

Federal Legislative Updates

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340B Report



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Shannon has no relevant financial relationship with ineligible companies to disclose.

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 dynamics of the current Congress;
- Recognize opportunities for covered entities to educate legislators.



Congress

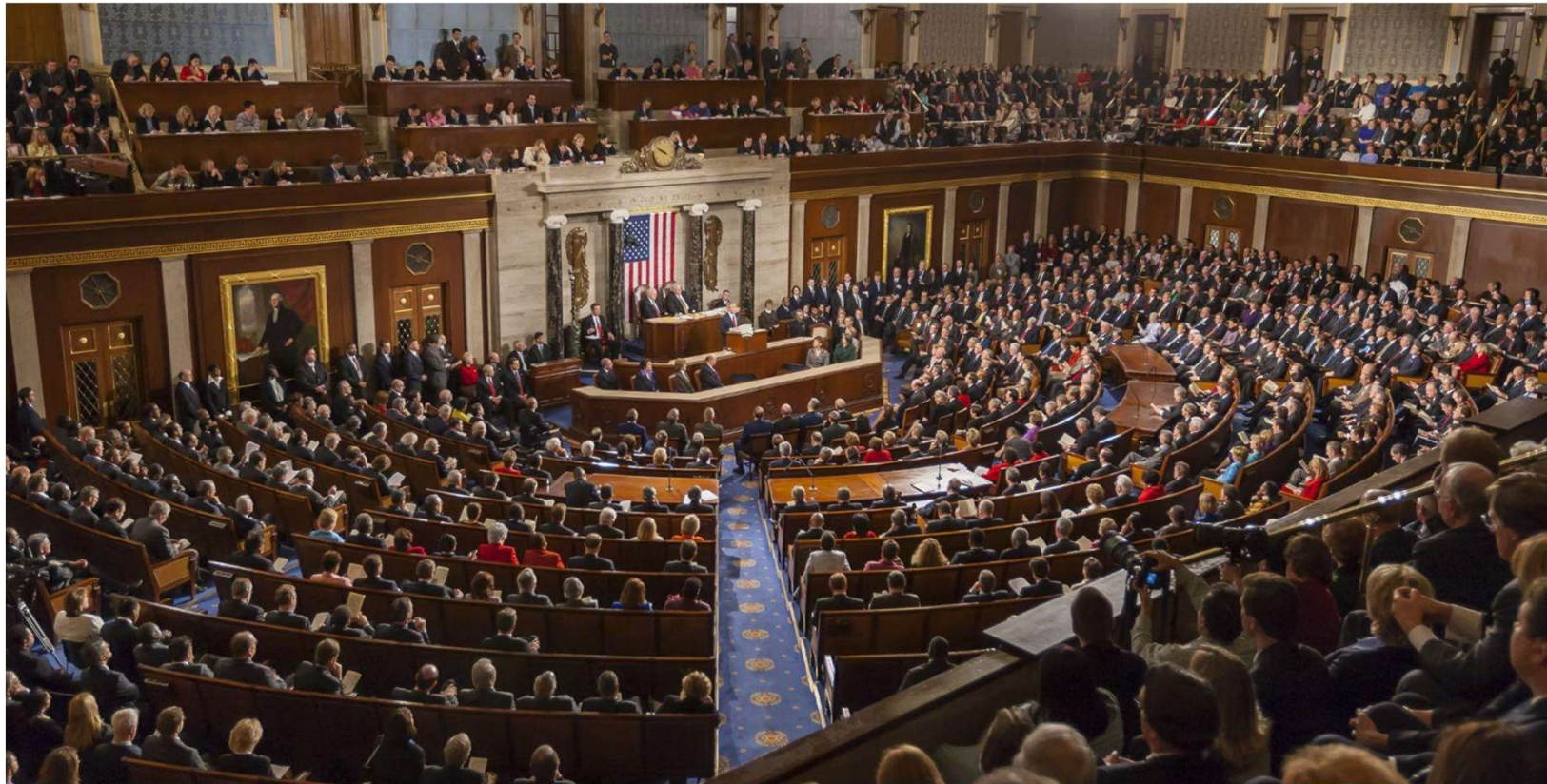


Congress

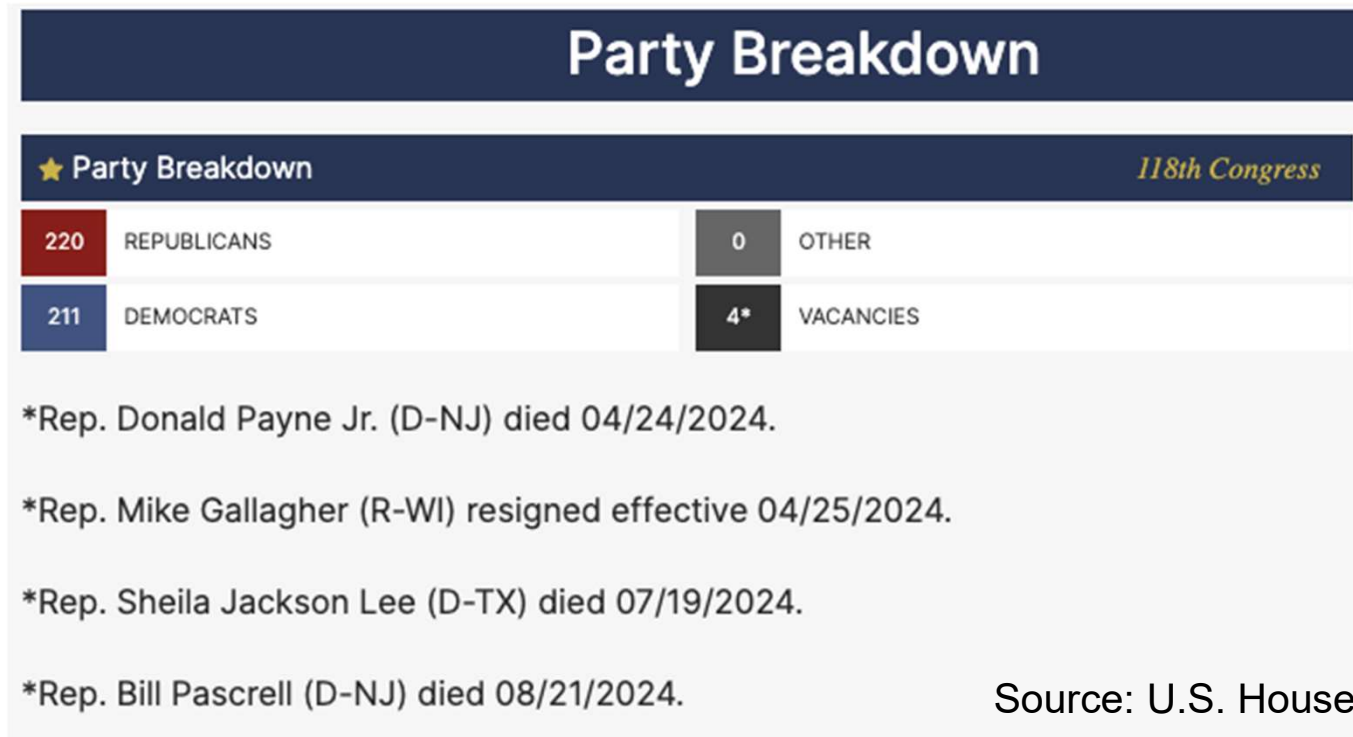
- The 118th Congress first convened in January 2023 and will wrap up its work at the end of 2024.
- Dems narrowly control Senate, while Republicans narrowly control the House.
- The partisan split has complicated efforts to pass one-party bills, including several 340B-related measures.
- Still, there's a chance a bipartisan 340B overhaul proposal could move after the 2024 elections in November, as lawmakers return for “lame duck” sessions.



U.S. House of Representatives



U.S. House of Representatives



- Republicans hold control in the House over Dems by a 220-211 margin.



U.S. House of Representatives

- With all 435 members on the ballot this Fall, the 2024 elections could shake up the chamber's partisan makeup.
- The GOP is expected to easily retain 185 seats, compared to Dems' 173, pollsters predict.
- Control of the House will likely come down to about 20 “toss up” races in Arizona, California, Maine, Michigan, New York, New Mexico and North Carolina.
- The outcome of the contests could also affect whether lawmakers take up 340B bills in the final weeks of 2024.



