340B MIDWEST REGIONAL CONFERENCE & EXPO

340B Program

A 2026 Legislative Update

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OHIO PHARMACISTS ASSOCIATION

340B Midwest Regional Conference & Expo

Speaker Introduction

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Mark Ogunsusi is a partner in the Healthcare and FDA practice group at K&L Gates, where he serves as a national leader in drug pricing, health systems, and pharmacy law. He represents hospitals, integrated delivery networks, GPOs, retail and specialty pharmacies, and pharmaceutical technology vendors.

He is widely recognized for his deep experience with the 340B program — including patient eligibility, virtual inventory management, contract-pharmacy design, HRSA audits, manufacturer disputes, and value-based care strategies. Mark also advises on PBM relationships, drug reimbursement, and limited-distribution models.

Mark's passion for safety-net providers stems from his years as a practicing pharmacist serving rural and underserved communities.

Conflict of Interest Disclosure

- Mark Ogunsusi represents 340B hospitals, integrated delivery networks, hospital associations, and other groups associated with the 340B program.
- Mark Ogunsusi holds minor stock in GSK, Novo Nordisk, Eli Lilly, and Merck.
- The materials and discussions contained in this presentation may not be relied upon as legal advice.

Agenda

01 Speaker Introduction & Conflict of Interest

02 Learning Objectives

03 Continuing Education Questions

04 **State Legislative Updates — Contract-Pharmacy Protection Laws & Litigation**

05 **Federal Legislative Updates — SECURE 340B Act, Senate (Cassidy) Draft & SUSTAIN 340B Act**

06 Continuing Education Questions — Answers

LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:

- Describe the key provisions of the House SECURE 340B Act, the Senate (Cassidy) discussion draft, and the bipartisan SUSTAIN 340B Act.
- Identify state contract-pharmacy protection laws and the manufacturer challenges to them.
- Explain the constitutional and statutory arguments in 340B contract-pharmacy litigation, including AbbVie v. Wrigley.
- Assess the practical implications of 2026 state and federal 340B legislative developments for covered entities.

Continuing Education Questions

Q1. Which is a component of the House SECURE 340B Act that could be harmful to Ohio covered entities?

A. Sec. 3 — Account Care Organizations
B. Sec. 5 — HIPAA Compliance Rules
C. Sec. 8 — Data "Clearinghouse" / Sec. 7 — Program Integrity
D. Sec. 9 — Data Interoperability Requirements

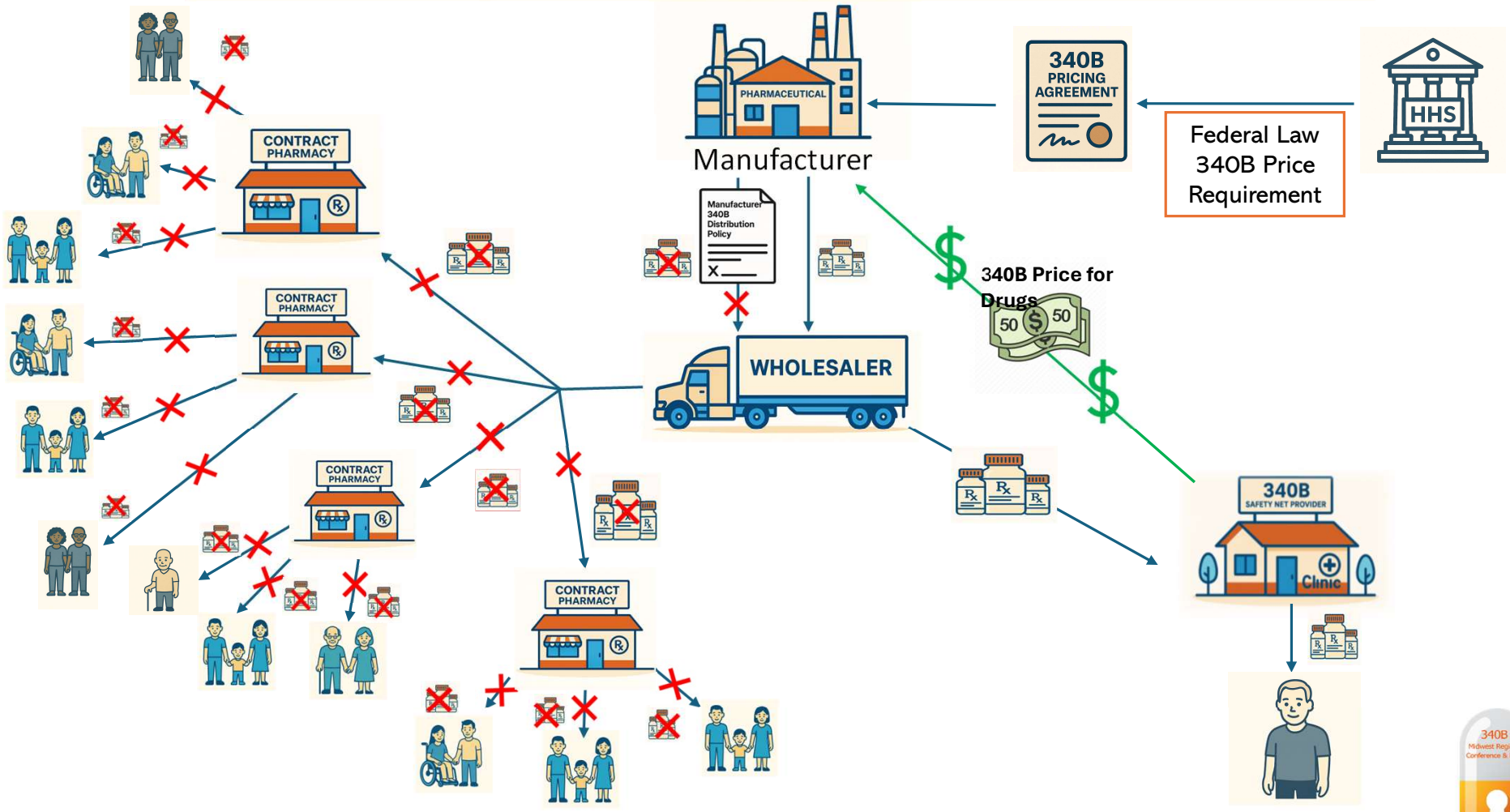
Q2. In AbbVie Inc. v. Wrigley, the North Dakota federal court addressed a state law that:

A. Repealed the 340B program in North Dakota
B. Protected covered entities' access to 340B pricing through contract pharmacies
C. Required manufacturers to pay cash rebates directly to the state
D. Protected distribution of 340B drugs to contract pharmacies

