Legislative & Litigative Update

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Chief Executive Officer
FQHC 340B Compliance

OHIO PHARMACISTS ASSOCIATION

340B Midwest Regional Conference & Expo
August 25 & 26, 2025

340B Midwest Regional Conference & Expo

DISCLOSURE STATEMENT

- Felicity Homsted has no relevant financial relationships with ineligible companies to disclose.

and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

LEARNING OBJECTIVES

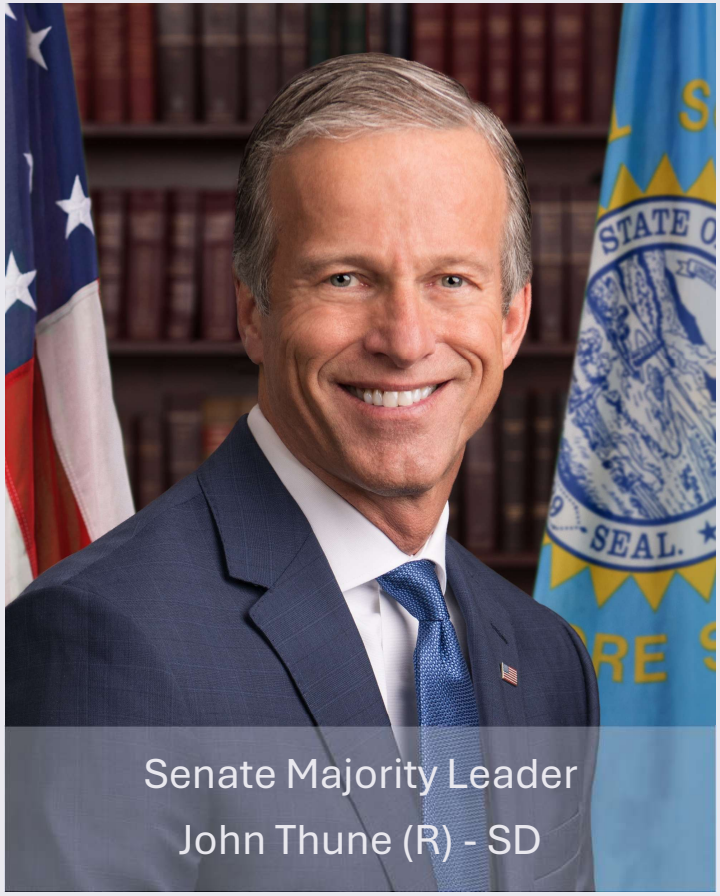
At the completion of this activity, the participant will be able to:

- Review the current pending legislation aiming to reform the 340B program;
- Describe the political and legal dynamics of the current 340B reform;
- Recognize opportunities for covered entities to educate legislators.

OHIO PHARMACISTS ASSOCIATION

Federal Legislative & Executive Leadership

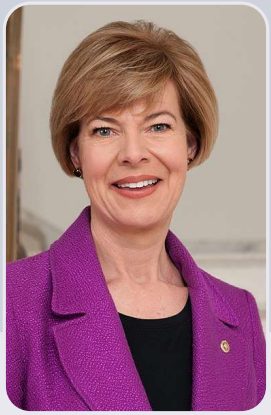
Senate Leadership



Senate Majority Leader
John Thune (R) - SD

Chair, Senate HELP Committee
Bill Cassidy (R) - LA

Senate Bipartisan 340B Working Group

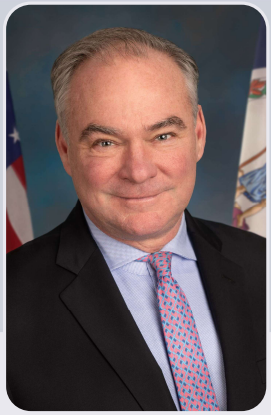


Tammy Baldwin

WI

John Hickenlooper

CO

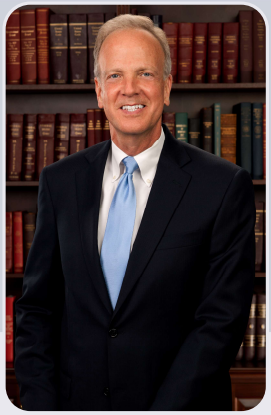


Tim Kaine

VA

Shelly Moore Capito

WV



Jerry Moran

KS

Markwayne Mullin

OK

Legislation

Federal 340B Reform Proposals Introduced

Rural 340B Access Act of 2025 (H.R. 44)

Sponsors: Rep. Jack **Bergman** (**R**-MI) and Rep. Debbie **Dingell** (**D**-MI)

Introduced: January 3, 2025, Referred to Energy & Commerce (E&C).

The bill would **add** facilities designated as **Rural Emergency Hospitals** (REH) as a **340B covered entity** (CE) type.

- In 2020, Congress established REHs as a new Medicare provider designation for **hospitals in rural areas providing emergency department** services, observation care, and other outpatient medical and health services with the annual per patient **average length of stay not exceeding 24 hours**.

https://340breport.com/staff-members-for-key-congressional-committees-that-oversee-340b-policy-announced-reh-bill-reintroduced/
https://www.congress.gov/bill/119th-congress/house-bill/44

340B PATIENTS Act of 2025 (H.R.4581)

Sponsors: **Rep**. Doris **Matsui** (D-CA) (10 Co-Sponsors) & **Sen**. Peter **Welch** (S.2372)

Introduced: July 22, 2025, Referred to Committee on Health, Education, Labor, & Pensions (HELP)(S) and E&C (H).

The legislation would **codify** 340B CEs' ability to use **contract pharmacies** to dispense 340B drugs.

- **Reaffirms** manufacturer **obligation to offer discounted** prices regardless of dispensing method or location.
- **Confirms** covered entities can **contract with pharmacies** to dispense drugs to their patients.
- **Prohibits** manufacturers from placing **conditions** on 340B drug purchases that limit delivery, purchase mechanisms, dispensing locations, or **require excessive data submissions**.
- Bars conditions not reflecting **customary business practices** or lacking Secretary approval.
    - Update from 2024 Version: Removes allowance for Secretary-specified conditions without advance approval.
- Imposes **civil monetary penalties**: Up to $2M/day for **intentional violations** of key distribution & data provisions, other than overcharges.
    - Update from 2024 Version: Changed from "knowing and intentional"
- Requires Secretary to establish **process for covered entities to assert claims** of violations within 180 days.

https://340breport.com/matsui-welch-reintroduce-patients-act-in-congress-during-340b-coalition-summer-conference/
https://www.congress.gov/bill/119th-congress/house-bill/4581/text

No 340B Savings for Transgender Care Act (H.R.2197)