U.S. House of Representatives

House panel that oversees 340B-related legislation and issues:

- The Energy & Commerce Committee (E&C) has primary jurisdiction.

The Ways & Means Committee on occasion takes up 340B bills that deal with Medicare.



Energy & Committee

The committee deals with: telecommunications; consumer protection; food and drug safety; public health and research; environmental quality; energy policy; and interstate and foreign commerce, among other issues.

- Most 340B-related bills go through the E&C's Health Subcommittee.
- The Oversight Subcommittee conducts probes and hearings related to the full committee's jurisdiction, including the 340B program.



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<https://340breport.com/key-house-hearing-intensifies-debate-on-340bs-future-amid-multiple-major-reform-efforts/>
Shannon Young, 8/26/2024

Energy & Committee

Ranking Member



Frank Pallone, Jr.
NJ 06

Chair



Cathy McMorris Rodgers
WA 05

- Rep. Cathy McMorris Rodgers (R-WA) chairs the E&C Committee. She is not seeking reelection in 2024. It is unclear who will succeed her as chair if Republicans retain control of the House.
- If Dems take control of the chamber, Rep. Frank Pallone (D-NJ), the panel's ranking member, is expected to become E&C chair.

Energy & Committee

GOP E&C Chair contenders include:

- Rep. Bob Latta (R-OH), who chairs E&C's Communications and Technology Subcommittee.
- Rep. Brett Guthrie (R-KY), who chairs E&C's Health Subcommittee.



Robert E. Latta
OH 05



Brett Guthrie
KY 02

U.S. Senate



U.S. Senate

- Dems control the U.S. Senate by a narrow 51-50 margin, thanks to 4 Independents, who regularly caucus and vote with the party.
- VP casts deciding vote in any tie-breaking situation. That gives Dems another edge in the chamber, at least through the end of 2024.

118th Congress (2023–2025)

Majority Party: Democrats (47 seats)

Minority Party: Republicans (49 seats)

Other Parties: 4 Independents

Total Seats: 100



U.S. Senate

- 34 Senate seats are on the ballot in 2024: 23 held by Dems or Independents and 11 held by GOP.
- A handful of Senate races are expected to be toss ups: U.S. Sens. Sherrod Brown (D-Ohio) and Jon Tester's (D-MT) seats. Seats in Maryland, Michigan and Arizona could be competitive. The GOP is expected to pick up a Dem-held seat in West Virginia.
- Control of the chamber will likely come down to these toss ups and other close races.



U.S. Senate

- The Senate Health, Education, Labor and Pensions (HELP) Committee has primary jurisdiction.
- Medicare and Medicaid issues are under Senate Finance Committee.



HELP Committee

- If Dems keep control of the Senate, U.S. Sen. Bernie Sanders (I-VT) is expected to remain the HELP Committee's chairman. He's on the ballot in 2024.
- Sanders has been a vocal critic of the drug industry, but not said much publicly about the 340B program besides blocking some proposed GOP restrictions.



HELP Committee

- If GOP wins control of the Senate, U.S. Sen. Bill Cassidy (R-LA) is expected to take over as HELP chairman.
- Cassidy, the panel's top Republican, is a longtime critic of 340B hospitals. He's called for placing more restrictions on the program and requiring providers better detail how they use 340B.
- In September 2023, Cassidy [launched a probe](#) into how certain hospitals, health centers and chain pharmacies use 340B revenue.



Pending Bills in Congress

- Lawmakers have introduced a dozen-plus bills in Congress dealing with the 340B program.
- Most have seen little action.
- Some have drawn widespread attention and one—a bipartisan Senate proposal—could see action before the end of the year.



Pending Bills in Congress

Federal lawmakers have introduced several 340B-related bills in the 118th Congress. Here's where some of those key measures stand in the U.S. House and Senate.

