

**#DEFEND340B**



**Community  
Voices**

*CV340B.org*

# **Contract Pharmacy.**

## **A Primer for the States**



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## What

- Section 340B of the Public Health Service Act (340B program) enables safety net health care providers to purchase outpatient drugs at deeply discounted prices
- Safety net providers serve a disproportionate share of uninsured, underinsured, and otherwise vulnerable patient populations



# What is 340B?

## Why

- Because 340B drugs typically cost less than commercial rates, safety net providers can “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services,” the law’s stated intent.

## How

- The 340B program enables these providers to dispense or administer those drugs to their patients, and, if the patient has insurance, to bill the payer for those drugs.



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## RWCs

Ryan White HIV/AIDS  
Program Grantees



# Who is Eligible?

## FQHCs

Federally Qualified Health  
Centers

- Health Center Program Award Recipients
- Health Center Program Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

## Hospitals

Non-Profit Public Hospitals

- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

## Specialty

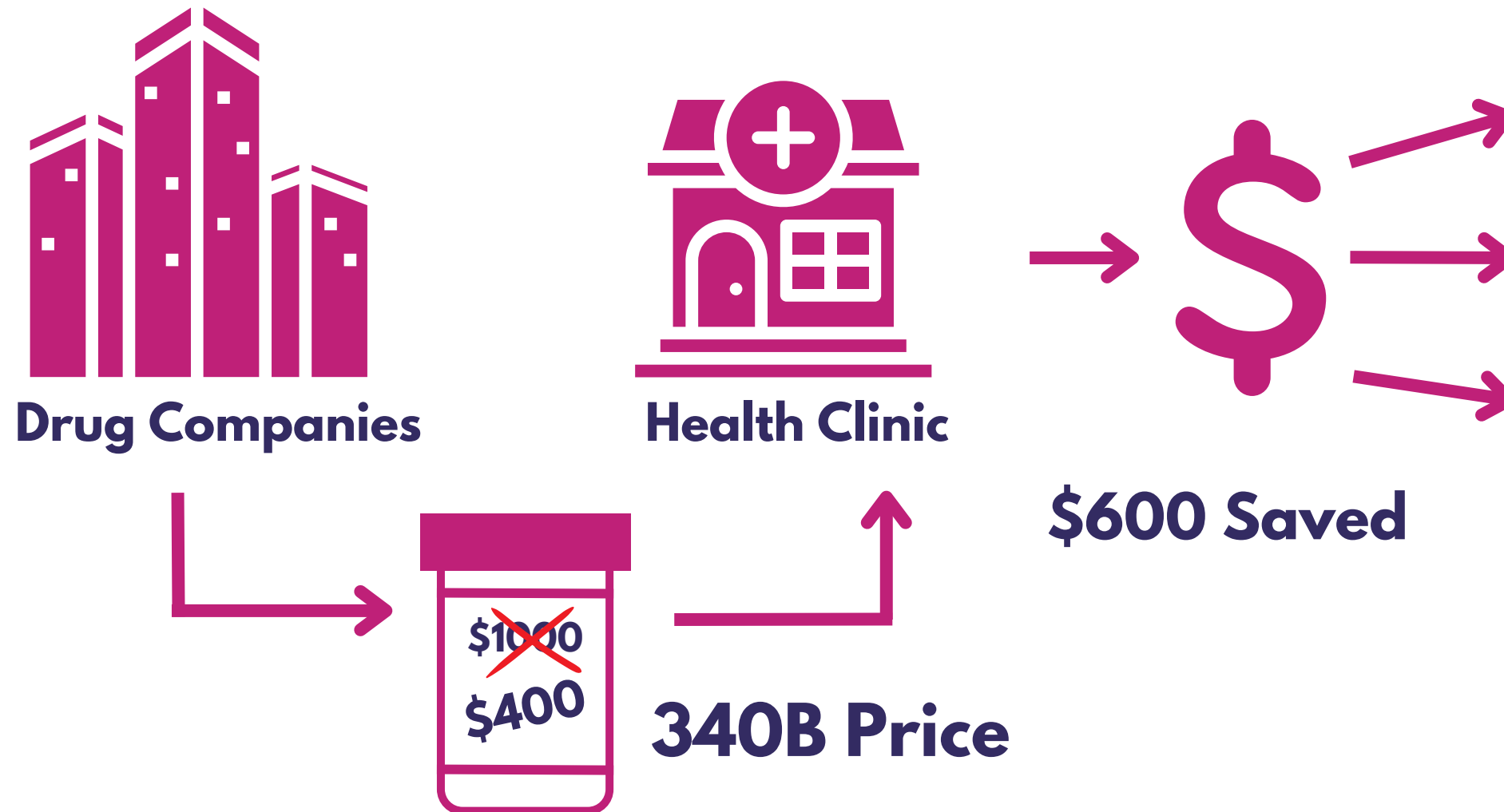
Specialized Clinics

- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics



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# How 340B Works



## 340B Supported Services

- Primary Care
- Dental Services
- Insurance Premiums
- Co-payments
- Outpatient Premiums
- Patient Transportation
- Mobile Testing Unit
- Covid Clinic
- Pediatrics Primary Care

# What is Contract Pharmacy?

## What

### What are Contract Pharmacies?

- Covered entities participating in the 340B Drug Pricing Program may contract with pharmacies to dispense drugs purchased through the program on their behalf. These pharmacies are referred to as “contract pharmacies.”

## Why

Congress chose providers that serve the underserved and uninsured to be eligible for 340B. These providers use contract pharmacies to increase access to care/services.

## How

### How do Contract Pharmacies Work?

- The pharmacy receives 340B drugs through a bill to/ship to arrangement, collects reimbursement for drugs from the patient’s payer (if any), and sends reimbursement to the provider. The provider pays a fee to the pharmacy for dispensing, billing services

