

Year in Review - 340B Developments and What They Mean for Health Centers

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Disclosure of Integrity & Independence Statement

I, Michael Lin PharmD declares no relevant financial relationships or commercial interests in any product or service mentioned in this activity including grants, employment, gifts, stock holdings, honoraria.

Dr. Michael Lin PharmD

- Chief Pharmacy Officer – Family Health Centers Louisville KY
- 7 Site FQHC
- 2025 UDS: 39,390 patients served through 118,857 visits. 97% of patients at or below 200% FPL; 76.5% of patients on Medicaid or uninsured.
- 389 FTE
- 52 Prescribers, 143 Clinical Support Staff, 63 Enabling Services staff
- 64 Contract pharmacies
- 5 Entity Owned pharmacies; 10 RPhs, 2 340B Coordinators, 19 techs, 3 drivers





Our Patients

Serving Louisville's Most Vulnerable

**1 in 3 Louisvillians
living in poverty**

1 in 5 Uninsured Louisvillians

39k

Patients

4.3k

Homeless

10k

School Age Patients

35k

Living In Poverty

10k

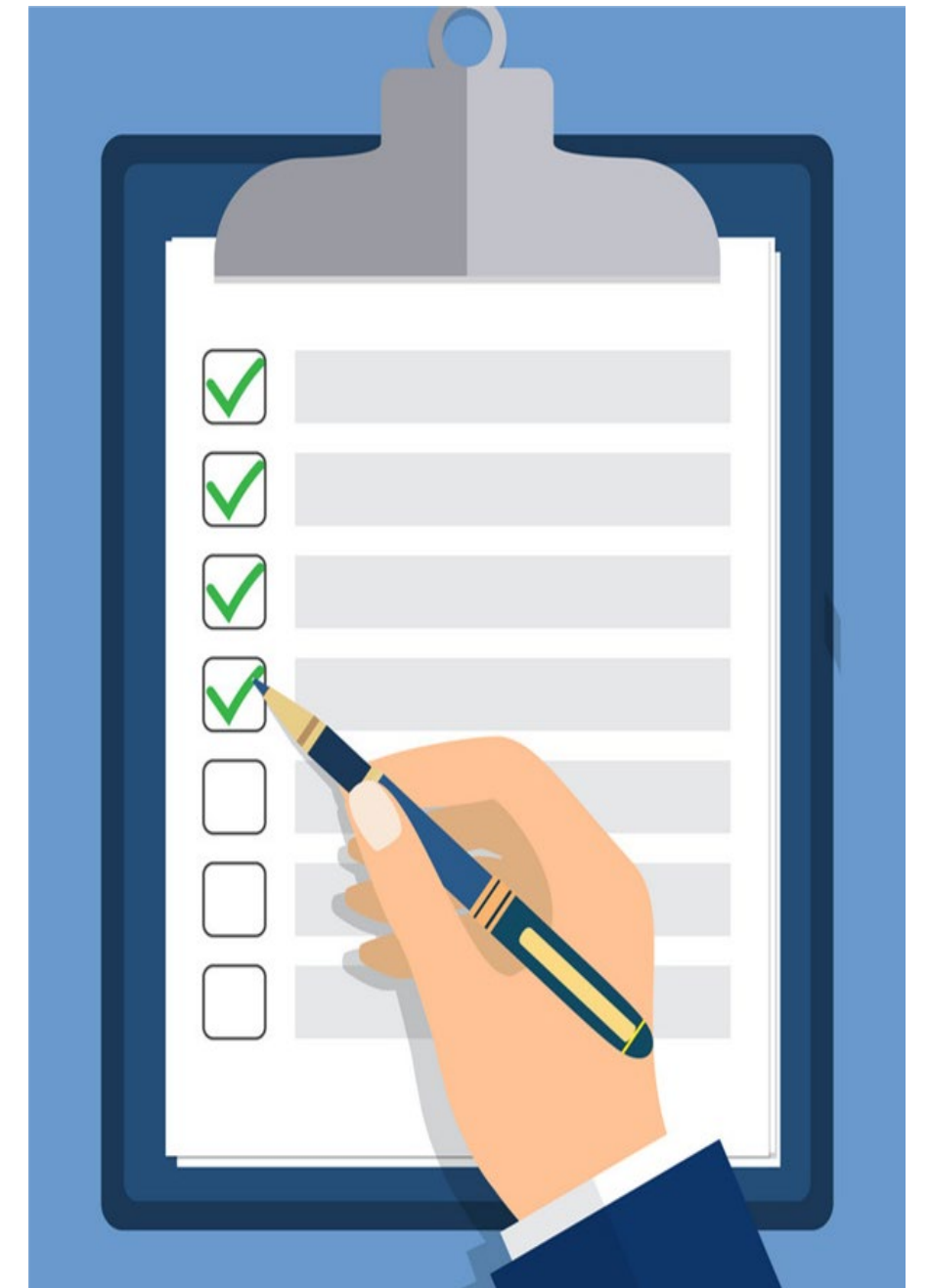
Uninsured

18k

Limited English

340B Year in Review

- The Big Picture
- The Four-Front Battle with Manufacturers
- The Battle with PBMs
- Legislation
- Meaningful Actions





The Big Picture

- PhRMA's #1 advocacy priority
- Total *purchases* in 2025: \$100 billion.
 - 340B opponents' favorite new talking point.
- Even if we “won” all the battles we’re currently fighting, total 304B savings would still be decreasing.