Sponsor: **Rep**. Dusty **Johnson** (R-SD) (9 Co-Sponsors)

Introduced: March 18, 2025, Referred to Energy & Commerce - 03/18/2025

Amends Section 340B of the Public Health Service Act to prohibits covered entities from using 340B savings for specific transgender services including:

- Gender reassignment surgeries.
- Hormone treatments aimed at gender alteration.

https://340breport.com/matsui-welch-reintroduce-patients-act-in-congress-during-340b-coalition-summer-conference/
https://www.congress.gov/bill/119th-congress/house-bill/2197

Other 340B Bills Introduced This Session

Bill #	Name	Purpose	Sponsors	Introduced	Senate	Last Action
H. R. 3222	SMART Health Care Act	The bill would require 340B providers to charge patients the 340B price for covered drugs, "less any additional discounts or rebates received by the covered entity." It would also authorize Health and Human Services secretary to reduce Medicare reimbursement for those drugs to the 340B price, eliminating providers' ability to generate 340B savings on Medicare patients. Covered entities would have to publicly report the total amount paid by Medicare and the amount received by the covered entity for covered outpatient drugs.	Rep. Victoria Spartz (R-IN)	6-May-25	House	Referred to E&C and Ways & Means on 5/6/2025.
H.R. 4317	PBM Reform Act	The bill would ban "spread pricing" in Medicaid, set new requirements for PBMs under Medicare Part D; require semi-annual reporting on drug spending, rebates and formulary determinations; and direct CMS to define and enforce "reasonable and relevant" contract terms in Medicare Part D pharmacy contracts and enforce oversight on reported violations.	Rep. Earl "Buddy" Carter (R-GA)	10-Jul-25	House	Referred to the E&C, Ways and Means and Labor and Workforce on 7/10/2025.

https://340breport.com/congressional-340b-bill-tracker/

Federal Reform Enacted

One Big Beautiful Bill (HR.1)

Signed July 4, 2025

- **Medicaid Overhaul & Coverage Reductions**
  - The bill imposes new **work or "community engagement" requirements**, mandating able-bodied adults—and later expanding to parents—to log at least 80 hours per month in employment, volunteering, or education to stay eligible for Medicaid.
  - It introduces **premium and co-pay contributions**, such as up to $35 per healthcare service for certain Medicaid recipients.
  - Policy shifts are projected to **reduce Medicaid enrollment by up to 12 million people**, with some estimates reaching nearly 12 million losing health insurance.

https://340breport.com/analysis-how-medicaid-cuts-in-big-beautiful-bill-could-push-certain-hospitals-out-of-340b-and-the-importance-of-planning-ahead/
https://www.congress.gov/bill/119th-congress/house-bill/1

One Big Beautiful Bill

OBBB Changes could mean more Pressure on 340B Safety-Net

- Medicaid coverage losses - more uninsured or underinsured patients.
  - Higher uncompensated care costs.
  - Greater dependence on 340B revenues to offset patient care losses.
  - Funding cuts threaten closures and reduced services.
- Decreased Disproportionate Share Hospital (DSH)%, potential loss of 340B eligibility.
- Though a **$50 billion** Rural Health Transformation Program (RHTP) was included, may be insufficient to counter the impact of over **$1 trillion in Medicaid funding cuts**.

https://340breport.com/analysis-how-medicaid-cuts-in-big-beautiful-bill-could-push-certain-hospitals-out-of-340b-and-the-importance-of-planning-ahead/
https://www.congress.gov/bill/119th-congress/house-bill/1

One Big Beautiful Bill

Area	Impact Description
Medicaid	Tightened eligibility, work-based requirements, increased costs → Millions potentially lose coverage.
Hospitals	Funding cuts threaten closures and reduced services. Decreased DSH%, loss of 340B eligibility.
Economy & Jobs	Job loss and regional economic decline in health sectors.
Support Programs	Reduction in SNAP, ACA subsidies, and broader safety net funding.

https://340breport.com/matsui-welch-reintroduce-patients-act-in-congress-during-340b-coalition-summer-conference/
https://www.congress.gov/bill/119th-congress/house-bill/2197

Rural Health Transformation Program

- **Initial distribution:** 50% of the total ($25 billion) is **divided equally among approved states**, meaning each state receives the same amount regardless of rural population size or need.
- **Remaining funds:** The other $25 billion is allocated by:
  - State rural population share
  - Number of rural health facilities
  - Financial status of rural hospitals serving low-income patients
- **Eligible expenditures:**
  - Disease prevention and chronic care management
  - Healthcare provider payments, workforce recruitment, and training initiatives
  - Technologies (telehealth, AI, data systems)
  - Behavioral health services & Infrastructure modernization
  - Planning for sustainable rural healthcare delivery systems

https://www.congress.gov/bill/119th-congress/house-bill/1

Federal 340B Reform Proposals Anticipated

SUSTAIN 340B Act

Discussion Draft (2024)

Originally Sen. Thune (R-SD), Sen. **Baldwin** (D-WI), Sen. **Moore Capito** (R-WV), Sen. Cardin (D-MD), Sen. **Moran** (R-KS) and Sen. Stabenow (D-MI)

Now Jerry Moran (R-Kan.), Shelley Moore Capito (R-W.V.), Tammy Baldwin (D-Wis.), Markwayne Mullin (R-Okla.), John Hickenlooper (D-Colo.) and Tim Kaine (D-Va.)

Would overhaul 340B program elements, including contract pharmacy use, patient definition, child sites, transparency requirements, audits, and duplicate discounts.

INTENT: To ensure the 340B program has improved integrity and stability, and that it continues to enable eligible health care providers to stretch federal resources to better provide healthcare for the patients they serve.

340B Stakeholders Clash on Patient Definition, 340B Spending Requirements in Comments on Senate 'Group of Six' Draft Overhaul
https://340breport.com/senate-help-committee-chairman-again-criticizes-340b-hospitals-and-calls-for-reforms-at-hearing/

340B ACCESS Act

H.R. 8574 (2024)

Rep. Larry Bucshon (R-IN), Rep. Earl “Buddy” Carter (R-GA) and Rep. Diana Harshbarger (R-TN)

