

340B Drug Pricing Program

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September 28, 2026 | 2026-R-0114

Issue

Provide an overview of the federal 340B Drug Pricing Program, including its history, program components, and recent state and federal legislative proposals.

Summary

The 340B Drug Pricing Program, established by Congress in 1992, requires drug manufacturers to provide significant discounts on outpatient drugs to eligible covered entities (certain hospitals and federally funded health clinics). The program, which is administered by the federal Health Resources and Services Administration (HRSA), was designed to help these safety-net providers stretch limited resources, expand services, support uncompensated care, and improve access to medications for vulnerable populations.

Since its inception, the program has grown significantly, with more than 64,000 covered entities and child sites (hospitals with offsite outpatient facilities) participating as of April 2026. In 2025, covered entities purchased approximately \$100 billion in discounted outpatient drugs, representing an estimated \$80 to \$100 billion in discounts.

Despite its benefits, the program has faced concerns about transparency, oversight, growth in covered entities (and pharmacies they contract with), and whether covered entities use program revenue to benefit patients.

Both federal and state policymakers are considering legislation to respond to these concerns. Current federal proposals would, among other things, reduce Medicare reimbursement for 340B drugs in 2027, require covered entities to report 340B revenue and how it is used, establish

requirements for contract pharmacies, and create a statutory definition of a 340B patient. Several states have already enacted laws protecting 340B covered entities from discriminatory practices by health insurers, pharmacy benefit managers, and third-party payors and prohibiting drug manufacturers from limiting contract pharmacy access to 340B discounts. Some states have also set annual reporting requirements for covered entities, requiring them to report detailed program data, including revenue they generate and how it is used.

Some states have faced legal challenges from drug manufacturers, who argue that laws that prohibit them from denying or limiting 340B covered entities' use of contract pharmacies are unconstitutional or preempted by the federal 340B statute. In most cases, courts have upheld these state laws, though federal judges blocked 340B laws in North Dakota and Oklahoma.

Additionally, HRSA recently announced a revised 340B Rebate Model Pilot Program scheduled to start in January 2027 that will give 340B discounts for certain drugs through a rebate that requires covered entities to purchase 340B drugs at non-discounted prices and receive post-sale rebates after submitting claims to manufacturers. (The agency first attempted the pilot program in July 2025, but the court vacated it after the American Hospital Association, Maine Hospital Association, and four hospitals sued before the program's 2026 launch.)

340 Drug Pricing Program

History

In 1990, Congress established the Medicaid Drug Rebate Program (MDRP) as part of the Omnibus Budget Reconciliation Act ([P.L. 101-508](#)). The program requires drug manufacturers to enter into rebate agreements with the federal Department of Health and Human Services (HHS) for their drugs to be covered by Medicaid and Medicare Part B. Under the MDRP, manufacturers pay state Medicaid programs quarterly rebates for covered outpatient drugs so that Medicaid pays no more than the lowest price paid by commercial insurers or public buyers ("best price discount"), with certain exceptions.

According to a [2023 JAMA Network study](#), prior to the MDRP, drug manufacturers voluntarily gave substantial direct discounts on outpatient drugs to safety net hospitals and federally-funded clinics. But once the MDRP began, many manufacturers stopped giving these voluntary discounts because they would then become the best price discount for Medicaid programs. This resulted in significant price increases for these safety net providers, limiting their ability to provide care to vulnerable populations.

In response to this unintended consequence, Congress enacted the [340B Drug Pricing Program](#) in 1992, under the Veterans Health Care Act ([P.L. 102-585](#), § 602, codified at § 340B of the Public Health Service Act ([42 U.S.C. § 256b](#) and [42 C.F.R. Part 10](#))). The program, which is administered by HRSA’s Office of Pharmacy Affairs, requires drug manufacturers to enter into pharmaceutical pricing agreements (PPAs) with HHS in exchange for having their drugs covered by Medicaid and Medicare Part B. Participation in the 340B Program is also a condition of participating in the MDRP.

Under the 340B program, drug manufacturers participating in Medicaid must sell discounted outpatient drugs to certain safety-net health care providers (called “covered entities”) and allow them to charge insurers non-discounted prices. According to a 2015 Government Accountability Office [report](#), these discounted prices are well below retail and wholesale prices and result in an estimated 20% to 50% discount for covered entities (see page 8 of the report).

The program’s [intention](#) is to allow covered entities to use the difference between the cost of the outpatient drugs and the amount reimbursed by insurers to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” However, the 340B statute does not set requirements for how covered entities must use savings generated from the program.

