



340B Current Issues and Policy Update

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Agenda

Current ESP Challenges

340B Program Opportunities

Manufacturer Contract Pharmacy Restriction Lawsuits

State & Federal Legislative Updates

Special Opportunity from Visante & 340B Report

Current ESP Challenges

1

340B ESP

- › Manufacturers requirements
- › Access to 340B pricing
- › Designation of pharmacy
- › Verifying access to 340B pricing
- › Reporting requirements

2

Compliance

- › Dedicated FTE's
- › “Gray” areas of the program
- › Audits
 - Internal/External
 - HRSA
 - Manufacturers

3

340B Education

- › Develop a training program
- › All staff has responsibilities
 - IT, Legal, Nursing
- › Financial Impact
 - Provide specific savings
 - Develop a community report

340B Program Opportunities

1

Outside Resources

- › TPA
- › External Audit firms
- › Apexus
 - 340B University & 340B ACE Certificate
- › 340B Health
- › 340B Report
- › Hospital Associations

2

Potential Growth

- › Home Infusion
- › Specialty Pharmacies
- › In-house pharmacy (CE owned)
- › Contract pharmacy expansion

3

Expansion of Care

- › Health Clinics
 - Free to public
- › Public Education
 - Town Halls & use of social media
- › Partnerships within the community
 - Transportation for patients
 - Delivery of medications to patient's home

Manufacturer Contract Pharmacy Restriction Lawsuits

Manufacturer Contract Pharmacy Restriction Lawsuits

HHS Challenges to Manufacturer Restrictions

Case	Federal Court	Status
Novartis v. Johnson	3 rd Circuit Court of Appeals	Judge upheld manufacturer policy restrictions January 2023
Eli Lilly v. Becerra	7 th Circuit Court of Appeals	Decision pending (court heard oral arguments October 2022)
Sanofi v. HHS	D.C. Circuit Court of Appeals	Decision pending (court heard oral arguments October 2022)

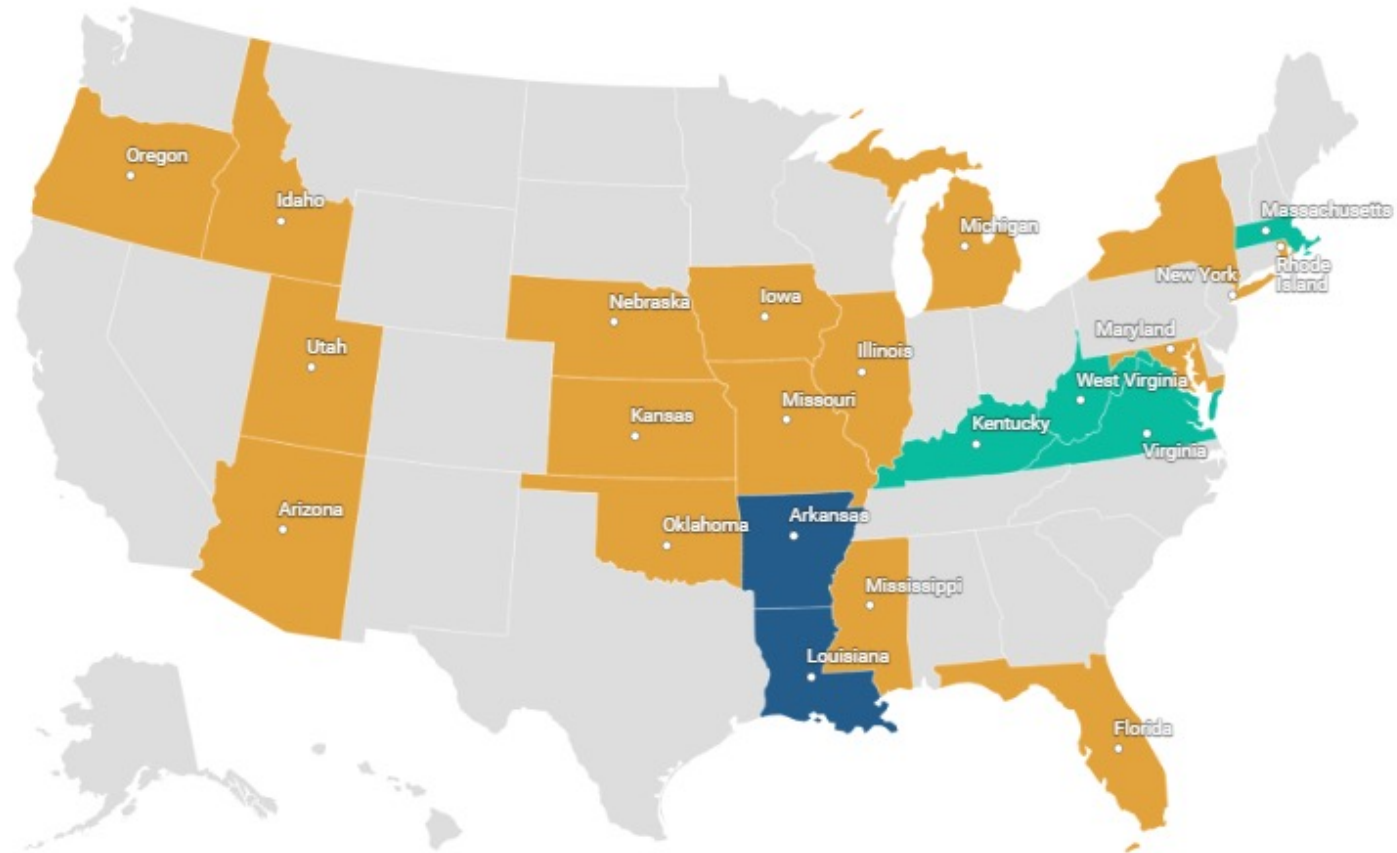
Manufacturer Challenges to State 340B Contract Pharmacy Laws