Pricing Origins

- CMS in collaboration with manufacturers set the 340B price

Factors that effect 340B pricing

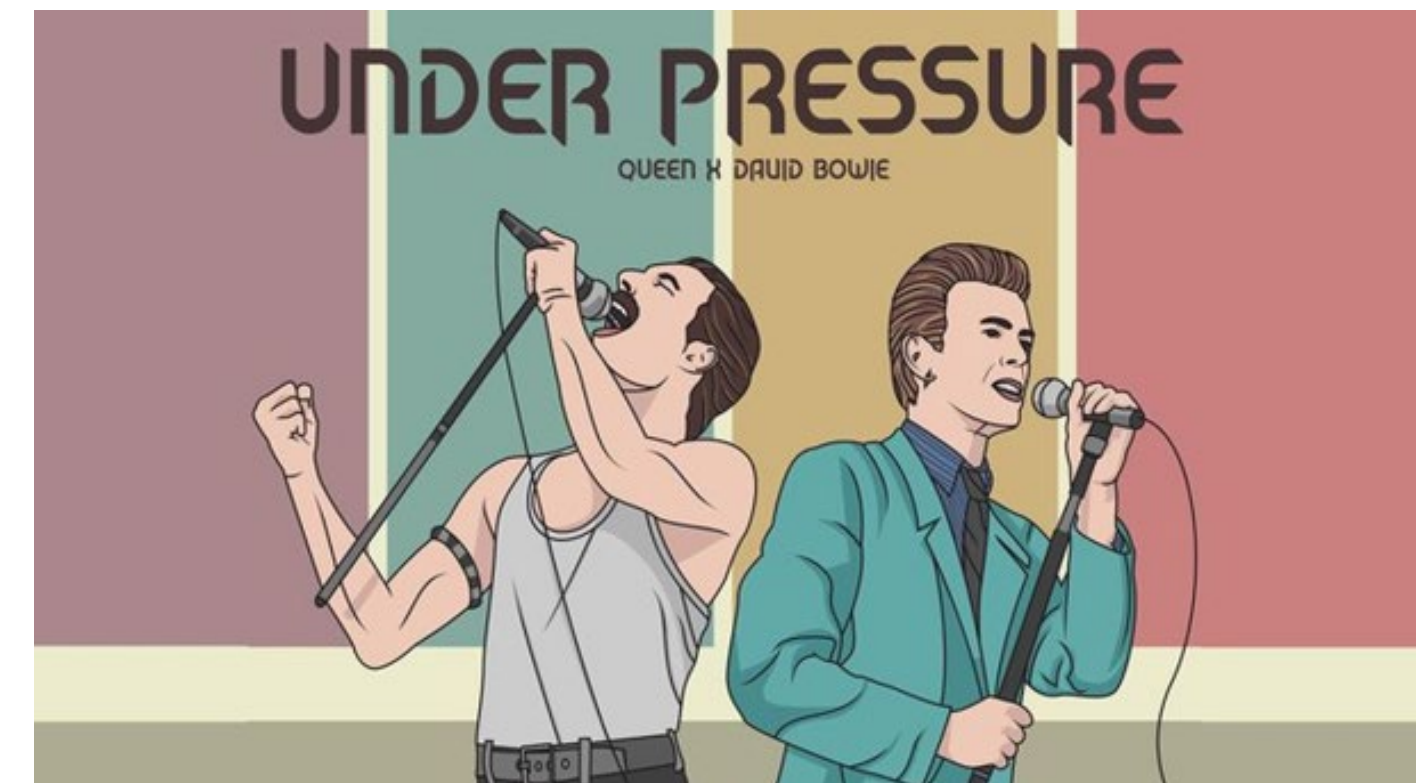
- New NDCs
- Mfg price increases or reductions
 - Lower WAC pricing may increase 340B prices

Example of WAC decrease → 340B ceiling price

		Dec. 2025	July 2026
WAC		\$1,000	\$200
	Mandatory 23% discount	\$230	\$46
	Inflationary discount - Provided only when the drugmaker raises the WAC price faster than inflation	\$750	\$0
340B price		\$20	\$154
Commercial payment		\$1,000	\$200
340B savings		\$980	\$46

Margin Pressures

- Inflation Reduction Act 2026
 - 10 Medicare negotiated medications
 - 8 of 10 medications commonly used at FQHCs
 - Account for 20% of total margin
 - 15 more meds in 2027
- PBM discriminatory reimbursement
 - Reimbursing below market average due to 340B status
- Manufacturer Voluntary WAC reductions
- HB 1 & Marketplace subsidies



What could be on the horizon in KY



- Currently entities enjoy 340B savings from MCO Rx's filled at both entity owned and contract pharmacies.
- This is policy, not law
- DMS is collecting data to prevent manufacturer rebate collection
- MFN pricing; GENEROUS model for state Medicaid will further reduce margins.



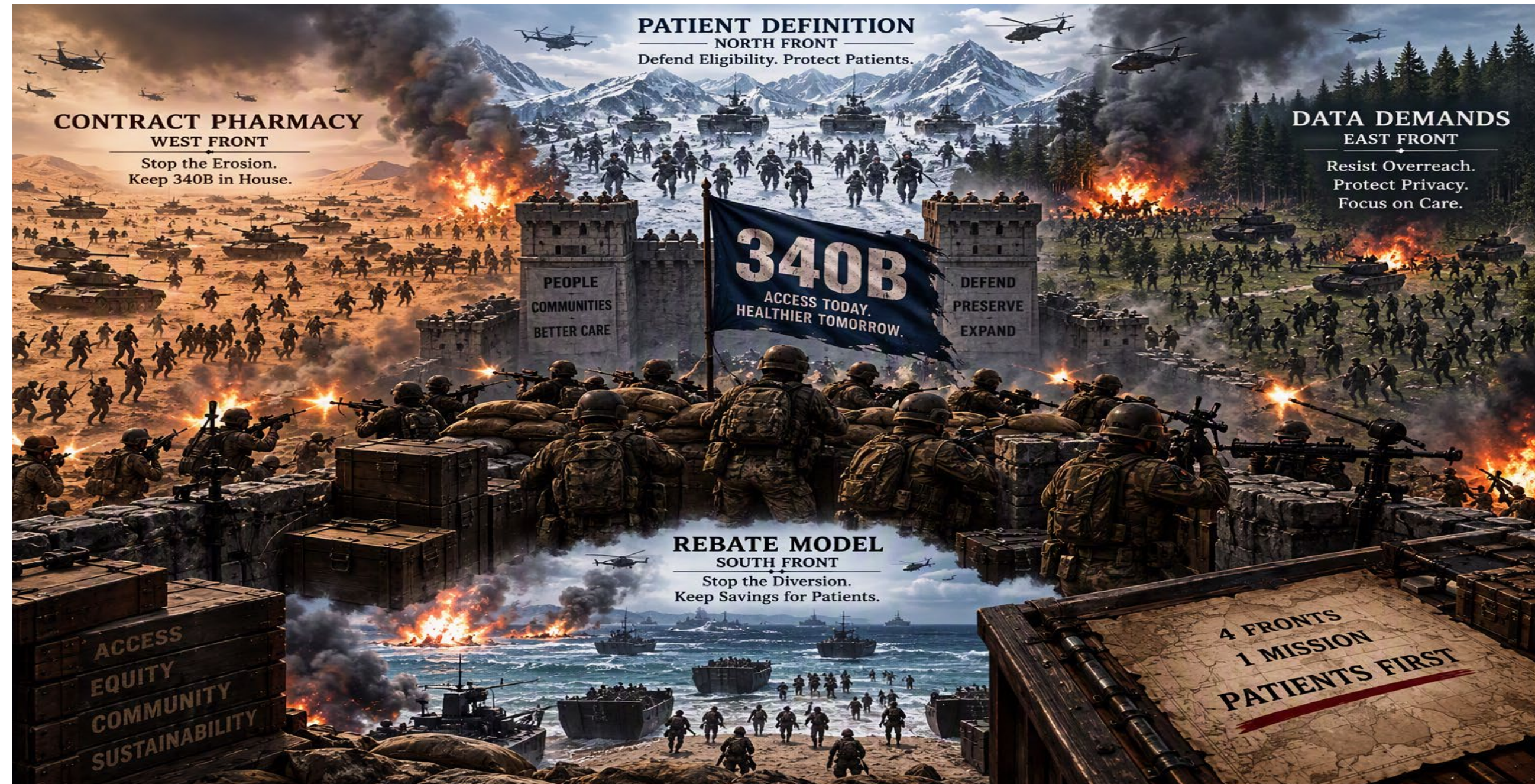
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Fighting with Manufacturers: A Four-Front War