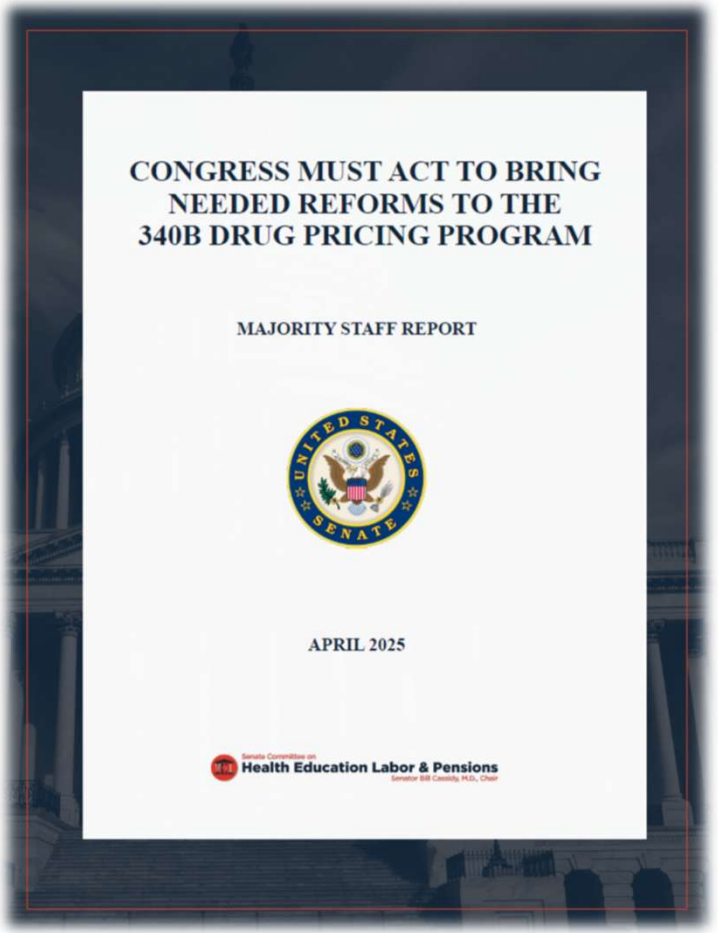
The legislation would overhaul the 340B program based on recommendations from **ASAP 340B**. It would: Codify a 340B patient definition, recognize contract pharmacies in statute, tighten eligibility requirements for hospitals, establish new standards for child site eligibility, restrict roles of pharmacy benefit managers and for-profit entities (including contract pharmacies), improve transparency similar to H.R.3290, and set patient affordability requirements.

https://340breport.com/asap-340b-backed-bill-introduced-in-house/

Legislative Inquiries & Reports

The Cassidy Report

- September 2023, Sen. Cassidy
- Goal: “To determine how covered entities spend 340B revenue in the wake of multiple reports of certain 340B covered entities announcing record-setting profits with no transparency surrounding if and how much of their 340B revenue directly benefits patients.”
- Inquiry letters were sent to:
  - Hospitals: Bon Secours Mercy Health & Cleveland Clinic
  - FQHCs: Sun River Health & Yakima Valley Farm Workers Clinic
  - Chain Pharmacies: CVS Health & Walgreens
  - Drug Manufacturers: Eli Lilly & Amgen
- April 2025, report was published with findings.

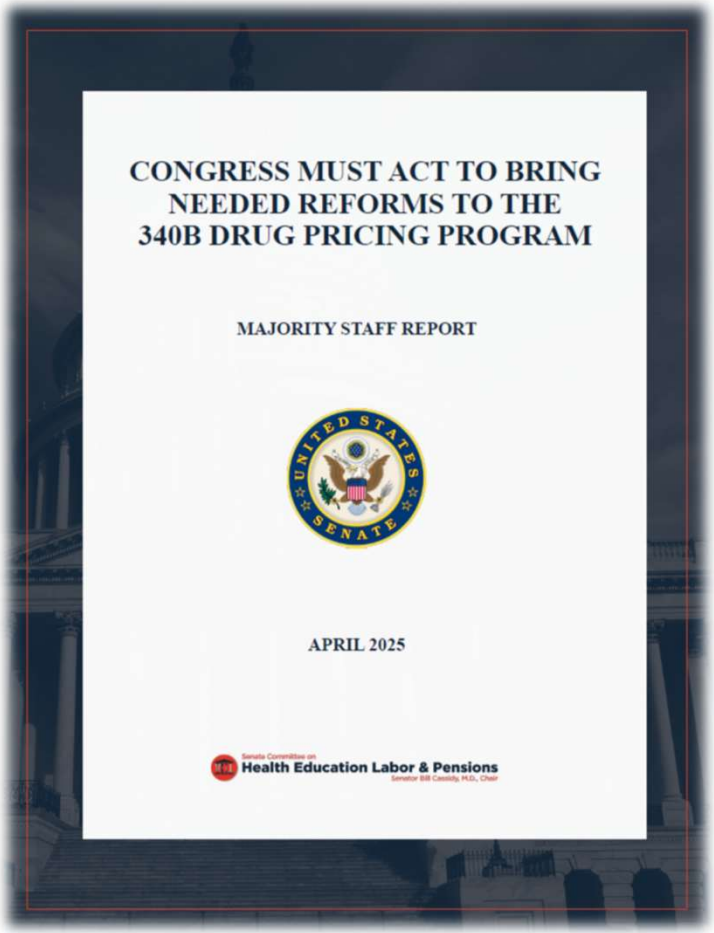


https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html
https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899

Cassidy Report Conclusions

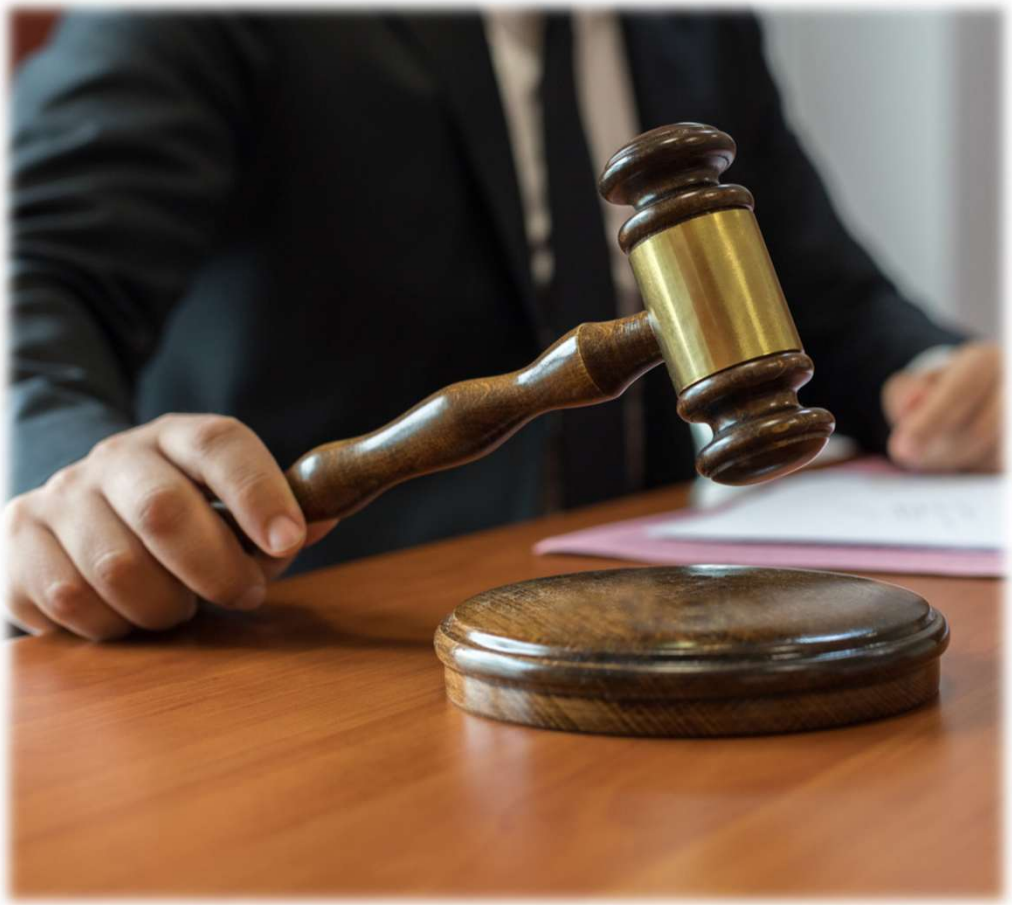
"This investigation underscores that there are **transparency and oversight concerns** that prevent 340B discounts from translating to better access or lower costs for patients. Congress needs to act to bring much-needed reform to the 340B Program, including:

