



We hope you all had a wonderful Thanksgiving! We are extremely thankful for you all, and your continued advocacy and engagement on 340B.



We need every health center advocate to educate Congress on priority issues like 340B, and we look forward to seeing you all at our 3rd Annual 340B Day on February 15th! Learn more about our 2024 Policy & Issues forum [here](#).

What's Next After the Genesis Decision?

On November 3, 2023, a South Carolina district court ruled in favor of Genesis Health Centers. The court determined that HRSA exceeded its authority under the 340B statute by imposing a restrictive interpretation of the term "patient" that required a covered entity to have initiated the healthcare service leading to an eligible patient's prescription. The judgment clarified that neither the 340B Statute nor the [1996 Patient Definition guidance](#) suggested the prescription must be initiated by or originate from the covered entity, or a service provided by the covered entity to be 340B eligible. The court case makes clear that since Congress opted not to define the term patient in the 340B statute, then we must rely on the plain language definition of a patient. The case ruling also referenced two- and three-year time

frames for defining a patient. To date, the government has less than 40 days to appeal this decision.

What does this mean for your health center?

- Even before the Genesis decision, NACHC recommended that health centers should expand their 340B Programs to include referral capture. We encourage you to review our [340B Referral Management Action Guide](#) to learn how to align your health centers' referral management process with your 340B program. Additionally, you can review [this presentation from 340B Day](#)
- Covered entities, like health centers, have to demonstrate that an individual is their patient and maintain an ongoing relationship with that individual, or as described in the patient definition, have ongoing responsibility for care.
- To maintain compliance with the 340B Program with respect to diversion, providing 340B drugs to ineligible patients, it's critical health centers develop policies and procedures that "close the loop" with outside specialists. This means maintaining the proper documentation to demonstrate "ongoing responsibility of care" for the patient.

For additional questions, please reach out to regulatoryaffairs@nachc.org.

Federal PBM Updates

Over the last several months, Congress has been working across the aisle to crack down on Pharmacy Benefit Managers (PBM) discriminatory practices. Despite the looming possibility of a government shutdown, the Senate has further advanced PBM legislation, heightening the possibility of passage this year.

Between the two chambers, at least 23 PBM-related bills have been introduced. A number of these bills were pulled together into packages to advance them forward through the committee process. Three bipartisan packages are highlighted below:

- **HR 5378, The Lower Costs, More Transparency Act:** This legislation is the joint work product of the House Energy and Commerce, Ways and Means, and Education and Workforce Committees. It includes a long-term increase and extension of funding for health centers and primary care workforce programs.
- **1339, Pharmacy Benefit Manager Reform Act:** This package was marked up by the Senate Committee on Health, Education, Labor, and Pensions in June 2023 and is focused on regulatory reform of PBM practices in the private health insurance sector. It does not address health center funding.
- **2973, Modernizing and Ensuring PBM Accountability (MEPA) Act:** This legislation, part of a broader healthcare package, passed unanimously in the Senate Finance Committee in early November 2023. This legislation addresses PBM and pharmacy practices in Medicaid and Medicare. It also does not address health center funding.

While the proposals vary on who they regulate and which health care programs their reforms pertain to, a combination of the following provisions are included in the bills above:

- **Banning spread pricing:** The amount that PBM charges the plan must equal the amount paid to the pharmacy.
- **Enhancing transparency:** Requiring PBMs to disclose detailed information to plans like remuneration and drug utilization, which could allow plan sponsors to make more informed decisions about contracts.
- **Taking on vertical integration:** When a single company owns its own supply chain i.e. when there is common ownership of a health plan, PBM, and pharmacy.
- **Limiting rebate pass through:** PBMs negotiate rebates from manufacturers in exchange for giving a manufacturer's drug preferred formulary status. PBMs may pass along a portion of those rebates to health plan clients but may keep a share for themselves (retained rebates).

NACHC appreciates Congress's efforts to hold PBMs accountable, as they hurt patient access to affordable medications and limit patient choice in choosing the best pharmacy for their needs.

Political Landscape – Capitol Hill's Impact on 340B

On June 16, a [bipartisan 340B working group](#) of six U.S. senators, known as the gang of 6, sought feedback from stakeholders on policies and provisions to ensure the proper oversight of the 340B drug discount program. After preparing responses, many organizations, including [NACHC](#) and [ASAP 340B](#), submitted comments on July 28 to provide recommendations to improve the oversight of this program, which is essential to many health centers' ability to provide a full range of services to uninsured and underserved populations.

This RFI reflects the progress of the ASAP 340B Coalition by creating more pressure and urgency for Congress to take action to strengthen the 340B Program. NACHC and ASAP have both had follow-up meetings with the working group to discuss how our 10 policy principles align with their existing efforts to reform the 340B Program.

