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The *voice* of the
community
pharmacist.

The 340B Landscape for Community Health Centers - What's at Stake?

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Disclosure Statement

There are no relevant financial relationships with ACPE-defined commercial interests for anyone else in control of the content of the activity.



Learning Objectives

- Describe the importance of the 340B program for safety net providers, like community health centers.
- Outline emerging policy updates that impact the 340B program and providers.
- Review tools you can use to engage in effective 340B advocacy.

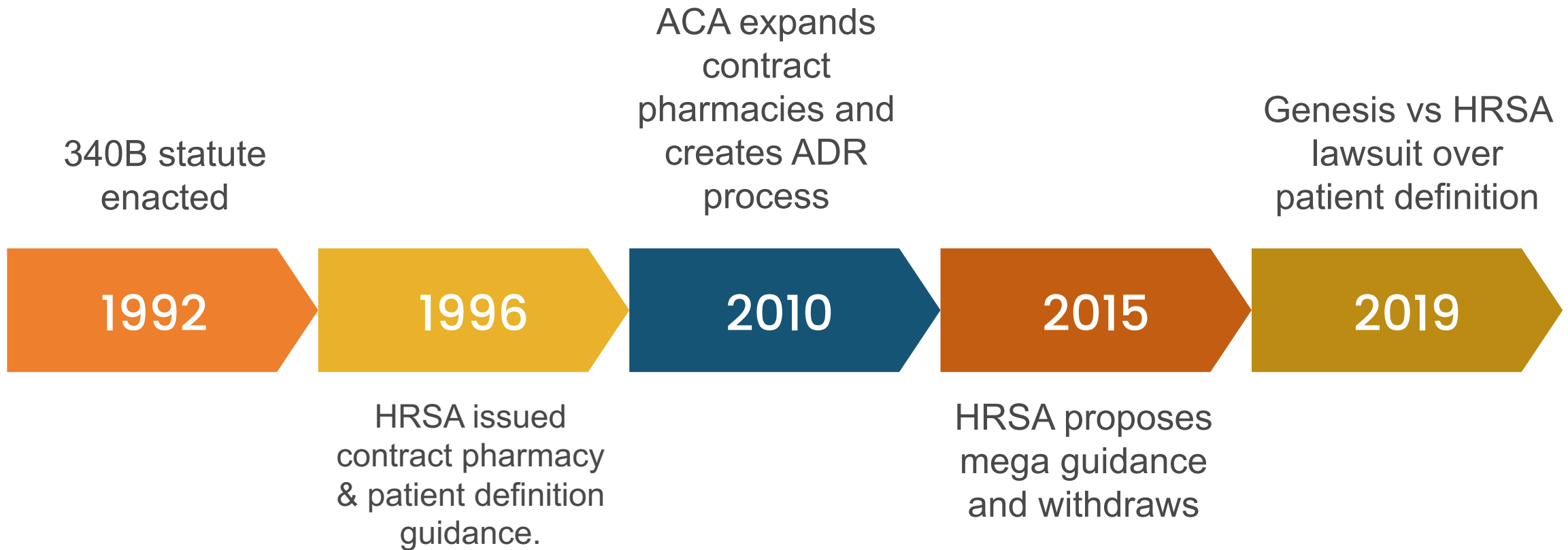
340B Basics & Advocacy

1 The History
of 340B

2 The Current
Landscape

3 Telling your
Story

340B History Timeline





23 Drug Manufacturers with Contract Pharmacy Restrictions

Eli Lilly

AstraZeneca

Sanofi

Novartis

United
Therapeutics

Novo
Nordisk

Boehringer
Ingelheim

Merck

UCB

Amgen

AbbVie

Bristol Myers
Squibb

Pfizer

Glaxo Smith
Kline