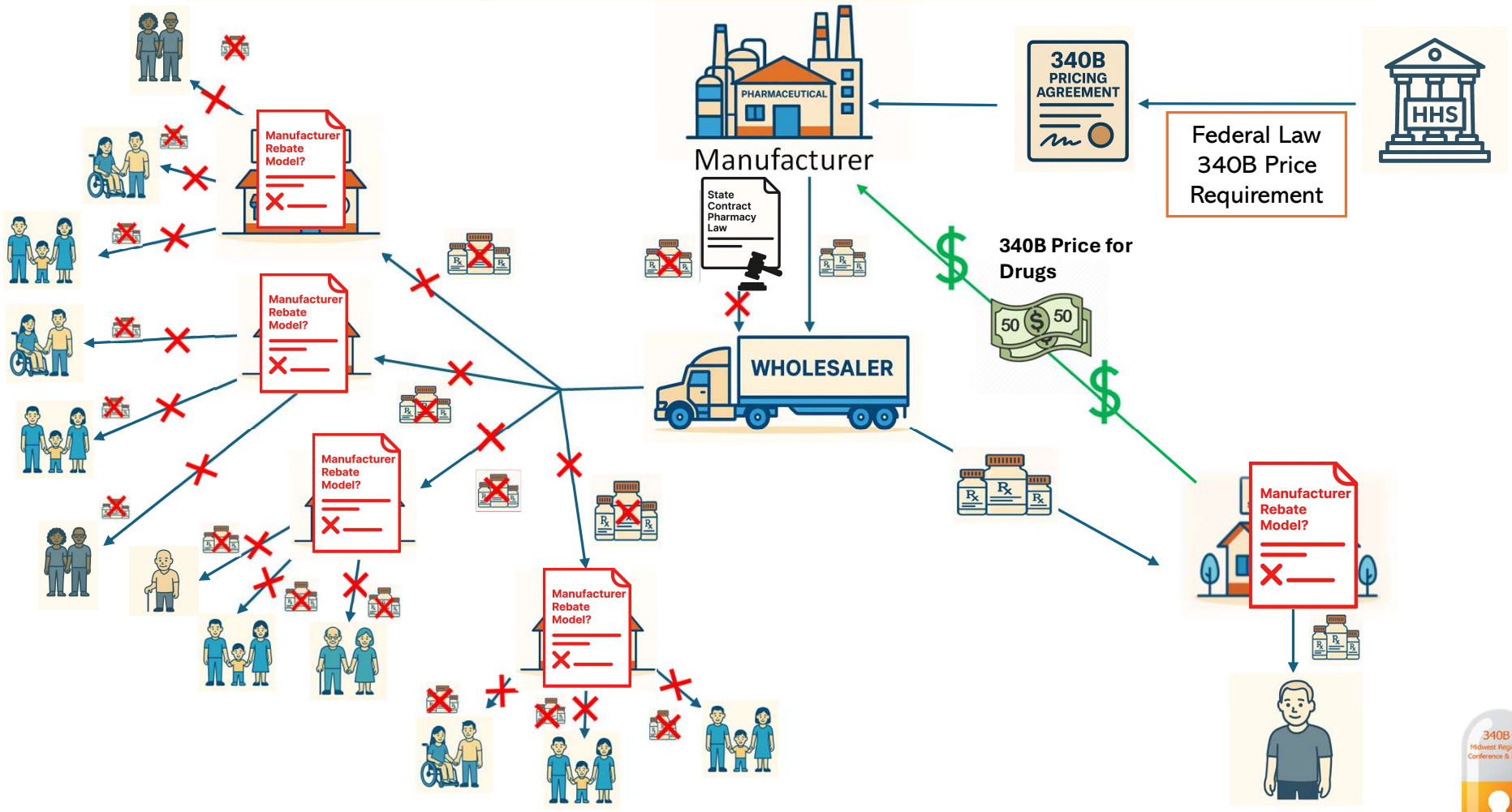
STATE LEGISLATIVE UPDATES

Contract Pharmacy Protection Laws Provider Reporting Mandates, and PBM Anti-Steering.

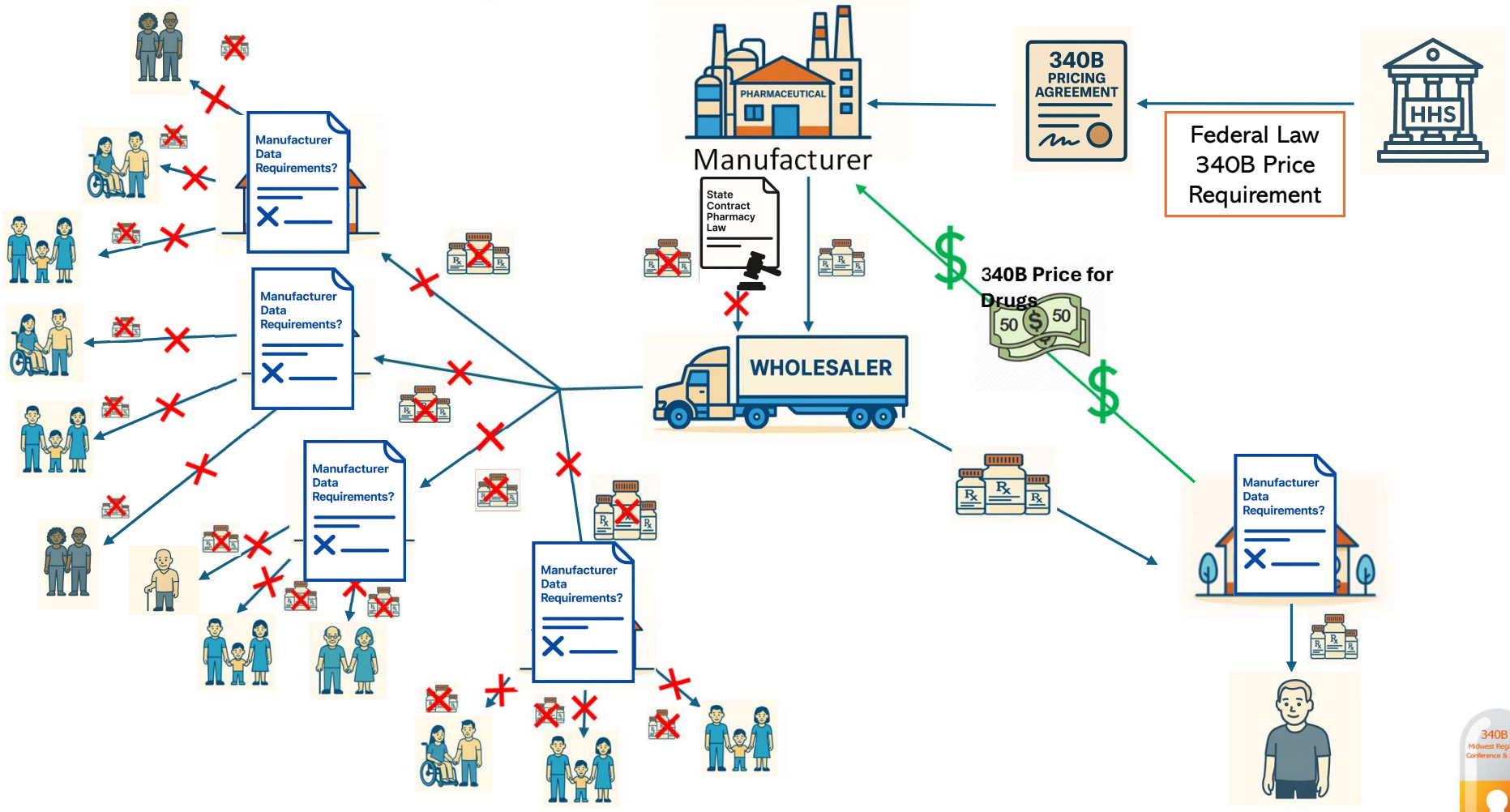
States' Rights to Protect Patient Access