1. Requiring covered entities to provide **detailed annual reporting** on how 340B revenue is used to ensure direct savings for patients, providing a more transparent link between program savings and patient benefit;
2. Addressing potential logistical challenges caused by increased **administrative complexity**, leading to burdens that may impede patient benefit from the program;
3. Investigating the types of **financial benefits contract pharmacies and TPAs receive** for administering the 340B Program to ensure that increasing fees do not disadvantage covered entities and patients;
4. Requiring **transparency and data reporting** for entities supporting participants in the 340B Program (i.e., contract pharmacies and TPAs); and
5. Providing clear guidelines to ensure that manufacturer **discounts actually benefit 340B-eligible patients**, including examining legislative changes to the definition of eligible patient and contract pharmacies' use of the inventory replenishment model.



https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html
https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899

Litigation



340B Statute:

"shall **require** that the manufacturer **offer each covered entity** covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

"COVERED ENTITY DEFINED. In this section, the term ''**covered entity**'' means an entity that meets the requirements described in paragraph (5) and is **one of the following**:

(A) **A Federally-qualified health center**

(as defined in section 1905(l)(2)(B) of the Social Security Act)."

https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

340B Supreme Court History

2011

Astra USA, Inc. v. Santa Clara County

March 29, 2011, in a **unanimous decision** authored by Justice Ruth Bader Ginsberg, the Supreme Court, held that third-party beneficiaries of government contracts between pharmaceutical manufacturers and the Secretary of the Department of Health and Human Services (HHS) could not bring suit to enforce those contracts.

Covered Entities Cannot Directly Sue Manufacturers to Enforce the 340B Statute

2022

American Hospital Association v. Becerra

Jun 15, 2022, in a **unanimous decision** authored by Justice Brett Kavanaugh, the Supreme Court, held that because HHS did not conduct a survey of hospitals' acquisition costs in 2018 and 2019, its decision to vary reimbursement rates only for 340B hospitals in those years was unlawful.

CMS decision to change reimbursement rates only for 340B hospitals without conducting a survey was unlawful.

Federal Appeals Circuit Contract Pharmacy Case

3rd

Sanofi*, Astra Zeneca, & Novo Nordisk, *v. HHS

Ruling: 1/30/2023, in favor of manufacturers.

"Legal duties do not spring from silence. Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies. So, by trying to enforce that supposed requirement, the government overstepped the statute's bounds. And HHS did not violate the APA by purporting to withdraw the proposed ADR Rule before later finalizing it."

7th

Lilly v. Becerra (HHS)

Ruling: Pending

?

DC

***Novartis* & United Therapeutics *v. Johnson* (HHS)**

Ruling: 5/21/2024, in favor of manufacturers.

"In sum, we hold that section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities. We further hold that the conditions at issue here do not violate section 340B on their face. We do not foreclose the possibility that other, more onerous conditions might violate the statute."

Decision Still Pending

Rebate Lawsuits

Novartis Pharmaceuticals Corporation, Plaintiff-Appellant, vs.
Robert F. Kennedy, Jr., et al., Defendants-Appellees, and
340B Health, et al., Intervenors-Appellees

United States Court Of Appeals - District Of Columbia Circuit

Circuit Judges Neomi Rao, Patricia Millett and Cornelia Pillard to hear oral arguments this September.

- Challenges two lower court rulings upholding Department of Health and Human Services' (HHS) statutory authority to preapprove 340B rebate models.

Plaintiffs	Intervenors
Bristol Myers Squibb Company	340B Health
Eli Lilly And Company	Genesis Healthcare System
Johnson & Johnson Health Care Systems Inc.	University of Massachusetts Memorial Medical Center
Novartis Pharmaceuticals Corporation	
Kalderos, Inc.	

OPA Response 340B Rebate Model Pilot

- **Pilot Program Purpose:** The pilot allows manufacturers to pay rebates post-purchase to covered entities, shifting from the traditional upfront discount model.
- **Eligibility and Scope:** Participation is limited to manufacturers with Medicare Drug Price Negotiation Program agreements for initial price applicability year 2026, covering drugs on the Medicare Drug Price Negotiation Selected Drug List.
- **Application and approval process:** Manufacturers must submit plans by September 15, 2025, with approvals announced by October 15, 2025, and an effective date of January 1, 2026; implementation requires prior approval from HRSA.
  - Manufacturer plans that exceed or go beyond criteria defined by OPA must include detailed justification and will be subject to additional review by OPA prior to implementation.