Gilead*

Bausch
Health

Biogen

Exelixis

Bayer

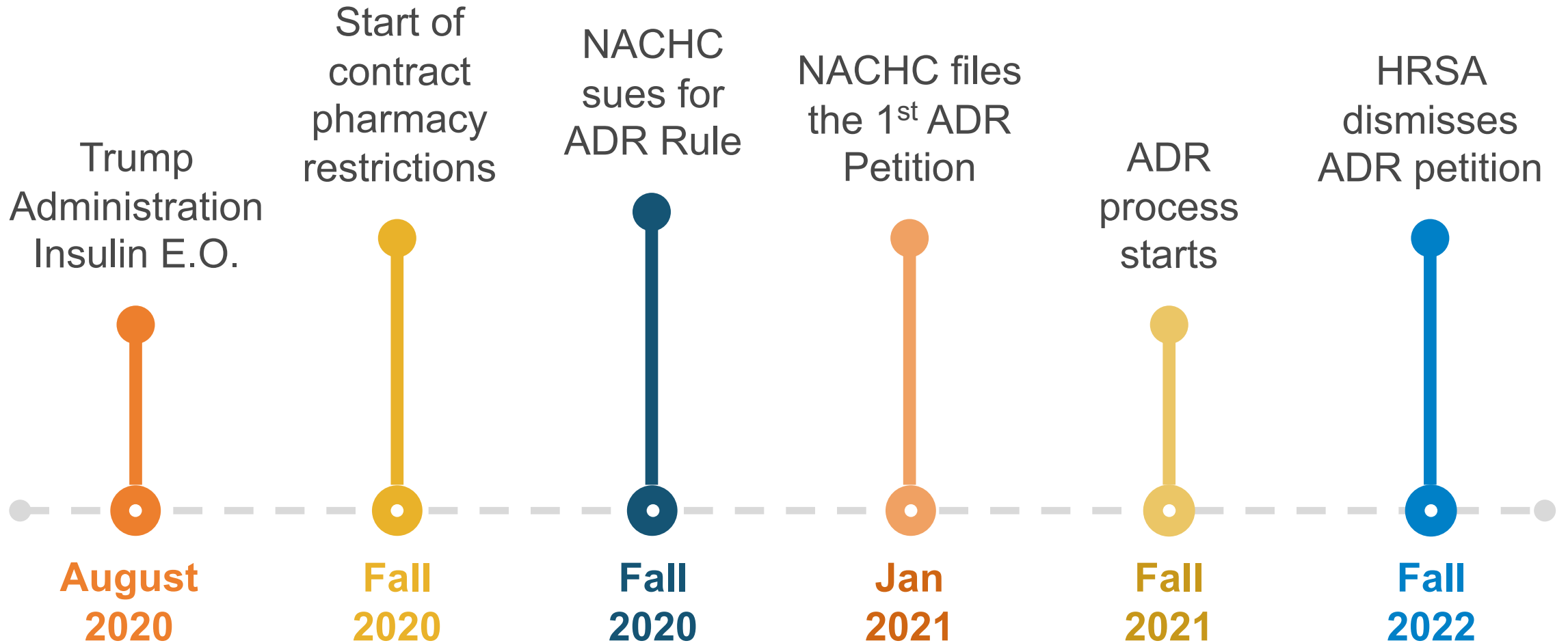
Organon

Teva

EMD Serono

Johnson &
Johnson
(Janssen)

How Did We Get Here?



Contract Pharmacy Litigation

The cases in red have been decided. In black are waiting decisions in the Appeals Courts. Blue is still pending at the District Court level.

U.S. 3rd Circuit

AstraZeneca
Novo Nordisk
Sanofi

Court found in favor of manufacturers' position that the 340B statute does not require delivery of 340B drugs to an unlimited number of contract pharmacies and the current restrictions do not violate the 340B statute.

DC Court of Appeals

Novartis
United Therapeutics

Lower Court found that the 340B statute does not stop manufacturers from attaching any conditions to 340B drug sales involving contract pharmacies. But noted that the statute does not permit all types of conditions.

U.S. 7th Circuit

Eli Lilly

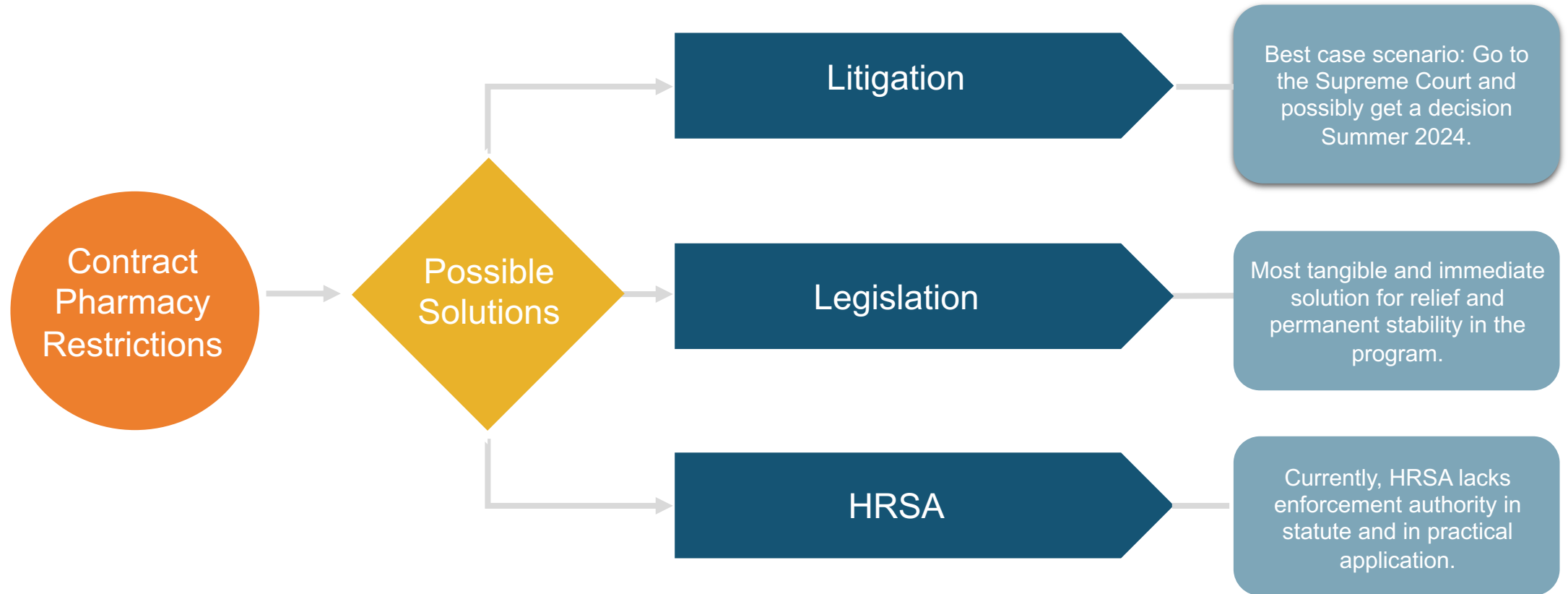
Judges are evaluating if they can review the lower Court's decision and the connection to the ADR process.

