

CAPITOL STREET

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340B Reform Unlikely to Pass This Year

Major Bill Provisions & Look to 2025+

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340B reform is unlikely to pass this year with competing priorities and a lack of federal momentum despite increased awareness of the 340B program costs. [340B ACCESS Act](#), introduced earlier this summer, clarifies what the Republican-led House prioritizes for reform, targeting large health systems in an effort to eliminate abuse of the controversial program. Cosponsored by Reps. Bucshon (R-IN), Carter (R-GA), and Harshbarger (R-TN), the bill contains some overlap with the bipartisan “Gang of Six” [Senate bill](#) from early February. Although the bills hit on key flawed issues with the program, there isn’t enough time to address it this fall, particularly as 340B legislation passes in many states. We predict additional oversight hearings. The “Gang of Six” framework is evolving, and we may see an updated version this fall. Overall, though the timeline still seems tight to pass during lame duck and we expect any 340B reforms to be punted to 2025 or later.

»» Key Points

340B reform is unlikely during lame duck (4Q24) but will have momentum 2025+ regardless of election outcome. Lawmakers know the 340B program has ballooned and needs to be addressed within a reasonable timeframe. Republicans and Democrats are equally concerned. Oversight will continue as bill drafts evolve. Moreover, federal 340B reform is expected to come together after myriad court cases in the states play out.

The *ACCESS (Affording Care for Communities and Ensuring a Strong Safety-Net) Act* prioritizes reporting (hospitals & pharmacies) among other low hanging fruit. It restores integrity to the program and would “uphold its original mission of providing affordable medications to those who need them most.” This includes (a) tightening up the reporting requirement for hospitals and pharmacies participating in the program, (b) adjusting the calculation for DSH hospital qualification, and (c) clarification of definitions and implementation.

340B has been a hotly debated topic this year with several oversight hearings as House & Senate legislation emerges (tweaks likely this fall). The *ACCESS Act* follows a recently introduced bipartisan Senate bill from the so-called “Gang of Six” (Sens. Thune [R-SD], Stabenow [D-MI], Moore Capito [R-WV], Baldwin [D-WI], Moran [R-KS], and Cardin [D-MD]). Below are a few key similarities between the two bills.

The Senate and House agree on what needs to be fixed within the program, however the methods of execution differ. For example, while both frameworks would require a fee to participate in the program, the Senate bill wants covered entities to pay a program administration fee (to be no greater than 0.01% of savings entity receives under 340B), while the House bill suggests a flat dollar fee amount for third party administrator fee (fair market value) and contract pharmacy fee (does not exceed 125% of the average per-prescription dispensing fee paid to such pharmacy by all third-party payors).

No one wants to get rid of 340B.

- House members and witnesses want to improve program transparency & prioritize patient savings (at the expense of hospitals).
- As a reminder, 340B was not a major Congressional issue previously and lawmakers will likely want a better understanding of the program (via oversight) before passing reform.
- In June, the House Oversight hearing (“Oversight of 340B Drug Pricing Program”) pharmacist Buddy Carter provoked Genesis HealthCare CEO Matthew Perry. While Perry does not like the type of transparency sought, Dr. Anthony DiGiorgio, neurosurgeon at UCSF Health, expressed support for transparency, including adjustments to DSH calculation and including outpatient child sites “having it targeted at a percentile of DSH hospitals, rather than an arbitrary cutoff.”

House & Senate 340B Bills: Side-by-Side

	<u>Senate</u>	<u>House</u>
Specify a patient definition specification	X	X
Child site clarity & reform	X	X
Provide access for 340B patients to all 340B drugs at requested pharmacy locations by the covered entity	X	X
Increasing reporting requirements for program savings, policies, patient and prescription information	X	X
Establish a data claims clearinghouse	X	X
Fees to participate in 340B	X	X

Source: House, Senate, Capitol Street, 2024

Child Sites: Facility that is part of a larger healthcare organization or network

Clearinghouse: A third-party institution that acts as a middleman between healthcare providers and payers

Covered Entity: Healthcare organization that receives full 340B benefits

Several lawsuits are ongoing with states increasingly becoming involved in forcing changes to the program. Several state laws seek to prohibit drugmakers from denying 340B discounts on drugs dispensed by contract hospitals. In DC, The US Court of Appeals ruled that manufacturers have the ability to limit sales and distribution of 340B drugs. Pending lawsuits include NVS & PhRMA’s case in West Virginia, NVS’s lawsuit in

Maryland, PhRMA lawsuit in Mississippi, AZN & ABBV lawsuits against Kanas. It's extremely likely that more lawsuits will appear in additional states to counter the federal 340B program. Under the next administration, there may be a push to pass 340B reform to clarify federal preemption over state laws regarding the program.

340B spending has ballooned, with an emphasis on oncology medicines. According to recent [CBO analysis](#), drugs purchased at 340B prices grew +19% annually from 2010-2021. 340B hospital spending quintupled from 2010-2021 (\$32.9 B increase compared to \$4.7 B for grantees). The biggest share (47%) of hospitals' 340B spending is on cancer drugs. This hospital spending explosion has caused drug manufacturers to highlight hospital abuse of 340B program, with lawmakers asking for more oversight.

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