2026 MFP Drugs		
Brand	Manufacturer	Lawsuit?
Eliquis	Bristol-Myers Squibb*	Yes
Enbrel	Amgen	
Entresto	Novartis*	Yes
Farxiga	AstraZeneca (& Prasco)	
Imbruvica	AbbVie	
Januvia	Merck	
Jardiance	BI/Lilly	Yes (Lilly)
Novolog/FIASP	Novo Nordisk	
Stelara	Johnson & Johnson*	Yes
Xarelto	Johnson & Johnson*	Yes

https://federalregister.gov/d/2025-14619

340B Rebate Model Pilot Program

Plan requirements:

- Ensure no additional administrative costs are passed to covered entities
- Provide 60 days' notice before implementation with instructions for registering for any IT platforms
- Maintain existing distribution mechanisms (e.g., 340B wholesaler accounts with pre-rebate prices loaded)
- Provide technical assistance and secure IT platforms for data submission, including HIPAA compliance
- Limit collection of the data to the pilot approved elements listed:

1. Date of Service
2. Date Prescribed
3. RX number
4. Fill Number
5. 11 Digit National Drug Code (NDC)
6. Quantity Dispensed
7. Prescriber ID
8. Service Provider ID
9. 340B ID
10. Rx Bank Identification Number (BIN)
11. Rx Processor Control Number (PCN)

https://federalregister.gov/d/2025-14619

Previously Proposed Rebate Model Elements

Manufacturer	Platform	Impacted Entities	Required Data Elements	Rebate Upon
Bristol Myers Squibb (BMS)	Beacon (BRG)	All CEs	Not specified in lawsuit	Dispense Unit or Full Package
Eli Lilly	Truzo (Kalderos)	All CEs	Utilization Data (CAD, EO Rx, & CRx)	Dispense Unit
Johnson & Johnson (J&J)	Beacon (BRG)	DSH	Purchase & Utilization Data (CAD, EO Rx, & CRx)	Full Package
Novartis	Not specified in lawsuit	DSH	Not specified in lawsuit	Full Package
Sanofi	Beacon (BRG)	CAH, DSH, RRC, SCH, CH/CHC	Purchase & Utilization Data (CAD, EO Rx, & CRx) Encounter Data (Hospitals only)	Full Package

Initially Proposed Impacted Drugs

BMS	Eli Lilly		J&J	Novartis			Sanofi	
Eliquis	Adcirca	Mounjaro	Stelara	Adakveo	Ilaris	Tabrecta	Admelog	Sevelamer
	Alimta	Olumiant	Xarelto	Afinitor	Jadenu	Taflinar	Ambien	Soliqua
	Amyvid	Omvoh		Aimovig	Kesimpta	Tasigna	Apidra	Toujeo
	Baqsimi	Retevmo		Alomide	Kisqali	Tegretol	Arava	Zolpidem
	Baricitinib	Reyvow		Arzerra	Kymriah	Tobradex	Avalide	
	Basaglar	Synjardy		Beovu	Leqvio	Tobrex	Av pro	
	Bebtelovimab	Taltz		Betopic S	Locametz	Trileptal	Doxe ferol	
	Cyramza	Tauvid		Coartem	Lutathera	Tykerb	Dupix	
	Ebglyss	Tradjenta		Cosentyx	Mayzent	Vijoice	Enoxaparin So	
	Emgality	Trijardy		Desferal	Mekinist	Votrient	Flomax	
	Erbitux	Trulicity		Diovan	Myfortic	Xolair	Insulin Glargin	
	Forteo	Verzenio		Diovan HCT	Neoral	Zolgensma	Ibesarta	
	Humalog	Zepbound		Egaten	Netspot	Zortress	Key	
	Humatrope			Entresto	Piqray	Zykadia	s	
	Humulin			Exforge	Pluvicto		Leflunomide	
	Insulin Lispro			Exforge HCT	Promacta		Lovenox	
	Jardiance			Exjade	Rydapt		Multaq	
	Jaypirca			Fabhalta	Sandimmune		Plavix	
	Jentadueto			Femara	Sandostatin		Priftin	
	Kisunla			Gilenya	Scemblix		Primaquine	
	Lyumjev			Gleevec	Simulect		Renvela	

*BMS, J&J, and Sanofi drugs not listed here still managed in 340B ESP, based on respective Contract Pharmacy Policies

Inflation Reduction Act

“(d) NONDUPLICATION WITH 340B CEILING PRICE.—Under an agreement entered into under this section, the manufacturer of a selected drug—

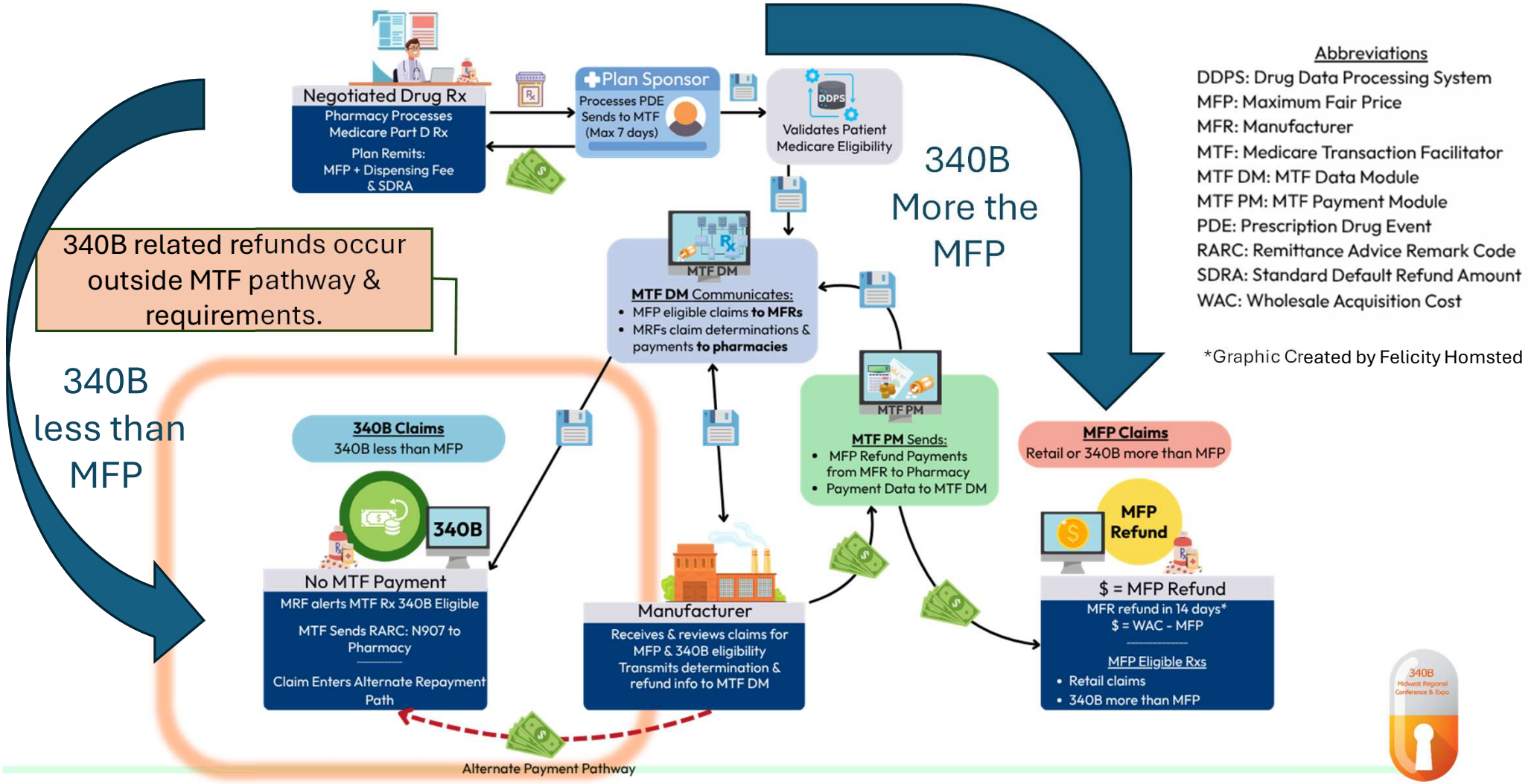
“(1) shall **not be required to provide access to the maximum fair price** under subsection (a)(3), with respect **to** such selected drug and maximum fair price eligible **individuals who are eligible** to be furnished, administered, or dispensed such selected drug **at a covered entity** described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act **and the ceiling price** (defined in section 340B(a)(1) of such Act) **is lower than the maximum fair price** for such selected drug; and