District Court

PhRMA
Merck
UCB
Kalderos
Boehringer Ingleheim
Amgen

Path Forward To Stability

To address the ongoing contract pharmacy restrictions, there are three types of solutions health centers can support or rely on. For 2.5 years, we have watched litigation and HRSA extend as far as possible without any tangible relief or results for covered entities.



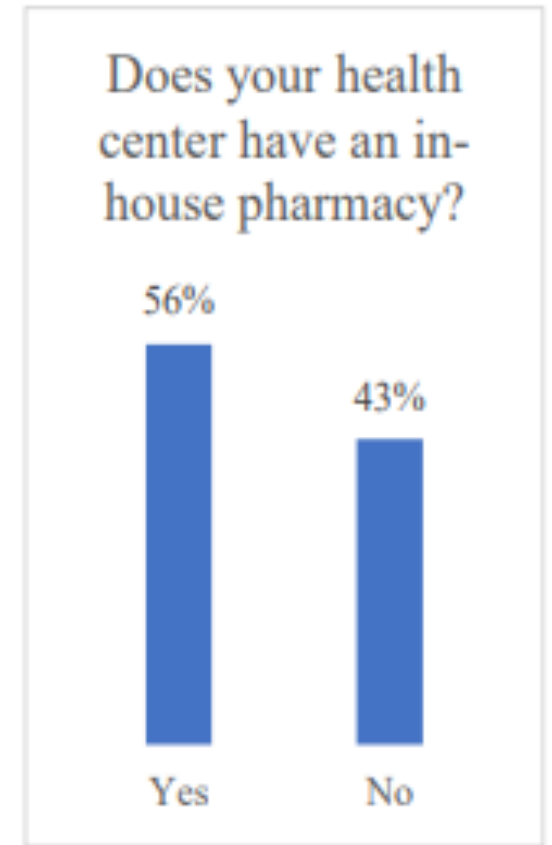
340B DRUG PRICING PROGRAM, PURCHASES BY COVERED ENTITIES, 2021

Entity type	Total 2021 purchases at 340B discounted prices	Share of total 2021 purchases	Change in total purchases vs. 2020
Hospital			
• Disproportionate Share Hospitals	\$34,288,472,705	78.1%	+15.1%
• Children's Hospitals	\$1,330,248,212	3.0%	+14.1%
• Rural Referral Centers	\$1,174,151,155	2.7%	+34.8%
• Critical Access Hospitals	\$620,923,559	1.4%	+18.6%
• Sole Community Hospitals	\$451,594,319	1.0%	+11.2%
• Free-standing Cancer Centers	<u>\$304,098,033</u>	<u>0.7%</u>	<u>+35.6%</u>
<i>Subtotal</i>	\$38,169,487,983	86.9%	+15.7%
Federal Grantee			
• Consolidated Health Center Programs	\$2,215,221,250	5.0%	+12.3%
• Ryan White HIV/AIDS Program Grantees	\$2,180,003,882	5.0%	+8.2%
• Sexually Transmitted Disease Clinics	\$871,036,833	2.0%	+54.2%
• Comprehensive Hemophilia Treatment Center	\$192,106,843	0.4%	-10.1%
• All other	<u>\$284,557,390</u>	<u>0.6%</u>	<u>+20.6%</u>
<i>Subtotal</i>	\$5,742,926,198	13.1%	+14.8%
Total	\$43,912,414,181	100.0%	+15.6%



