340B Price Restrictions:
What Covered Entities Can Do

In July 2020, drug manufacturers started announcing that they would restrict access to 340B discounts on drugs purchased by safety net hospitals and federal grantees dispensed through community pharmacies. To date, 14 companies have formally restricted access.

The Situation

340B Program Intent: In 1992, the 340B drug pricing program required drug manufacturers to provide reduced prices to eligible covered entities in exchange for access to Medicare B and Medicaid formularies. This program was created to allow entities that serve certain underserved, low income, and other at-risk patient populations "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Manufacturers with Formal Restrictions: Although the majority of the 700+ manufacturers participating in the 340B program have continued to grant access, as has been the precedent in the program, 14 companies have formally restricted access—each with its own policies.

	CE* Type Affected		Data Sharing Not Required		Data Sharing Required
Manufacturer	Hospitals	Federal Grantees	Allow Wholly/ Common Ownership CPs**	External CP Allowed if No Entity Owned Pharmacy	Multiple External CPs Allowed
AbbVie	X		X	X	X
Amgen	X		X	X	X
AstraZeneca	X	X		X	
Boehringer Ingelheim	X		X	X[1]	
Bristol Myer Squibb	X	X	X	X[2]	
Eli Lilly	X	X	X	X	X
GSK	X		X	X	X
Merck	X			X	X
Novartis	X			X[3]	
Novo Nordisk	X		X	X[4]	
Pfizer	X		X	X	X
Sanofi	X			X	X
UBC	X		X	X	
United Therapeutics	X	X			X

Manufacturer Restriction Table Updated: February 14, 2022
*** CE = covered entities**
**** CP = contract pharmacies**

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Legal Milestones: The Health Resources and Services Administration (HRSA) has stated that the unilateral development and implementation of these restrictions by manufacturers is unlawful and has referred several cases to the Department of Health and Human Services (HHS) Office of the Inspector General (OIG). The court decisions have had mixed results for health systems and other providers, which at a minimum suggests the challenges from manufacturers will continue and could even possibly become more complex, requiring a proactive response from qualifying entities.

Possible Penalties for Manufacturers: The direct risk to pharmaceutical manufacturers could include:

- Civil monetary penalties can be imposed at $6,000 per incident.
- Repayment of excess charges above 340B pricing to covered entities.
- Loss of access to Medicare B and Medicaid formularies.
- Damage to public image, given current context of pressure on community hospitals and covered entities due to rising drug prices and the pandemic, among other challenges.

What This Means for Providers

Safety net hospitals impacted by these restrictions have seen savings losses that range from 23% for larger covered entities to as much as 39% on average for Critical Access Hospitals.

Adding to the pressures from rising drug prices, the pandemic, and other challenges, these reductions in 340B savings could lead to the reduction of services and closure of facilities that care for communities that often already have limited access to healthcare.

What Providers Can Do Now

We recommend that covered entities refresh and re-evaluate their current strategies across their 340B program to ensure they are meeting the intent for their communities. Given the complexity of the various types of restrictions, covered entities are now forced to understand and customize strategies at the manufacturer level. Some of the key tactics and strategies to consider are:

- Review program fundamentals to identify optimization and compliance opportunities.
- Assess your current "entity owned" retail/specialty/other ambulatory pharmacy services plan.
- Evaluate performance of your current contract pharmacy network and consider options for revision and/or enhancement (to include data sharing requirements proposed by certain manufacturers).
- Assess ambulatory formulary and prescribing patterns to ensure manufacturer restrictions are accounted for.
- Advocate for your position in the 340B program through organizations such as 340B Health.

Are You Ready?

We can help. Contact us to learn more about the steps you can take to minimize current savings losses and optimize your program efficiencies.

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LEGAL DECISION TIMELINE BREAKOUT

October 20, 2021: A U.S. District Court judge in Indiana found that HRSA's enforcement letter did not exceed HRSA's authority and that the agency's interpretation of the statute was the most reasonable. However, the court did find the enforcement letter "arbitrary" and "capricious," given HRSA's changing position over the years regarding contract pharmacy use, and, therefore, found it invalid. Subsequently, both the manufacturer and the government appealed to the U.S. Court of Appeals. The Court of Appeals issued an order consolidating the appeals on January 4, 2022, specifying that a review of the record raised questions as to whether the district court's judgment is appealable.

November 5, 2021: A U.S. District Court judge in New Jersey issued a consolidated decision, finding that the 340B statute permits contract pharmacy arrangements and that the 2 manufacturers' policies violated the statute because they cannot unilaterally restrict access to 340B pricing. The court partially vacated the enforcement letters, due to concerns with HRSA's conclusion that the manufacturers owe credits or refunds to providers and face civil monetary penalties. The court could not determine whether HRSA can require manufacturers to deliver their drugs to unlimited contract pharmacies and remanded the question to the agency for further consideration. Both the manufacturer and the government appealed the decision.

November 5, 2021: A U.S. District Court in D.C. issued a decision regarding 2 manufacturers' policies, finding that they do not violate the 340B statute, while also setting aside HRSA's enforcement letters. The court believes that the statute does not prohibit manufacturers from imposing any conditions on access to 340B pricing and took issue with HRSA's position. There was no declaration from the court on permissibility of the manufacturer policies, which left the question open. The government is appealing the decision.

Disclaimer: The above is a general overview and not intended to represent all details of individual manufacturer restrictions such as specific NDC (National Drug Codes) inclusion/exclusion.

Notes

1. Allow second contract pharmacy designation for OFEV if first contract pharmacy selection is unable to dispense
2. Will recognize up to 2 contract pharmacy locations per 340B hospital that lacks an entity-owned pharmacy (one for IMiDs and one for non-IMiDs)
3. Allow multiple contract pharmacies within 40 miles of CE
4. Will recognize up to 2 contract pharmacy locations per 340B hospital that lacks an entity-owned pharmacy (one specialty and one retail)

Sources

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5. Government Appeals Decisions in 340B Contract Pharmacy Litigation | Bass, Berry & Sims PLC (bassberry.com)
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