Case	Federal Court	Status
PhRMA v. McClain (Arkansas)	8 th Circuit Court of Appeals	Court upheld legality of Arkansas law (March 12, 2024)
PhRMA v. Murrill (Louisiana)	Western District of Louisiana	Decision pending (initial complaint filed in July 2023)
AstraZeneca v. Murrill (Louisiana)	Western District of Louisiana	Decision pending (initial complaint filed in August 2023)
AbbVie v. Murrill (Louisiana)	Western District of Louisiana	Decision pending (initial complaint filed in September 2023)

340B Contract Pharmacy Protection Bills

340B REPORT Legislation Tracker: 2023-2024 State Bills and Laws that Prohibit Drugmaker 340B Contract Pharmacy Restrictions

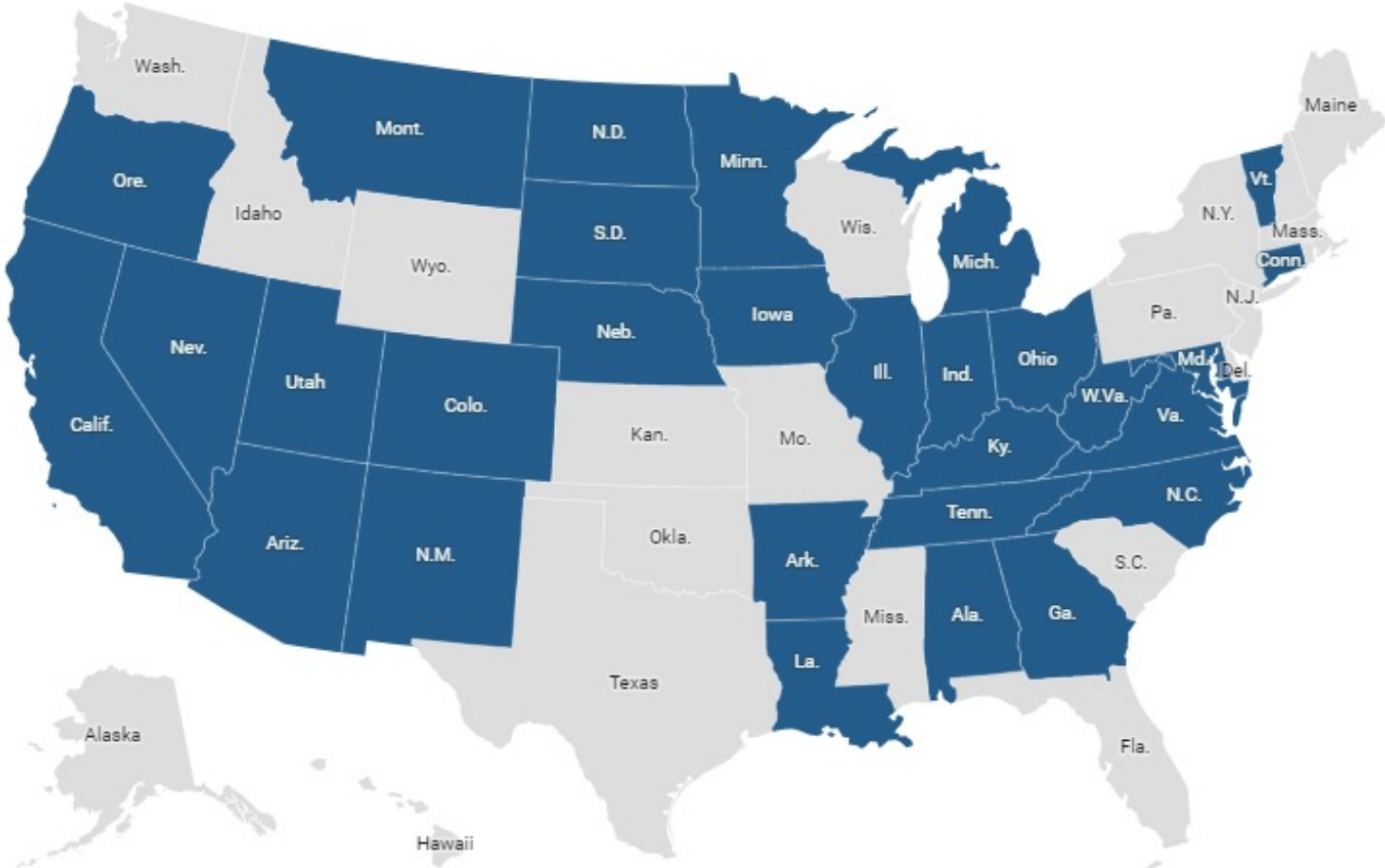
■ Bill passed ■ Bill cleared a legislative chamber ■ Bill introduced