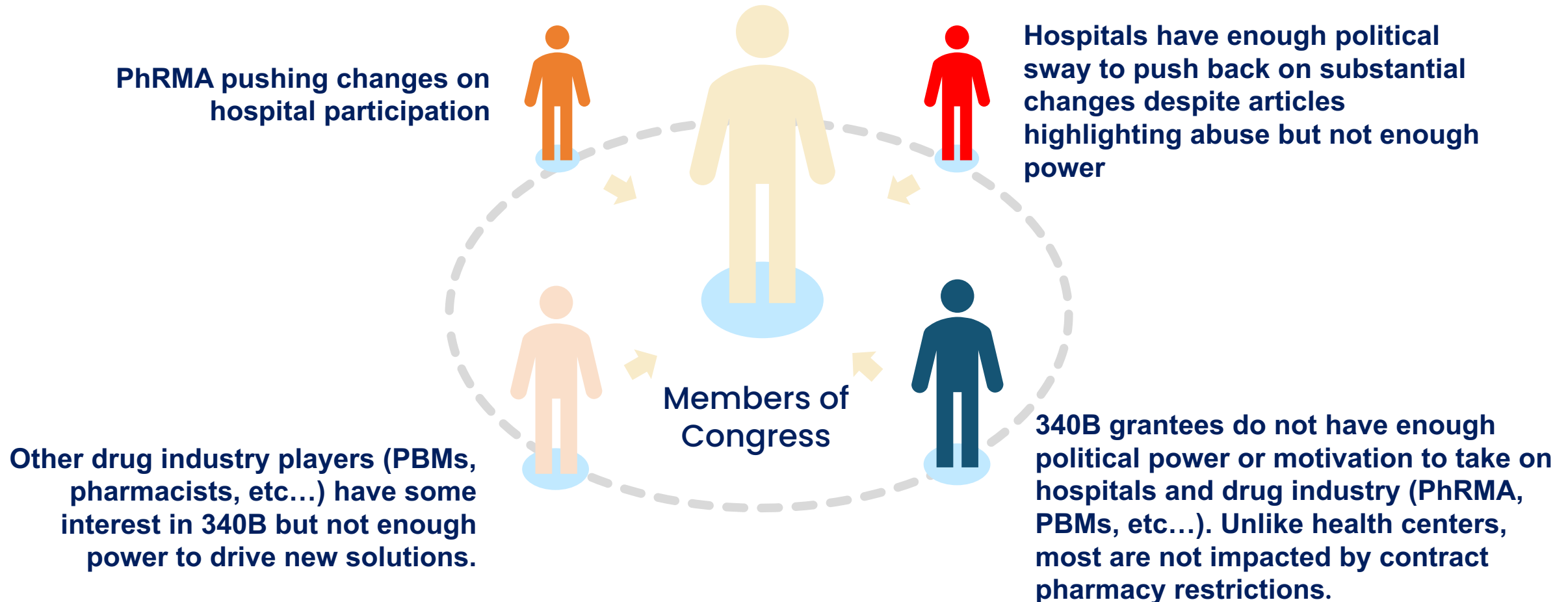
Health Center Patients Depend on Access to 340B Medications

Health centers provide access to affordable medication to millions of uninsured and underinsured patients through pharmacy services. Over half (56%) of survey respondents report having an in-house pharmacy, while **86% of respondents utilize contract pharmacies**. Contract pharmacies play a crucial role in increasing access for health center patients by easing transportation challenges or other barriers that prevent patients from picking up vital medications. Survey respondents reported being able to serve dozens of zip codes through their contract pharmacies, with some reporting services to one hundred or more zip codes. Health centers strategically utilize contract pharmacies to reach their patients, partnering with local independent pharmacies and nationally recognized pharmacy groups.



340B Status Quo is Product of Competing Interests and Inertia

Current dynamics have led to a stalemate that has punished health centers



Latest Congressional 340B Developments

Medicaid Actual Acquisition Cost

Legislation that came out of the House Energy & Commerce Committee would impact 340B within Medicaid Managed Care at contract pharmacies.

NACHC continues to work with the impacted states and their congressional delegations.

340B Transparency



Understanding how 340B savings are used and benefit patients has long been a priority for House Republicans.

The key Republican House members know that more must be done but this was a first step as part of a transparency package. The partisan vote complicates the path forward.

340B REPORT

NEWS ALERT

Six Democratic and Republican U.S. Senators Ask 340B Stakeholders for “Bipartisan Policy Solutions”

In Federal, Legislative, News Alert June 16, 2023 Tom Mirga

Six Senators (John Thune (R-SD), Debbie Stabenow (D-MI), Shelley Moore Capito (R-WV), Tammy Baldwin (D-WI), Jerry Moran (R-KS), and Ben Cardin (D-MD)) announced that they are seeking input on bipartisan policies to improve the program.

ASAP 340B is a major driver in providing the proof of concept for compromise.



The **Pharmacy Benefit Manager Transparency Act of 2023** was introduced by Senate Commerce Science, and Transportation Committee Chair Maria Cantwell and Senate Judiciary Committee Ranking Member Chuck Grassley to shine a light on the Pharmacy Benefit Manager (“PBM”) market and empower the Federal Trade Commission (“FTC”) and state attorneys general to stop unfair and deceptive PBM business practices.