Covered Entities

Federal law defines which health care providers are covered entities that may participate in the program ([42 U.S.C. § 256b\(a\)\(4\)](#)). Eligible facilities fall into two main categories: federally funded clinics and hospital-based facilities that serve a certain percentage of low-income patients. In 2010, Congress expanded the number and types of eligible covered entities through the federal Affordable Care Act (ACA) ([P.L. 111-148](#) § 7101(a)). Currently, eligible covered entities include those listed in Table 1 below.

Table 1: Covered Entities Under the 340B Drug Pricing Program

Hospital-Based Facilities	Federally Funded Clinics	
disproportionate share hospitals (DSH)	federally qualified health centers (FQHCs)	FQHC “look alike” (centers eligible for but that do not receive federal Public Health Service Act Section 330 grant funds)
children’s hospitals excluded from Medicare’s prospective payment system	Ryan White HIV/AIDS program clinics	State AIDS drug assistance programs
critical access hospitals	Native Hawaiian health centers	Tribal and urban Indian health centers

Table 1 (continued)

Hospital-Based Facilities	Federally Funded Clinics	
• freestanding cancer hospitals excluded from Medicare’s prospective payment system	• black lung clinics	• comprehensive hemophilia diagnostic treatment centers
• rural referral centers	• sexually transmitted disease clinics	• tuberculosis clinics
• sole community hospitals	• Title X family planning clinics	

*Source: HRSA 340B Drug Pricing Program [website](#), last accessed September 28, 2026.

The hospital-based facilities listed above must be (1) private nonprofit organizations contracted with a state or local government to provide care to low-income people ineligible for Medicaid or Medicare, (2) owned or operated by state or local government, or (3) public or private nonprofit corporations formally granted governmental powers by state or local government. (For-profit hospitals are not eligible to participate in the program.) Most of these hospitals must also have a certain share of low-income patients (“disproportionate share adjustment percentage”). For example, DSHs must have a disproportionate share adjustment percentage of at least 11.75% for their most recently filed cost report.

Additionally, hospitals with offsite outpatient facilities (called “[child sites](#)”) are eligible to participate in the program if they are listed as a reimbursable facility on the hospital’s most recently filed Medicare cost report.

The [2023 JAMA Network study](#) notes that in 1992, there were approximately 1,000 covered entities (including child sites) which increased significantly to over 50,000 in 2021. The majority (60%) of these covered entities were hospitals. [HRSA](#) reports that as of April 1, 2026, the number of covered entities increased to 64,463 (15,249 covered entities and 49,214 child sites).

Contract Pharmacies

Covered entities participating in the 340B program can choose how to provide pharmacy services to patients, either by directly administering drugs at their facilities using in-house pharmacies to dispense them or contracting with off-site retail or specialty pharmacies (“contract pharmacies”) to dispense drugs on their behalf. (Contract pharmacies, such as CVS and Walgreens, are generally paid a fee for each prescription dispensed or a percentage of the revenue from the prescription.)

Historically, HRSA guidance only allowed covered entities to use a single pharmacy (either an in-house or contract pharmacy) to provide pharmacy services to patients ([61 FR 43549](#), August 23, 1996). In 2001, HRSA created the Alternative Methods Demonstration Project (AMDP), which

allowed covered entities to apply for approval of other types of pharmacy arrangements, such as using a contract pharmacy to supplement an in-house pharmacy. But in 2010, federal guidance removed this requirement, allowing covered entities to contract with multiple pharmacies without needing AMDP approval ([75 FR 10272](#), April 5, 2010).

According to the [Congressional Budget Office](#), after the 2010 change in program guidance, the use of contract pharmacies grew significantly, from approximately 2,000 in 2010 to almost 130,000 in 2021. In response to this growth, some drug manufacturers began restricting covered entities' ability to distribute medications using contract pharmacies. A 2025 Congressional Research Services (CRS) [report](#) notes that HRSA started issuing violation letters to manufacturers, some of whom then sued HRSA, arguing that the 340B law allowed them to set these restrictions. More specifically, HRSA contends that federal law requires manufacturers to allow 340B purchases through an unlimited number of contract pharmacies, whereas manufacturers argue that they are only required to offer the 340B discounted price to covered entities and not ship drugs to an unlimited number of contract pharmacies that are not covered entities themselves (see [Sanofi-Aventis U.S. LLC v. HHS](#), 58 F.4th 696 (3d Cir. 2023) and [Novartis Pharms. Corp. v. Johnson](#), 102 F.4th 452 (D.C. Cir. 2024)). Several states then passed laws prohibiting manufacturers from denying or limiting 340B drug shipments to contract pharmacies, leading to additional lawsuits between states and drug manufactures (see below). (For more detailed information on this litigation, see the CRS [report](#).)