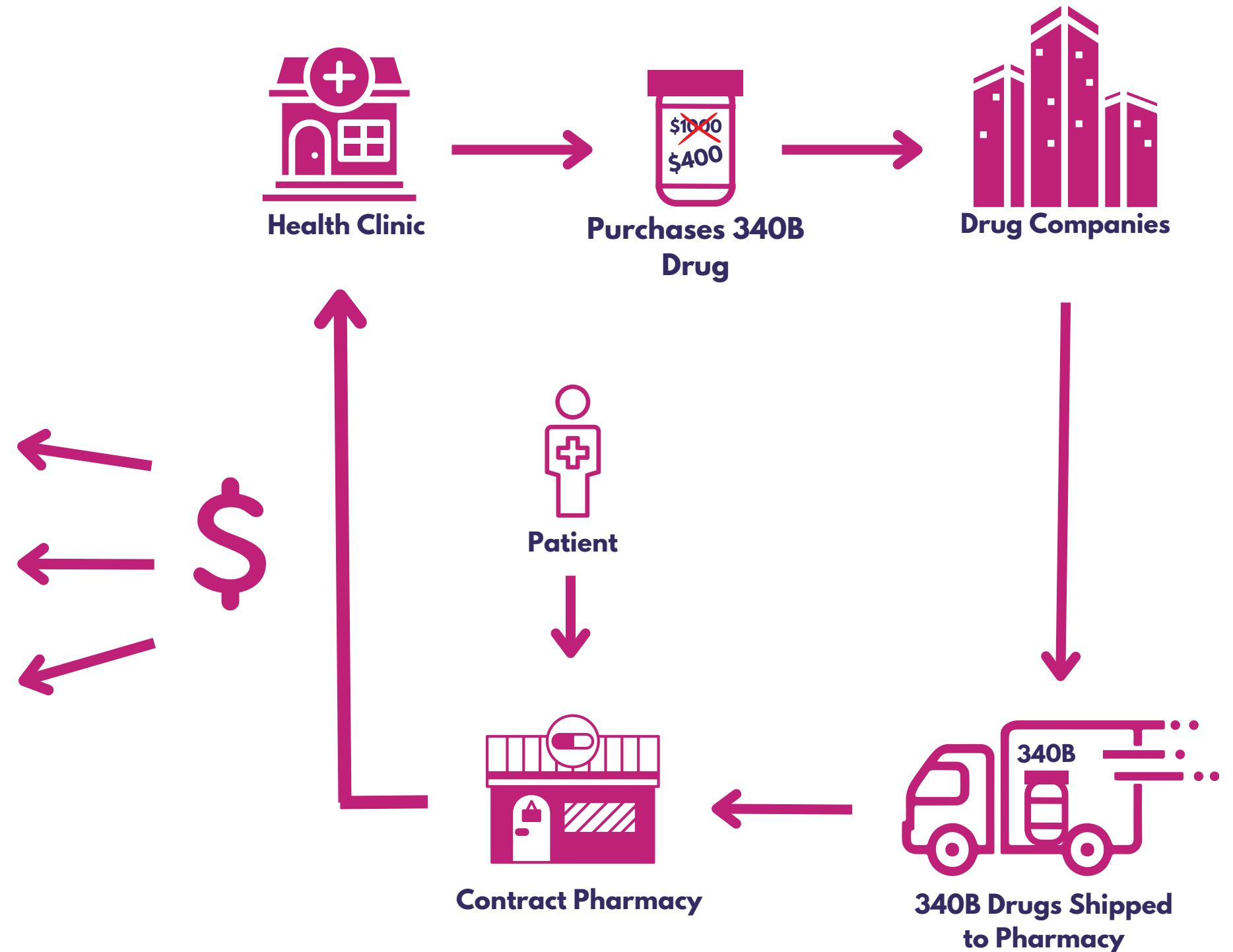


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# How Contract Pharmacy Works

## 340B Supported Services

- Primary Care
- Dental Services
- Insurance Premiums
- Co-payments
- Outpatient Premiums
- Patient Transportation
- Mobile Testing Unit
- Covid Clinic
- Medication Adherence
- Pediatrics





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# While Healthcare Workers Were Doing This...

**Drug Companies Unilaterally, Illegally Changed Rules**

**In 2020 while frontline healthcare workers were battling the COVID-19 Pandemic, manufacturers began to block shipment of 340B drugs to contract pharmacies and/or subject such arrangements to onerous conditions.**





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# These Restrictions are Harmful



For these providers, contract pharmacy arrangements are often the only way they can fill their patients' prescriptions with 340B drugs.



Access to 340B discounts allows safety net providers to absorb the enormous financial burden of providing uncompensated care that would otherwise fall on taxpayer shoulders.

## Drug Company Actions Harm Public Safety

- Dramatically reduce resources available to safety net providers.
- Compromise critical safety net programs.
- Harm the ability to meet the needs of vulnerable patients.
- Threaten the ability of the safety net to prepare and respond to public health crises.
- Jeopardizes safety-net services such as discounted medications, uncompensated health care, and fulfilling the unmet health care needs of their patients.
- Threaten access to affordable drugs and care.
- Serve to increase drug company profits.





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# Drug Companies

Unilaterally and illegally restricting contract pharmacies

Johnson & Johnson



Boehringer Ingelheim

abbvie



United Therapeutics CORPORATION

Lilly



SANOFI

EXELIXIS

AstraZeneca



novo nordisk



Biogen



MERCK



NOVARTIS

BAUSCH Health

EMD SERONO



Bristol Myers Squibb

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# Who Can Help?



