POLICY BRIEF

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COMMUNITY ACCESS NATIONAL NETWORK

CONFLICTS BETWEEN STATE 340B LAWS & PROPOSED FEDERAL REFORMS

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Executive Summary

Over the past several years, states have enacted statutes to limit or reshape how 340B discounts operate (e.g., unrestricted contract pharmacy participation or requiring state-specific discount mandates).

State-level actions are increasingly colliding with federal proposals to reform the 340B program, including the 340B ACCESS Act (HR 5256), the SUSTAIN 340B discussion draft, the 340B Rebate Model Pilot introduced by the Health Resources & Services Administration (HRSA), downstream effects of drug pricing provisions within the Inflation Reduction Act (IRA), and Medicare Part D's as-of-current "voluntary" claims submissions form.

These federal-state conflicts produce legal preemption fights, operational fragmentation (different compliance regimes across state and federal programs), threats to patient access and affordability, and incentives that could undermine program integrity.

Absent clear federal-state alignment, patient-facing harms and litigation will continue.

Background

The federal 340B Drug Pricing Program requires manufacturers to provide steep discounts on covered outpatient drugs to qualifying "covered entities" so providers can "stretch scarce federal resources to reach more eligible patients and provide more comprehensive services."

Statutory language makes clear that the program's intended beneficiaries are patients, not covered entities. While proposed federal legislation and rulemaking (such as those outlined above) interact with 340B purchasing and reimbursement in complex ways, the vast majority of state-enacted legislation do not require covered entity transparency as to the use of 340B revenue or direct patient benefit.

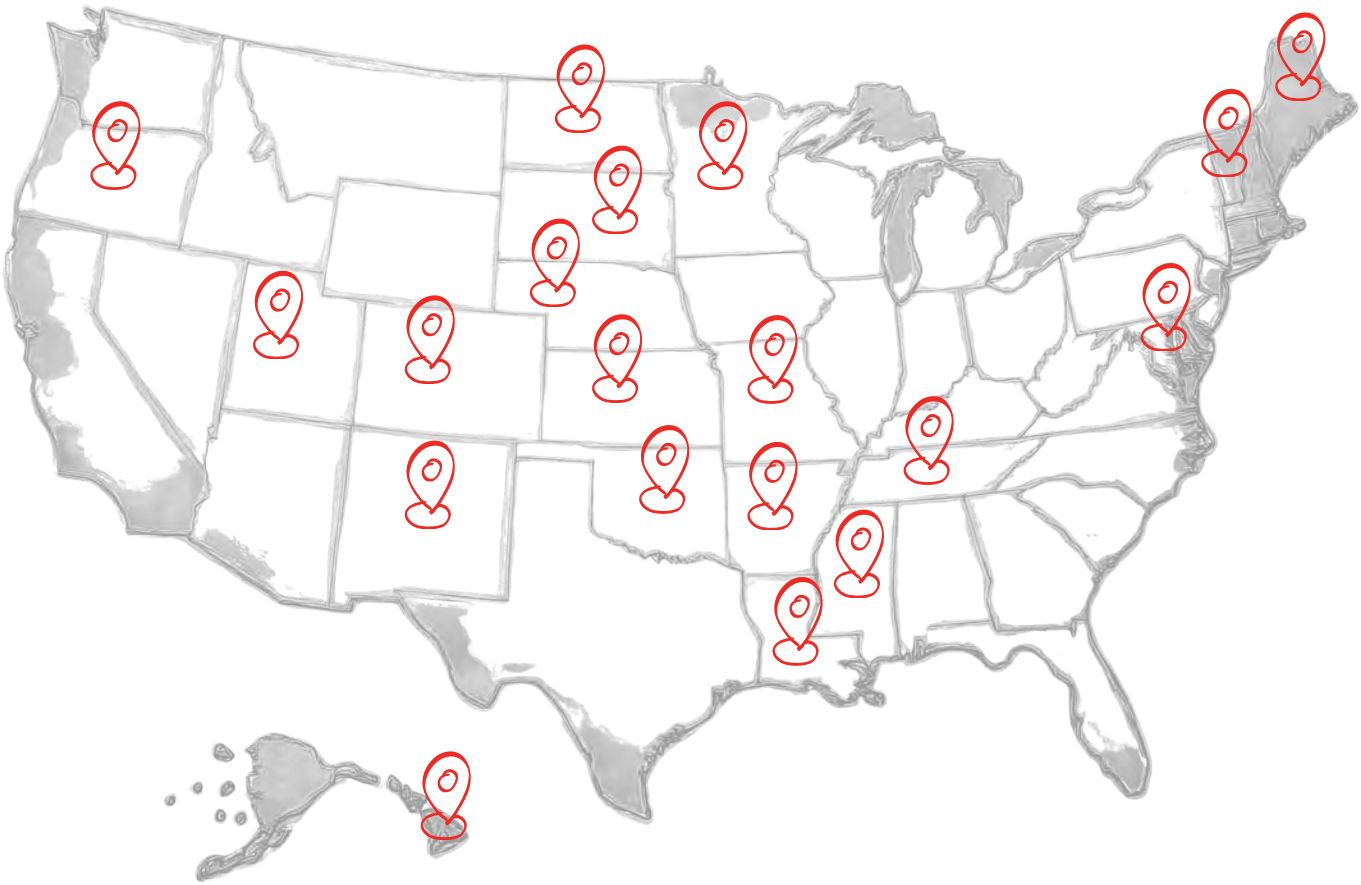
In fact, state efforts to expand 340B arrangements (e.g., mandating manufacturer participation with contract pharmacies or restricting manufacturer audits) have produced litigation and court rulings that further complicate the landscape and ignore patient affordability concerns.