Drug Pricing

Under the 340B program, drug manufacturers must enter into pharmaceutical pricing agreements with HRSA to sell outpatient drugs at discounted prices (typically 20% to 50%) to covered entities. Drugs covered under the program include FDA-approved prescription drugs, over-the-counter drugs listed on a prescription, certain biologics, and insulin. Generally, vaccines, orphan drugs (those used to treat rare diseases and conditions), and drugs purchased by certain hospitals through a group purchasing organization are excluded from the program ([42 U.S.C. § 256b\(a\)\(4\)](#) and [42 U.S.C. § 1396r-8\(k\)](#)).

Federal law sets the maximum price that manufacturers may charge ("ceiling price") for 340B drugs using a [formula](#) that subtracts a drug's Medicaid Unit Rebate Amount (URA) from its Average Manufacturer Price (AMP). The AMP is the average price wholesalers and retail pharmacies pay manufacturers for an outpatient drug. The URA is the average Medicaid rebate for a unit of a drug during the prior quarter (generally 23.1% for most brand-name drugs and 13% for generic and over-the-counter drugs). HRSA calculates the ceiling price based on quarterly cost reports manufacturers send to the Centers for Medicare and Medicaid Services (CMS).

Federal law also establishes a [Prime Vendor Program \(PVP\)](#) to negotiate additional 340B discounts (“sub-ceiling” discounts) with manufacturers on behalf of covered entities as well as provide them information and technical support ([42 U.S.C. § 256b\(a\)\(8\)](#)). Participation in the PVP is voluntary and covered entities may negotiate sub-ceiling discounts independently, though approximately 90% of covered entities participate in the program. The current prime vendor, [Apexus](#), notes that the program participants receive an additional 5% to 20% on 340B drug purchases. Because not all covered entities participate in the program, covered entities may pay different prices for the same drug.

Revenue

Under the 340B program, covered entities purchase outpatient drugs at discounted rates for all patients who receive clinical services at their facilities, regardless of patients’ income or insurance status. These entities generate revenue when the drugs are sold to patients with public (Medicare or Medicaid) or private insurance that reimburse the covered entities at a higher rate than what they paid for the drugs. Generally, the amount of revenue remaining depends on the amount and types of drugs purchased, insurance reimbursement amounts, patient population served, and costs of administering the program.

Federal law does not specify how covered entities must use 340B revenue and it does not require these entities to report how the revenue is used. However covered entities that are federally funded clinics must use their 340B revenue according to their grant requirements. For example, FQHCs must reinvest revenue (including 340B revenue) into patient care, by providing direct patient discounts and expanding or supporting clinical services, among other things ([42 U.S.C. § 254b\(e\)\(5\)\(D\)](#)).

While the exact amount of revenue covered entities generate from the 340B program is unknown, according to [HRSA](#), covered entities purchased \$100 billion in discounted outpatient drugs in 2025, a 22.8% increase from 2024. (In contrast, prescription drug spending in the U.S. grew only 9.08% in 2025.) With an estimated list price value of between \$180 and \$200 billion, covered entities received approximately \$80 to \$100 billion in discounts in 2025. Disproportionate share hospitals accounted for the majority of these purchases (approximately 80% or \$79.2 billion), generating the most revenue.

Program Requirements

Participation in the 340B program is voluntary. Covered entities that choose to participate must recertify annually and keep accurate and timely records in the program’s online database, Office of Pharmacy Affairs Information System ([OPAIS](#)). Participants are also prohibited from (1) receiving

[duplicate discounts](#) from both the MDRP and 340B programs and (2) reselling or transferring 340B drugs to ineligible patients (called “diversion”) ([42 U.S.C. § 256b\(a\)\(5\)](#)).

Duplicate Discounts. Under federal law, manufacturers are not required to provide a 340B discount and a Medicaid drug rebate for the same drug. To prevent duplicate discounts, covered entities must decide whether they will use 340B drugs for their Medicaid patients (“carve-in”) or forgo these discounts and allow states to collect Medicaid rebates (“carve-out”). Covered entities that choose to carve-in may bill Medicaid for the acquisition cost of 340B drugs plus a dispensing fee (forgoing the MDRP rebate) ([42 U.S.C. § 256b\(a\)\(5\)\(A\)\(i\)](#)).

Diversion. Covered entities may only sell, transfer, or dispense 340B drugs to their patients, which 1996 HRSA guidance generally defines as people who (1) the covered entity has established a relationship with and maintains their health records; (2) receive care from a health professional the covered entity employs or contracts with; and (3) for federally funded clinics, receive health care services consistent with the scope of their grant funding (DSH are exempt from this requirement). This definition prevents people who only receive prescription drugs from a covered entity from receiving 340B drugs ([42 U.S.C. § 256b\(a\)\(5\)\(B\)](#)).

