

California Prohibits PBM Discriminatory Practices Against 340B Program Covered Entities and Contract Pharmacies

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The 340B Drug Program requires pharmaceutical manufacturers participating in the Medicaid program to provide covered outpatient drugs at significantly reduced prices to certain health care organizations and programs, referred to as “Covered Entities” [42 United States Code (USC) §256b].

What are Covered Entities?

Covered Entities include:

- Federal grantee organizations - Federally Qualified Health Centers and Look-Alikes, Native Hawaiian, and Tribal/Urban Indian Health Centers);
- Ryan White HIV/AIDS Program Clinics;
- Specialty Clinics - Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics; and
- Several types of hospitals, including critical access hospitals, sole community hospitals, rural referral centers, and public and nonprofit disproportionate share hospitals that serve a significantly disproportionate number of low-income patients and receive payments from the Centers for Medicaid and Medicare Services to cover the costs of providing care to uninsured patients.

The savings Covered Entities obtain through purchasing 340B Program outpatient drugs at a discount allow them to utilize the savings to provide a range of programs and services that benefit their patients.

What are Pharmacy Benefit Managers (PBM)?

California law defines a pharmacy benefit manager (PBM) as a person, business, or other entity that, under a contract or an employment relationship with a carrier, health benefit plan sponsor, or other third-party payer,

either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other third-party payer, including, but not limited to:

- the processing and payment of claims for prescription drugs,
- the performance of drug utilization review,
- the processing of drug prior authorization requests,
- the adjudication of appeals or grievances related to prescription drug coverage,
- contracting with network pharmacies,
- and controlling covered prescription drug costs [California Business and Professions Code §4430].

What is a Contract Pharmacy?

Covered Entities may dispense 340B outpatient drugs through on-site or off-site contract pharmacies. A “Contract Pharmacy” is a pharmacy owned by or under contract with a Covered Entity registered with the 340B drug program to dispense covered drugs on behalf of the Covered Entity, whether in person or via mail.

Senate Bill 786

According to the sponsors of SB 786 (Senator Anthony Portantino and the AIDS Healthcare Foundation), PBMs have been increasingly demanding that Covered Entities accept less in payment for pharmacy services than other non-Covered Entity pharmacies.

Effective January 1, 2024, SB 786 (which has been codified at Health and Safety Code §127470) will prohibit PBMs from requiring Covered Entities to comply with any terms or conditions that either discriminate against 340B entities and/or their Contracted Pharmacies in connection with dispensing 340B-priced drugs or that prevent a Covered Entity from retaining the benefit of the 340B program discount pricing for covered drugs.

PBM Discrimination

SB 786 specifies that prohibited discrimination includes, but is not limited to, all the following:

Payment or Reimbursement Terms and Conditions

- Payment terms, reimbursement methodologies, or other terms and conditions that distinguish between covered drugs and other drugs account for the availability of discounts under the 340B discount drug purchasing program in determining reimbursement or are less favorable than the payment terms or reimbursement methodologies for similarly situated entities that are not furnishing or dispensing covered

Network Participation Conditions

- Terms or conditions applied to Covered Entities or Contract Pharmacies based on the furnishing or dispensing of covered drugs or their status as a Covered Entity or Contract Pharmacy, including restrictions or requirements for participation in specialty, standard, or preferred pharmacy networks or requirements related to the frequency or scope of audits.

Covered Entity Discrimination

- Refusing to contract with or terminating a contract with a Covered Entity or Contract Pharmacy, or otherwise excluding a Covered Entity or Contract Pharmacy from a specialty, standard, or preferred network solely because of its status as a Covered Entity or a Contract Pharmacy or for reasons other than those that apply equally to entities or pharmacies that are not Covered Entities or Contract Pharmacies;

Retaliation

1. Retaliation against a Covered Entity or Contract Pharmacy based on its exercise of any right or remedy under the law.

Patient Choice Interference

- Interfering with an individual's choice to receive a covered drug from a Covered Entity or Contract Pharmacy, whether in person or via direct delivery, mail, or other form of shipment; and,

Complaint Prohibitions and Gag Orders

- Restricting or prohibiting a Covered Entity from raising a grievance or speaking publicly about any PBM violating the law or filing a legal action against a PBM for violating the law.

Scope of Application

SB 786 applies to any entity that meets the California definition of a PBM, including wholly and partially owned and controlled entities of a PBM, and applies to commercial payors and managed care plans that serve Medicare and Medicaid members. The fee-for-service California Medicaid Program ("Medi-Cal") and the fee-for-service federal Medicare Program are exempt from the new law.

Contract Waiver

The new law's provisions may not be waived, voided, or nullified by contract between the PBMs, Covered Entities, or Contract Pharmacies.

Common PBM 340B Discriminatory Practices Likely to be Prohibited by SB 786

Network Participation

- Prohibit PBMs and plans from excluding 340B-covered entities and/or their contract pharmacies from PBM provider networks.

Differential Payment for Drugs

- Prohibits reimbursing covered entities and/or their contract pharmacies less for 340B drugs than non-340B drugs.

Claims Processing and Data Requirements

- Prohibit PBMs/plans from conditioning payment for 340B drugs on using a specific data system or claims platform or requiring a covered entity to reverse, resubmit, or clarify a claim after the initial adjudication.

Patient Steering

- Ensure that patients can utilize the pharmacy of their choice and will not be penalized or steered away from 340B covered entities to a mail order pharmacy or PBM affiliate; and

Surcharges

- Charging or assessing any fee, chargeback, clawback, or adjustment on the basis that a pharmacy dispenses a 340B drug.

Claims Data Requirements

- Imposing administrative requirements specific to 340B covered entities or contract pharmacies, such as requiring them to use claim modifiers to identify 340B drugs.

Audits and Inventory Management

- Treating 340B providers and their contract pharmacies differently from other similarly situated providers and pharmacies regarding the frequency and scope of audits and/or inventory management.

SB 786 Enforcement Mechanisms

Health and Safety Code Section 127470 (SB 786) does not include any meaningful enforcement penalties for PBMs or plans that violate nondiscrimination prohibitions.

However, it is presumed that enforcement provisions will be included in future regulations promulgated by the California Department of Health Care Services, which enforces hospital and emergency physician fair pricing provisions codified in the same chapter as the new PBM nondiscrimination law.

PBMs operating in the State of California must register with the California Department of Managed Health Care (“DMHC”) as required by California Health & Safety Code Section 1385.005. However, the DMHC is not expected to enforce the prohibition of the SB 786 340B program PBM discriminatory practices.

Hinshaw attorneys have significant experience advising health care organizations on pharmacy law matters. For further information, please contact Michael A. Dowell or your Hinshaw attorney.

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