State Policy Updates

In a significant victory for health center patients and covered entities, California enacted [SB 786](#) on October 7, a groundbreaking law that protects against unfair practices by PBMs. This comprehensive bill includes measures to curb PBM abuses and promote transparency and accountability:

- Prevents PBMs from discriminating against covered entities or their pharmacies with the dispensing of drugs.
- Prohibits PBMs from arbitrarily denying contracts, terminating existing contracts, or excluding covered entities or specified pharmacies from their networks.

- Protects covered entities and specified pharmacies from retaliation for exercising their rights under the law.
- Ensures patients' freedom of choice by prohibiting PBMs from interfering with their decision to receive covered drugs from a covered entity or specified pharmacy.
- Empowers covered entities to speak out against PBM misconduct by preventing PBMs from restricting or prohibiting covered entities from raising grievances or publicly addressing PBM violations.

For the most up-to-date information on state 340B legislation, please view the [State 340B Legislation Chart](#).

Drug Manufacturer Restriction Updates

In a positive development, five pharmaceutical companies—Merck, Teva, Organon, Astellas, and GlaxoSmithKline—have reversed their restrictions on 340B contract pharmacy arrangements in Louisiana and Arkansas following the enactment of new state laws safeguarding 340B covered entities. Louisiana Governor John Bel Edwards [signed into law state-level protections on June 19, 2023](#). The Louisiana law explicitly prohibits drug companies from interfering with the 340B drug acquisition or delivery process at contract pharmacies. The growing trend of state-level protections for the 340B Drug Pricing Program signals a strong commitment to ensuring that healthcare providers can continue to utilize the 340B Drug Discount Program for its intended use.

The reversal of restrictions by pharmaceutical companies in Louisiana and Arkansas is a welcome step in this direction. This reversal comes as the number of drug manufacturers imposing restrictions on the 340B Drug Pricing Program continues to rise, with 28 manufacturers now implementing 10 distinct restrictions affecting health centers. The reversal of restrictions in Louisiana and Arkansas highlights the growing effectiveness of state-level measures to protect the 340B Drug Pricing Program, which provides discounted medications to eligible healthcare providers that serve low-income and uninsured patients. As of now, please view NACHC's most up to date [340B manufacturer restrictions on contract pharmacies chart](#).

[The 340B Manufacturer Restriction Chart](#) - The most recent manufacturer restriction change impacting health centers comes from [Eli Lilly](#). Before, Eli Lilly allowed covered entities to submit claims data to 340B ESP to unlock multiple contract pharmacies. Their most recent update only allows covered entities to designate a single contract pharmacy location and register it along with voluntary data submission through 340BESP.com by November 13, 2023, to maintain access to 340B pricing for that pharmacy. We understand this change will impact health centers particularly hard. Please review this [drug alternatives chart](#) to see other 340B medication options.

Upcoming Drug Supply Chain and Security Act (DSCSA) Deadline Important to Your Health Center

The Drug Supply Chain and Security Act (DSCSA) establishes a national system for tracing prescription drugs through the supply chain and sets national licensing standards to enhance the U.S. Food and Drug Administration's (FDA) ability to help protect consumers from suspicious drugs. Starting November 27, 2023, health centers must obtain a Global Location Number (GLN) for each site receiving products. The GLN helps businesses know who is involved in transactions and where things are located throughout the supply chain. Review our DSCSA factsheet [here](#) to understand how to obtain GLNs and to learn more about DSCSA.

For further information on DSCSA, please see past recordings and resources from 340B Office Hours.

- [September 340B Office Hour Recording](#), [September 340B DSCSA Q&A](#)
- [October 340B Office Hours Recording](#), [October 340B DSCSA Q&A](#)

340B Office Hours

Our December Office hours will be *Monday, December 18, 2023, from 3:00 – 4:00 PM ET*. We will be discussing how to make medications affordable through outside entities followed by different ways to use Prescription Assistance Programs. Register for December's office hours, and office hours for the first half of 2024, [here](#).

340B Advocacy Resources

NACHC encourages you to continue to talk with your state and federal legislators about the importance of the 340B program to your health center. See some useful resources below:

- [340B Impact Profile](#) - Health centers can customize and share with your legislators to show how your CHC uses 340B savings to benefit your patients
- [340B Advocacy Toolkit](#) - See new talking points on ASAP 340B and updated talking points on the importance of contract pharmacy. These can help Congress understand why the status quo of the 340B program is hurting CHC patients.
- Social Media [graphics](#) that highlight how health centers reinvest 340B savings.
- Infographics – Use these infographics to support advocacy efforts with your legislators.
 - [340B & Health Equity](#)
 - [340B Improves Health Access for Patients](#)
 - [340B: A Critical Program for Health Centers](#)

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