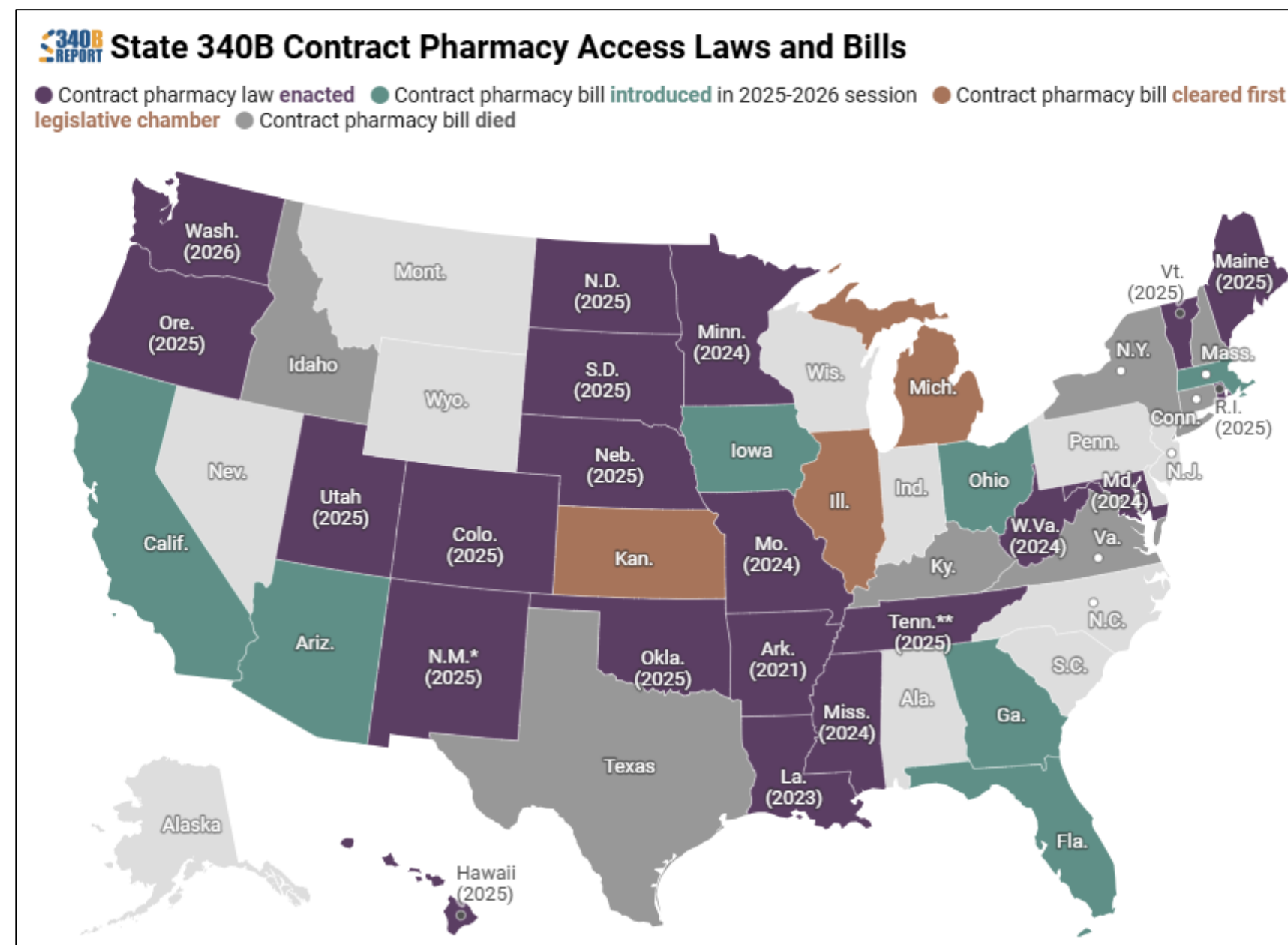
The Four Fronts in the 340B War

- . Contract Pharmacy
- . Patient Definition
- . Data demands
- . Rebate Model
(including “deduplication”)



Contract Pharmacy

- 28 manufacturers now restrict CHCs' access to contract pharmacies.
- 22 states have laws banning these restrictions.
 - Manufacturers have a “hit-or-miss” approach to compliance.
 - Each state's law is tied up in litigation
 - Overall the state laws are holding up in courts, but the issue could end up at the Supreme Court.



Patient Definition

- Restricting “patient definition” is the Holy Grail of manufacturers’ 340B goals.
 - They aim to make many prescriptions our patients receive ineligible for 340B – e.g., referral prescriptions, discharge prescriptions from ERs and inpatient stays, or based on Dx codes.
- Drugmaker AbbVie is suing to overturn HRSA’s patient definition that has been effect since 1996.
- NACHC, along with RWCs and 340B have requested to intervene lawsuit.



Data Demands – What & Where

WHAT:

- Drugmakers are increasingly demanding that CHCs submit claims data for all 3 types of drugs – contract pharmacy, in-house pharmacy, and clinic-administered.
- Policymakers are joining in. Starting next January, CHCs must report Medicare Part D data to CMS.

WHERE:

	Platform	Type of Data	Notes
1	Your state	Medicaid data	May involve carving out rather than data reporting
2	ESP	Contract, in-house, & clinic-administered	
3	Truzo		
4	Beacon	Deduplication for Medicare MFP drugs	
5	CMS "Data Repository"	Medicare Part D	Mandatory starting 1/1/27

Summary of most Restrictions & Data Demands, by Manufacturer

Summary of 340B Contract Pharmacy Restrictions and Data Demands by Manufacturer						
As of 8/4/26 - Most recent changes highlighted in GREEN						
	Manufacturer	IN-HOUSE	CONTRACT PHARMACY (340B pricing generally available only for CEs with no in-house pharmacies)			
		Requires data for in-house and clinic-administered drugs?	Maximum number of contract sites manufacturer will ship to	Must CEs submit data for the single contract pharmacy?	Data collection platform	Notes
1	AbbVie	No	Unlimited, as long as CE provides data on all of them. Without data, only one.	No	ESP	
2	Alkermes	No	One	Yes	Truzo (eff. 12/1/25)	
3	Amgen	Yes (eff. 6/1/26)	One (see note)	Yes	ESP	For CEs with both in-house and contract pharmacies, Amgen allows CEs a single contract pharmacy site if they submit data on both in-house and contract pharmacy claims.
4	Amphastar (see note)	No	One (eff 7/1/26)	Yes	Truzo	Applies only to drug Baqsimi
5	Astra-Zeneca	Yes (eff 5/1/26)	One	Yes	ESP	
6	Bausch + Lomb	No	One		ESP	
7	Bayer	No	One	Yes	ESP	
8	Biogen	Yes (eff 6/1/26)	One	Yes	ESP	
9	Boehringer Ingelheim	Yes (eff 7/6/26)	One	Yes	ESP	
10	Bristol Myers Squibb	Yes (eff 5/1/26)	One	Yes	ESP	
11	Eli Lilly	Yes (eff 2/1/26)	One	Yes	ESP	
12	EMD Serono	No	One	No	ESP	
13	Genetech	Yes (eff 8/31/26)	One	Yes	ESP	Single contract pharmacy must be within 40 miles
14	Gilead	No	Unlimited, as long as CE provides data on all of them. Without data, only one.	No	Truzo (eff 6-15-26)	

See the
[Online Resource Spreadsheet](#)
 , Tab 1, for
 the full
 chart



Rebate Model

- . HRSA issued a Federal Register Notice announcing a rebate model starting 1/1/27, for all drugs subject to Medicare-negotiated prices starting in 2026-2027.
 - These drugs account for around 35% of all Part D spending.
- . The Notice:
 - Does not request public comment.
 - Explicitly declines to exempt CHCs.
 - Is clearly written to address the court's concerns.
 - Feels slightly dismissive of covered entities' concerns.