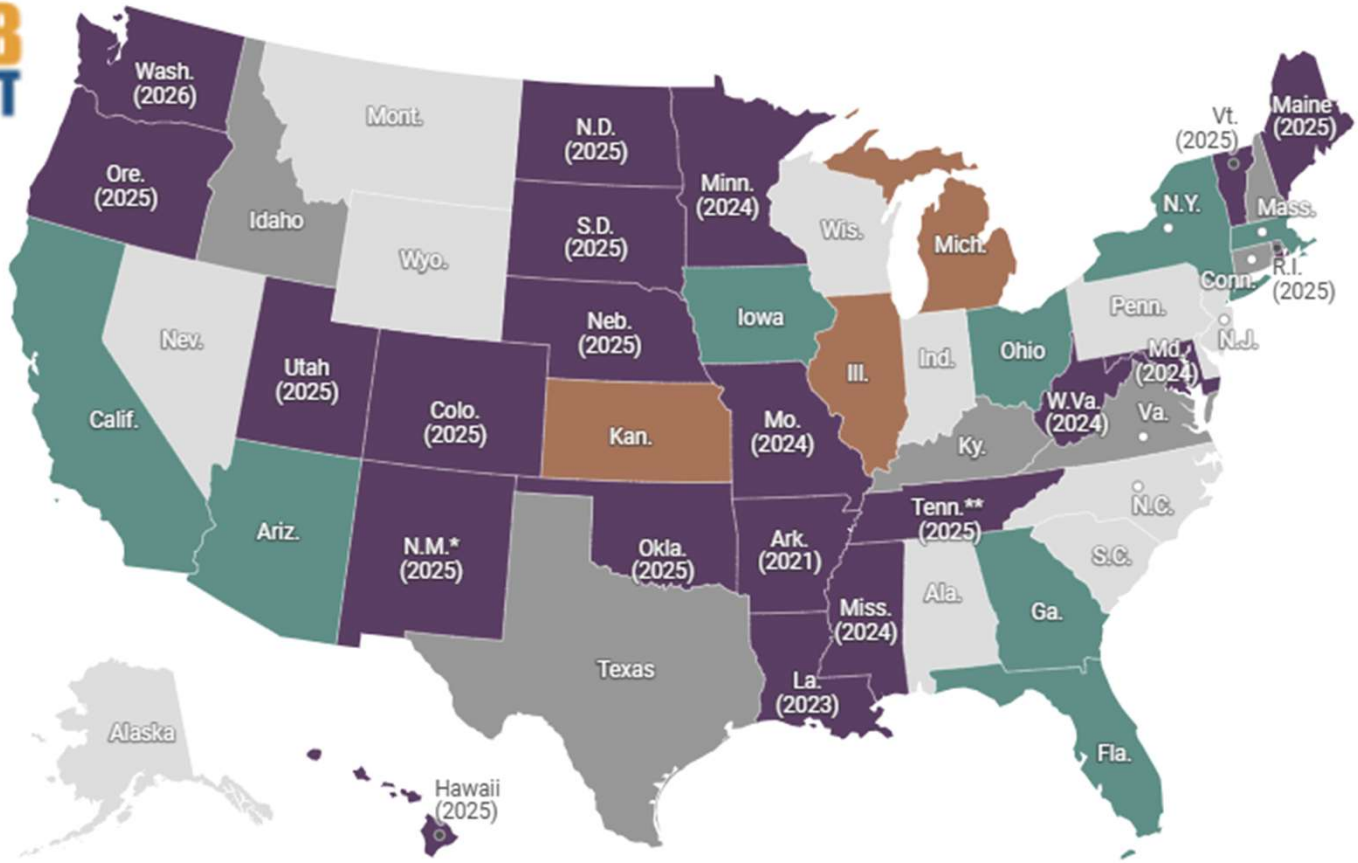
States' Rights to Protect Patient Access



States' Rights to Protect Patient Access

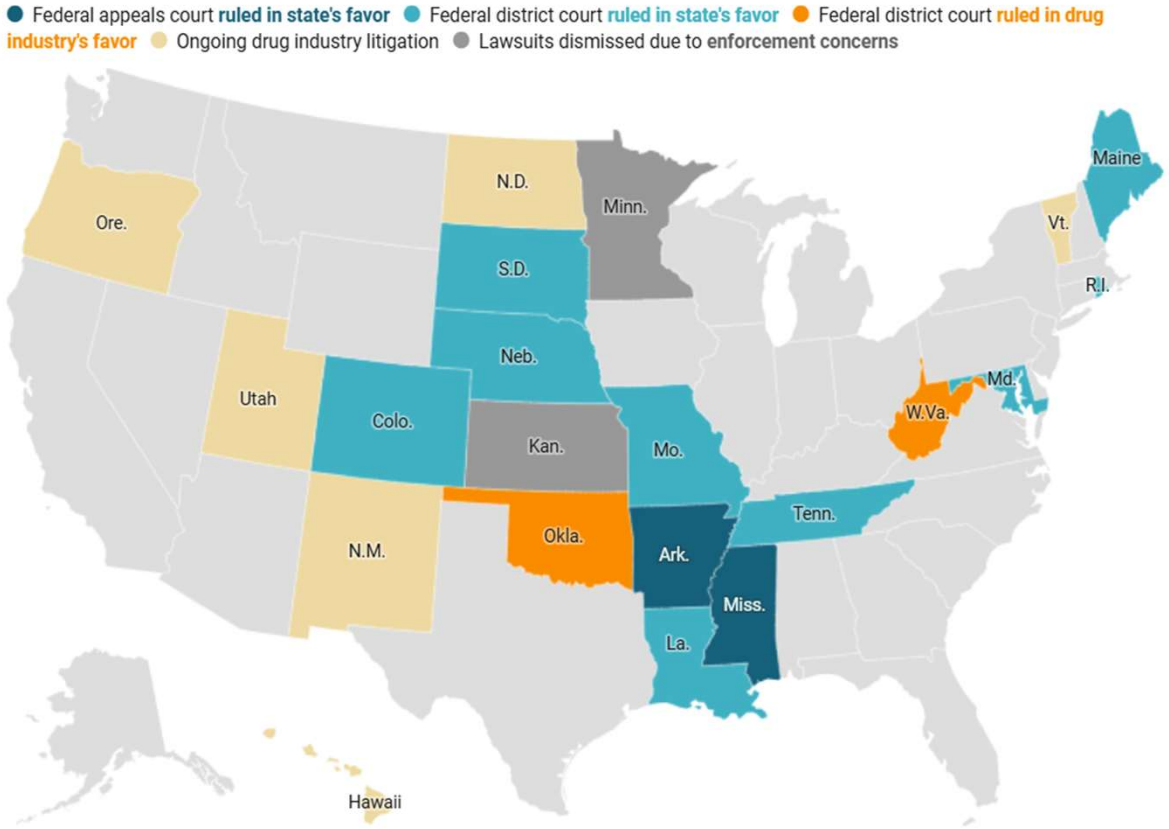


State 340B Contract Pharmacy Laws and Bills



● Contract pharmacy law **enacted** ● Contract pharmacy bill **introduced** in 2025-2026 session ● Contract pharmacy bill **cleared first legislative chamber** ● Contract pharmacy bill **died**

Federal Court Cases and Rulings on State 340B Contract Pharmacy Access Laws



Note: Most federal court rulings are currently under appeal. Hover over states for additional details.

Key Manufacturer Arguments: Contract Pharmacy Litigation

1. US Constitution - Preemption: **340B Statute, Supremacy Clause, and 10th Amendment**
2. Violates the US Constitution - Preemption: **Contracts Clause**
3. Violates US and State Constitution - Due Process "Takings": **5th and 14th Amendments**
4. Violates the US Constitution - Extraterritoriality: **Dormant Commerce Clause**
5. Violates US and State Constitutions – **Excessive Fines**
6. State Constitution - **Single-subject, Clear title, and Original Purpose**
7. ***Spending Clause; Intergovernmental Immunity**

Chart: most recent federal appellate 340B decisions

Court	Issue	Holding	Practical impact
8th Cir. (NEW)	Missouri contract-pharmacy protection law, S.B. 751 (Novartis v. Hanaway appeal)	Affirmed denial of preliminary injunction; found no likely dormant Commerce Clause violation and no field or conflict/obstacle preemption of S.B. 751.	Cements Eighth Circuit support for state contract-pharmacy laws, extending McClain from Arkansas to Missouri.
8th Cir.	Arkansas state contract-pharmacy protection law	Upheld Arkansas law against manufacturer challenge.	Encouraged states to legislate despite unresolved national split.
5th Cir.	Louisiana contract-pharmacy protection law	Upheld Louisiana Act 358 against preemption, vagueness, takings, and Contract Clause challenges.	Strong appellate support for state 340B contract-pharmacy protections in the Fifth Circuit.
5th Cir.	Mississippi contract-pharmacy protection law (AbbVie PI appeal)	Affirmed denial of preliminary injunction; found no likely preemption or takings violation.	Early Fifth Circuit support for state protection laws even after 3d and D.C. Circuit federal decisions.
5th Cir.	Mississippi contract-pharmacy protection law (Novartis and PhRMA appeals)	Again upheld Mississippi law and rejected renewed efforts to block enforcement.	Reinforces that state noninterference laws can survive manufacturer challenges in this circuit.
4th Cir.	West Virginia and Maryland contract-pharmacy statutes	Found significant preemption risk and blocked state-law protection efforts.	Shows state protection laws still face serious preemption headwinds outside the Fifth and Eighth Circuits.

