

What Health Systems Need to Know About the Latest 340B Manufacturer Pricing Restrictions

Manufacturer 340B pricing restrictions continue to escalate and threaten to reduce 340B savings for participating organizations by anywhere from 25% to 50%. Health systems need to act to update and incorporate these changes into their strategy.

- Manufacturers are tightening existing 340B pricing restrictions.** In 2023, 7 manufacturers (Johnson & Johnson, Amgen, AbbVie, Pfizer, GSK, Novartis, and Bayer) have modified and further restricted pricing access for covered entities in the 340B program. Many of these manufacturers previously allowed the use of multiple contract pharmacies if covered entities agreed to share data through the 340B ESP platform. See Figure 1 below.
- Data-sharing may still be required, despite restricted access to pricing.** These manufacturers have generally walked back covered entities' ability to use multiple contract pharmacies through the 340B ESP data-sharing platform and are now restricting 340B pricing to entity-owned pharmacies and/or a single contract pharmacy. But in some cases, they are still requiring data-sharing for covered entities to leverage 340B pricing for single locations.
- Manufacturer lawsuits are gaining traction.** Lawsuits filed in 2020 have been making their way through the court system. A decision on the first of these lawsuits was handed down by the Third Circuit Court of Appeals on Jan. 30, 2023. The ruling sided with the manufacturers (AstraZeneca, Sanofi, and Novo Nordisk) and against the Health Resources and Services Administration's position that restrictions instituted by these manufacturers were unlawful. Rulings are expected soon for two additional lawsuits in the circuit courts.

Figure 1: Summary of Recent Restriction Changes as of May 2023

Manufacturer	Allow Wholly/ Common Ownership CPs	Without In-House Pharmacy			With In-House Pharmacy			CP Location Allowed for Specified Drugs
		One CP Allowed	CP Must Be Within 40 Miles	Data Sharing Required	One CP Allowed	Must Be Within 40 Miles	Data Sharing Required	
J&J		X	X	X	X	X	X	X ²
Amgen		X			X	X	X	
AbbVie		X	X	X				
Pfizer ¹		X						
GSK	X	X						X ³
Novartis	X	X						
Bayer		X	X					X ⁴

Notes

- New restrictions apply only to Xeljanz; restrictions are unchanged for Pfizer's Defined Oncology Distribution Network.
- Covered entities are allowed to designate a separate contract pharmacy (CP) location for pulmonary arterial hypertension drugs. Data-sharing is required for this location.
- Covered entities not able to dispense GlaxoSmithKline specialty/oncology products will need to designate a single specialty pharmacy for each of GlaxoSmithKline's limited pharmacy network products.
- Covered entities allowed to select a separate CP within Bayer's limited distribution system for Adempas.

What This Means for Provider Organizations

- **Expect existing restrictions to stay and further tightening to occur.** Prior to the Jan. 30 court ruling, manufacturers that had instituted 340B pricing restrictions fell into 2 camps. The first group included manufacturers that generally limited 340B pricing to entity-owned pharmacies and/or a single contract pharmacy location. The second group initially took less restrictive measures and allowed the continued use of multiple contract pharmacies with the condition of data-sharing through the 340B ESP platform. The court ruling appears to have emboldened many of the manufacturers that originally instituted less strict restrictions to establish more narrow policies in line with the first group.
- **Expect continued data-sharing with 340B ESP.** Recently updated restrictions indicate that data-sharing will still be necessary for health systems to recoup value for certain manufacturers. However, that value will be concentrated with a narrower group of pharmacies and will likely be less significant than previous policies allowed.

What Provider Organizations Need to Do Now

- **Prioritize growth and development of your owned retail and specialty pharmacies.** Optimizing pharmacy services for your employees and patients is a key to adjusting existing strategies to the pricing restrictions at contract pharmacies.
- **Review your 340B program fundamentals.** Compliance management and purchasing optimization are more important than ever as the complexity of the 340B program continues to increase.
- **Evaluate your current contract pharmacy strategy and performance.** Although there is still potential value in contract pharmacies, the dynamics have changed so significantly that previous strategies need to be fully re-evaluated to ensure 340B optimization.
- **Develop a pharmacy benefit manager (PBM) network inclusion strategy for your entity-owned pharmacies.** Ensuring that your pharmacies are carved into PBM networks will enable you to extend your prescription services to your employees and patients and utilize 340B pricing.
- **Assess your ambulatory formulary and prescribing patterns.** As part of your formulary decision-making process, make sure you understand how pricing restrictions impact your current ambulatory pharmacy programs.
- **Refresh your overall pharmacy strategic plans beyond 340B.** The changes in the 340B program and the associated negative financial impacts require safety net hospitals to find savings and revenue across all pharmacy services and programs to ensure the financial health of their organization.



➤ Are You Ready?

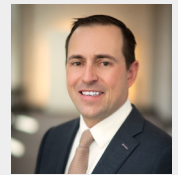
We can help. Contact us to learn more about how to improve pharmacy-related financial performance amid increasing pricing restrictions.

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