Compliance

To ensure program compliance, HRSA audits covered entities and manufacturers, conducting approximately 200 audits per year. Manufacturers may also [audit](#) covered entities’ records, with HRSA approval, to ensure compliance with prohibitions on duplicate discounts and diversion. (HRSA’s audit process and annual results are available on its program integrity [website](#).)

HRSA may impose sanctions against covered entities and manufacturers noncompliant with program requirements. Covered entities that fail to comply with the program’s duplicate discount or diversion prohibitions may be required to refund the discounts back to the manufacturer. Moreover, covered entities that knowingly and intentionally engage in diversion must pay interest on these manufacturer refunds. And if the diversion violation is also systematic and egregious, entities may be removed from the program for a reasonable time HRSA determines ([42 U.S.C. §§ 256b\(a\)\(5\)\(D\) & -256b\(d\)\(2\)\(B\)\(v\)](#)).

For manufacturers, those that charge more than a drug’s ceiling price must refund the overcharges to covered entities. HHS may also impose up to a \$5,000 [civil penalty](#) against manufacturers who knowingly and intentionally overcharge a covered entity for a 340B drug ([42 U.S.C. § 256b\(d\)\(1\)\(B\)\(vi\)\(II\)](#) and [42 C.F.R. § 10.11](#)). Additionally, HHS may terminate the manufacturer’s

PPA, which would then exclude the manufacturer's covered outpatient drugs from the Medicaid program ([42 U.S.C. § 256b\(a\)\(1\)](#) and [42 U.S.C. § 1396r-8\(a\)\(1\)](#)).

Additionally, in 2024, HRSA established an administrative dispute resolution [process](#) to resolve claims by (1) covered entities that manufacturers overcharged them for drugs and (2) manufacturers, after the manufacturer audited a covered entity, that the entity violated the prohibition on diversion or duplicate discounts.

Challenges

The 340B program was created to increase access to safety-net health providers for under- and uninsured patients by allowing covered entities to use the revenue they generate from purchasing discounted 340B drugs to help subsidize uncompensated care, expand services, and give patients free or low-cost medications.

However, critics of the program have expressed several concerns, including the following:

1. **Reporting Requirements:** the program does not require covered entities to report revenue they generate from purchasing 340B drugs or how that revenue is used, making it difficult to study their activities and ensure the program benefits patients;
2. **Price Transparency:** the program does not list 340B drug prices and whether manufacturers are providing required discounts;
3. **Compliance Rates:** the program has historically had low compliance rates (one or more program violations) among covered entities (for example, almost half of covered entities had adverse findings in HRSA audits in 2025);
4. **Program Growth:** after the federal ACA expanded the types of eligible covered entities, the program grew significantly (from approximately 1,000 covered entities in 1992 to over 64,000 in 2026) which has raised concerns that the program now (a) is too large for HRSA to oversee effectively and (b) contributes to health care consolidations, incentivizing hospitals to acquire provider practices and clinics (sometimes in high income areas) to give these sites 340B discounts and increase revenue;
5. **Contract Pharmacies:** there has been significant growth in the number of contract pharmacies, many of which are retail pharmacies (CVS and Walgreens) that generate profits that are not required to be reinvested into patient care; it is also difficult to track contract pharmacy compliance with program requirements, increasing risk for diversion and duplicate discounts;
6. **Duplicate Discounts:** states and providers face difficulties tracking whether a 340B drug also received a Medicaid rebate because of inadequate coordination between covered entities, contract pharmacies, manufacturers, and Medicaid programs (for example, federal

tracking tools were generally designed for Medicaid fee-for-service systems rather than managed care plans); and

7. **Diversion:** because the definition of a 340B patient was established by HRSA guidance and not by law, it has been interpreted inconsistently among covered entities, enabling some to provide 340B discounts to patients with limited contact (or only a single contact) with them.

Recent Federal Activity

Proposed CMS Rule

In July 2026, CMS proposed a 2027 Hospital Outpatient Prospective Payment System (OPPS) [rule](#) that, among other things, would reduce Medicare reimbursement for 340B drugs in 2027 from the average sales price (ASP) plus 6% (what Medicare generally pays providers for Part B outpatient drugs) to ASP minus 33.4%. According to CMS, this approximate 37% reduction is intended to align Medicare reimbursement with actual hospital acquisition costs for 340B medications.

According to the [Kaiser Family Foundation](#), CMS based the proposed payment reduction on a cost acquisition [survey](#) of 340B drugs completed by hospitals earlier this year. The proposal is based on a 2018 CMS [rule](#) (and authorized under [Executive Order 14273 \(2025\)](#)) to reduce Medicare payments for 340B drugs by almost 30%, but the rule was overturned in 2022 by the Supreme Court because CMS had not first conducted a cost acquisition survey.