This chart highlights the current split dynamic: the Eighth and Fifth Circuits have sustained state contract-pharmacy protections — now including Missouri S.B. 751 in Novartis Pharmaceuticals Corp. v. Hanaway, No. 25-1619 (8th Cir. July 1, 2026) — while Fourth Circuit decisions still create meaningful preemption risk.

But see North Dakota 340B Contract Pharmacy Decision

AbbVie Inc. v. Wrigley, No. 1:25-cv-00081, slip op. at 16–24 (D.N.D. Apr. 27, 2026)

Holding

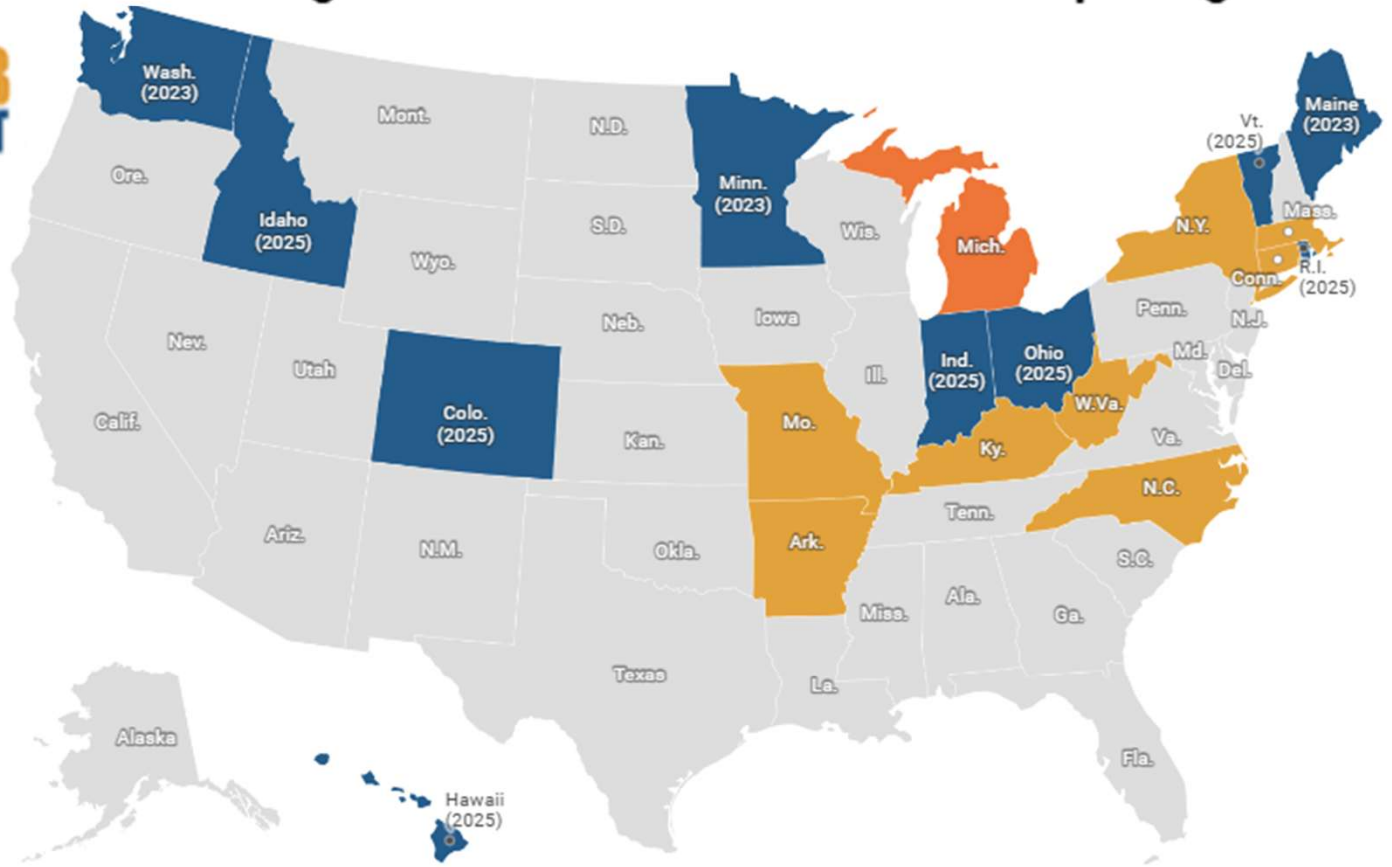
- Court distinguished Arkansas's McClain decision because **North Dakota did not limit H.B. 1473 to delivery regulation.**
- Court read H.B. 1473 to bar manufacturer contract conditions on 340B sales, including single-pharmacy and claims-data requirements.
- On that reading, the statute intruded into a federally structured 340B regime and was field preempted.

Implications

- First summary judgment ruling striking down a state 340B contract pharmacy law on the merits.
- Gives manufacturers a roadmap to distinguish state laws from Arkansas's delivery-only framework.
- Strengthens Spending Clause and federal-program structure arguments in future challenges to similar statutes.

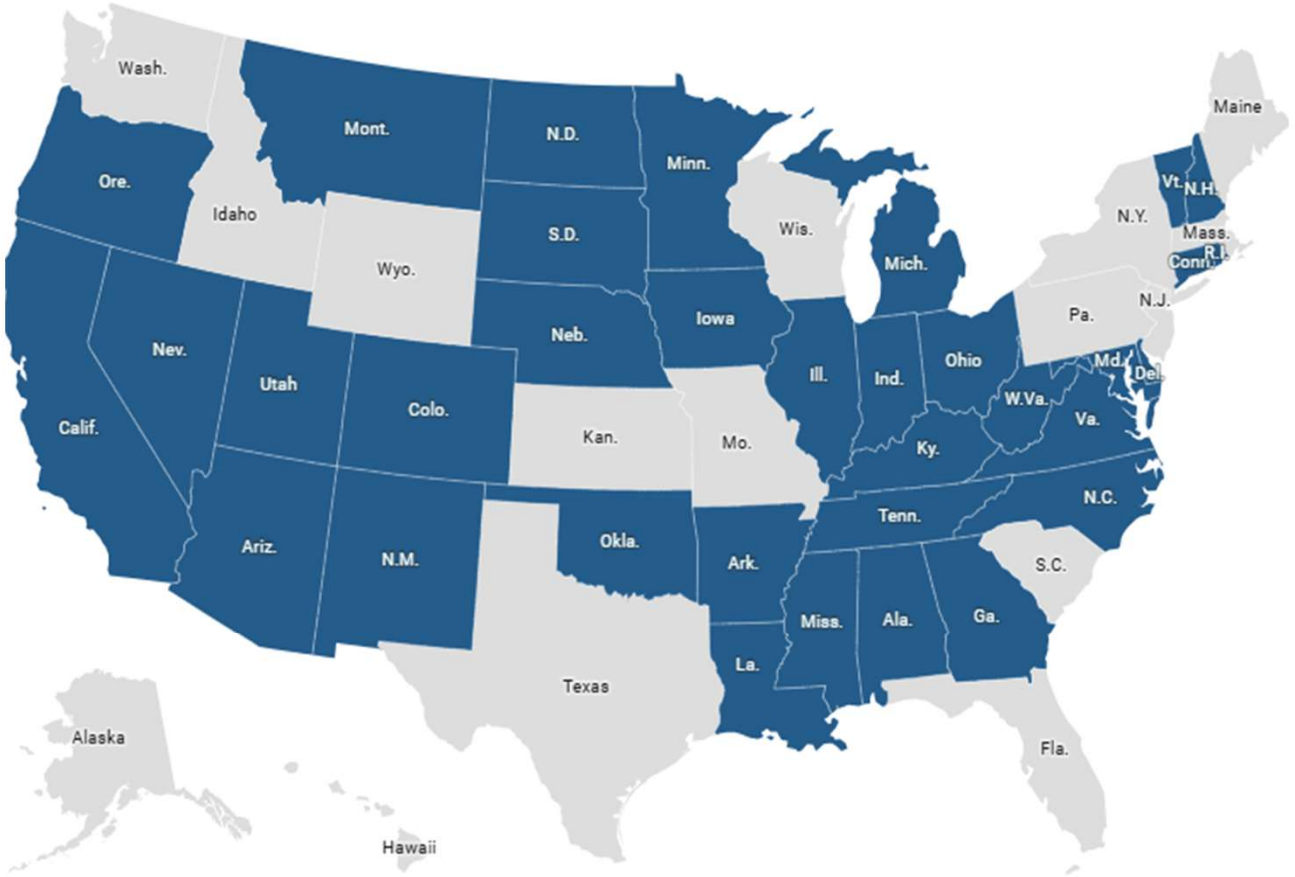
Significance: This is the earliest known merits-stage summary judgment decision invalidating a state 340B contract pharmacy statute.