“(2) shall be **required to provide access to the maximum fair price** to such covered entity with respect **to maximum fair price eligible individuals** who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price **if** such **maximum fair price is below the ceiling price** for such selected drug."

136 STAT. 1842 PUBLIC LAW 117–169—AUG. 16, 2022

Initial 10 MFPs negotiated take effect January 1st, 2026, & apply to Medicare Part D only, for first 2 years.

Medicare Transaction Facilitator Workflow



Abbreviations

DDPS: Drug Data Processing System
MFP: Maximum Fair Price
MFR: Manufacturer
MTF: Medicare Transaction Facilitator
MTF DM: MTF Data Module
MTF PM: MTF Payment Module
PDE: Prescription Drug Event
RARC: Remittance Advice Remark Code
SDRA: Standard Default Refund Amount
WAC: Wholesale Acquisition Cost

*Graphic Created by Felicity Homsted

MFP Impact at FQHC Entity-Owned Pharmacies

MEDICARE IRA 2026 – PROJECTED REVENUE LOSS FROM MFP DRUGS			
Pharmacy Size	**Medicare (%)**	**2026 MFP Drugs as % of Rx Filled**	**Estimated Revenue Loss (%)**
Small	16%	1%	13%
Medium	37%	1%	6%
Medium	45%	2%	15%
Large	49%	3%	16%
Large	40%	2%	10%

Estimated impact across pharmacies is approximately 13% loss in overall entity-owned pharmacy revenue

Other Key Litigation

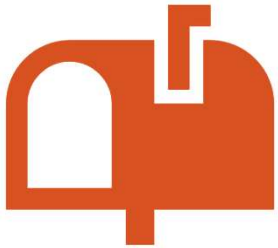
- **Amgen Inc et al, vs. Robert F. Kennedy Jr., et al.** United States District Court, District Of Columbia, James E. Boasberg, Chief Judge - Motion to Dismiss Denied (8/4/25)
  - Amgen, Eli Lilly, and UCB allege that the Secretary improperly **certified** a string of **ineligible clinics** (STD - Sagebrush Health Services), costing Plaintiffs millions of dollars in improper 340B discounts.
- **Mosaic Health, Inc. v. Sanofi-Aventis**. U.S. 2nd Circuit Court of Appeals - Vacated & Remanded (8/6/25)
  - Vacated U.S. Western District of New York District Court Judge's February 2024 denial of Mosaic Health and Central Virginia Health Services' (CVHS) claims that insulin drugmakers **AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi violated antitrust** law by **coordinating** their **contract pharmacy restrictions**. Sent back to lower court.
- **Oregon Health & Science University v. Engels**, U.S. District Court for the District of Columbia, Judge Rudolph Contreras - Motion to Dismiss granted (6/17/25)
  - Five hospitals (Oregon Health & Science University, Maine General Medical Center, the University of Rochester, Children's National Medical Center, and University of Washington Medical Center) **sued HRSA & HHS for authorizing Johnson & Johnson to audit** their 340B program records.

https://340breport.com/wp-content/uploads/2025/08/Mosiac-v.-Sanofi-Opinon-8.6.25.pdf