Bill Number	Bill Name	Bill Purpose	Bill Sponsors	Introduced	Current Chamber	Status	Committee Assignments
H.R. 9127	The Equitable Access to 340B Act	The legislation would establish disproportionate share hospitals (DSHs) located in U.S. territories as a qualifying 340B covered entity type.	Del. Gregorio Kilili Camacho Sablan (D-MP-At Large)	July 24, 2024	House	In Committee	Energy & Commerce
S.4587	A bill to amend the Public Health Service Act to include rural emergency hospitals in the definition of a covered entity for purposes of	The bill would add facilities designated as Rural Emergency Hospitals as a 340B covered	Sen. Gary Peters (D-MI)	June 18, 2024	Senate	In Committee	Health, Education, Labor and Pensions



340B PATIENTS Act (H.R. 7635)

- Rep. Doris Matsui (D-CA) [introduced](#) the 340B PATIENTS Act in March 2024. It is currently in the E&C Committee. Sen. Peter Welch (D-Vt.) is sponsoring a similar bill.
- The bill codifies 340B providers' ability to use contract pharmacies to dispense 340B discounted drugs.
- It would: require manufacturers to offer 340B discounts regardless of where/how a drug is dispensed; bar conditions on a CE's purchase and use of 340B drugs; and impose CMPs for violations.



340B PATIENTS Act (H.R. 7635)

- Several House Dems have signed on to co-sponsor the bill. No Republicans have endorsed it.
- The PATIENTS Act has drawn widespread support from 340B provider advocates and hospital groups.
- ASAP 340B, the nonprofit group the Pharmaceutical Research and Manufacturers of America (PhRMA) and the National Association of Community Health Centers (NACHC) formed, say broader legislation is needed.



340B ACCESS Act (H.R. 8574)

- Reps. Bucshon (R-IN.), Carter (R-GA) and Harshbarger (R-TN) introduced the 340B ACCESS Act in May. It's in the E&C and W&M Committees.
- Major overhaul of program based on recommendations from ASAP 340B.
- Significantly narrows patient definition for hospitals; recognizes contract pharmacies in statute, but places significant limits on number for hospitals and geographic reach; and outlaws discharge scripts and mail-order use for hospitals.
- New restrictions on PBMs and for-profit entities (including contract pharmacies); places new patient affordability requirements.



340B ACCESS Act (H.R. 8574)

- ASAP 340B leaders have called the bill “comprehensive, meaningful solution that is needed to ensure the 340B program can live up to its mission.”
- NACHC said the bill “marks an important milestone in its longstanding efforts to protect 340B and bring together diverse stakeholders to align around a comprehensive solution.”
- PhRMA said it shows “the value of stakeholders coming together to solve our nation’s health care problems.”



340B ACCESS Act (H.R. 8574)

- Most 340B provider groups oppose the legislation, including Advocates for Community Health, Ryan White Clinics for 340B Access, the American Hospital Association, America's Essential Hospitals, 340B Health & Hemophilia Alliance.
- Critics have taken issue with bill language to supersede existing and prevent future state laws related to 340B, which could invalidate contract pharmacy access laws in eight states.
- Also cautioned that it could lead most, if not all, of the pharmacies to exit the 340B program.



340B ACCESS Act (H.R. 8574)

- Critics say it would create disincentives for chain and independent pharmacies to partner with health centers and other 340B providers.
- They include: cutting payments to pharmacies, increasing pharmacist workload and imposing fines on pharmacies that make a mistake in identifying a claim.
- The bill includes new civil monetary penalties (nearly \$14,000 for each claim) for failing to comply with contract pharmacy regulations and limits on payments to pharmacies.
- Critics warn it would prevent most 340B hospitals from using the program for insured patients, essentially gutting it as they depend on revenue from insured patients to offset other losses.



SUSTAIN 340B Act

- A bipartisan group of senators began crafting the SUSTAIN Act in 2023.
- Their stated goal has been to improve the 340B program's integrity and stability.



SUSTAIN 340B Act

- Lawmakers scrapped an August unveiling, but expected to introduce it as soon as September.
- A February draft addressed: program intent, contract pharmacy use, transparency requirements, funding for oversight of program, duplicate discount prevention and protections against PBM discrimination. Included an accompanying RFI for further guidance on patient definition, child sites
- April 2024 deadline to submit comments. Providers and drug industry disagreed on most areas, except both supported a neutral clearinghouse to resolve duplicate discount challenges.