PBMs are intermediaries that negotiate and manage prescription drug benefits on behalf of health insurance companies, self-insured employers, and government programs. Currently, three PBMs control nearly 80 percent of the prescription drug market and operate with little oversight by federal regulators and out of the view of consumers. PBMs influence prescription drug costs, determine which drugs are covered by an insurance plan, and pocket unknown sums of money that might otherwise be passed along as savings to consumers. This lack of transparency makes it difficult for the public and regulators to fully understand how the market drives up costs for consumers.

PROHIBITS UNFAIR OR DECEPTIVE PRICING PRACTICES

The legislation would make it illegal for PBMs to engage in “spread pricing” in which they charge health plans and payers more for a prescription drug than what they reimburse to the pharmacy, and then pocket the difference – the “spread” – as profit. This practice can result in pharmacies being reimbursed less than their acquisition cost for a drug. And consumers may face higher health insurance plan premiums to cover these middleman costs.

The bill would also prohibit PBMs from arbitrarily, unfairly, or deceptively clawing back payments made to pharmacies, or arbitrarily, unfairly, or deceptively increasing fees or lowering reimbursements to offset reimbursement changes in federally-funded health plans.

INCENTIVIZES FAIR AND TRANSPARENT PBM PRACTICES

The bill would encourage fair and transparent PBM practices that benefit local pharmacies and consumers by making clear that a PBM would not be in violation of the Act if it:

- Passes along 100 percent of any rebate to the health plan or payer; and
- Provides full and complete disclosure of:
 - the cost, price, and reimbursement of prescription drugs to the health plans and pharmacies;
 - all fees, markups, and discounts the PBM charges or imposes on health plans and pharmacies; or
 - the aggregate remuneration fees it receives from drug makers to health plans, payers, and any federal agency.

MANDATES TRANSPARENCY

The bill would require PBMs to file an annual report with the FTC, shining a brighter light on how they charge health plans and pharmacies for prescription drugs. Specifically, it would require PBMs to disclose:

- The aggregate amount of the difference between how much each health plan paid the PBM for prescription drugs, and how much the PBM paid each pharmacy on behalf of health plans for such drugs;
- The aggregate total amount of fees the PBM charged to pharmacies and the total amount of reimbursements the PBM clawed back from pharmacies;
- Why the cost, copay, coinsurance, or deductible for a consumer increased, or why the reimbursement rate to a pharmacy decreased for a prescription drug; and
- For PBMs that control or are affiliated with a pharmacy, a description of any differences between what they reimburse or charge affiliated and nonaffiliated pharmacies.

Congressional Efforts to Hold PBMs Accountable



Prescription Pricing for the People Act of 2023

Sens. Grassley, Cantwell, Blackburn, Blumenthal, Braun, Capito, Lankford, Tillis, Tuberville

Pharmacy Benefit Managers (PBMs) are companies that manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, and large employers. PBMs are middlemen in the distribution of prescription drugs developing lists of covered medications, negotiating rebates from drug manufacturers, and contracting with pharmacies for reimbursement.

PBMs operate with little to no transparency, making it very difficult if not impossible to understand the flow of money in the prescription drug marketplace and how PBMs determine the prices for prescription drugs.

Recent consolidations between PBMs and insurance providers has resulted in vertical integration whereby a small number of companies now manage the vast majority of prescription drug benefits and often own other players in the health care industry.

Prescription Pricing for the People Act (S. 113)

The *Prescription Pricing for the People Act* will help to provide better transparency of the PBM industry by examining the effects of consolidation on pricing and other potentially abusive behavior. Specifically, the legislation directs the FTC to issue a report within one year addressing:

- Whether PBMs:
 - Charge certain payers, including Medicare and Medicaid, a higher price than reimbursement rates for competing pharmacies while reimbursing pharmacies in which the PBMs have an ownership interest at the rate charged to payers;
 - Steer patients to pharmacies in which the PBM has an ownership stake;
 - Audit or review proprietary data of pharmacies not owned by the pharmacy benefit manager and use such data for competitive advantage; and
 - Use formulary designs to depress the market share of low-cost, lower rebate prescription drugs.
- Trends or observations on the state of competition in the healthcare supply chain.
- Whether more information about the roles of intermediaries would benefit consumers.
- Legal or regulatory obstacles for the FTC to enforce antitrust and consumer protection laws in the pharmaceutical supply chain.

The FTC would also provide policy or legislative recommendations to Congress on improving transparency, preventing anticompetitive behavior, and ensuring consumers benefit from any cost savings.

