

340B Drug Discount Program Update

Presented by:

Daniel Soldato

Partner

Bricker Graydon Wyatt LLP

dsoldato@bricker.com

(859) 288-7631

Shona Carr, MBA, 340B ACE

Director, 340B & Ambulatory Pharmacies

Genesis HealthCare System

Legal Disclaimer

- The purpose of this presentation is to provide you with information on the 340B Drug Discount Program.
- The information in these slides and in our presentation is provided for reference only and is not to be considered legal advice.

Brief Overview

- Congress enacted Section 340B of the Public Health Service Act via the Veterans Healthcare Act of 1992.
- Section 340B is intended to provide additional resources to covered entities that furnish services to patients who are uninsured or underinsured.
- Section 340B requires pharmaceutical manufacturers to enter into an agreement with the Health Resources and Services Administration whereby those companies agree to sell outpatient medications to eligible covered entities (e.g., certain hospitals) at a reduced price in exchange for Medicaid reimbursement eligibility.
- According to HRSA, in 2024, covered entities purchased \$81.4 Billion of covered outpatient drugs under the Program.

Key
Compliance
Issues for
Covered
Entities



Prevention of
Diversion



Prevention of
Medicaid duplicate
discounts

Diversions

- Covered outpatient drugs may only be provided by a covered entity to patients of that entity.
- Three criteria must be met for an individual to be considered a patient of a covered entity under the Program: the covered entity must maintain records of the individual's health care, the individual must be actually cared for by the covered entity, and the individual must receive services consistent with the services for which grant funding has been provided if the covered entity's eligibility is based upon grant funding.
- *HRSA Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55156-55158 (October 24, 1996), available at <https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf>.
 - This definition is being challenged currently by at least one manufacturer that claims that the definition is too broad.

Policies To Prevent Diversion

- Site Eligibility
 - Inpatient vs. Outpatient Services
- Patient Eligibility/Definition
- Prescriber Eligibility
- Oversight and Monitoring
- Use of Third-Party Vendors
- Reporting of Noncompliance
 - Material Breach Policy



Duplicate Discounts - Medicaid

- Covered entities may not receive a “duplicate discount”.
- A duplicate discount occurs when a covered entity obtains the pricing discount under the 340B Program and also requests a rebate under a State Medicaid Program.
- For compliance purposes, covered entities must either elect to use 340B drugs for Medicaid patients or elect not to use 340B drugs for Medicaid patients.
- This process is called “opting in” or “opting out”.
- If a covered entity “opts in”, it must have a way to ensure that it does not request a rebate under Medicaid for a covered outpatient drug if it also received 340B pricing for that drug.

Policies To Prevent Duplicate Discounts

- Opt In
 - Medicaid Exclusion File (MEF)
 - Register all Medicaid Provider Numbers and associated NPI numbers on OPAIS for each state
 - Audit MEF to ensure associated numbers are listed
 - Coordination with Medicaid
 - Hospital Provider Claims
 - Ohio requires the “SE” modifier on 340B claims along with submission of the drug’s actual acquisition cost
 - Entity-Owned Outpatient Pharmacies
 - Ohio requires the “20” submission clarification code along with submission of the drug’s actual acquisition cost
 - Contracted Pharmacies
 - No 340B billing permitted for Medicaid FFS prescriptions
- Opt Out
 - No 340B Drug Billing for Medicaid
- Oversight and Monitoring
- Use of Third-Party Vendors



Covered Entity 340B Drugs



Register Medicaid Provider #s & NPI Numbers on Medicaid Exclusion File

Comply with Ohio Medicaid 340B Regulations



No 340B Billing to Medicaid at Contracted Pharmacies

Rebate Model – Maximum Fair Price

- Certain manufacturers are seeking to institute a “rebate” model.
- This is a significant departure from the operation of the Program since its inception. Specifically, the 340B discount has traditionally been provided upon sale rather than through a rebate.
- The “rebate” model grew out of manufacturer concerns related to the limits on 340B discounts for drugs that are also subject to Maximum Fair Price under the Inflation Reduction Act.

Rebate Model – Maximum Fair Price (Cont.)

- The Medicare Drug Price Negotiation Program is part of the Inflation Reduction Act and provides that the Federal Government may negotiate pricing with manufacturers for certain designated drugs (starting with 10 drugs in 2026 and increasing each year).
- The negotiation establishes a Maximum Fair Price for the selected drugs. See 42 U.S.C. 1320f-2(a).
- Manufacturers that agree to a Maximum Fair Price for a drug that is also subject to a 340B drug discount are not required to provide the 340B discount if the Maximum Fair Price is lower than the 340B drug discount. See 42 U.S.C. 1320f-2(d).

Rebate Pilot Program and Resulting Litigation

- In August 2025, HRSA published a notice establishing criteria for certain manufacturers to participate in a limited rebate pilot program.
- Covered entities filed suit to block the pilot program, and, based upon a court order by the U.S. District Court for the District of Maine in *American Hospital Association et al. v. Kennedy et al.*, No. 25-cv-600 (D. Me.), HRSA paused the pilot program.
- The same court vacated the program notices and application process in February 2026.
- Following the Court's orders, HRSA issued a Request for Information (RFI) to determine the viability of a rebate program and its potential benefits and burdens for covered entities and other stakeholders in the 340B Program, including manufacturers.
- Responses to the RFI were due April 20, 2026.