## Courts

### Tied Up In Courts

- **3 cases (AstraZeneca, Sanofi, NovoNordisk) consolidated:**
  - **APPEAL: Unfavorable Decision**
- **Eli Lilly, S. District of Indiana: Favorable Decision.**
  - **APPEAL: Decision Pending**
- **2 cases (Novartis, United Therapeutics in District of Columbia: Unfavorable Decision.**
  - **APPEAL: Decision Pending**



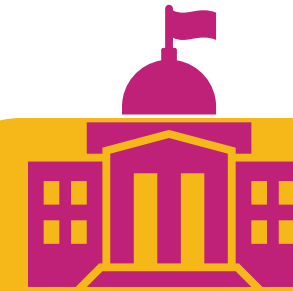
# Who Can Help?



## Congress

**Support In Congress, But Delays in Courts, Lack Of Bipartisanship Stalling Change**

- Multiple letters from hundreds of members of Congress
- Strong base of Congressional allies supporting 340B, 3 letters with more than 217 signers.
- Congress stalled in enacting legislation as they state that they are waiting for the courts or compromise legislation.
- Senate 340B Working Group took comment from nearly 270 groups, working on possible compromise.



## Fed. Agencies

**Agencies Fighting in Courts, Issued Guidance**

- Every administration, Republican and Democrat, has consistently interpreted the 340B statute as allowing contract pharmacy arrangements.
- The Health Resources and Services Administration (HRSA), the federal agency that administers the 340B program, issued guidance reminding 340B providers of their right under state law to dispense 340B drugs through an agent (contract pharmacies).

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340B

Pharm  
340B

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PHARMA THINKS STATE  
LEGISLATORS DO NOT HAVE  
THE RIGHT TO REGULATE  
PHARMACEUTICAL  
MANUFACTURERS  
IN THEIR STATES.

**FALSE**



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# What can State Policymakers do to help?