Fighting with PBM's





PBM pricing diverts 340B savings from patient care

Predatory pricing concerns: 340B-specific practices reported by safety-net advocates

01

Lower reimbursement

Paying less for the same drug because the provider participates in 340B reduces retained savings.

02

Added fees & clawbacks

340B-specific fees, chargebacks and payment adjustments can further reduce net revenue.

03

Costly contract terms

Extra claims-processing requirements and restrictions can add administrative costs for 340B entities.

Less retained savings means fewer resources for patient care.

Sources: NACHC, Prevent Discriminatory Contracting (2024); HRSA, 340B Program; W. Va. Code §33-51-9. Protections vary by state and plan.

CVS/ Caremark/ Wellpartner

- We have good reason to suspect that CVS/ Caremark has been under-reimbursing CHCs (and other 340B providers) for specialty drugs.
- Colleen has been working with lawyer to develop a joint legal effort to enable CHCs to recover some of the lost funds.
- Unfortunately, CVS et al is using its market power to severely limit our options....

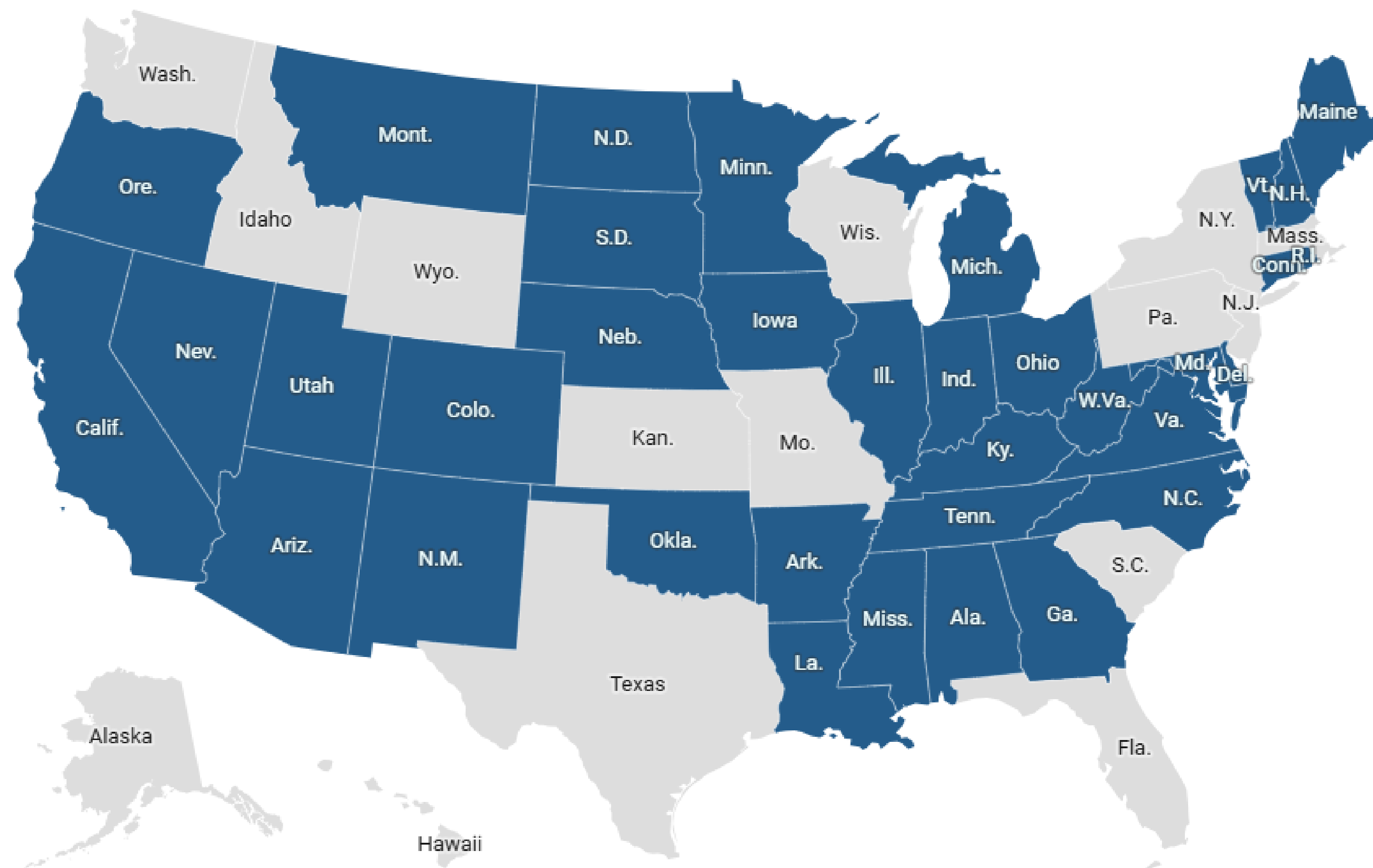


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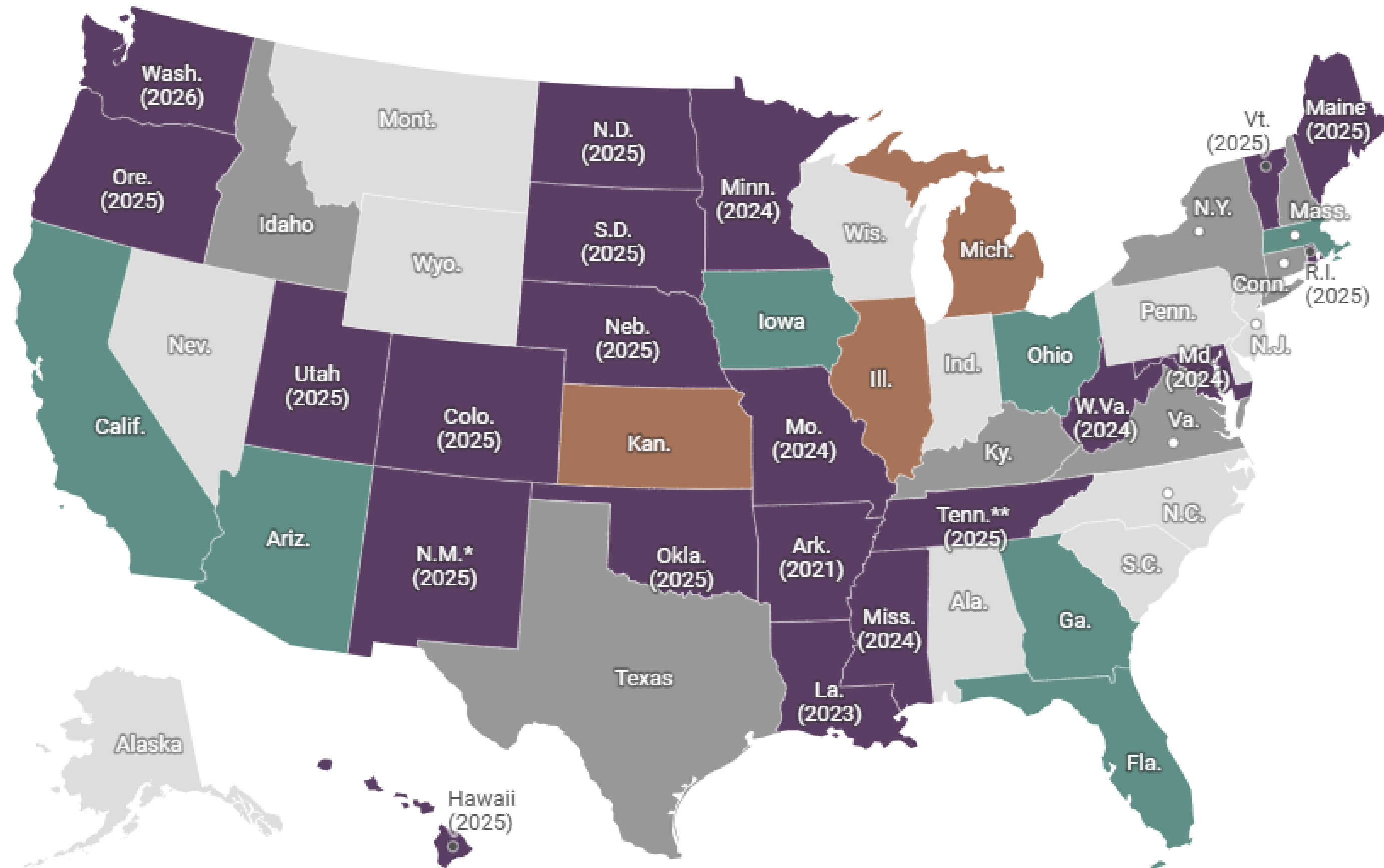
Legislation