1. State Level Anti-Transparency Legislation

Beginning in 2021, various states introduced, passed, and enacted legislation to expand the federal 340B Drug Pricing Program without any transparency requirements. Despite growing evidence of large health systems, for-profit chain pharmacies, and their Third-Party Administrators' abuse of the program, state legislative efforts looked to extend contract pharmacy arrangements and prohibit manufacturer requirements such as claims modifier dates, audits, or further reporting on covered entities.

These states include:

- Arkansas Act 1103
- Colorado SB 71
- Hawaii HB 712
- Kansas SB 236
- Louisiana Act 358
- Maine LD 210
- Maryland HB 1056
- Minnesota HF 4757
- Mississippi HB 728
- Missouri SB 751
- Nebraska LB 168
- New Mexico HB 78
- North Dakota HB 1473
- Oklahoma HB 2048
- Oregon HB 2385
- South Dakota SB 154
- Tennessee SB 1414
- Utah SB 69
- Vermont H 266



2. Federal Legislation and Rulemaking

In 2025, Congress and the U.S. Department of Health & Human Services (HHS) began pursuing multiple changes to the 340B program: the 340B ACCESS Act (HR 5256) and the bipartisan SUSTAIN discussion draft seek to codify program objectives and add requirements/guardrails; HRSA's Rebate Model Pilot tests the process of moving from upfront discounts to post-sale rebates; the IRA's drug price negotiation provides a retrospective reimbursement architecture; and the Medicare Part D voluntary claims submission form continues to affect manufacturer pricing strategy — all of which impact how discounts and rebates are implemented operationally.

Also in 2025, Senator Bill Cassidy (R-Louisiana), Chair of the Senate Health, Education, Labor, and Pensions (HELP) Committee, concluded a years-long investigation of covered entities, health centers, and contract pharmacies to understand if the revenue these entities and companies were making from the 340B program was actually benefitting the patients this program was intended to serve.

The findings confirmed what advocates have long known: the 340B program has strayed off course.

Senator Cassidy's investigation found that entities are not segregating revenue meant to lower health care and prescription costs for low-income patients. Instead, 340B revenue (or the "spread" from purchasing discounted medications and then charging insurers full price) is treated as any other form of income. This creates a perverse incentive for entities to charge patients more for what would otherwise be considered profit-driven interests.