CMS's proposed cut to 340B drug reimbursement would reduce Medicare spending on these drugs by approximately \$4.85 billion in 2027, while increasing spending on non-drug outpatient services by the same amount because of federal law's budget neutrality requirements. (The law generally requires CMS to maintain the same amount of aggregate spending through OPPS regardless of reimbursement changes.) This means that savings from reductions in 340B payments to hospitals would be redistributed to both 340B and non-340B hospitals through higher payments for non-drug outpatient services.

The proposed rule exempts from the reduction in Medicare reimbursement for 340B drugs (1) rural sole community hospitals (those that are a region's only source of short-term, acute inpatient care), (2) children's hospitals, and (3) cancer hospitals exempt from prospective payment systems. Additionally, critical access hospitals are not subject to this reduction because they are not reimbursed under the OPPS (see this Kaiser Family Foundation [article](#) for a more detailed analysis of the proposed rule's effect on hospital revenues).

New HRSA Grant Requirement for FQHCs

In June 2025, HRSA [issued](#) new grant terms for FQHCs that require them to offer insulin and injectable epinephrine (EpiPen) products to low-income patients at or below the discounted 340B price the centers paid for the medications. This means that FQHCs must pass along savings from purchasing these medications at 340B discounts directly to patients and not use the savings for other purposes. HRSA set the new grant terms as part of its implementation of presidential [Executive Order 13937 \(2020\)](#), Access to Affordable Life-Saving Medications.

340B Rebate Model Pilot Program

In July 2026, HRSA announced a revised [340B Rebate Model Pilot Program](#) that will give 340B discounts for certain drugs through a [rebate model](#) that requires covered entities to purchase 340B drugs at non-discounted prices and receive post-sale rebates after submitting claims to manufacturers. The agency first attempted the pilot program in July 2025, but the American Hospital Association, Maine Hospital Association, and four hospitals sued before the program's scheduled January 1, 2026, launch arguing that HRSA violated the Administrative Procedure Act when establishing the program ([Am. Hosp. Ass'n v. Kennedy](#), (D. Me. Dec. 1, 2025)). A federal court in Maine blocked the pilot, a decision upheld by the First Circuit, and the pilot was vacated.

In February 2026, HRSA issued a request for information (RFI) soliciting public comments from various stakeholders on a revised program. Relatedly, in July, a separate lawsuit ruled that drug manufacturers cannot implement 340B rebate programs on their own without HHS approval, ([Novartis Pharms. Corp. v. Sec'y, U.S. Dep't of Health & Human Servs.](#), 155 F.4th 223 (3d Cir. 2025)).

The revised pilot program, which begins January 1, 2027, covers certain drugs under the [Medicare Drug Price Negotiation Program](#). Participating manufacturers must submit rebate plans to HRSA for approval and commit to the pilot program for at least one year. Covered entities must be given at least 45 days after dispensing a drug to submit a claim to the manufacturer, who must then pay the rebate (or issue a denial) within 10 days after receiving it.

Legislative Proposals

At the federal level, Congress may consider modifying the 340B program in line with one or more of the following proposals:

340B Drug Pricing and Affordability for Patients Act. This [discussion draft](#) was issued by Sen. Cassidy in June after a year-long [investigation](#) of how covered entities generate and use 340B program revenue. Among other things, the discussion draft would (1) require hospital covered

entities to use an income-based, sliding-fee scale for patients to lower their out-of-pocket costs for 340B drugs; (2) require hospitals to annually report (and HHS to make publicly available) specified information, such as charity care expenditures and the number of patients receiving 340B medications; (3) set requirements for contract pharmacy arrangements, such as requiring them to annually register and certify compliance with program requirements and subjecting them to financial penalties and potential program removal for violations; and (4) establish a statutory definition of a 340B patient.

HHS FY 26 and FY 27 Proposed Budgets. HHS budgets proposed in both [FY 26](#) and [FY 27](#) transfer 340B program oversight from HRSA to CMS, including eligibility assessment, participant recertifications, audits, and the OPAIS. (The transfer has not yet occurred.)

Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act (SECURE 340B Act, ([H.R. 9599](#))). This bipartisan bill proposes several changes to the 340B program, such as (1) setting standards and HHS oversight for contract pharmacy arrangements; (2) establishing a statutory definition of a 340B patient; (3) requiring covered entities to annually report to HHS their program revenue and how it is used, charity care levels, and prescriptions by insurance type; and (4) starting federal FY 27, assessing an annual user fee on covered entities to fund the program's administration and oversight. The bill is currently under consideration by the House Committees on Education and Workforce, Energy and Commerce, and Ways and Means.