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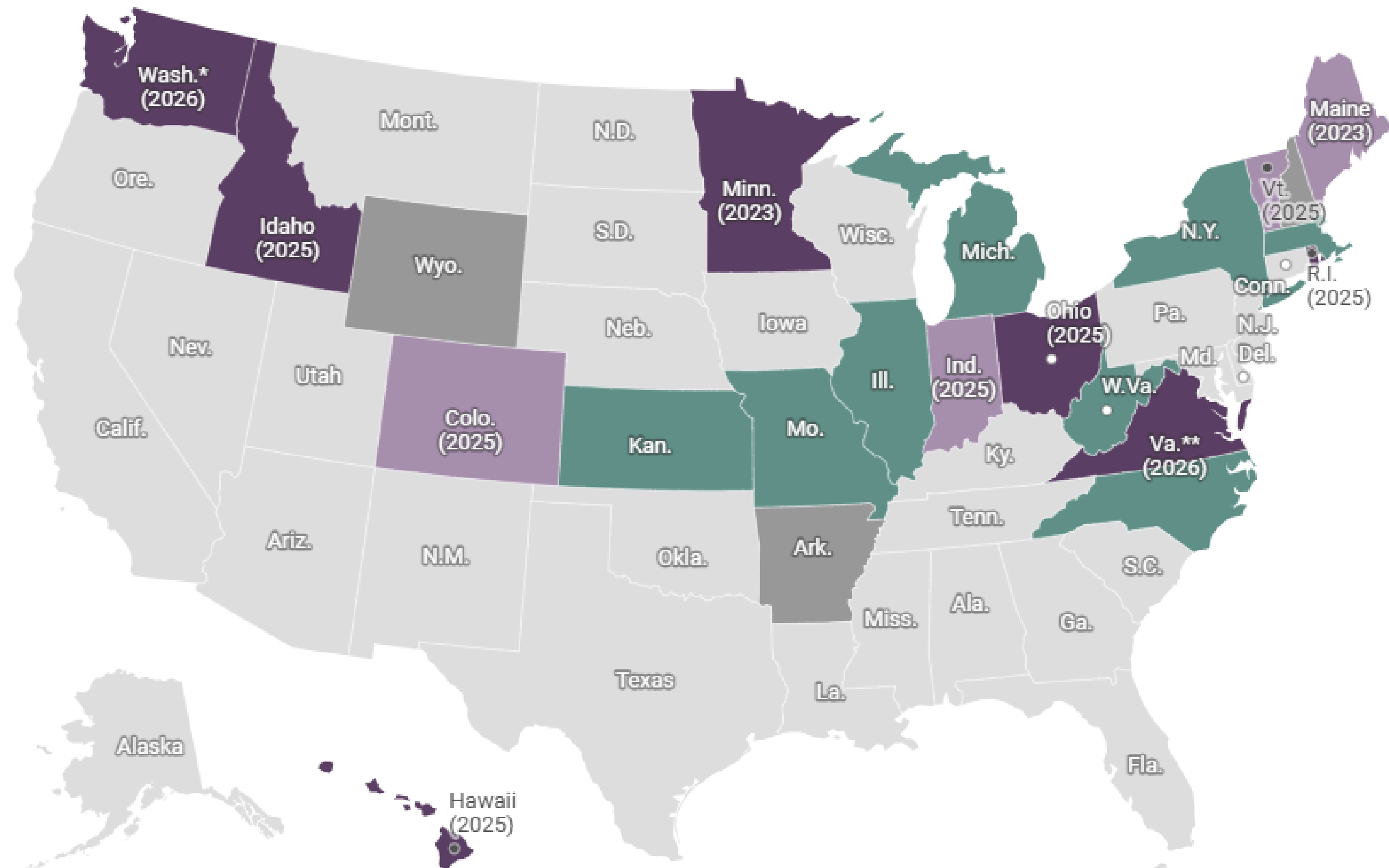




● Contract pharmacy law **enacted** ● Contract pharmacy bill **introduced** in 2025-2026 session ● Contract pharmacy bill **cleared first legislative chamber** ● Contract pharmacy bill **died**



● Reporting law for **all 340B providers** enacted ● Reporting law for **340B hospitals only** enacted ● 340B provider reporting bill **active** in 2025-2026 legislative session ● Reporting bill died/inactive





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Federal Legislation

- SECURE 340B
- SUSTAIN 340B
- Bergman Bill
- 340B Rebate Delay Bill

Summary

- 2027 brings great financial challenges
- 340B Savings will be reduced
- Rebate model starts 1/1/2027
- CMS Medicare D Reporting starts 1/1/2027
- 15 more medications added to IRA
- For KY - No regulation of manufacturer data demands in sight & no PBM protection enforcement
- Program compliance has become exponentially more difficult and time consuming



Take Aways:

- Get in-front of your legislators! **ADVOCATE**
- We need action **NOW!**
- We must force our legislators to act against unreasonable manufacturer demands!
- **SUSTAIN, SECURE, Bergman Bill**





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Additional Questions?

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Year in Review: Key 340B Developments and What They Mean for Health Centers

Ronnah Alexander/RPh. MBA Apexus 340B ACE | Regional
Health Care Affiliates DBA Health First CHC

Two Reform Bills, One 340B Program

SUSTAIN and SECURE both tighten 340B — but SECURE narrows who counts as a patient, and that is where health center revenue can live.