SUSTAIN 340B Act

Provider and drugmaker advocacy groups were generally supportive of the 51-page draft legislation.

- Hospital groups and most provider groups lauded the draft bill's intent language, contract pharmacy proposal and comprehensive approach.
- PhRMA expressed support for clarifying the definition of a 340B-eligible patient.
- The AIDS Healthcare Foundation, the largest U.S. provider of HIV/AIDS care, cautioned that “any legislation will result in a ‘peace’ that is temporary at best, because drug companies will still want to shrink the program.”



SUSTAIN 340B Act

- Defines program intent in statute for the 1st time. Reflects government and provider view that it's intended to help “stretch scarce federal resources and help safety-net providers maintain, improve and expand patient access to healthcare services.”
- Drug industry has narrower view of 340B's purpose: It's intended to help indigent patients.
- Draft broadly restores contract pharmacy program, but requires pharmacies to provide discounts at the counter.
- Stakeholders largely supportive of this goal, but there's some differences on how it can be accomplished.



Other Noteworthy Pending Bills

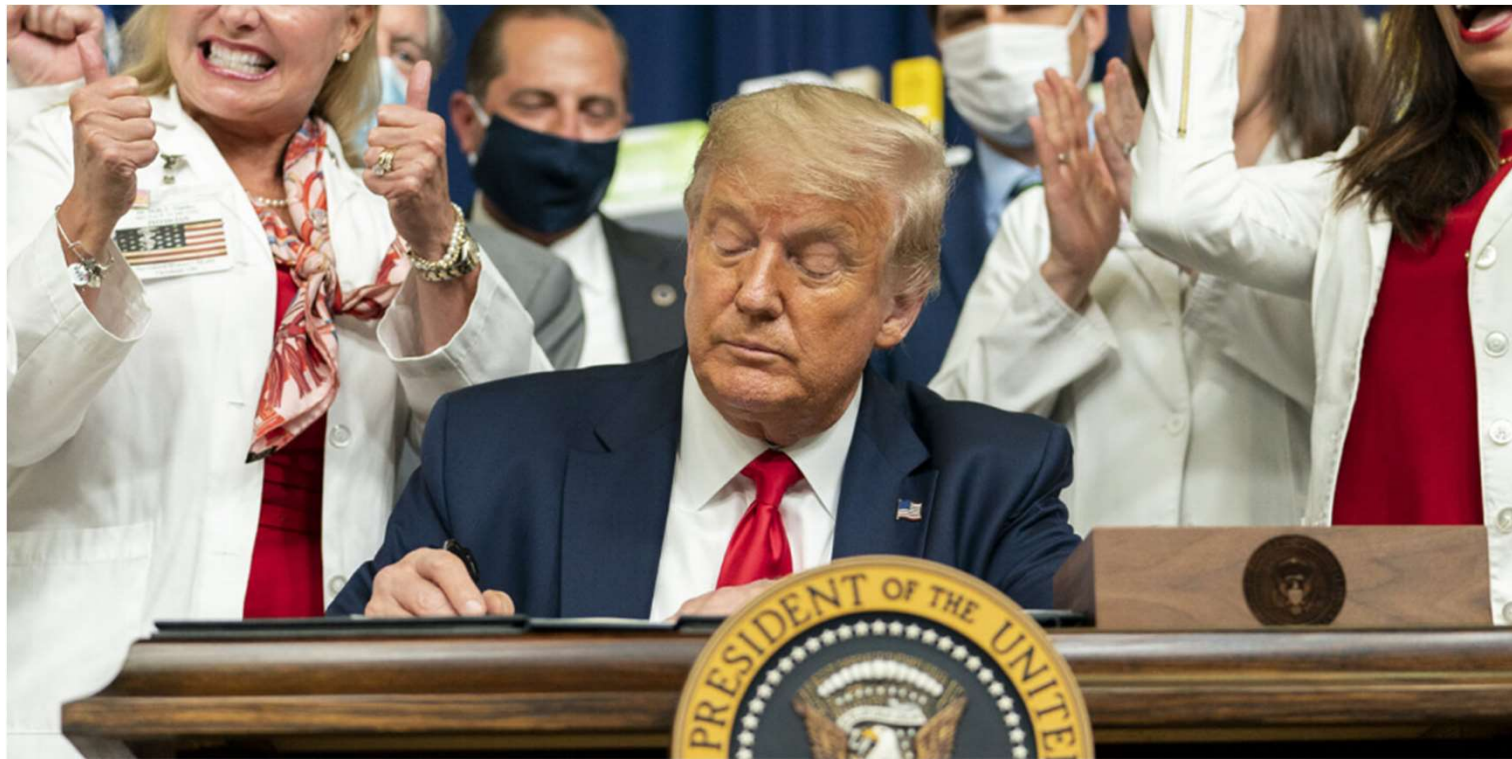
- **The Medicare PBM Accountability Act (H.R. 5385):** The E&C Committee in December 2023 passed the bill, which requires PBMs and their affiliated pharmacies to annually report a list of drugs for which they have contracts with a 340B covered entity.
- **The Lower Costs, More Transparency Act (H.R. 5378):** The House in December 2023 passed the bill, which requires providers to report the difference between their acquisition cost for 340B drugs and payments from MCOs.
 - Only applies to states that allow reimbursing above acquisition cost.
 - The Senate has yet to take up the bill.