## Trend Setting States

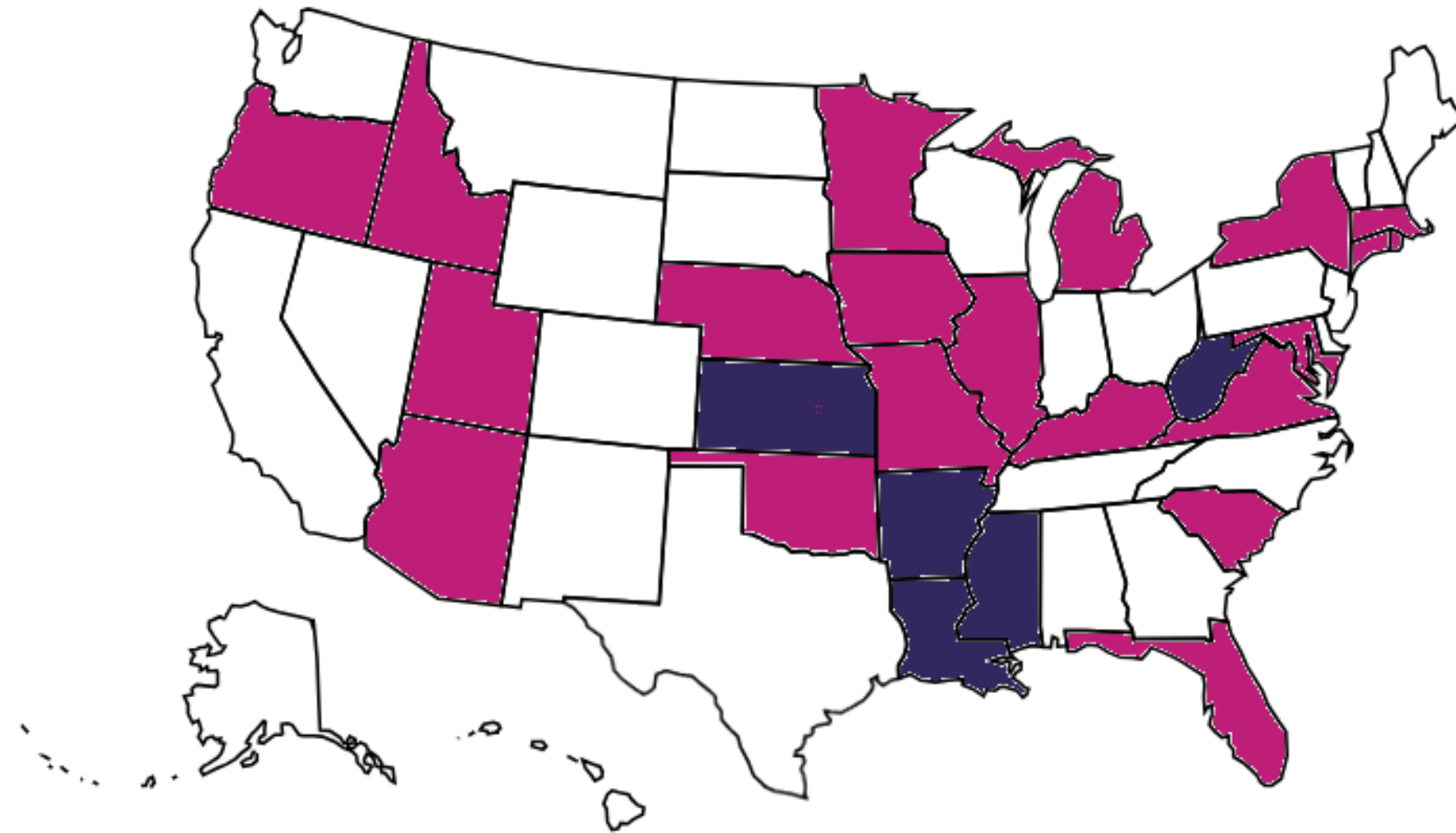
- Two states – Arkansas and Louisiana – enacted laws to protect contract pharmacy arrangements.
- The drug industry is challenging Arkansas and Louisiana laws, arguing that states lack authority to protect public health by regulating 340B drug distribution.
- Drug company efforts have been unsuccessful primarily because...
  - drug distribution is traditionally regulated by states,
  - the 340B statute is silent on drug distribution, and
  - Congress never intended to limit state rights under the program.