Issue	Senate SUSTAIN 340B Act	House SECURE 340B Act	What it means for your program
Program intent	Codifies original intent: discounts at point of purchase as a condition of Medicaid and Medicare Part B participation	Does not address intent	SUSTAIN preferred — protects the upfront discount model
Patient definition	Patient-based: outpatient service within 24 months, auditable record kept 3 years, drug tied to a service or referral	Prescription-by-prescription; service must be Medicare-covered and within the scope of the grant	SUSTAIN preferred — SECURE's Rx-by-Rx and scope-of-grant tests are far narrower
Referrals	New specialty-referral rules and volume-triggered audits; discharge-prescription exception; annual referral reporting	Referral use limited to FQHCs, CAHs and sole community hospitals; corrective action if referrals exceed 35% of purchases	SUSTAIN preferred — SECURE excludes Ryan White clinics entirely
Contract pharmacy	Statutory right to multiple contract pharmacies; no manufacturer conditions or claims-data demands; registration plus standard contract terms	Manufacturers must ship regardless of contract pharmacy use; registration and standard terms set by the Secretary	SUSTAIN preferred — SECURE leaves too much to Secretarial discretion
Clearinghouse and rebates	Neutral third-party clearinghouse; non-hospital CEs may submit aggregate data; rebate pilot sunsets one year after enactment	Clearinghouse with a four-year rebate ban that continues only if strict performance metrics are certified	SUSTAIN preferred — SECURE's rebate ban is time-limited and metric-dependent
User fees	\$50M per year in total fees, allocated by share of 340B dispensing volume	0.01% fee on all covered-entity drug purchases	Both place the cost on covered entities — manufacturers should share it
Eligibility, child sites, reporting	Child-site ownership and integration tests; annual savings and charity-care reporting; Secretary and manufacturer audits	Adds subgrantee registration, scope-of-grant limits, community-need standard, and biennial independent audits	Both add burden — SECURE's self-audit and subgrantee rules are the heaviest lift

The Cassidy Framework: An unlikely Third Path

Senate HELP Chair Bill Cassidy's published 340B oversight work points toward transparency-first reform — directional, not yet introduced text, so treat this column as illustrative.

Theme	Cassidy framework emphasis	SUSTAIN	SECURE	Read for 340B grantees
Transparency and reporting of savings	Central: detailed reporting on how much 340B revenue is generated and how it is spent, entity by entity	Annual savings and charity-care reporting, published by covered entity	Similar reporting, plus published use-of-savings detail	Health centers already report; the cost is administrative, not existential
Patient definition clarity	Calls for a clear statutory definition after years of litigation, without prescribing the narrowest option	Patient-based, 24-month look-back	Rx-by-Rx and scope-of-grant	A clarity-first approach could land closer to SUSTAIN than to SECURE
Contract pharmacy guardrails	Favors defining and limiting contract pharmacy arrangements with registration and oversight	Statutory right to multiple contract pharmacies	Delivery required, with Secretary-set terms	Watch for caps or distance tests that would shrink health center networks
Hospital versus grantee distinction	Oversight focus has centered on large hospital systems, not federal grantees	Hospital-specific limits on referrals and child sites	Hospital child-site community-need standard	Grantees should press to stay carved out of hospital-driven restrictions
Rebates and manufacturer conduct	Less developed publicly; emphasis on program integrity and duplicate-discount prevention	Sunsets the rebate pilot one year after enactment	Four-year, metric-dependent rebate ban	A framework without a firm rebate ban is the main risk to upfront pricing

The Ground Has Shifted

For the first time in Medicare's history, the federal government is directly negotiating drug prices — and the spread your 340B program depends on is now permanently narrower.

- Effective **January 1, 2026**, Medicare's Maximum Fair Price (MFP) took effect for **10 high-cost Part D drugs** [\[3\]](#)
- MFP prices run **38% to 79% below** those drugs' 2023 list prices [\[4\]](#)
- The 10 drugs represented approximately **\$50.5 billion** in gross Part D spending, used by roughly **9 million Medicare enrollees** [\[4\]](#)
- This is **not a temporary shift** — additional drugs enter the program each year: **15 more in 2027**, up to 20 per year thereafter [\[3\]](#)
- For covered entities, **lower Medicare reimbursement** means lower margins on the very claims that drove 340B savings



The 10 Drugs on the 2026 MFP List

These are not obscure medications — **Eliquis**, **Jardiance**, **Xarelto**, and **Farxiga** are likely in your top dispensed drug list today.

Drug Name	Indication	2023 List Price (30-day supply)	2026 MFP Price	Reduction
Januvia	Type 2 diabetes	\$527	\$113	79%
NovoLog / Fiasp	Insulin	\$495	\$119	76%
Farxiga	Diabetes, heart failure, CKD	\$556	\$178	68%
Jardiance	Type 2 diabetes, heart failure	\$573	\$197	66%
Xarelto	Blood clots, stroke prevention	\$517	\$197	62%
Eliquis	Blood clots, stroke prevention	\$521	\$231	56%
Entresto	Heart failure	\$628	\$295	53%
Enbrel	Rheumatoid arthritis, psoriasis	\$7,106	\$2,355	67%
Stelara	Crohn's disease, psoriasis	\$13,836	\$4,695	66%
Imbruvica	Blood cancers	\$14,934	\$9,319	38%

Source: [10 Medicare-Negotiated Drug Prices for 2026](#) — Medicar...

25 Drugs Under MFP as of January 2027

The 15 second-cycle drugs join the original 10 on January 1, 2027 — GLP-1s, inhalers, and oncology agents widen the exposure well beyond diabetes and anticoagulants.

 25 Total MFP Drugs by 2027

 2027 adds GLP-1s, oncology, pulmonary, and psychiatric agents — exposure grows significantly

NEW FOR JANUARY 2027 — 15 DRUGS	
Drug	Primary Use
Ozempic / Rybelsus / Wegovy	Type 2 diabetes, weight management
Trelegy Ellipta	COPD, asthma
Xtandi	Prostate cancer
Pomalyst	Multiple myeloma
Ibrance	Breast cancer
Ofev	Pulmonary fibrosis
Linzess	IBS with constipation
Calquence	Blood cancers
Austedo / Austedo XR	Tardive dyskinesia, Huntington's chorea
Breo Ellipta	Asthma, COPD
Tradjenta	Type 2 diabetes
Xifaxan	IBS-D, hepatic encephalopathy
Vraylar	Bipolar disorder, schizophrenia, depression
Janumet / Janumet XR	Type 2 diabetes
Otezla	Psoriasis, psoriatic arthritis

CONTINUING FROM 2026 — 10 DRUGS	
Drug	Primary Use
Januvia	Type 2 diabetes
NovoLog / Fiasp	Insulin
Farxiga	Diabetes, heart failure, CKD
Jardiance	Type 2 diabetes, heart failure
Xarelto	Blood clots, stroke prevention
Eliquis	Blood clots, stroke prevention
Entresto	Heart failure
Enbrel	Rheumatoid arthritis, psoriasis
Stelara	Crohn's disease, psoriasis
Imbruvica	Blood cancers

Drugs on 2026 MFP but Not on 2027 List

According to CMS and industry updates, the following 2026 MFP drugs will no longer be in the Medicare Drug Price Negotiation Program starting Jan. 1, 2027 — all removed due to generic or biosimilar competition.

Drug	Manufacturer	Therapeutic Category	Reason Removed from 2027 List
Entresto	Novartis	Heart failure	Generic/biosimilar competition
Stelara	Johnson & Johnson	Crohn's disease, psoriasis	Generic/biosimilar competition
Xarelto	Janssen (J&J)	Blood clots, stroke prevention	Generic/biosimilar competition
Fiasp / Fiasp FlexTouch / Fiasp PenFill	Novo Nordisk	Insulin	Generic/biosimilar competition
NovoLog / NovoLog FlexPen / NovoLog PenFill	Novo Nordisk	Insulin	Generic/biosimilar competition



5 drugs exit MFP for 2027 — check your 340B portfolio against the updated list
Source: CMS Medicare Drug Price Negotiation Program updates; industry analysis

How 340B Revenue Works — and Where MFP Hits

The 340B model is built on a spread; MFP compresses that spread from the reimbursement side while acquisition cost stays the same.