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PBM Anti-Discrimination Bills

340B REPORT Legislation Tracker: Laws Passed that Prohibit PBMs from Limiting Payment to Providers
Based on 340B Status

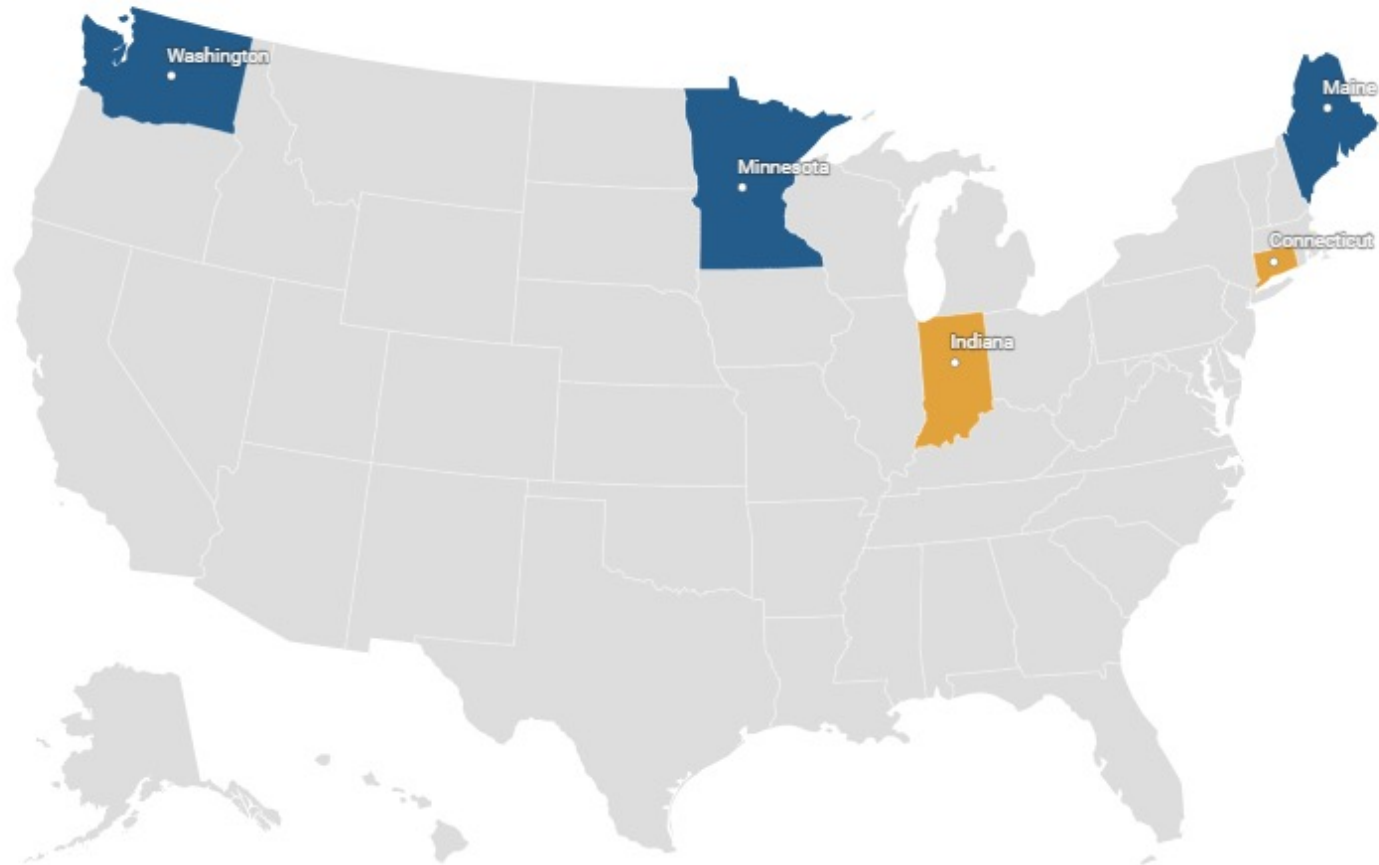


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340B Provider Reporting Requirement Bills

