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Your Guide to Legislation on the 340B Drug Pricing Program



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One pressing health care issue facing the 119th Congress is how to improve the 340B Drug Pricing Program. This little-known, and sometimes misunderstood, federal program requires pharmaceutical manufactures to provide steep discounts to hospitals and other health care providers. With 2,600 hospitals collecting \$48 billion in annual revenue from this program, there is increased attention on whether 340B is in line with its intent from 1992: to enable covered entities to stretch scarce federal resources as far as possible. As a result, there have been seven recent bills in Congress seeking to make changes to the 340B program.

Below, we outline each of recent proposals introduced in the previous Congress that would impact the 340B program and the problems they seek to address.

The 340B ACCESS Act

Quick Facts:

- **Formal Name:** The 340B Affording Care for Communities and Ensuring a Strong Safety-Net Act
- **Champions:** Introduced by former Rep. Larry Bucshon (R-IN), Rep. Buddy Carter (R-GA), and Rep. Diana Harshbarger (R-TN) last Congress.
- **Overview:** A comprehensive proposal that would reform the 340B program to work better for patients.
- **Links:** [bill text](#), [press release](#)

Additional Background:

There are three main components to this comprehensive bill focusing on 1. patient affordability, 2. transparency and program integrity, and 3. regulating contract pharmacies.

Ensuring Patient Affordability

Many providers in 340B, such as community health centers and Ryan-White HIV/AIDS clinics, are required by law to provide direct benefits to patients. However, hospitals don't have the same requirements. As a result, hospitals are making more money off the program—even more than they are providing in charity care for low-income patients. In 2022, disproportionate share hospitals, which account for nearly 80% of 340B benefits, received \$44 billion in manufacturer discounts while providing only \$18.5 billion in charity care.

To ensure patients are at the center of the 340B Program, the 340B ACCESS Act would:

1. Require 340B hospitals to provide charity care based on patient incomes, in line with other 340B providers.
2. Ban 340B hospitals from using aggressive medical debt collection tactics to go after patients.
3. Ensure hospital-affiliated clinics (which are called “child sites”) meet the same standards as their parent hospitals to prevent consolidation in wealthier areas aimed at maximizing discounts.

Creating Transparency and Program Integrity

A major issue in the 340B program is the lack of a clear “**patient**” definition, leading to legal disputes and compliance concerns. The **340B ACCESS Act** would establish a clear, uniform definition to ensure

that discounted drugs are only provided to patients with a **direct and ongoing relationship** with a 340B provider. To qualify, a patient must:

1. Have an established **provider-patient relationship** with a 340B entity.
2. Receive a prescription as a result of the services provided by the 340B entity.
3. Have an ongoing relationship with the provider and have had an **in-person visit within the past two years**.

Because there is no transparency in the 340B Program, the bill also requires hospitals to report critical financial data, including **operating margins on discounted drugs and how savings are used**. To further improve oversight and streamline claims, the bill would establish a **340B data information exchange**.

Another ongoing issue in 340B is duplicate discounts, where a drug is both discounted under 340B and also subject to a Medicaid rebate. This problem arises from **poor coordination** between health care providers and state Medicaid programs. The bill requires **HHS to establish regulations** for identifying and preventing duplicate discounts, ensuring proper oversight.

Regulating Contract Pharmacies

Before 2010, hospitals would distribute 340B medications to patients through in-house pharmacies located in the hospital. In 2010, hospitals were permitted by the Health Resources and Services Administration to contract with an unlimited number of pharmacies to increase the number of patients they could claim discounts for. As a result, the number of contract pharmacies has increased from below 1,300 to over 30,000, mostly in wealthier and less diverse communities. Due to this significant growth beyond 340B's purpose, and the lack of authorization in the law, contract pharmacies have been subject to litigation over the extent of their use.

To address this issue, the 340B ACCESS Act would:

1. Codify the use of contract pharmacies into statute.
2. Prevent hospitals from unlimited use of contract pharmacies and expansions into wealthier, less diverse areas.
3. Requires contract pharmacies to serve the same communities being served by the hospital itself.

The SUSTAIN 340B Act

Quick Facts:

- **Formal Name:** The Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act
- **Champions:** Discussion draft circulated by Sen. John Thune (R-SD), former Sen. Debbie Stabenow (D-MI), Sen. Shelley Moore Capito (R-WV), Sen. Tammy Baldwin (D-WI), Sen. Jerry Moran (R-KS), and former Sen. Ben Cardin (D-MD) last Congress. The new members of this working group are Sens. Tim Kaine (D-VA) and John Hickenlooper (D-CO).
- **Overview:** A comprehensive proposal to create balance in the 340B program and improve transparency.
- **Links:** [discussion draft text](#), [press release](#)

Additional Background:

There are two main components to this comprehensive bill focused on 1. transparency and program integrity and 2. regulating contract pharmacies.

Transparency and Program Integrity

First, the discussion draft seeks to create a statutory definition of a patient. However, because it is not yet formal legislation, the framework does not explicitly state what that definition would be but does solicit feedback on what it should be. The framework also elicits public input regarding child sites, including what oversight might be needed, and if there should be regulation concerning child sites located in service areas outside the community in which the parent hospital serves.