Core Issues

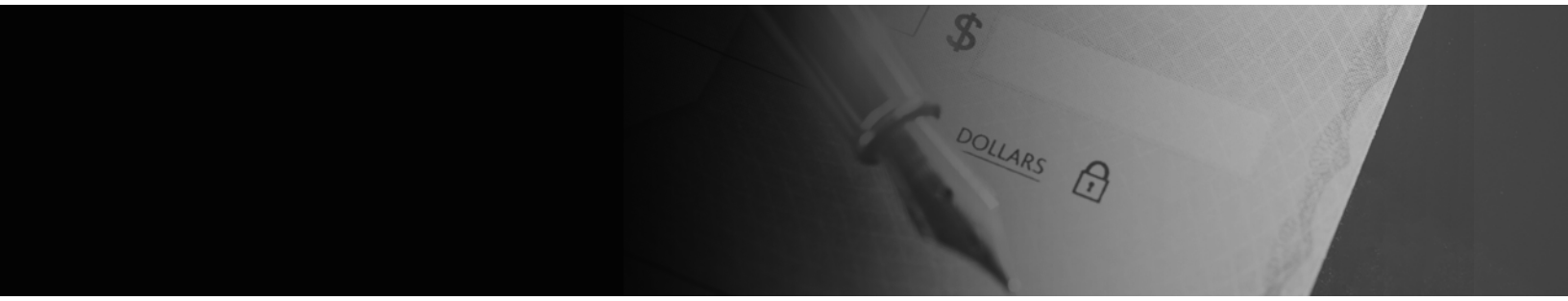
where the conflicts arise

Preemption & Litigation Risk

State laws that mandate particular behaviors by manufacturers or restrict contract pharmacy arrangements can be argued to conflict with the federal statutory scheme and HRSA policy. Manufacturers have sued to block state laws they say unlawfully intrude on interstate commerce and federal administration of 340B. Those suits create uncertainty for covered entities and threaten patient access if state laws are enjoined or if litigation limits manufacturer cooperation. Recent litigation (e.g., Novartis v. Maryland; injunctions in West Virginia and Oklahoma) demonstrate real-world friction. If Congress passes 340B reform bills with specific federal rules (or HRSA implements a uniform rebate pilot), overlapping state mandates will generate legal fights about whether federal legislation preempts state laws — delaying implementation and creating a patchwork enforcement environment.

Operational Fragmentation & Compliance Burdens

Definitions and rules vary between states (description of "patient," contract pharmacy access rules, reporting requirements, or mandatory discounts), while federal proposals may adopt different definitions, reporting standards, or mechanics (e.g., shift from discounts to rebates under the HRSA pilot). Covered entities and manufacturers operating across state lines would therefore face duplicative or conflicting compliance obligations, increased administrative costs, and resource diversion away from patient services. And, smaller covered entities risk being crowded out because they cannot absorb compliance complexity.



Mismatch Between State Mandates & Proposed Federal Rebate Model

HRSA's Rebate Model Pilot contemplates post-sale rebates for selected drugs rather than upfront manufacturer discounts. For all intents and purposes, the proposed model is reflective of how state AIDS Drug Assistance Programs have operated since their inception. Several state laws, however, presuppose the existence of upfront discounts (or explicitly require contract pharmacies to provide discounts at the pharmacy counter).

Mismatches can create payment and reconciliation problems: who credits patients and payers, how to avoid duplicate discounts, and how to audit/value transactions. Billing systems, contract pharmacy agreements, and manufacturer systems will need an overhaul to ensure compliance. In states that mandate upfront discounts, manufacturers or pharmacies could face conflicting legal obligations when HRSA-approved rebates apply at the federal level.

Mismatch Between State Laws Prohibiting Claims Modifiers & Medicare Part D CY26 Payment Policies

On October 31, 2025, the Centers for Medicare and Medicaid Services (CMS) issued a final rule, solidifying guidance on Medicare Part D for calendar year 2026. Included in the guidance was an as-of-yet "voluntary" claims submission form as CMS tests a federal claims repository known as a "clearing house."

Claims modifiers, already used elsewhere in Medicare are a best practice to ensure appropriate claims adjudication.

This regulation, which is expected to become mandatory after a period of testing by CMS, generates a potential conflict with states that have enacted strict prohibitions on the use of claims modifiers.

Duplicate Discount & Rebate Interaction (Medicaid, IRA Negotiation List)

IRA negotiations and Medicare drug price changes, plus Medicaid rebate rules, interact with 340B discount mechanics. States that attempt to impose discount rules on manufacturers (e.g., requiring discounts at contract pharmacies) risk creating situations where duplicate discounts or rebate offsets occur, or where federal duplicate discount prohibitions are difficult to administer.

Federal reconciliation (Medicaid duplicate discount rules) assumes a federal approach; state variations complicate enforcement. The IRA's rebate/inflation provisions and negotiated price ceilings create new incentives for manufacturers and plans.

Meanwhile, state laws trying to regulate Pharmacy Benefit Managers (e.g., forcing flat-fees, forbidding spread-pricing) may alter existing business models. If a state prohibits PBMs from tying compensation to drug list price (as in some laws) but the IRA regime still incentivizes list-price dynamics (e.g., through inflation rebates, negotiation anchor points), there could be internal tension about how PBMs and plans respond.

Conclusion

The combination of varied state 340B statutes and an evolving federal reform agenda (340B ACCESS Act, SUSTAIN discussion draft, HRSA's rebate pilot, IRA-driven pricing dynamics, and Medicare's anticipated adoption of additional claims modifiers) has produced significant legal and operational friction.

Without timely harmonization — via clear federal preemption/compatibility language, transitional safe harbors for pilots, common definitions, and central reconciliation tools — covered entities, manufacturers, and, most importantly, patients will suffer from increased costs, reduced access, and prolonged litigation.

Lawmakers should prioritize narrowly tailored federal alignment measures that preserve state authority to regulate entity transparency and accountability while creating a predictable, single source of truth for the 340B program's operation -- the federal government.