2025 State Legislation Tracker: 340B Provider Reporting Bills and Laws



Provider reporting law passed | Bill introduced | Bill cleared first legislative chamber | Bill with state governor

Legislation Tracker: Laws Enacted that Bar PBMs from Differentially Reimbursing 340B Providers



Common Legal Objections To Manufacturer Conditions

- Covered entities argue that the 340B statute requires the ceiling price and does not authorize manufacturers to condition access on new data transfer obligations.
- Provider advocates also argue that unilateral conditions undermine the pharmaceutical pricing agreement executed with HHS.
- Manufacturers respond that claims-level controls are needed to prevent duplicate discounts and diversion in evolving distribution environments.
- Absent a definitive nationwide resolution, Hospitals should expect continued policy fragmentation and disputes.

STATE CONTRACT PHARMACY BILLS

Anatomy of a State 340B Contract Pharmacy Statute — The Common Clauses, Illustrated By Louisiana, Missouri, And Colorado.

Anatomy of a State 340B Bills

State 340B contract-pharmacy bills share a recurring architecture. Most combine some or all of the following clauses:

- **Manufacturer / distributor non-interference** — protects delivery of 340B drugs to contract pharmacies.
- **PBM / payer anti-discrimination** — bars reimbursement and contracting penalties tied to 340B status.
- **Data / claims restrictions** — limits mandatory submission of claims, utilization, and pricing data.
- **Enforcement & penalties** — unfair-trade-practice liability, per-package violations, Board of Pharmacy discipline.
- **Hospital transparency (e.g., Colorado)** — restricts and reports how hospitals use 340B savings.

Comparison 1 — Who Is Protected? ("340B / Covered Entity")

LOUISIANA
La. R.S. 40:2882(2)

"'340B entity' means an entity participating... in the 340B... program... including its pharmacy, or any pharmacy contracted with the participating entity to dispense" 340B drugs.

▸ Pharmacies ARE inside the definition — the contract pharmacy is itself a "340B entity."

MISSOURI
Mo. Rev. Stat. §376.414.1(2)

"'Covered entity', the same meaning given... in Section 340B(a)(4) of the Public Health Service Act, 42 U.S.C. §256b(a)(4)."

▸ Federal definition only — does NOT include pharmacies. Pharmacies are reached through the §2 prohibition, not the definition.

COLORADO
Colo. SB25-071, §6-29-103(1)

"'340B covered entity' or 'covered entity' has the meaning set forth in Section 340B(a)(4)... 42 U.S.C. §256b(a)(4)."

▸ Federal definition only — does NOT include pharmacies. "Pharmacy" is defined separately and protected in the operative text.

Source: La. R.S. 40:2882 · Mo. Rev. Stat. §376.414 · Colo. SB25-071

Comparison 2 — Manufacturer Prohibition: Which Actors?

LOUISIANA
La. R.S. 40:2884(A)

"A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly," acquisition or delivery to a contract pharmacy.

▸ **Manufacturer + distributor; "directly or indirectly." No 3PL / agent / affiliate language.**

MISSOURI
Mo. Rev. Stat. §376.414.2

"A pharmaceutical manufacturer, third-party logistics provider, or an agent or affiliate… shall not deny, restrict, or prohibit, either directly or indirectly"… A "wholesale drug distributor… shall not be considered an agent or affiliate."

▸ **Adds 3PL + agent + affiliate; "directly or indirectly." Expressly CARVES OUT wholesale distributors.**

COLORADO
Colo. SB25-071, §6-29-105(1)(a)

"A manufacturer, third-party logistics provider, or repackager, or an agent, contractor, or affiliate… including an entity that collects or processes health information, shall not, directly or indirectly, deny, restrict, prohibit, discriminate against, or otherwise limit"…

▸ **Broadest: adds repackager, contractor, and data-clearinghouse entities. No wholesaler carve-out.**

Source: La. R.S. 40:2884 · Mo. Rev. Stat. §376.414 · Colo. SB25-071

Comparison 3 — Health-Information / Data Prohibition

LOUISIANA
La. R.S. 40:2883 (PBM list)

No manufacturer data-submission ban. The only data limit is on PAYERS/PBMs: "requiring… the submission of ingredient costs or pricing data pertaining to 340B drugs."

▸ **N/A as to manufacturers — LA has no manufacturer health-information prohibition (only a narrow PBM pricing-data limit).**

MISSOURI
Mo. Rev. Stat. §376.414

No health-information or data-submission prohibition. The statute reaches only denial/restriction of acquisition or delivery.

▸ **N/A — Missouri has no data-submission prohibition at all.**

COLORADO
Colo. SB25-071, §6-29-105(1)(b)

"A manufacturer shall not directly or indirectly require… [a CE or contract pharmacy] to submit any health information, claims or utilization data, purchasing data, payment data," unless voluntary or federally required.

▸ **Only Colorado bars compelled data submission by manufacturers — aimed squarely at "designated pharmacy" claims-data mandates.**

Source: La. R.S. 40:2884 · Mo. Rev. Stat. §376.414 · Colo. SB25-071

Comparison 4 — Enforcement & Penalties

LOUISIANA

La. R.S. 40:2885; 51:1407

Violation of the Unfair Trade Practices & Consumer Protection Law; "a violation occurs each time a prohibited act is committed." AG-enforced; "no right to bring a private action."

▸ Per-ACT (not per-package). Up to $5,000 per violation (intent to defraud). No private suit.

MISSOURI

Mo. Rev. Stat. §376.414.3–.4

"unlawful practice" under §407.020; "Each package… shall constitute a separate violation." Board of Pharmacy may "discipline, suspend, or revoke" a license.

▸ Per-PACKAGE. AG civil penalty up to $1,000/violation (§407.100) + Board licensure discipline.

COLORADO

Colo. SB25-071, §6-29-105(3)

"unfair or deceptive trade practice" under §6-1-105; "Each package… constitutes a separate violation." AG investigates; Board discipline under §12-280-108.

▸ Per-PACKAGE. CCPA civil penalty up to $20,000/violation (§6-1-112) + Board discipline.

Source: La. R.S. 40:2885 · La. R.S. 51:1407 · Mo. Rev. Stat. §376.414 · Mo. Rev. Stat. §407.100 · Colo. SB25-071 · C.R.S. §6-1-112

Clause 5 — Colorado Hospital Transparency

Colorado pairs its access protections with a hospital-transparency regime governing how reporting hospitals use “340B savings” (aggregated market-rate costs minus aggregated acquisition costs).

Prohibited uses of 340B savings (§6-29-105(2)):

- No more than 35% of board compensation / expense reimbursement; no tax penalties or fines; no image-promoting advertising; no lobbying or influence costs; no board/officer travel, lodging, food; no gifts or entertainment.

Annual transparency report (§25-3-134):

- Annual 340B savings; a description of how savings are used; the aggregated market-rate and acquisition costs used to calculate savings; and total operating costs plus charity-care costs.

Source: Colo. SB25-071, C.R.S. §25-3-134

FEDERAL LEGISLATIVE UPDATES

The House SECURE 340B Act, The Senate (Cassidy) Discussion Draft, and The SUSTAIN 340B Act — Section-by-section.