Tax Exempt Hospital Transparency Act ([H.R. 9504](#)). This bill would require tax-exempt hospitals to report 340B program information on their IRS filings, including the (1) total number of patients administered 340B drugs; (2) amount of revenue generated from the program; and (3) program costs incurred (such as legal, administrative, compliance, and educational costs). The bill is currently under consideration by the House Committee on Ways and Means.

Recent State Activity

Legislation

We found over 50 bills enacted in other states over the past five years that address components of the 340B program. Several states (such as Arkansas, California, Colorado, Delaware, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Virginia, and West Virginia) enacted anti-discrimination laws that prohibit health insurers, pharmacy benefit managers (PBMs), or other third-party payors from discriminating against 340B covered entities and contract pharmacies. These laws generally prohibit health insurers from paying lower reimbursement rates for 340B drugs or imposing additional fees or requirements on a covered entity because they participate in the 340B

program. Some laws also prohibit manufacturers from denying or limiting acquisition or delivery of 340B drugs for covered entities and their contract pharmacies.

Other states (such as Colorado, Hawaii, Idaho, Indiana, Maine, Minnesota, Ohio, Vermont, and Washington) enacted laws requiring 340B covered entities to annually report specified information, such as 340B drug acquisition costs, savings generated from the 340B program, and how those savings were used. (Some states limit the reporting requirements only to hospital covered entities.) We provide examples of these laws in Table 2 below.

Table 2: Examples of Recent 340B Legislation Enacted in Other States

State	Legislation	Description
Arkansas	2021 HB 1881 (codified at Ark. Code § 23-92-601 et seq.)	• Enacted the 340B Drug Pricing Nondiscrimination Act, which prohibits third parties (payors and PBMs) from engaging in “discriminatory contracting,” such as (1) refusing to cover or offering lower reimbursement rates for 340B drugs, (2) refusing to allow 340B contract pharmacies to participate in networks, or (3) transferring the benefit of 340B savings away from 340B providers • Prohibits third parties from (1) coercing or requiring patients to use a mail-order pharmacy; (2) discriminate, lower reimbursement, or impose separate terms on a 340B pharmacy because it participates in the program; or (3) change a patient’s copayment because their pharmacy participates in the 340B program, among other things • Prohibits drug manufacturers from banning a pharmacy from contracting with a covered entity by denying access to their drugs or (2) denying or prohibiting 340B drug pricing for an in-state community pharmacy that receives 340B drugs from covered entities
Colorado	2022 HB 22-1122 (codified at Colo. Rev. Stat. § 10-16-1501 et seq.)	• Enacted the “Colorado 340B Prescription Drug Program Anti-Discrimination Act” that prohibits health insurers, PBMs, and other third-party payors from discriminating against covered entities (including their contract pharmacies) • Prohibited activities include, among other things, (1) refusing to reimburse covered entities or contract pharmacies for dispensing 340B drugs, (2) assessing a fee or charge back against these entities and pharmacies because they participate in the 340B program, (3) requiring covered entities and contract pharmacies to contract with a specific pharmacy or health plan in order to access the third-party payor’s pharmacy network, or (4) restricting the ways a covered entity or contract pharmacy may dispense or deliver 340B drugs

Table 2 (continued)

State	Legislation	Description
Delaware	2024 sHB 383 (codified at Del. Code § 3374A)	• Prohibits PBMs and purchasers from discriminating against covered entities and contract pharmacies because they participate in the 340B program, including by (1) reimbursing them for a 340B drug at a rate lower than the national average drug acquisition cost; (2) imposing terms or conditions different than those imposed on non-340B entities and pharmacies (such as charging additional fees, restricting pharmacy network access, requiring more frequent auditing, or interfering with patient access to 340B drugs); and (3) imposing provisions the insurance commissioner determines are interfering with the ability of covered entities and contract pharmacies to maximize 340B discounts • Violations of the law are deemed an unfair business practice
Hawaii	2025 HB 712 (codified at Hawaii Rev. Stat. § 481N-1 et seq.)	• Prohibits drug manufacturers from denying, restricting, or prohibiting the acquisition, shipping, or delivery of a 340B drug to 340B contract pharmacies; • Authorizes 340B covered entities and the attorney general to bring a civil action against manufacturers within four years of a violation; • Requires 340B covered entities to report certain information annually to the state's hospital trade association (Healthcare Association of Hawaii) and the association to publicly post annual reports of aggregated information it receives
Idaho	2025 H. 0136a (codified at Id. Code § 41-351)	• Requires covered entities to annually report specified information to the Department of Health and Welfare, State Controller's Office, and attorney general, such as drug acquisition costs, 340B revenue generated by payor type, and how the revenue was used
Illinois	2026 HB 4327 (to be codified at 30 ILCS 5/3-1B)	• Requires the state auditor to conduct a comprehensive investigation of how 340B covered entities in Illinois participate in the 340B program, including program participation impacts on state health programs, such as Medicaid and the State Employees Group Insurance Program • Requires the state auditor to make recommendations to the legislature based on the investigation findings