2024 Presidential Race



Former President Donald Trump (R)



Former President Donald Trump (R)

The Trump administration was not supportive of 340B program.

- Recommendations focused on reining in the program. White paper said 340B contributed to rising drug prices and criticized program expansion and “abuse.”
- Cut Medicare Part B reimbursement to 340B hospitals by close to 30%. Supreme Court overturned the policy 9-0.
- Executive order required health centers to charge no more than acquisition cost for insulin and EpiPens for most patients. (NACHC opposed and it did not go into effect.)



Former President Donald Trump (R)

- Rhetoric about Medicare accessing drug prices similar to other countries, but no concrete proposal emerged.
- Political observers expect a 2nd Trump admin. to try to tackle drug shortages and pursue PBM reform. The 2024 GOP platform does not specifically mention the 340B program. It references “out of control” prescription drug costs.
- Unclear if it would continue to implement Inflation Reduction Act (IRA).
- Project 2025, a proposal from Trump allies and the Heritage Foundation, wants to “restructure the 340B drug subsidies toward beneficiaries rather than hospitals.” Trump has attempted to distance himself from Project 2025.



U.S. Sen. JD Vance (R)



U.S. Sen. JD Vance (R)

Trump's VP pick has remained fairly silent on the 340B program, except for his co-sponsorship of legislation that calls for a government report on 340B and its alleged ties to people who entered the country without legal permission.

- Vance has expressed support for Medicare drug pricing negotiations and reimportation of drugs from overseas, but has not made it a key area of focus.
- His positions on the drug pricing matters are largely considered more populist than traditional GOP orthodoxy, but fit with Trump's rhetoric against big business and the pharmaceutical industry.



U.S. Sen. JD Vance (R)

- Vance's support for the Protect Medicaid Act could be significant given recent attempts to link the 340B program to immigration.
- Stand for US PAC has run numerous ads linking 340B to illegal immigration in red states considering contract pharmacy access bills in 2024.
- Stand for US PAC Chair Katie Miller is a principal at a D.C.-based PR firm and married to Steven Miller, a former top Trump official.



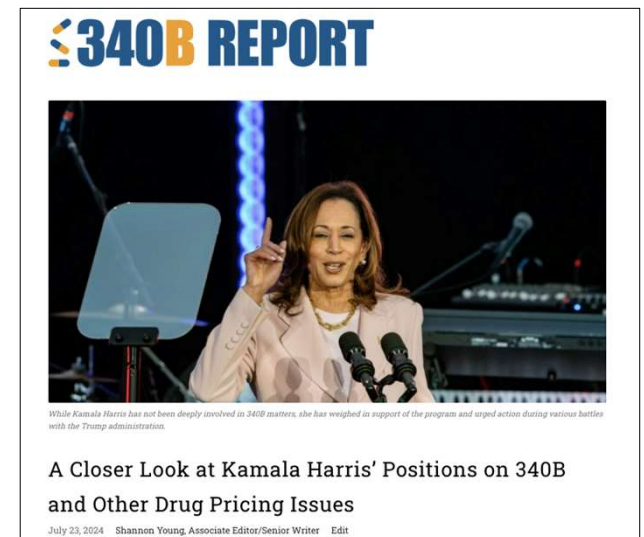
Vice President Kamala Harris (D)



Vice President Kamala Harris (D)

Harris is not considered a major player when it comes to 340B. She has expressed support for the program.