The discussion draft also includes transparency requirements. It would require hospitals to report basic information to the federal government, such as the mix of patients by coverage type, charity care being provided, demographics, pharmacies being contracted with to dispense medications, discounts accumulated, and what those savings are being used for. It would also require the Secretary of Health and Human Services to conduct audits to ensure compliance and, like the previous legislation, establish a clearinghouse to collect data and protect against duplicate discounts from 340B and the Medicaid Drug Rebate Program.

Regulating Contract Pharmacies

Like the previously discussed legislation, this discussion draft highlights concerns regarding contract pharmacies. However, it does not specifically outline how those should be addressed. Instead, it solicits public input regarding proposed limitations on contract pharmacies, how contract pharmacy arrangements aid rural hospitals and community health centers, their impact on access to specialty medications, and the role of pharmacy benefit managers.

The 340B Transparency Act

Quick Facts:

- **Champion:** Introduced by former Rep. Larry Bucshon (R-IN).
- **Overview:** A proposal that would create transparency in the 340B program.
- **Progress:** Last Congress, this legislation was approved by the House Energy and Commerce Committee.
- **Link:** [bill text](#)

Additional Background:

The bill would require 340B hospitals to be transparent and report data on the patients they serve, hospital costs, charity care, and savings from 340B discounts. As previously discussed, hospitals in 340B are currently not required to report any of this information to the federal government.

Meanwhile, federal grantees such as community health centers and Ryan-White clinics are required to submit specific data to the Health Resources and Services Administration.

The 340B PATIENTS Act

Quick Facts:

- **Formal Name:** The 340B Pharmaceutical Access To Invest in Essential, Needed Treatments & Support Act
- **Champions:** Introduced by Rep. Doris Matsui (D-CA) and Sen. Peter Welch (D-VT) last Congress.
- **Overview:** A proposal that would codify 340B providers' unlimited use of contract pharmacies.
- **Links:** [bill text](#), [press release](#)

Additional Background:

Before 2010, 340B providers could only contract with a single pharmacy if they did not have the ability to dispense prescriptions themselves. Then, the Department of Health and Human Services reversed this longstanding policy to allow for unlimited contracts with outside pharmacies, resulting in an increase from 1,300 in 2010 to 30,000 in 2023. The 340B PATIENTS Act would codify this policy.

A recent Government Accountability Office report found that only half of contract pharmacies pass any benefit from 340B discounts along to the patients, and another study found that contract pharmacies are often located in less diverse, wealthier areas outside the 340B provider's community. Several federal courts have ruled against hospitals' unlimited use of contract pharmacies. These include the US Courts of Appeals for the Third and D.C. Circuits, with the Seventh Circuit expected to rule on their own case soon. No Appeals Court has ruled in providers' favor. Codifying the unlimited use of contract pharmacies would not only go against the mainstream position of the Courts, but it would solidify pharmacy profits from 340B rather than ensuring patient benefits.

The PROTECT 340B Act

Quick Facts:

- **Formal Name:** The Preserving Rules Ordered for the Entities Covered Through 340B Act
- **Champions:** Introduced by former Rep. Abigail Spanberger (D-VA) and Rep. Dusty Johnson (R-SD) last Congress.
- **Overview:** A proposal that would prevent employers, health plans, and pharmacy benefit managers from lowering prices for 340B drugs and steering away from contract pharmacies.
- **Links:** [bill text](#), [press release](#)

Additional Background:

340B providers should have protections against outright discrimination, such as coverage denials or network exclusion based solely on their participation in 340B. However, this bill would drastically reduce the ability for employers and health plans to ensure 340B discounts aren't resulting in higher prices.

Without requirements for 340B to share 340B discount benefits with patients, this legislation would embolden hospitals to further raise prices on discounted drugs to generate larger profits. Employers and health plan employers should be permitted to prevent higher costs by encouraging patients to receive care at the highest quality for an affordable price, regardless of 340B status.

The Rural 340B Access Act

Quick Facts:

- **Champions:** Introduced by Congressman Jack Bergman (R-MI) this Congress and Senator Gary Peters (D-MI) last Congress.

- **Overview:** A proposal that would extend 340B qualification to Rural Emergency Hospitals.
- **Links:** [bill text](#), [press release](#)

Additional Background:

The designation for Rural Emergency Hospitals was created in 2021 to preserve access for emergency services in rural communities. As rural hospitals struggle with financial insecurity, this designation boosts funding for those that must scale down services but remain available for emergency care. To qualify, these rural hospitals must be small (with no more than 50 beds) or a Critical Access Hospital (rural hospitals with no more than 25 beds) and not provide most inpatient services. They receive a 5% payment boost for every service but do not qualify for 340B discounts.

The Rural 340B Access Act would correct this oversight by extending discounts to Rural Emergency Hospitals. As of now, more than 1,500 rural hospitals qualify for the designation but don't apply because they may lose their current 340B discounts if they do so. This bill is also included in the previously discussed 340B ACCESS Act.

The Equitable Access to 340B Act

Quick Facts:

- **Champions:** Introduced by Gregorio Kilili Camacho Sablan (D-MP) last Congress.
- **Overview:** A proposal that would extend 340B discounts to territorial disproportionate share hospitals.
- **Link:** [bill text](#)

Additional Background:

This legislation would expand the types of medical providers under the 340B Program to include territorial disproportionate share hospitals, which do not currently qualify. This expansion would apply to each of the five US territories: Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, and the US Virgin Islands.