340B REPORT Legislation Tracker: 2023-2024 State Bills and Laws that Implement 340B Provider Reporting Requirements

■ Bill passed ■ Bill introduced



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Federal Legislative Update

Potential & Pending 340B Bills/Provisions

- New 340B provider reporting requirements
- Other drug industry-friendly bills
- 340B provider-friendly bills
 - 340B Protect Act (H.R. 2534)
 - SUSTAIN 340B Act
 - 340B PATIENTS Act - Rep. Matsui contract pharmacy bill
- Various new coalitions forming
 - ASAP 340B
 - Advocates for Community Health – 340C
 - 340B Working Table
- Senate 340B working group
- Sen. Cassidy investigation



House Action

➤ Patient Act, H.R. 3561 – part of larger PBM bill – Bipartisan bill

- Passed the House 320-71 on Dec. 11
- Requires providers to bill MCOs at ingredient cost plus a dispensing fee
- Gives states option to let 340B providers bill at above cost and keep the spread
- Annual reporting on how much they make from billing at above cost; amount to be posted on a searchable federal website
- Similar bill passes Senate committee without website reporting requirement

➤ 340B Transparency Act, H.R. 3290 (Sponsored by Rep. Bucshon (R-Ind))

- Party line vote with only one Democrat in favor, awaiting floor action
- Requires DSH hospitals to report on patients receiving 340B drugs, charity care spending, public-payer payment shortfalls, 340B savings, and how savings are used
- Allows HHS to impose reporting requirements on other covered entities and to audit health care provider records to determine how they use their 340B drug purchases net income
- Institutes civil monetary penalties for non-compliance



Chair Cathy McMorris Rodgers (R-WA)



Rep. Larry Bucshon (R-Ind)

Senate 340B Working Group

WHO THEY ARE

- Long-time supporters of the 340B program.
- Released an RFI last year, over 250 submissions.

LATEST ACTION

- Released discussion draft of a comprehensive 340B reform bill on Feb. 2 - SUSTAIN 340B Act.
- Included an additional RFI on the three most controversial issues:
 - Patient definition
 - Contract pharmacy arrangements
 - Child sites

CONTRACT PHARMACY PROVISIONS IN DISCUSSION DRAFT & RFI

- Imposes no restrictions or limitations on contract pharmacy use but requires CEs to extend their financial assistance policies to contract pharmacies.
- Invites stakeholders to explain how and why they contend restrictions should be placed on the number and/or location of contract pharmacies.
- Would also extend financial assistance requirements at child sites.
- Comments due by April 1.



John Thune (R-SD)



Tammy Baldwin (D-WI)



Shelley M. Capito (R-WV)



Ben Cardin (D-MD)



Jerry Moran (R-KS)



Debbie Stabenow (D-MI)

Two Leaders, Different Directions

340B REPORT



Sen. Bernie Sanders (I-Vt) and 10 Democrats on an influential committee invited the CEOs of three pharma companies to testify at a January hearing.

Senate Democrats Seek Drug Pricing Testimony from Three Pharma CEOs

November 28, 2023 William Newton Washington Correspondent

Senate Democrats on an influential committee invited the CEOs of three major pharmaceutical companies to testify at a January hearing on rising prescription drug costs.

The hearing announcement and letters to the drugmaker executives did not specifically mention the 340B program, though two lobbyists said they anticipated 340B would come up at the hearing. The Senate Health, Education, Labor, and Pensions (HELP) Committee, which will hold the hearing, has jurisdiction over the 340B program, the Food and Drug Administration, and the National Institutes of

340B REPORT



Sen. Bill Cassidy (R-La.) sent letters to two community health centers that asked for detailed financial information on their 340B program revenue.

NEWS ALERT

Influential Senator Extends 340B Inquiry to Community Health Centers

November 16, 2023 William Newton Washington Correspondent

The top Republican on an influential Senate committee today asked two community health centers to submit detailed financial information on their use of 340B program revenue.

The new query followed a similar probe the same senator opened into two 340B health systems in September.

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Questions?

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340B Current Issues and Policy Update

Questions/Discussion

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