitted disease clinics, tuberculosis clinics). For more information, refer to the 340B Drug Pricing Program page of the HRSA website.

Billing for 340B Drugs

The California Department of Health Care Services (DHCS) administers the Medi-Cal program and implements applicable federal and state 340B billing and reimbursement requirements for Medi-Cal. Supplement 2 to Attachment 4.19-B of California's State Medicaid Plan and *Welfare and Institutions Code* (W&I Code), Section 14105.46, require the following conditions to be met when dispensing 340B-purchased drugs to eligible Medi-Cal members:

- A Medi-Cal provider who is a covered entity and purchases 340B drugs is required to use 340B-purchased drugs when dispensing drugs to Medi-Cal members.
- If a covered entity cannot purchase a 340B drug, it may dispense a drug purchased at wholesale rates to a Medi-Cal member. The covered entity must maintain documentation of their inability to obtain the 340B drug for at least five (5) years.
- 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 *United States Code*, Title 42, plus the professional dispensing fee.
- A covered entity shall identify a 340B-purchased drug on the claim submitted to the Medi-Cal program for reimbursement.

These requirements apply to all Medi-Cal claims for 340B-purchased drugs, including PAD claims submitted for reimbursement, regardless of fee-for-service or Medi-Cal managed care coverage.

Duplicate Discounts

Federal law prohibits duplicate discounts. A manufacturer may not be subject to both a 340B discount and a Medicaid drug rebate for the same drug. Duplicate discounts can result in significant financial harm to both the Medicaid program and manufacturers.

Pursuant to federal Medicaid drug rebate requirements (*United States Code*, Title 42, Section 1396r-8), DHCS collects the Medicaid drug rebate on any eligible claim, including PADs. To prevent DHCS from invoicing for Medicaid rebates and causing a duplicate discount, providers must properly identify all 340B-purchased drugs on both pharmacy and PAD claims. If the 340B identifier is not present, DHCS will invoice for Medicaid rebates.

Medi-Cal policy uses modifier UD to identify claims involving a 340B drug to ensure the claim is not included in the manufacturer's Medicaid drug rebate invoice. See "Medi-Cal Fee-for-Service and Family PACT" and "Medi-Cal Managed Care Plans" in this section for information about when modifier UD is required.

For non-340B drugs, federal and state rebates occur after dispensing and billing. If a 340B drug is dispensed but not properly identified using the applicable 340B indicator or modifier, a duplicate discount may occur.

For more information about Medi-Cal drug rebates, see the Frequently Asked Questions about Medi-Cal Drug Rebates page of the DHCS website.

Medi-Cal Fee-for-Service and Family PACT

For Medi-Cal fee-for-service and Family PACT Program claims, 340B-purchased drugs must be billed with modifier UD and the applicable HCPCS code and National Drug Code (NDC) on the *CMS-1500* (Box 24D), 837 Professional, 837 Institutional and the *UB-04* (Box 44). Modifier UD is required on all Medi-Cal and Family PACT PAD claims where 340B drugs are used in the procedure.

Note: This requirement applies to both pharmacy claims submitted through the DHCS pharmacy Fiscal Intermediary (Medi-Cal Rx) and medical claims submitted through the DHCS medical Fiscal Intermediary (California Medicaid Management Information System [MMIS]).

Family PACT requires certain drugs to be billed with HCPCS code J3490 (unclassified drugs) followed by modifier U6 or U8. In these cases, modifier UD should appear in the modifier area of Box 24D to the right of, or in second position to, modifier U6 or U8 (for example, J3490 U8 UD).

Refer to the Medi-Cal Rx Provider Manual for NDC-billed medications.

Medi-Cal Managed Care Plans

If 340B-covered entities are billing 340B drugs to Medi-Cal Managed Care Plans (MCPs), then the entities must contact each individual plan to verify the correct method used to identify 340B drugs and prevent duplicate discounts.

Note: The method may differ from Medi-Cal fee-for-service and Family PACT and may not include modifier UD. It is essential to validate the correct method with the MCP.

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.