Congressional Efforts to Hold PBMs Accountable

Spanberger, Johnson Introduce Bipartisan Bill to Protect 340B Program, Prevent Higher Drug Prices

Apr 06, 2023



Healthcare



Press

The PROTECT 340B Act Would Block Health Insurers & Pharmacy Benefit Managers from Treating 340B Pharmacies and Providers Differently than Other Healthcare Providers



2023 PBM Legislation

Arizona	Arkansas	California	Colorado	Connecticut	Florida	Georgia
Illinois	Indiana	Iowa	Kansas	Kentucky	Maine	Maryland
Massachusetts	Michigan	Minnesota	Mississippi	Missouri	Montana	Nebraska
New Hampshire	New Jersey	New Mexico	Nevada	New York	North Carolina	North Dakota
Oklahoma	Oregon	Pennsylvania	Rhode Island	South Carolina	South Dakota	Texas
Utah	Vermont	Virginia	Washington	West Virginia	Wisconsin	Wyoming



23 states have enacted anti-discriminatory contracting legislation (2019 – 2022)

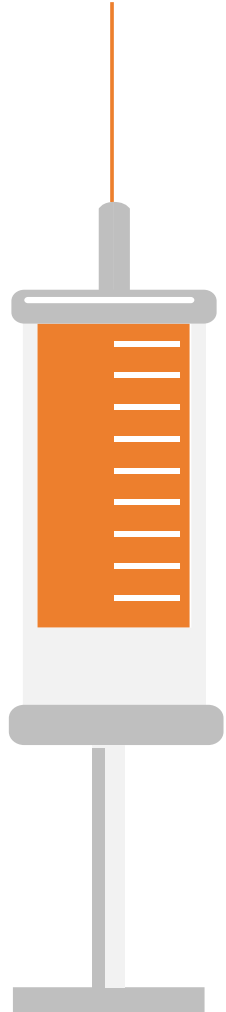
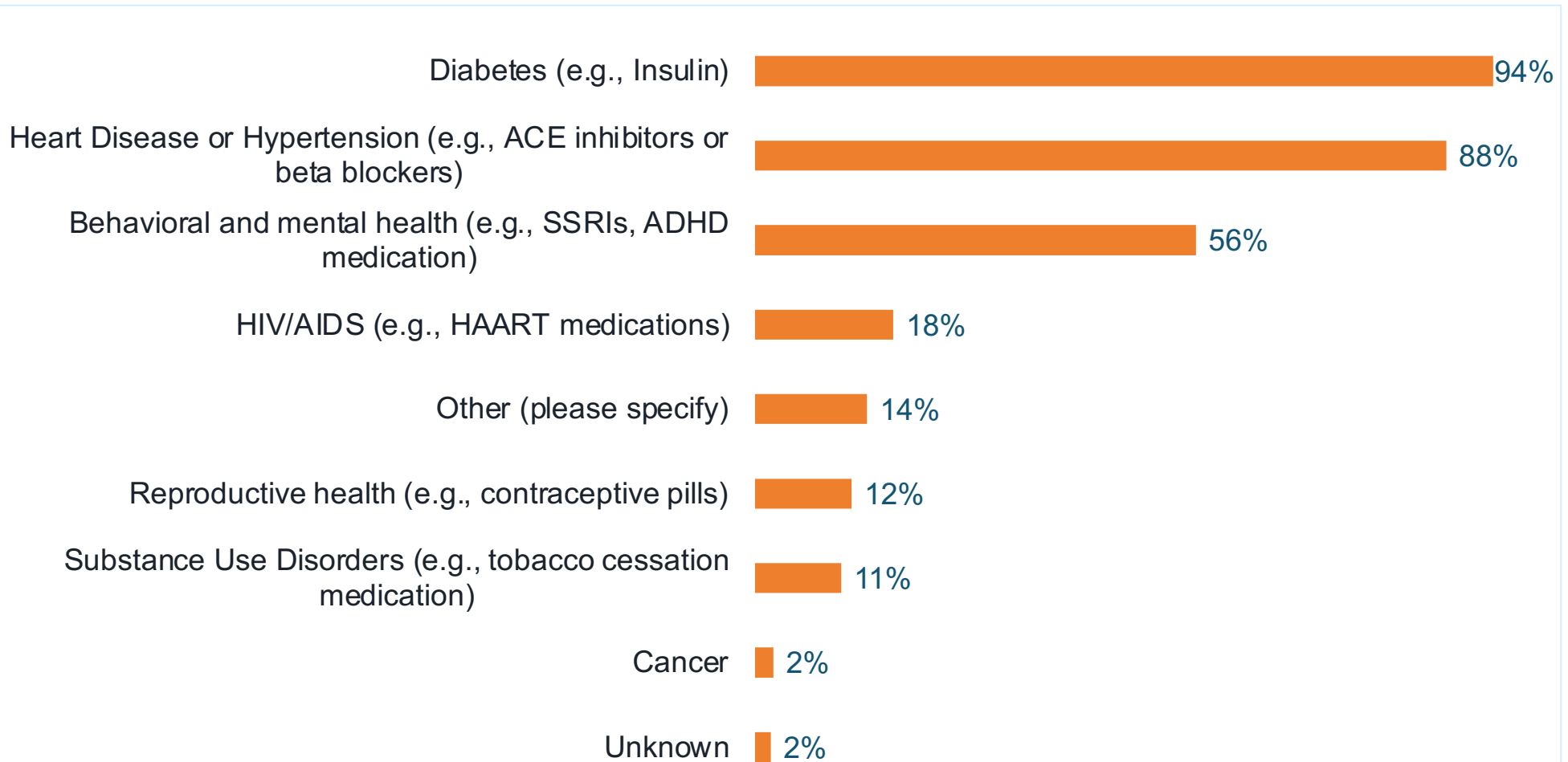
- ❖ Alabama
- ❖ Arizona (2022)
- ❖ Arkansas – currently under litigation
- ❖ Colorado (2022)
- ❖ Georgia
- ❖ Illinois
- ❖ Indiana
- ❖ Kentucky
- ❖ Maryland (2022)
- ❖ Michigan (2022)
- ❖ Minnesota
- ❖ Montana
- ❖ Nebraska (2022)
- ❖ North Carolina
- ❖ North Dakota
- ❖ Ohio
- ❖ Oregon
- ❖ South Dakota
- ❖ Tennessee
- ❖ Utah
- ❖ Vermont (another bill 2022)
- ❖ Virginia (2022)
- ❖ West Virginia