State Litigation

Key Statutory Silences

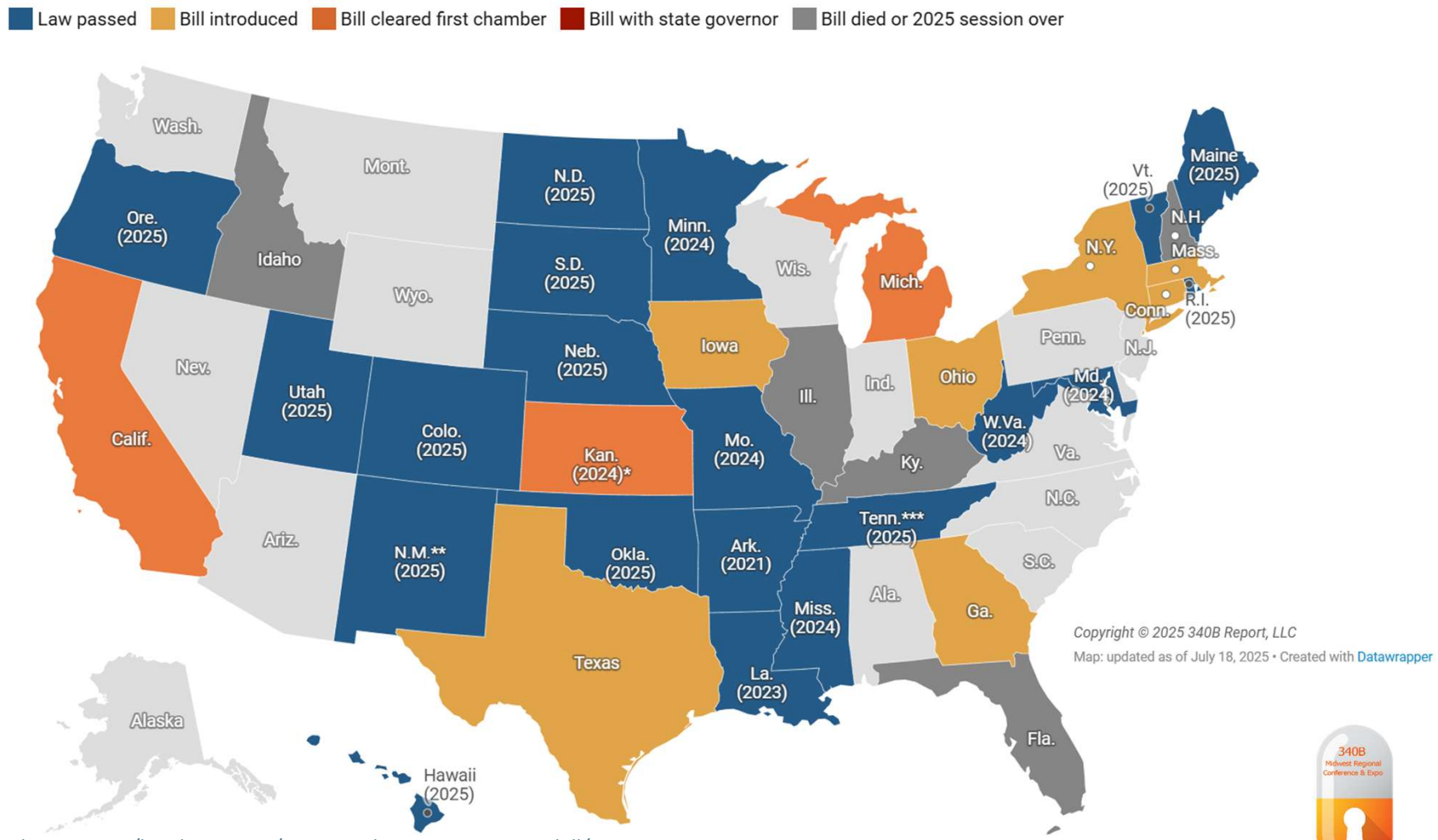
Contract Pharmacy



Delivery

Traditionally, states have regulated in the areas of distribution, pharmacy, and contractual arrangements

340B REPORT 2025 State Legislation Tracker: Contract Pharmacy Access Bills and Laws



https://340breport.com/legislative-map/contract-pharmacy-protection-bill/

Contract Pharmacy Protection Bill Elements

Interference with acquisition or delivery of 340B drugs prohibited

- May not deny acquisition / delivery of a 340B drug to 340B contract pharmacy unless prohibited by HHS

Submission of claims or utilization data prohibited

- May not require a 340B entity to submit any claims unless required by HHS

Other interference prohibited

- May not interfere with a 340B entity unless expressly authorized by HHS

Exclude 340B claims that would result in a net loss to the covered entity.

- Unique to Tennessee

State Contract Pharmacy Protection Bills

Depending on the state, enforcement and rulemaking authority may be delegated to different agencies.

- This can have significant impact on bills success once signed into law
  - Some states have drafted initial versions with private rights of action for CEs (e.g. Maine but it has not made it to any final versions (yet)

Enforcement Authority	Rule-Making Authority
State Pharmacy Board	State Pharmacy Board
Attorney General	Attorney General
Consumer Protection Agencies	Department of Health
Insurance Commissioner	Insurance Commissioner

Contract Pharmacy Protections V. Manufacturers

Key Legal Arguments:

1. US Constitution Conflict Preemption - **Federal Supremacy Clause, 340B Statute, & 10th Amendment**
2. US Constitution Conflict Preemption Under Federal **Patents Law**
3. US Constitution Due Process Clause **- Vagueness**
4. Violations of the US Constitution - **Contracts Clause**
5. Violations of the US Constitution - **Takings Clause** (5th and 14th Amendments)
6. Violates the US Constitution - Extraterritoriality: **Dormant Commerce Clause**
7. Violates the US Constitution – **Excessive Fines** (8th Amendment)
8. Violation of State Constitution - One Subject Rule, Due Process, Clear Title, Original Purpose & Excessive Fines