- Harris signed a Dems letter condemning Trump admin.'s foot dragging on a final oversight rule requiring the drug industry to post 340B prices on HRSA's website.
- Signed a bipartisan letter urging HHS and CMS "to carefully consider stakeholder concerns" before finalizing a proposal to reduce hospital Medicare Part B reimbursement for 340B-purchased drugs.
- Providers have generally been happy with Biden/Harris admin. on 340B. The drug industry hasn't.



Gov. Tim Walz (D)



Gov. Tim Walz (D)

Harris' VP pick has been a vocal advocate of lowering prescription drug costs, but also supported legislation not backed by 340B providers.

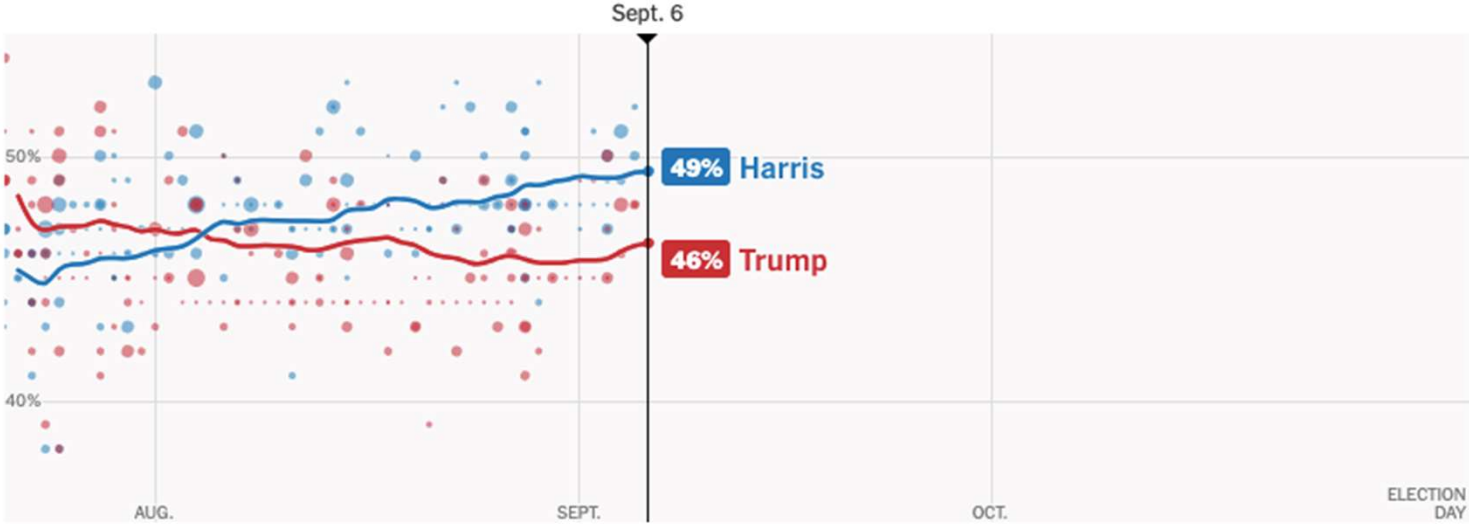
- Signed bill in May to prohibit drugmakers from restricting access to 340B pricing in contract pharmacy setting. Also signed bills requiring more 340B provider transparency.
- The CP law included more provider reporting requirements. Providers have expressed concern with the bills.
- In Congress, Walz criticized a Trump admin. policy that cut Medicare Part B reimbursement to 340B hospitals and voted for the IRA.



State of the Presidential Race

Who's leading the polls?