Tell your story!



340B Drugs Treating Leading Health Conditions

What are the TOP 3 disease states treated at your health center with drugs purchased through the 340B program?



Connecting 340B to our 30 Million Patients

As members of Congress develop their policy agenda, highlight how health centers are providing essential services ONLY through the 340B program. It's bigger than \$\$\$, it's patients' lives at stake!

Diabetes

Majority of drugs impacted by contract pharmacy restrictions are related to diabetic care.

Food Insecurity

CHCs create programs to address SDOH, like food insecurity, which can be barriers to improve patient outcomes.

Behavioral Health

CHCs are well positioned to reach low-income Americans that need mental health services. Many critical positions are funded by 340B.



Hypertension

Over 88% of CHCs use the 340B program to purchase medications to treat heart disease and hypertension.

Substance Use Disorder

CHCs are leaders in integrating SUD treatment with primary care and providing Medication-Assisted Treatments for opioid addiction.

Natural Disasters

CHCs are still serving patients during natural disasters and use 340B savings to prepare, sustain, and innovate.

340B Impact Profile

Community Health Centers & 340B

Name of health center:

Community Health Center

City & State:

Washington, DC

For 30 years, the 340B Program has provided critical resources that enable Community Health Centers to deliver affordable and accessible health care services to the most underserved and vulnerable communities. The 340B Program allows health centers to purchase outpatient medications at lower prices. Health centers reinvest the savings into activities that further the mission of improving patients' lives, as required by health center grants.

How does 340B help make medications affordable?

It allows us to offer all medications for lower prices to ensure our patients don't have to worry about cost being a barrier. It really helps lower higher priced drugs like insulin and medications to help alleviate asthma.

How does 340B help support health equity?

It helps fund programs that address social drivers of health. We are able to provide free transportation to our patients needing to come in for medical appointments. 340B also allows us to fund a medication transportation van to help our homebound patients get timely access to their medications/

How does 340B help support your health center?

Our 340B savings help us fund staff that aren't reimbursed. For example, it funds our three clinical pharmacists at our in-house pharmacy. It also helps fund our Community Health Workers who connect our patients to different social services and serve as a trusted resource.

How have the contract pharmacy restrictions impacted your health center?

In some instances, patients have had to switch medications to be able to afford their prescriptions. Other patients have decided to drive to a farther away pharmacy to still get their same prescription for a similar price, but it's quite inconvenient for them. These restrictions have also depleted our 340B savings that fund many services and programs.



Why does Congress need to act this year on 340B?

**Why does
Congress need
to act this year
on 340B?**

#340B

Why does Congress need to act this year on 340B?



upload
(max 2GB)

[Start Your Video >](#)

[What type of services/programs will be impacted at your health center if legislation is not passed to protect the 340B program?](#)



[Why does Congress need to act this year on 340B?](#)



Health center services/programs at risk

**What type of
services/programs will
be impacted at your
health center if
legislation is not
passed to protect the
340B program?
#340B**

What type of services/programs will be impacted at your health center if legislation is not passed to protect the 340B program?



upload
(max 2GB)

[Start Your Video >](#)

Updated 340B Advocacy Toolkit

- Talking points on all 340B issues!
 - ASAP 340B
 - Contract pharmacies
 - PBMs
 - Medicaid Carve out
- Sample 340B script
- Sample Social Media
- Sample email to Congress