Three Bills in Play — The House SECURE 340B Act

- **SECURE 340B Act**: "Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act" (119th Cong.); 142 pages; introduced July 6, 2026 (no bill number yet).
- **Sponsors**: Reps. Scott Peters (D-Cal.) and John Joyce (R-Pa.), joined by Reps. Jake Auchincloss (D-Mass.), Dan Crenshaw (R-Tex.), and Nanette Barragán (D-Cal.); all five sit on House Energy & Commerce, which has 340B jurisdiction.
- **Core Architecture:** Pauses manufacturer 340B rebate models for four years while a new statutory patient definition, contract-pharmacy standards, and a data "clearinghouse" are stood up. Amends PHSA § 340B and adds SSA § 1150D.
- **Framing vs. Reality:** Styled as a program-integrity measure, but on close reading *nearly every operative section would contract eligibility, reduce program savings, or shift proprietary data and value from covered entities to manufacturers, plans, and PBMs*.
- **Lineage:** Closely tracks the 340B ACCESS Act (H.R. 5256, 119th Cong.), developed from PhRMA-aligned ASAP 340B principles; the hospital field calls that family a "pharmaceutical industry wish list."

Source: SECURE 340B Act (H. bill text), Peters press release

Sec. 2 — Patient Definition (Harmful)

- **WHAT IT DOES**
  - Adds § 340B(a)(11) codifying a narrow, prescription-based patient test in place of HRSA's relationship-based 1996 guidance.
  - **24-month look-back**: Patient must have received a qualifying outpatient service within the preceding 24 months (the 1996 test has no time window).
  - **Prescription-origination test**: The prescription must originate with a covered-entity provider — reviving the "prescription-by-prescription" standard HRSA proposed in 2015 and withdrew in 2017.
  - **Per-prescription application**: Eligibility must be independently satisfied for each order (§ 340B(a)(11)(B)).

- **HOSPITAL IMPACT — SEVERE**
  - Disqualifies drugs prescribed by outside specialists on referral — a routine, clinically necessary pattern — stripping 340B pricing from a large share of lawfully dispensed drugs.
  - Converts a status-based relationship test into a transaction-by-transaction test, multiplying audit exposure and inviting retroactive claim-by-claim disqualification.
  - Sec. 2(c) referral pathway is facially accommodating but functionally restrictive (documentation chains, 25% audit trigger, 35% authorization cliff, penalties payable to the manufacturer).
  - One Hospital Industry Opinion: provisions of this kind would "render the 340B program unrecognizable."

Source: SECURE 340B Act (H. bill text), 42 U.S.C. § 256b

Sec. 3 & 4 — Contract Pharmacies & Child Sites

- **SEC. 3 — CONTRACT PHARMACIES (Good but Onerous)**
  - Adds § 340B(a)(13). Usefully codifies that manufacturers may not condition ceiling-price access on contract-pharmacy use — a protection hospitals support.
  - But layers on a dense registration, pre-approval, written-agreement, and public-disclosure regime (location, distance from CE, dispensing volume).
  - Pre-implementation registration gate can delay patient access; public disclosure creates competitive exposure without a matching integrity benefit.
- **SEC. 4 — CHILD SITES (HARMFUL)**
  - Adds § 340B(a)(14): **Conditions child-site eligibility on a new "community need standard" keyed to a Community Vulnerability Score and "qualifying ZIP code" threshold, plus an integration checklist.**
  - ZIP-based test disqualifies child sites serving substantial low-income populations that fall outside designated ZIP codes.
  - Removal mechanism subjects existing sites to de-registration at recertification — contracting the program's geographic footprint and the clinics through which systems extend 340B care.

Source: SECURE 340B Act (H. bill text), 42 U.S.C. § 256b

Sec. 5 & 6 — Affordability Mandates & Transparency Reporting

- **SEC. 5 — AFFORDABILITY / MEDICAL DEBT (MODERATE)**
  - Adds §§ 340B(a)(15)–(16): Financial-assistance-policy, sliding-fee, notice, and medical-debt restrictions, enforced by CMPs up to $5,000 per instance plus OIG/IRS referral.
  - No funding to entities for compliance mandates, many of which are aimed chiefly at the (L)–(O) hospital classes, layered on top of existing IRC § 501(r) duties — with duplicative penalty exposure for the same conduct.
- **SEC. 6 — DATA REPORTING (MODERATE–HIGH)**
  - Adds § 340B(d)(5): An extensive annual savings report broken out by payer type — including the commercial/group market — plus charity-care fractions, patient demographics, government contracts, and contract-pharmacy locations.
  - The commercial-payer breakdown discloses competitively sensitive payer-mix data and feeds the narrative that 340B savings on insured patients are illegitimate — a framing hospitals reject.

Consider drafting comments; seek 340B counsel

Source: SECURE 340B Act (H. bill text), 42 U.S.C. § 256b

Sec. 7 & 8 — Program Integrity & the Data "Clearinghouse"

- **SEC. 7 — PROGRAM INTEGRITY (HARMFUL)**
  - Adds §§ 340B(g)–(h): Broad Secretary audits, mandatory biennial independent audits at CE expense, and repayment-with-interest to manufacturers based on audit findings.
  - § 340B(g)(4) forces CEs to use only vendors that agree to submit data to the Secretary and auditors; graduated disenrollment + CMPs, including a "pattern of noncompliance" removal trigger.
  - Nonprofit-status verification can strip eligibility for technical lapses, not genuine mission failure.
- **SEC. 8 — CLEARINGHOUSE (USEFUL BUT HARMFUL DATA PROVISION)**
  - Adds SSA § 1150D: CEs must route claims-level data through a third-party clearinghouse — and, on the bill's face, it reaches commercially paid claims (§ 1150D(g)(2)(C), (g)(6)).
  - Enumerates dozens of granular elements (prescriber, plan, NDC, wholesaler account numbers) — a competitively sensitive map manufacturers could use well beyond duplicate-discount prevention.
  - § 1150D(i)(3) lets a manufacturer suspend 340B discounts if a data "deficiency" is not cured in 30 days — a unilateral shut-off valve.

Source: SECURE 340B Act (H. bill text), SSA § 1150D framework

Sec. 9–11 & 13 — Value Extraction, User Fee & Studies

- **SEC. 9 — "PERMISSIBLE ARRANGEMENTS" (USEFUL, BUT HIDDEN MAJOR RESTRICTION)**
  - Adds PHSA § 2730. Subs. (a)–(b) are genuine anti-discrimination protections against PBMs/plans that hospitals support.
  - But § 2730(c) *bars a CE from any arrangement that shares 340B discount/savings with a plan, issuer, or PBM — removing flexibility hospitals use to sustain services on insured patients through preferential pricing arrangements*.
- **SEC. 13 — Nonprofit-only requirement for nonhospital CEs; narrows health care access points (grantee-specific).**
- **SEC. 10 — USER FEE (MODERATE)**
  - Adds § 340B(a)(17): An annual 0.1% user fee on covered-drug spend, with eligibility conditioned on payment — a direct extraction from safety-net providers to fund the oversight apparatus.
- **SEC. 11 — STUDIES (FRAMING RISK)**
  - Commissions "340B discount retention" studies structured to quantify how much of the discount CEs, pharmacies, and PBMs "retain" — presupposing that CE retention of savings is a problem, seeding future cuts.
  - SEC. 14 — Effective on enactment with only a 180-day transition — inadequate for a codified patient test, clearinghouse build-out, and user fee.

Source: SECURE 340B Act (H. bill text), 42 U.S.C. § 256b

House Bill — Harm Ranking & Bottom Line

- HARMFUL —
  - Sec. 8 clearinghouse (compelled surrender of proprietary, commercially paid claims data to manufacturers) and Sec. 2 patient definition (strips savings from referral and chronic-care prescriptions).
  - Sec. 4 child-site ZIP/community-need test (contracts the hospital footprint); Sec. 7 audit + data-surrender + manufacturer repayment; Sec. 9(c) prohibition on sharing 340B value with plans/PBMs.
  - Sec. 3 contract-pharmacy registration burden; Sec. 5 affordability/medical-debt CMPs; Sec. 6 commercial-payer transparency reporting; Sec. 10 user fee.
  - Cross-cutting harms — (1) restricted patient definition; (2) compelled surrender of claims data; (3) narrowed eligibility of access points; (4) handover of proprietary commercial data; (5) pervasive burden, penalty, and value-extraction provisions.