340B Savings Formula

Revenue =
Reimbursement
— **Acquisition Cost**

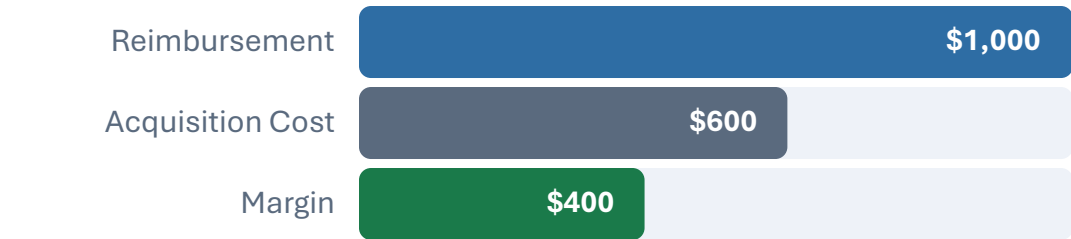
Illustrative examples [2]



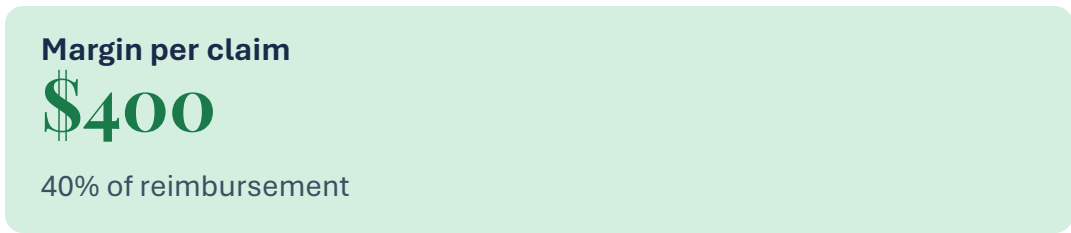
Acquisition cost is unchanged in the beginning. Only Medicare reimbursement falls — yet it drives a 50% margin reduction on the same claim. Later during the third quarter the 340B discount will be altered and will rise further reducing the spread.



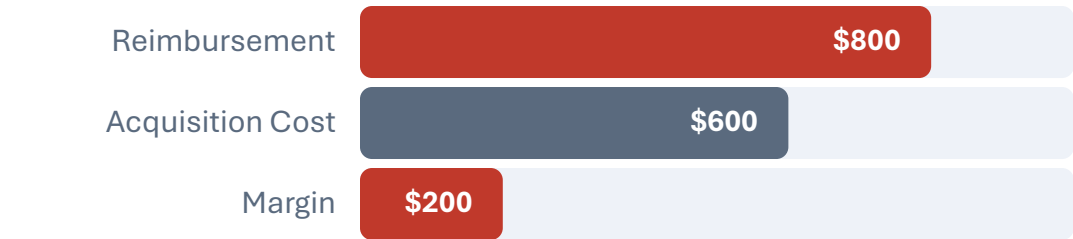
✓ Pre-MFP (Illustrative)



Medicare reimbursement	\$1,000
340B acquisition cost	\$600



! Post-MFP (Illustrative)

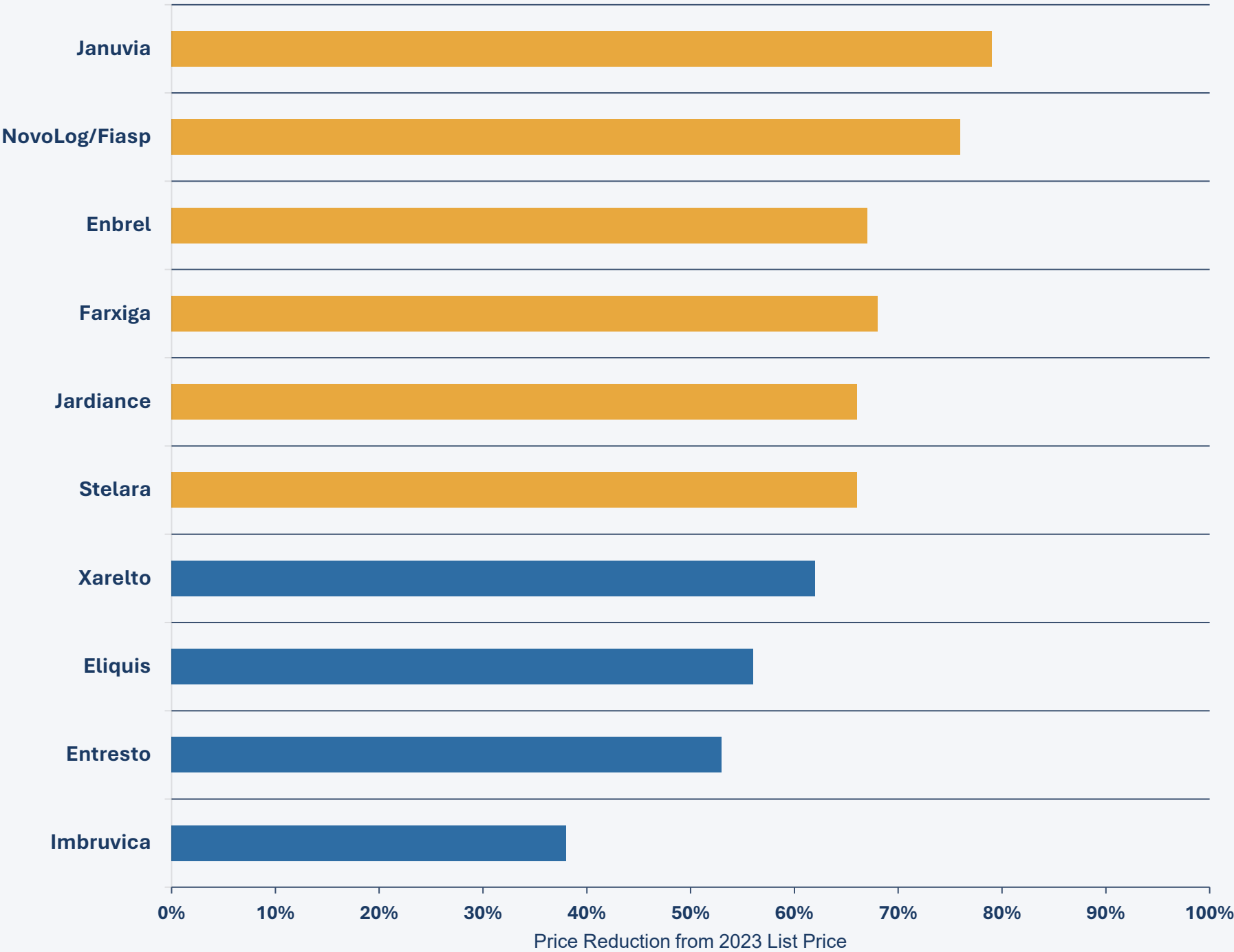


Medicare reimbursement (MFP)	\$800
340B acquisition cost	\$600



⚠ Result: **50% reduction in margin on the same claim** — acquisition cost unchanged, reimbursement lowered [2]

2026 MFP Price Reduction by Drug (%)



Which Drugs in Your Program Are Exposed?