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# States Stepping in to Regulate Pharma's Overreach

 **Bill Introduced**       **Bill Passed**



## State Bills

1. Oregon
2. Idaho
3. Utah
4. Arizona
5. Nebraska
6. Kansas
7. Oklahoma
8. Minnesota
9. Iowa
10. Missouri
11. Illinois
12. Arkansas
13. Louisiana
14. Mississippi
15. South Carolina
16. Kentucky
17. West Virginia
18. Virginia
19. Maryland
20. Massachusetts
21. New York
22. Rhode Island
23. Connecticut
24. Florida

As of 4.17.2024

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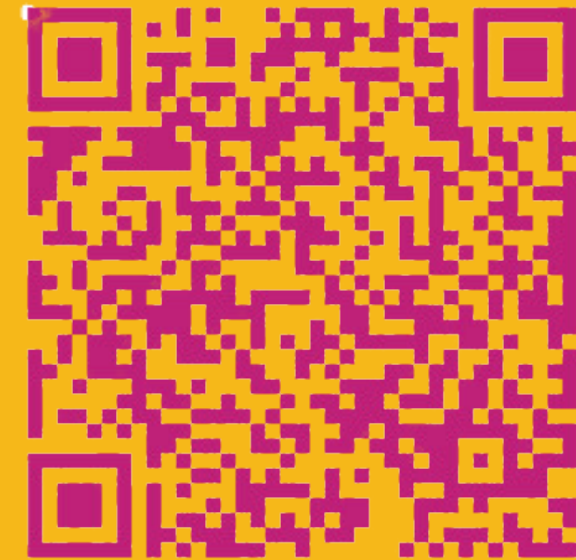


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