NATIONAL ASSOCIATION OF
Community Health Centers®

340B Advocacy Toolkit

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Social Media Tools

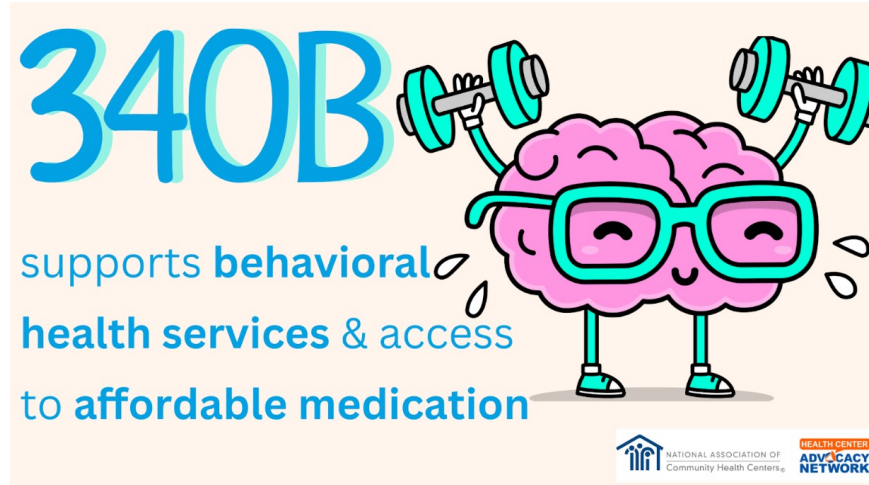


Graphics


Use on Twitter!

Sample Tweets

In NACHC's Updated 340B Advocacy Toolkit



Alliance to Save America's 340B Program



ASAP 
340B

Our Policy Principles

1/

Make 340B a true safety-net program for patients.

2/

Ensure 340B prescriptions are offered to patients at a discount.

3/

Update the 340B patient definition with strong safeguards.

4/

Establish clear criteria for 340B contract pharmacy arrangements to improve access.

5/

Prevent middlemen and for-profit entities from profiting off the 340B program.

6/

Update and strengthen 340B hospital eligibility requirements.

7/

Address standards for 340B child sites and subgrantee eligibility.

8/

Create a neutral 340B claims data clearinghouse.

9/

Facilitate public reporting on 340B program data.

10/

Establish enforceable rules and enhance federal administration and oversight of the 340B program.

Resources

ASAP 340B Video



About ASAP 340B



340B FAQs



ASAP 340B Policy Principles



340B Problems. Our Solutions



How Our Principles Help CHCs



How Our Principles Help HIV & STD Providers



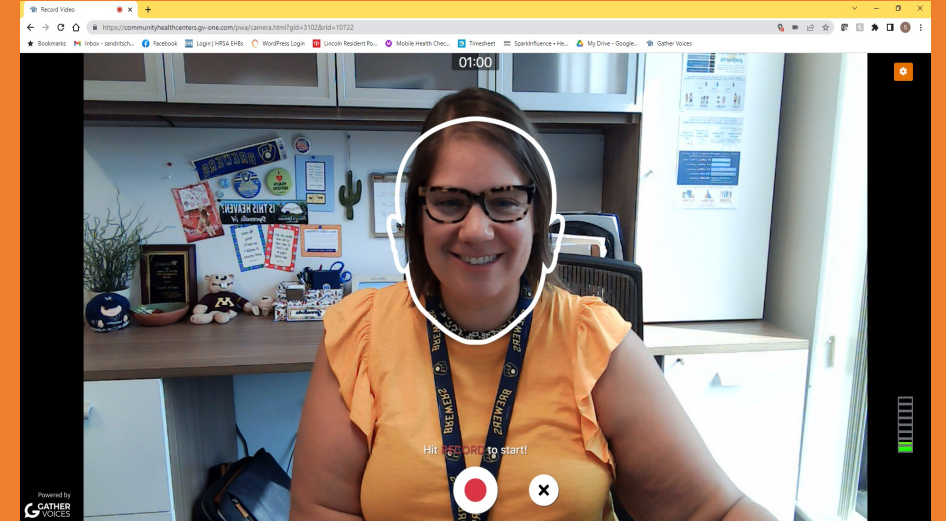
How Our Principles Help Rural Hospitals



**Creating Clarity Around Patient
Definition in the 340B Program**



Advocate for 340B!



NACHC's Gather Voices tool allows you to record short advocacy videos that can be shared on social media, websites and other virtual platforms.

Answer one of these two questions:

- 1) Why does Congress need to act this year on 340B?
- 2) What types of services/programs will be impacted at your health center if legislation is not passed to protect the 340B program?

340B Resources

- 340B Advocacy Noddlepod
 - Connect with colleagues, share info/ask questions on Noddlepod
 - Email Elizabeth Linderbaum, elinderbaum@nachc.org, to get added
- [Drug Manufacturer Restrictions Chart](#)
 - Updated as needed on [NACHC's 340B website](#)
- Infographics
 - 340B & [Health equity](#)
 - CHCs & [Contract pharmacy](#)



Questions



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