- Read as a whole, the bill is not a neutral integrity measure — it would shrink the program, transfer data and savings to manufacturers and PBMs, and raise compliance costs for the very safety-net providers 340B exists to support.

Source: SECURE 340B Act (H. bill text), 42 U.S.C. § 256b

The Senate Bill — Cassidy Discussion Draft

- **OVERVIEW**
  - 340B Drug Pricing Integrity and Affordability for Patients Act — discussion draft released June 25, 2026 by Sen. Bill Cassidy (R-La.), Chair, Senate HELP; not yet a formal bill.
  - Uncertain path: Cassidy lost his 2026 GOP primary, limiting his ability to advance key provisions in the 119th Congress.
  - Codifies rebates as a valid 340B discount for all drugs (broader than HRSA's expected 25-drug pilot); undisputed retroactive rebates payable within 10 days.

Source: Senate discussion draft, Section-by-section summary

- **HOSPITAL IMPACTS**
  - **Sliding fee scale**: CEs must pass 340B savings to patients (below FPL owe $0; 100–200% FPL owe lesser of 20% cost-share or $35; above 200% owe lesser of 30% or $50); $2,500-per-instance penalty.
  - **Narrower patient definition**: outpatient care within 2 years + ongoing relationship + prescription by a CE practitioner — aligning with manufacturers (e.g., AbbVie litigation).
  - **Child Site Restrictions**: Child sites must be wholly owned, meet Medicare provider-based standards, offer services beyond drug administration, sit in a shortage area, and meet charity-care minimums.
  - **Contract Pharmacies**: DSH, cancer, and rural referral centers capped at 5; must sit within the CE's PUMA-based service area; first violation repay + interest, then $3,000/claim, third violation = 2-year ban.
  - **Reporting**: entities > $200M NPR disclose government contract terms; > $1B NPR disclose 340B patient counts, payer mix, and charity-care spending.

The SUSTAIN 340B Act — The Bipartisan Senate Vehicle

- **OVERVIEW**
  - Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act; 97 pages, 16 sections; introduced Aug. 5, 2026 (no bill number yet).
  - Sponsors: the Senate 340B Bipartisan Working Group — Sens. Moran (R-Kan.), Baldwin (D-Wis.), Capito (R-W.Va.), Kaine (D-Va.), Boozman (R-Ark.), and Hickenlooper (D-Colo.).
  - Builds on the 2024 SUSTAIN discussion draft, adding new provisions on rebate models, the patient definition, and referral prescriptions.
  - Core architecture — a trade: codified contract-pharmacy and payer protections in exchange for patient-definition, child-site, transparency, audit, financial-assistance, and user-fee conditions.
  - Effective on enactment (Sec. 16), but staged: rebate-pilot sunset at 1 year; user fees begin FY 2031; child-site and contract-pharmacy financial-assistance duties at 3 years.

- **WHAT MAKES IT DIFFERENT**
  - Like the House bill, it codifies contract-pharmacy access — but adds an affirmative manufacturer duty to sell at ceiling price "regardless of whether the drug is dispensed directly" or through a contract pharmacy (§ 340B(a)(12)(A)).
  - Manufacturers may not demand claims data outside the new clearinghouse; refusing to offer or deliver, or conditioning purchase, becomes a sanctionable intentional violation under § 340B(d)(1)(B)(vi)(III).
  - Sunsets the 340B rebate model pilot within one year and bars its expansion (Sec. 5).
  - No numeric or geographic cap on contract pharmacies — unlike the Cassidy draft's five-pharmacy limit and PUMA service area.
  - Adds insurer and PBM nondiscrimination with civil monetary penalties up to $5,000 per violation per day (new PHSA § 2729A).

Source: SUSTAIN 340B Act bill text, Senate 340B Working Group release (Aug. 5, 2026)

Sec. 3 — Contract Pharmacy: Codified, But Conditioned

- **WHAT IT PROTECTS — § 340B(a)(11)–(12)**
  - Covered entities may use wholly owned pharmacies and one or more contract pharmacies to acquire and dispense 340B drugs to their patients.
  - Manufacturers must offer the ceiling price regardless of the dispensing channel, and must deliver — or allow delivery — to the pharmacy locations the entity requests.
  - Manufacturers may not restrict distribution options, require claims-data submission (except to the § 1150D clearinghouse contractor), or impose other conditions later barred by rulemaking.
  - Refusal to offer or deliver at the ceiling price, or conditioning a purchase, is added to the manufacturer civil monetary penalty provision.

- **WHAT IT COSTS — REGISTRATION, CONTRACTS, AUDITS**
  - Cancellation duty: end any contract-pharmacy contract with no 340B dispensing in the most recent 12 months, subject to exceptions for ownership change, service-area change, emergency or contingency access, or Secretary discretion.
  - Register and annually recertify each arrangement; submit every agreement before implementation; attest to compliance; HHS reviews the agreements.
  - Mandatory standard contract terms — patient choice of pharmacy, eligibility verification, a reported Medicaid duplicate-discount arrangement, annual independent audits commissioned by the entity, and record retention of at least 3 years.
  - Public HHS posting for each arrangement: entity and child-site name, pharmacy address, effective date, last year of dispensing, annual dispensing volume, and mail-order or payer-mandated status.
  - Manufacturer audits on credible allegations after written notice and a 30-day cure period, at the auditor's expense; a corporate officer is accountable for corrections. HHS may increase audits of entities using a "high number" of contract pharmacies — a term the bill leaves undefined.

Source: SUSTAIN 340B Act bill text, Senate 340B Working Group release (Aug. 5, 2026)

Sec. 4 — Patient Definition and the Referral Pathway

- **THE TEST — § 340B(b)(3)–(5)**
  - Three elements: an outpatient health care service from the entity within the preceding 2 years; an auditable medical record for each prescription, retained at least 3 years; and a prescription from a covered-entity practitioner or a qualifying referral.
  - Practitioner: an employee or contractor the entity bills for, a provider under an ongoing contractual obligation or § 330 cooperative arrangement, or medical staff where contracting is prohibited — and not excluded under SSA § 1128.
  - Excluded: individuals whose only service was drug administration, dispensing for later self- or home administration, or infusion.
  - Preserved: ADAP registrants; § 318-funded state and local programs; and emergency-department or inpatient discharge prescriptions, which are deemed to establish a patient.

- **REFERRALS — A PATHWAY WITH A METER (§ 340B(a)(13))**
  - Entities under (A)–(K), (N), and sole community hospitals may furnish a 340B drug prescribed by a non-covered-entity provider within 12 months after a documented referral.
  - Conditions: documented care and consultation by both providers, proof the entity made the referral, dispensing through a wholly owned or contract pharmacy, 3 years of records, and no sharing of savings with the prescriber.
  - Infused and clinician-administered drugs are excluded, with narrow § 330 exceptions for health centers.
  - Audit trigger: referral prescriptions exceeding the lesser of 20% of the entity's 340B drugs for the year or its 3-year average; HHS must set hardship criteria, and HRSA publishes aggregate, non-identifying data.
  - Noncompliance: a corrective action plan; failure within 180 days forfeits the referral pathway for up to 3 years, plus penalties under 42 C.F.R. pt. 1003, subpt. O. OIG studies referral prescriptions annually for 12 years.

Source: SUSTAIN 340B Act bill text, Senate 340B Working Group release (Aug. 5, 2026)

Secs. 5 & 6 — Rebate-Pilot Sunset and Child Sites

- **SEC. 5 — REBATE MODEL SUNSET (FAVORABLE)**
  - HHS must conclude the 340B Rebate Model Pilot Program — or any "substantially similar" program — within 1 year of enactment, and the program "shall not be expanded" in the interim.
  - Duplicate-discount administration moves instead to the SSA § 1150D data clearinghouse created by Sec. 9.
  - Watch item: "substantially similar program" is undefined, so the perimeter of the sunset will be set by HHS implementation.
  - Contrast: the Cassidy draft would codify rebates as a valid 340B discount for all drugs.