Internal dispensing data shows MFP-affected drugs are already among the highest-volume claims — this is not a theoretical risk.

- Your monthly 340B slide reports already capture: dispensed item name, acquisition cost, total price paid, and gross profit per claim [\[1\]](#)
- **Eliquis, Jardiance, and Farxiga** appear in internal reports and are on the 2026 MFP list — cross-reference dispensing volume to estimate exposure [\[5\]](#)
- **Action:** Pull claim-level data by NDC, identify MFP-affected products, and calculate current vs. projected margin per drug
- In 2027, **15 additional Part D drugs** will enter MFP — the monitoring list grows to 25 drugs [\[1\]](#)
- Specialty and high-cost medications carry the **highest per-claim margin risk**

2027: 15 more drugs enter MFP — monitor now

The "Lower Of" Rule — A Second Layer of Pressure

Beyond spread compression, the "lower of" pricing requirement can reduce the benefit of the 340B discount itself.

01



The "Lower Of" Requirement

- Manufacturers must ensure covered entities receive the lower of: **340B ceiling price** OR the **MFP** [\[2\]](#)
- This prevents duplicate discounts — and may further reduce financial benefit [\[2\]](#)

02



Revenue Pressure Points in 2026

- Part D is the initial area of impact in 2026; future expansion to Part B will increase exposure [\[2\]](#)
- Reduced contract pharmacy revenue, lower margins on high-cost and specialty medications, erosion of historically reliable 340B spread income [\[2\]](#)

03



HRSA Rebate Pilot — Added Complexity

- The HRSA 340B Rebate Pilot Program set currently to initiate January 2027, will introduce an additional layer of complexity.
- A December 2025 court injunction has temporarily blocked its implementation — but litigation is ongoing [\[7\]](#)

! Monitor litigation status

Contract Language That Sounds Protective — but May Not Be

The words in your agreement define the model; your data reveals whether the model actually performs.

"Net"

Net of what exactly: actual drug cost, estimated cost, WAC, fees, reversals?

"Acquisition Cost"

Which source, which date, which NDC — are credits and replenishment adjustments included?

"Reimbursement"

Gross paid, net paid, patient share, DIR-like adjustments, recoupments, or final settled amount?

"Savings"

Calculated per claim, per prescription, per month, or after aggregation and exclusions?



Recommended Action

Read the **definitions and exhibits** in your agreement, then reproduce the result independently using **claim-level data**.

Each of these terms has a definition somewhere in your contract — or it should. Ambiguity in the definition means ambiguity in the calculation, and that ambiguity typically resolves in your partner's favor.



Gross-revenue percentages and fixed-fee structures offer no MFP protection. [1]

The Hidden Risk — When Your Partner's Economics Stay Stable While Yours Fall

If your TPA or contract pharmacy formula does not use actual acquisition cost, you may absorb 100% of the MFP-driven cost increase while your partner's retained amount is unchanged. [1]

Before Cost Change		After Cost Change	
Third-party reimbursement	\$100.00	Third-party reimbursement	\$100.00 No change
Actual acquisition cost	\$0.31	Actual acquisition cost	\$3.00 +\$2.69
Partner retention (fixed fee formula)	\$25.00	Partner retention (fixed fee formula)	\$25.00 No change
FQHC / Health Center retained margin	\$74.69	FQHC / Health Center retained margin	\$72.00 -\$2.69

KEY TAKEAWAY

If cost is excluded from the sharing formula, the covered entity bears **100% of the cost increase** — while the partner retains the same fixed amount.

CHECK YOUR CONTRACTS NOW

- ✗ Gross-revenue percentage structures offer no MFP protection
- ✗ Fixed-fee formulas do not adjust for rising acquisition cost
- 🔍 Demand actual cost basis language in every new or renewed agreement

! Illustrative example from internal leadership briefing. The formula type — not the dollar amount — is the structural risk. Gross-revenue percentage and fixed-fee structures do not share cost increases with the covered entity. [1]

FQHC Governance — This Is a Leadership-Level Issue

Material 340B revenue risk must be visible, quantified, assigned, and monitored — not just tracked in the pharmacy department.



Board Oversight

MFP-related revenue risk should appear in board reporting with dollar estimates and trend monitoring.



Financial Reporting

UDS data includes costs and revenues — any material 340B margin compression will surface in audits.



Program Accountability

The covered entity remains responsible for its 340B contract pharmacy operations and auditable records, regardless of TPA involvement.



Vendor Governance

A TPA or partner can perform calculations, but accountability for oversight cannot be outsourced.

Defensible Evidence Package:

Contract

Data Dictionary

Claim Sample

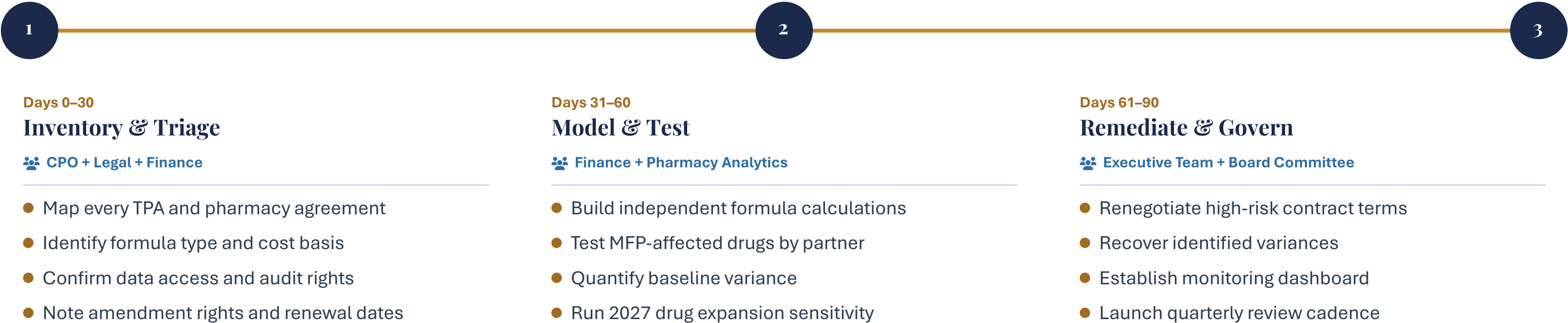
Independent Recalculation

Variance Resolution

Leadership Reporting

Your 90-Day Action Plan

Move from awareness to financial assurance before the next contract renewal cycle.



5 Contract Protections to Demand:

Actual cost basis

Transparent formula

Data & audit rights

Regulatory reopener

True-up & recovery

References

[1] [MFP_340B_FQHC_Fiduciary_Oversight 1](#)

[2] [MFP](#)

[3] [Factsheet: Medicare Drug Price Negotiation Program](#)

[4] [Medicare's 10 Negotiated Drug Prices for 2026 | Brevy...](#)

[5] [10 Medicare-Negotiated Drug Prices for 2026 — Medicar...](#)

[6] [INFLATION REDUCTION ACT AND REVENUE IMPACT](#)

[7] [Navigating the Intersection of the IRA’s MFP and the ...](#)