Hospital Challenges Related to a Rebate Model



State Laws Related to the 340B Program

- The 340B Drug Discount Program was created by Federal law.
- However, due to HRSA's limited regulatory authority and the nature of the Program, certain states have enacted (or attempted to enact) laws that impact the Program's operation to protect certain stakeholders, such as hospitals and other covered entities.
- In other words, certain states have attempted to regulate the conduct of Program stakeholders in areas of controversy or uncertainty when the Federal oversight agency does not have direct rulemaking authority or is silent on a particular issue.

Examples of State Laws

- Contract Pharmacy Protection Laws
 - Ark. Code. Ann. § 23-92-604(c)(1)–(2)
 - Colorado Revised Statute § 6-29-101
- Laws Prohibiting Discrimination in Reimbursement Against 340B Covered Entities
 - 215 ILCS 5/513b1
 - Nebraska Revised Statutes §§ 44-4601 to 44-4617
- Laws Requiring 340B Covered Entity Reporting
 - RI Gen L § 5-19.3-6
 - IC 16-40-6

Ohio Laws Related to the 340B Program

- Ohio Revised Code §3701.88 (Covered Entity Reporting Requirements)
 - Aggregate 340B acquisition costs
 - Aggregate third-party payments
 - Total prescriptions and % that are 340B
 - Percentage of patients served on a sliding fee scale for 340B drugs
 - 340B Program operating cost
 - Payments to contract pharmacies and TPAs
 - Detailed accounting of how 340B profits are used
 - Number of contract pharmacies and prescriptions filled at them
- Ohio Revised Code §3701.88 (MCO Reimbursement of 340B grantees)
 - MCOs may not impose additional fees or different requirements on 340B providers

Current Litigation Related to 340B Program

- Challenges to State Contract Pharmacy Laws
 - Certain states have enacted laws prohibiting manufacturers from regulating covered entities' use of or relationship to contract pharmacies under the 340B Program.
 - Manufacturers and certain trade groups have challenged these laws in a variety of lawsuits.
 - In February 2026, the Fifth Circuit Court of Appeals upheld a Louisiana law that prohibited manufacturers from interfering with covered entities' use of contract pharmacies to deliver 340B drugs to patients.
 - *See AbbVie, Inc. v. Murrill*, 166 F.4th 528 (5th Cir. 2026).
 - The ruling in this case was in part based upon the Fifth Circuit's ruling on a similar law enacted by the State of Mississippi. *See AbbVie, Inc. v. Fitch*, 152 F.4th 635 (5th Cir. 2025).
 - Recently, however, the Court of Appeals for the Fourth Circuit ruled for the manufacturers challenging a West Virginia law that sought to restrict manufacturers from interfering with contract pharmacy arrangements. *See Pharmaceutical Research and Manufacturers of America v. McCuskey*, No. 25-1054, 2026 WL 898259 (4th Cir. Mar. 31, 2026).

Current Litigation Related to 340B Program (cont.)

- Challenges to State Contract Pharmacy Laws (cont.)
 - Will this circuit split on a key issue for 340B stakeholders lead to a decision by the United States Supreme Court?
 - The Court of Appeals for the First Circuit and the Court of Appeals for the Tenth Circuit are both currently considering challenges by pharmaceutical manufacturers on similar laws.
 - The case before the Court of Appeals for the First Circuit is *Pharmaceutical Research and Manufacturers of America v. Neronha et al*, which is a challenge to Rhode Island's law.
 - The case before the Court of Appeals for the Tenth Circuit is *AbbVie Inc. et al v. Weiser et al*, which is a challenge to Colorado's law.
 - The Trump Administration has filed amicus briefs in support of the manufacturers in both cases.

Current Litigation Related to 340B Program (cont.)

- Legal Challenge Related to Child Site Registration
 - HRSA adopted a policy requiring that a covered entity hospital's child site may only be an eligible child site once it was listed on the hospital's most recently filed Medicare Cost Report and then registered with OPAIS.
 - This caused delays in obtaining eligibility for such sites.
 - In March 2026, in the case *Albany Med Health System v. Health Resources and Services Administration*, the U.S. District Court for the District of Columbia ruled in favor of covered entities, finding that HRSA's policy should be vacated because the 340B Statute does not provide authority for HRSA to adopt such a policy.

Data Requests

- Certain Drug Manufacturers have requested or required that 340B covered entities submit claims data regarding certain drugs in order to access 340B pricing.
 - On April 27, 2026, the American Hospital Association sent a letter to HRSA urging HRSA to take action against Eli Lilly related to a letter that the company sent to 340B entities requiring them to register with a third party through which the entities will submit required data.
 - [AHA-Request-for-HRSA-Action-on-Drug-Company-340B-Data-Policies.pdf](#)

Questions?