- **SEC. 6 — CHILD SITES (RESTRICTIVE)**
  - Hospitals under (L)–(O) must document and annually recertify that each child site is wholly owned, clinically and financially integrated, and operated consistently with entity policies.
  - Alternative criteria require 100% ownership, a common governing body and bylaws, operation under the entity's license, unified medical records, shared income and expenses, Medicare cost-report inclusion, and public holding-out as part of the entity.
  - A CMS provider-based determination under 42 C.F.R. § 413.65 is deemed to satisfy the criteria.
  - Sites acquired after enactment are ineligible for 3 years, with a case-by-case hardship exception at 180 days; newly constructed sites must meet every criterion.
  - Rulemaking due 180 days after the first post-enactment recertification will determine the status of existing deemed sites; 3-year record retention, GAO review, and biennial HHS reports follow.

Source: SUSTAIN 340B Act bill text, Senate 340B Working Group release (Aug. 5, 2026)

Secs. 7–9 — Transparency, Integrity, and the Clearinghouse

- **SEC. 7 — TRANSPARENCY / SEC. 8 — PROGRAM INTEGRITY**
  - Annual entity reporting begins 1 year after enactment and covers all child sites and contract arrangements: patients served, prescriptions by payer type (Medicare, Medicaid, CHIP, commercial, uninsured), the Worksheet S-10 charity-care fraction, a standardized savings-use description with CEO, CFO, or COO attestation, patient demographics, third-party administrators, and program operating costs.
  - HHS publishes the data within 90 days in a searchable public format, in aggregate and by covered-entity type, and may audit the underlying records at its own expense.
  - Sec. 8 adds Secretary audits of entities, child sites, and contract pharmacies; an audit may not close until a corrective action plan is fully implemented, and eligibility failures are not retroactively curable.
  - Entities may contract only with 340B vendors that agree to supply data to HHS and to independent auditors; disenrollment follows a failure to implement a plan within 180 days.
  - Private nonprofit hospitals: HHS must verify a signed, active state or local government contract with five specified elements at registration, recertification, and audit — and must verify all currently registered entities within 1 year.
- **SEC. 9 — DUPLICATE DISCOUNTS (NEW SSA § 1150D)**
  - Within 1 year, HHS must contract with an independent, conflict-free third party, for a 4-year term, to operate a 340B data clearinghouse.
  - The contractor receives state Medicaid § 1927 rebate-file data and covered-entity claims-level data, and gives each manufacturer only its own data to identify units — it also computes total 340B sales for the user-fee base.
  - Guardrails: no direct contracts with entities, payers, or manufacturers; no sale, license, or revenue use of the data; no collection of non-340B pricing; use limited to preventing duplicate discounts and diversion; HIPAA rules apply, with penalties for misuse.
  - The lowest decile of (A)–(K) entities by patient volume may report aggregated data, and HHS may grant case-by-case relief where claims-level reporting is infeasible.
  - Repayment runs to affected manufacturers from the entity, and from state Medicaid programs that improperly claimed the rebate or received the benefit. Plans, issuers, and PBMs may not interfere with recoupment.

Source: SUSTAIN 340B Act bill text, Senate 340B Working Group release (Aug. 5, 2026)

Secs. 10–15 — Financial Assistance, Payer Rules, User Fee

- **SEC. 10 — PATIENT FINANCIAL ASSISTANCE / SEC. 12 — USER FEE**
  - Every covered entity must make its financial-assistance policy transparent at the point of care, report it publicly, apply it to child-site and contract-pharmacy patients in plain language, and keep at least 3 years of auditable records.
  - Policy floor: an IRC § 501(r)(4)(A) policy reaching patients at or below 200% of the federal poverty level, plus a sliding fee scale for 340B drugs — or a Secretary-approved alternative. Compliance is not a prohibited act under SSA §§ 1128A, 1128B(b), or 1877; child sites and contract pharmacies have 3 years.
  - User fees begin in FY 2031 at $50 million in the aggregate, CPI-U adjusted thereafter, allocated by each entity's share of 340B prescriptions — and payment becomes a condition of participation.
  - Fees fund the clearinghouse, OPAIS improvements, compliance tools, and audits; they supplement rather than supplant appropriations, regulations must include an exception process, and OIG reviews the program annually for 5 years.

Source: SUSTAIN 340B Act bill text, Senate 340B Working Group release (Aug. 5, 2026)

- **SEC. 11 — EQUITABLE TREATMENT / SECS. 13–15**
  - New PHSA § 2729A bars plans, issuers, and PBMs from paying less, or imposing different fees, chargebacks, clawbacks, network terms, audit conditions, or inventory-accounting requirements, because of 340B status.
  - It also bars interference with a patient's choice of in-person, delivery, or mail dispensing; compelled identification of 340B claims; refusal to contract; coverage denial for 340B drugs; and shared BIN and PCN numbers that mask Medicaid from commercial claims.
  - Penalties reach $5,000 per violation per day, with proposed rules due in 180 days and final rules within 1 year; Part D and MA–PD sponsors face a parallel limit under SSA § 1860D-12(i).
  - Studies (Sec. 13): GAO on hospital debt-collection practices and HHS on reasonable dispensing fees, each within 2 years, plus an ASPE review of clearinghouse and related data systems.
  - Resources and definitions: $3 million annually for FY 2027–2031 for OIG oversight and $9 million annually for FY 2027–2030 for implementation; HRSA hiring authority; "child site" means wholly owned and operated, and "contract pharmacy" includes mail distribution.

Three Bills Compared — and What Covered Entities Should Do Now

- **WHERE THE BILLS DIVERGE**
  - Contract pharmacy: SUSTAIN codifies access with no numeric or geographic cap; SECURE codifies access but adds pre-approval and public disclosure; the Cassidy draft caps DSH, cancer, and rural referral centers at five within a PUMA-based service area.
  - Data: SUSTAIN bars manufacturer claims-data conditions outside the clearinghouse, while SECURE's clearinghouse reaches commercially paid claims and lets a manufacturer suspend discounts over an uncured 30-day deficiency.
  - Rebates: SUSTAIN sunsets the rebate pilot within a year; the Cassidy draft would codify rebates as a valid discount for all drugs.
  - Patient definition: all three narrow it, but only SUSTAIN pairs the narrowing with a statutory referral pathway and a discharge-prescription rule.
  - Cost: SUSTAIN's user fee is $50 million in the aggregate beginning FY 2031; SECURE would impose an annual 0.1% fee on covered-drug spend.

- **PRACTICAL TAKEAWAYS**
  - SUSTAIN is the bipartisan vehicle most likely to move — treat its architecture as the working baseline for any 2027 package.
  - Begin the compliance build now: contract-pharmacy registration, standard contract terms, 3-year record retention, and clearinghouse data feeds.
  - Test child-site portfolios against the 100%-ownership, integration, and cost-report criteria, and diligence any pending acquisition for the 3-year eligibility delay.
  - Inventory referral-based volume against the 20% audit trigger and document referral and consultation chains today.
  - Comment priorities: the meaning of a "substantially similar" rebate program, a "high number" of contract pharmacies, user-fee exceptions, and referral hardship criteria.

Source: SUSTAIN 340B Act bill text, Senate 340B Working Group release (Aug. 5, 2026)

Continuing Education Questions

Q1. Which is a component of the House SECURE 340B Act that could be harmful to Ohio covered entities?

A. Sec. 3 — Account Care Organizations
B. Sec. 5 — HIPAA Compliance Rules
C. Sec. 8 — Data "Clearinghouse" / Sec. 7 — Program Integrity
D. Sec. 9 — Data Interoperability Requirements

Q2. In AbbVie Inc. v. Wrigley, the North Dakota federal court addressed a state law that:

A. Repealed the 340B program in North Dakota
B. Protected covered entities' access to 340B pricing through contract pharmacies
C. Required manufacturers to pay cash rebates directly to the state
D. Protected distribution of 340B drugs to contract pharmacies

Thank You

Questions & Discussion

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