Table 2 (continued)

State	Legislation	Description
Indiana	2021 HB 1405 (codified at Ind. Code § 27-1-24.5-19.5)	• Prohibits contracts between PBMs and 340B covered entities from including provisions that (1) establish reimbursement rates that would diminish the 340B benefit to a covered entity, (2) impose a fee that is higher than or not imposed on a non-340B pharmacy, (3) exclude covered entities from PBM networks because the entities participate in the 340B program, or (4) otherwise discriminate against covered entities • Violations of the law are deemed an unfair or deceptive business practice
Louisiana	2023 HB 548 (codified at La. Rev. Stat. §§ 40:2882 to 2886)	• Establishes the “Defending Affordable Prescription Drug Costs Act,” which prohibits third-party payors from engaging in discriminatory practices against 340B covered entities • Prohibited practices include, among other things, (1) reimbursing 340B covered entities less for 340B drugs than they do for the same drugs to non-340B entities; (2) interfering with patient choice; and (3) imposing fees, clawbacks, restrictions, or other adjustments that differ than those applied to non-340B entities • Also prohibits drug manufacturers and distributors from directly or indirectly interfering with the acquisition by, or delivery of 340B drugs to, contract pharmacies • Violations of the law are deemed an unfair trade practice
Maine	2023 LD 1395 and 2025 LD 210, Part P (codified at 22 Maine Rev. Stat. Ann. § 1728)	• Requires hospital covered entities to annually report specified information to the Maine Health Data Organization, such as (1) how the hospital uses 340B savings to benefit the community through programs and services, (2) annual estimated savings from the 340B program compared to total drug expenditures, and (3) a description of the hospital’s internal review and oversight of the program (the Maine Health Data Organization must post the reports on its website) • Expands the information hospital covered entities must annually report to include specified data, such as the aggregated acquisition costs and payments received for 340B drugs by payor type and the number of drugs dispensed to patients

Table 2 (continued)

State	Legislation	Description
Minnesota	2023 SF 2995 and 2025 HF 2 (codified at Minn. Stat. § 62J.461)	• Requires 340B covered entities with a service address in the state to annually certify and report to the state Department of Health 340B data, such as drug acquisition costs and program expenses • Generally subjects covered entities who fail to comply with reporting requirements to a fine of up to \$500 for each day the report is past due • Requires the insurance commissioner to annually report the information it receives from covered entities to the legislature
Nevada	2023 AB 434 (codified at Nev. Rev. Stat. §§ 683A.1785 and 687B.805)	• Among other things, the act prohibits PBMs and health insurers from (1) discriminating against 340B covered entities and contract pharmacies regarding reimbursements; (2) taking certain actions to limit the ability of covered entities and contract pharmacies to receive the full benefit of participating in the 340B program; (3) excluding these entities or pharmacies from an insurance network because they participate in the 340B program; (4) restricting a patient's ability to receive a 340B drug (for example, by imposing additional cost sharing requirements); or (5) taking certain other actions to limit these entities and pharmacies from participating in the 340B program
Rhode Island	2025 SB 114 (codified at RI Gen. Laws § 5-19.3)	• Prohibits health insurers, PBMs, third-party payors, and drug manufacturers from discriminating against 340B covered entities and contract pharmacies • Prohibited practices include, among other things, (1) imposing additional fees, chargebacks, or other adjustments for 340B covered entities that are not imposed on non-340B entities, (2) interfering with the delivery of 340B drugs to contract pharmacies, (3) restricting access to pharmacy networks for 340B entities and pharmacies, (4) providing lower reimbursement rates for 340B drugs than non-340B drugs, and (5) imposing audit requirements for 340B entities and pharmacies that are inconsistent with federal requirements

Table 2 (continued)