National polling average



Source: New York Times



State of the Presidential Race

Tossup states

STATE	ELEC. VOTES	2020 MARGIN	2024 POLLING
Pennsylvania	19	D +1.2	Harris <1 >
Georgia	16	D +0.2	Harris <1 >
North Carolina	16	R +1.3	Trump <1 >
Michigan	15	D +2.8	Harris +2 >
Arizona	11	D +0.3	Trump <1 >
Wisconsin	10	D +0.6	Harris +2 >
Nevada	6	D +2.4	Harris <1 >

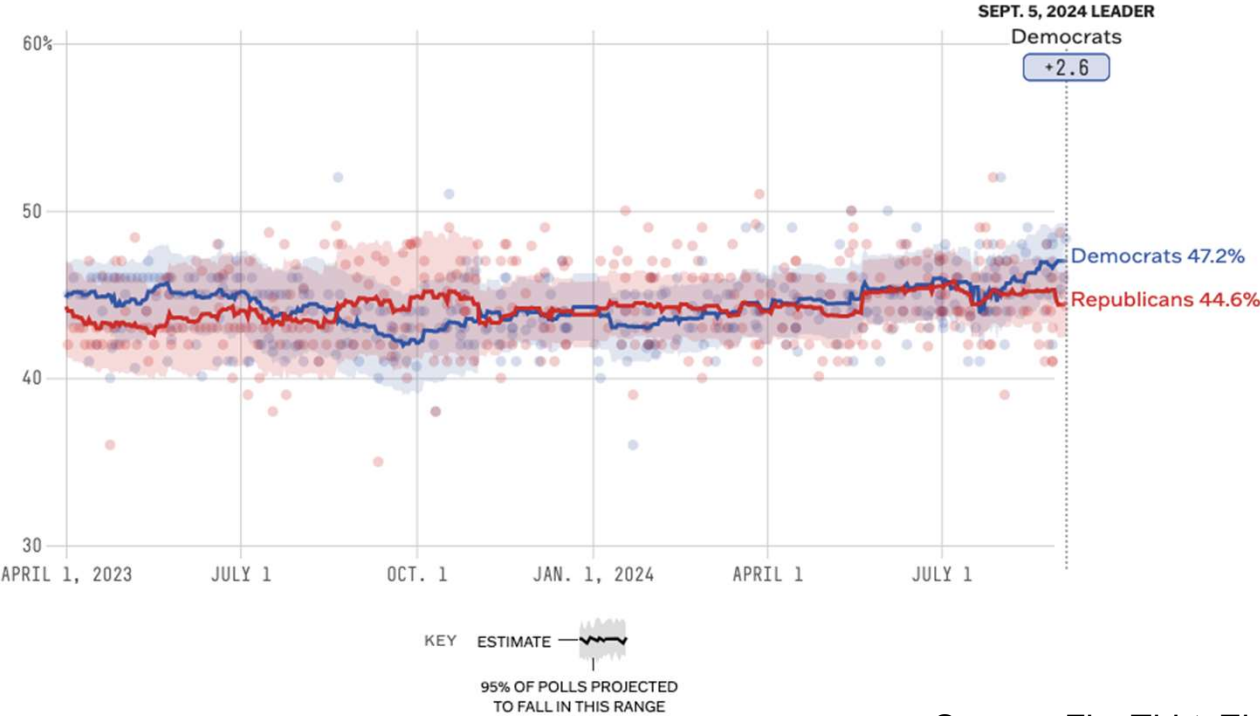
Source: Cook Political Report (race ratings); [New York Times polling averages](#)



State of Congressional Support

Do voters want Republicans or Democrats in Congress?

An updating estimate of the generic congressional ballot, based on polls that ask people which party they would support in an election.



Source: FiveThirtyEight

Supreme Court



Supreme Court

- Justices agreed to review an appeals court decision in *Advocate Christ Medical Center v. Becerra* that sided with HHS over how it applies a congressional formula to calculate DSH payments for Supplemental Security Income benefits. The outcome could affect hospital 340B eligibility.
- PhRMA has asked the court to review the constitutionality of Arkansas Act 1103, which prohibits drugmakers from restricting 340B contract pharmacy access in that state. It's a long shot it would be taken up, unless there's a split circuit decision.
- Supreme Court decision overturning the Chevron doctrine could increase pressure for Congress to overhaul the 340B program.



Questions?

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