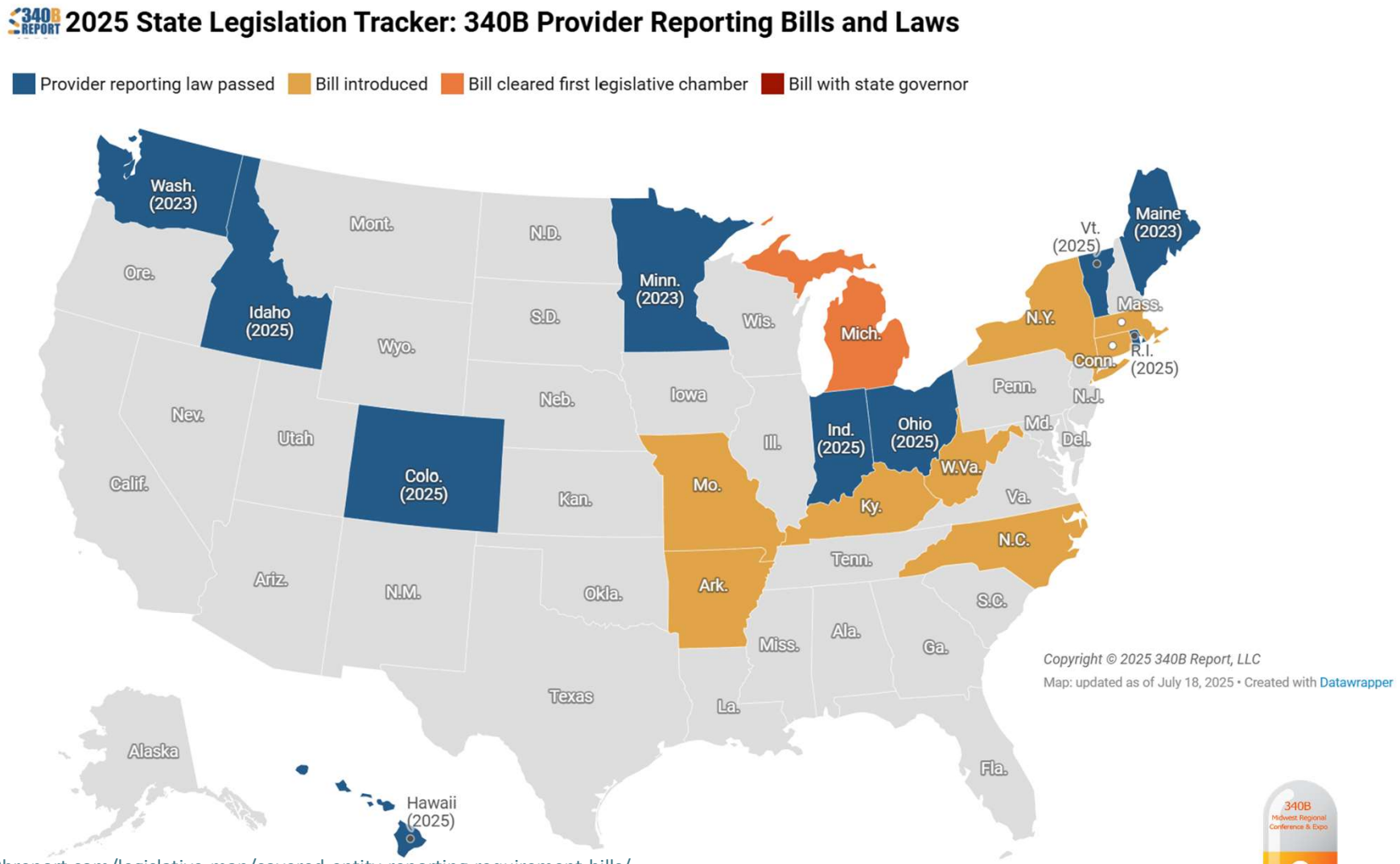
Other 340B Related State Bill Types

Reporting & Transparency Measures

- Quantitative – CEs provide data only (MN, ID, HI)
- Qualitative – CEs provide narratives in addition to data (WA, CO, IN, VT,ME)
- Newly proposed - Manufacturer Reporting (MI)
- Sample measures:
  - 340B Revenue = Reimbursement – 340B Cost
  - 340B Revenue = Non-340B Purchase Price – 340B Cost
  - Expenses related to administering the 340B program
  - May be all CEs or limited

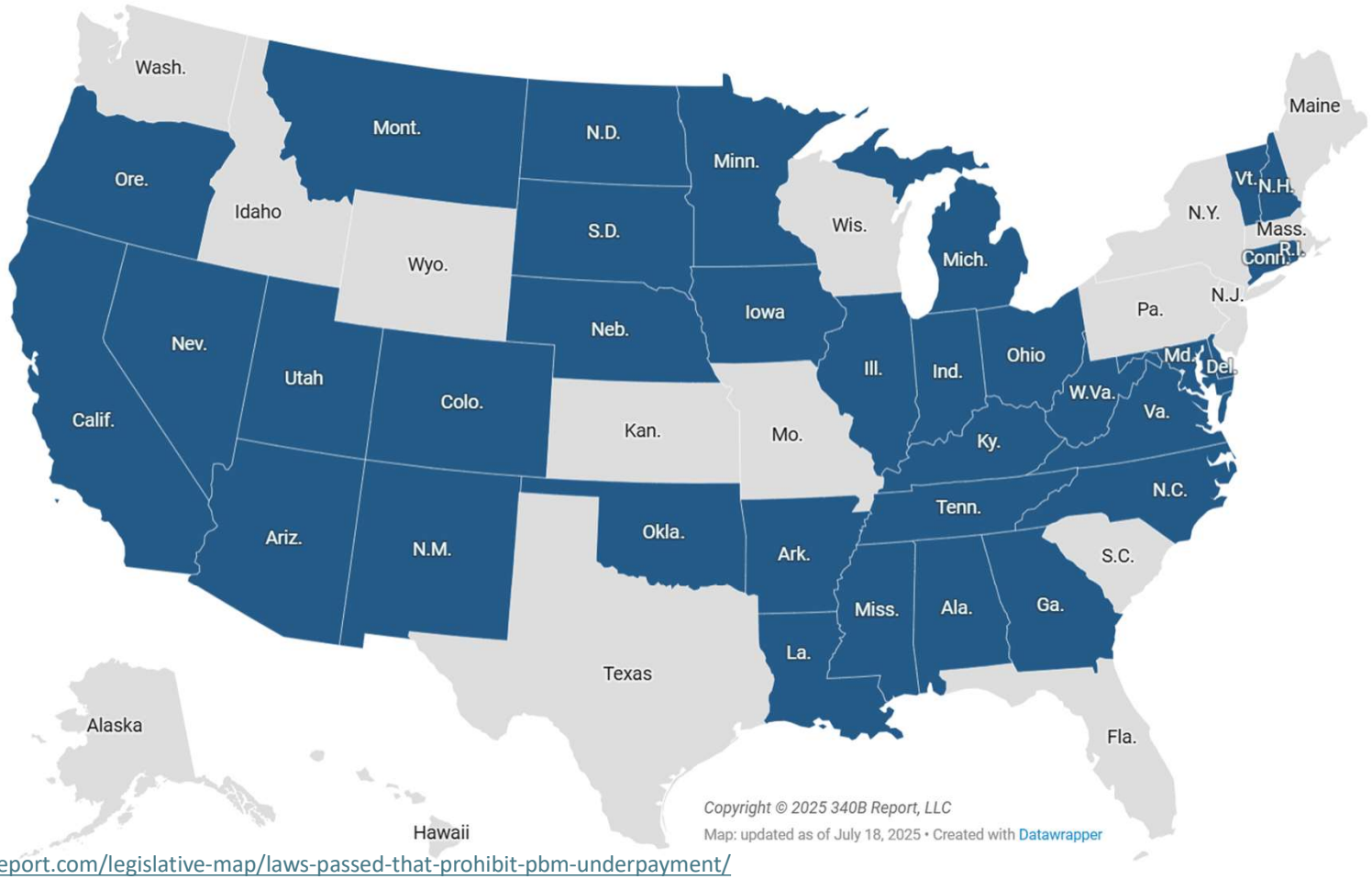
PBM Reimbursement Protections

- Prohibition of certain discriminatory actions with respect to 340B entities e.g.
  - Reimbursement at lower rate
  - Imposition of different terms and conditions
  - Discrimination against 340B entity that interferes with patient choice
  - Submission of data pertaining to ingredient costs or pricing of 340B drugs (e.g. AAC or claims modifiers)



https://340breport.com/legislative-map/covered-entity-reporting-requirement-bills/

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



https://340breport.com/legislative-map/laws-passed-that-prohibit-pbm-underpayment/

Advocacy

Advocacy Tips for Contract Pharmacy Protection Bills

- Health Centers already report 340B elements in the annual UDS submission
- If transparency looks inevitable, push manufacturer and PBM transparency
- Try not to combine PBM & Contract Pharmacy protections
- Do not include wholesalers in contract pharmacy bills

Bill Testimony

- Can be Written and/or In-Person
- Generally, legislators are easy on constituent testimony
- If you don't know the answer, say so.
  - Follow-up when you do

Just tell your story!

SPECIAL THANKS TO

Mark Ogunsusi, PharmD, JD, Partner, K&L Gates

&

Peggy Tighe, JD, Principal, Powers Law

For sharing content which helped inform this presentation.

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NEED MORE INFORMATION?

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