State	Legislation	Description
South Dakota	2025 SB 154 (codified at S.D. Codified Laws § 58-29G)	• Prohibits drug manufacturers from directly or indirectly (1) denying, restricting, or banning the order or delivery of a 340B drug to a location authorized to receive the drug by a 340B covered entity or contract pharmacy, unless prohibited by federal law or (2) requiring 340B covered entities or contract pharmacies to submit claims or utilization data as a condition of allowing them to acquire or deliver a 340B drug unless required by federal law • Expressly provides that this law does not require manufacturers to provide 340B discounts to a pharmacy or prohibit them from limiting distribution of a drug or auditing 340B covered entities in authorized under federal law • Authorizes 340B covered entities and contract pharmacies to file a civil action against a manufacturer for violating the act's requirements
Vermont	2025 H. 266 (codified at 18 V.S.A. §§ 4681 to 4685 & 9406 to 9407)	• Prohibits drug manufacturers from (1) interfering with a 340B contract pharmacy's acquisition or dispensing of a 340B drug or (2) requiring 340B covered entities to submit specific information as a condition for allowing covered entities to acquire 340B drugs • Requires manufacturers to provide 340B discounts upfront instead of through post-sale rebates • Allows covered entities and contract pharmacies to bring a civil action against manufacturers that violate the law • Requires hospital covered entities to annually report, until January 1, 2031, specified information to the Green Mountain Care Board, such as 340B drug acquisition costs, payments received, and the use of contract pharmacies • Generally caps the amount hospital covered entities can charge for outpatient drugs
Virginia	2026 SB 278	• Requires the Health and Human Resources secretary to convene a stakeholder working group to evaluate the impact of the 340B program in Virginia, focusing on governance, transparency, and pharmacy service access in rural and underserved communities • Requires the secretary to report the working group's findings and recommendations to the legislature by November 1, 2026

Table 2 (continued)

State	Legislation	Description
Washington	2023 sSB 5187 , §211 (budget act) 2026 SB 5981 (codified at Rev. Code of Wash. §§ 43.71C.010 et seq. and 69.65.010 et seq.)	• Requires the Washington State Health Care Authority (the state's Medicaid agency) to establish annual reporting requirements for 340B covered entities and provide aggregate data on the cost and benefits of carving-in or carving-out Medicaid beneficiaries from the 340B program • Prohibits drug manufacturers from discriminating against 340B covered entities and contract pharmacies by, among other things, (1) restricting, denying, or changing 340B discount pricing; or (2) requiring covered entities to submit claims or utilization data as a condition of purchasing 340B drugs • Subjects manufacturers to civil penalties of up to \$5,000 per day for violating the act's requirements • Expands the information covered entities must annually report to include, among other things, claims data, aggregate drug acquisition costs, program revenue generated, and how revenue was used • Authorizes 340B covered entities to file a civil action against a manufacturer for violating the act's requirements

Litigation

As states began enacting laws to prohibit drug manufacturers from denying or limiting 340B covered entities' use of contract pharmacies (which lowers manufacturer revenue), manufacturers have challenged several of these laws, generally arguing that they are preempted by the federal 340B law and violate the U.S. Constitution's Dormant Commerce Clause. (This clause prohibits states from enacting laws that excessively burden interstate commerce.)

As an example, in 2021, Arkansas passed the first 340B nondiscrimination law ([Act 1103](#)) that, among other things, prohibits drug manufacturers from limiting or denying contract pharmacy access to 340B medications. The Pharmaceutical Research and Manufacturers of America (PhRMA) challenged the law, arguing that it was preempted by the federal 340B statute. In 2024, the U.S. Court of Appeals for the 8th Circuit upheld a lower court's ruling that the federal 340B law does not preempt Arkansas law ([PhRMA v. McClain](#), 95 F.4th 1136 (8th Cir. 2024)). The U.S. Supreme Court declined to hear the appeal, leaving the Arkansas law in effect. In July 2026, the state's attorney general filed a lawsuit against drug manufacturers for engaging in business practices that undermine access to 340B drug discounts ([State ex rel. Griffin v. AbbVie Inc.](#), No. 57CV-26-184 (Ark. Cir. Ct. Polk Cnty. July 21, 2026)).

In most cases, courts have [upheld](#) state 340B laws challenged by drug manufacturers. However, a federal judge permanently blocked North Dakota's 340B law, ruling it violated both the U.S.

Constitution's Supremacy and Commerce clauses by interfering with a federal drug pricing program ([AbbVie Inc. v. Wrigley](#), 832 F. Supp. 3d 920 (D.N.D. 2026)). A federal judge also temporarily blocked Oklahoma's law before it took effect, ruling it was preempted by federal law ([AbbVie Inc. v. Drummond](#) 808 F. Supp. 3d 1266 (W.D. Okla. 2025)). The state's subsequent appeal of the ruling is pending ([AbbVie Inc. v. Drummond](#), No. 25-6184 (10th Cir. Nov. 14, 2025)). (A list of court decisions on state contract pharmacy laws is available on the American Hospital Association [website](#).)

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