



Seven Steps For Overcoming 340B ESP

AND
OTHER
MANUFACTURER
RESTRICTIONS
ON 340B
PRICING

Our process for recovering lost 340B savings and revenue

As we've noted in multiple posts on the ProxsysRx blog, [340B ESP](#) is nothing short of a blatant, lawless tactic used by scores of drug manufacturers to disallow the discounts they are legally obligated to offer eligible entities.

At the same time, a number of additional manufacturers are placing — separate from 340B ESP — similarly-unlawful, and unnecessary, reporting burdens on hospitals submitting claims for 340B savings.

A brief history of 340B-related manufacturer restrictions

The drug manufacturing industry first implemented 340B restrictions with the June, 2020 launch of 340B ESP — an online portal operated by [Second Sight Solutions](#), which is a privately owned corporation created and run by a man with a long history of drug-industry advocacy. According to HRSA, the site has no legal right to impose its restrictions on covered entities.

[Merck](#) was the first manufacturer to *force* (for all practical purposes) eligible entities to use 340B ESP, when it issued [a letter](#) “requesting” that 340B Covered Entities submit their 340B contract pharmacy claims data through the website.

Several other manufacturers soon followed Merck’s lead in jumping-on the 340B ESP manufacturing bandwagon to impose unlawful restrictions on 340B prescription discounts. At present, fourteen manufacturers are eluding their legal obligations to 340B covered entities — and the contract pharmacies working with them — through 340B ESP:

- [AbbVie](#)
- [Amgen](#)
- [Bausch](#)
- [Boehringer Ingelheim](#)
- [Biogen](#)
- [Bristol Myers Squibb](#)**
- [Exelixis](#)
- [Gilead](#)
- [GSK](#)
- [Johnson & Johnson](#)
- [Merck](#)
- [Pfizer](#)
- [Sanofi](#)
- [UCB](#)

***NOTE:** *Bristol Myers Squibb employs a hybrid model: Designation through ESP, data [IMiDs only] to the company directly.*

That said, four other manufacturers currently impose unlawful restrictions on 340B-eligible health systems *independent* of 340B ESP.

- [AstraZeneca](#)
- [Eli Lilly](#)
- [Novo Nordisk](#)**
- [United](#)

***NOTE:** Novo Nordisk moved into the ESP manufacturing platform effective 1/4/23.

A brief history of 340B-related manufacturer restrictions

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[Novartis](#) imposes no additional prescription-submission requirements on 340B health systems. However, they honor prescriptions from only ONE Contract Pharmacy outside a 40-mile radius of a hospital's campus. Why? Very few 340B Specialty pharmacies are located within 40 miles of the health systems they serve.

As we noted in a [previous post](#), the average cost is significantly higher for specialty drugs, and the savings potential of these 340B covered outpatient drugs can be astronomical. According to a [drug trend report](#) by [Evernorth](#), specialty drugs were used by less than 2% of the population in 2020, but accounted for more than 50% of prescription spending.

FINALLY: Seven manufacturers do not allow the 340B covered entities to provide claims data to expand pricing to additional contract pharmacies.

- AstraZeneca
- Boehringer Ingelheim
- Biogen
- Bristol Meyers Squibb
- Novartis
- Novo (will allow effective 1/1/23)
- UCB

LET'S REMEMBER: The 340B program was established by Congress to support non-profit, community and charitable hospitals and clinics — most of which operate at a loss, many with annual deficits in the tens of millions. The 340B revenues lost to manufacturer restrictions often have a direct impact on eligible entities' charitable-giving prescription programs. Which means that the people hurt worst by manufacturer restrictions are those who can least afford the medication they need.

How ProxsysRx overcomes manufacturer restrictions on 340B pricing

As much as we'd love to report that we've discovered the proverbial magic bullet for piercing manufacturer barriers to optimizing 340B cost savings and revenue, we can't. Dealing with restrictions is significantly more complicated, and the process involves painstakingly thorough diligence — leaving no stone unturned in ensuring that no 340B cost savings are missed.

Our process starts with an in-depth assessment of a health system's current 340B-program status (assuming the health system has an active 340B program). Once we've conducted that analysis, we work with the health system's 340B professionals to develop strategies for improvement in every area of its program — including: ESP data reporting, 340B price monitoring, tactics and resources for identifying matching data missed by its TPAs, and its contract pharmacy partnerships. ProxsysRx's 340B support team then implements software-supported processes for auditing missed opportunities.

For most of the hospitals we serve, ProxsysRx's team also provides hands-on support in managing their 340B programs.

The good news is, our process is producing results. And while those results vary from system to system, one of the small rural hospitals we serve has seen a monthly net savings increase of more than 900% over their historical averages since manufacturer restrictions were implemented.

Ahead: The seven key elements of our process.

Establishing communications between health system providers and their outpatient pharmacies

With manufacturer restrictions, it's more important than ever that health systems have onsite pharmacies partnering with them to capture as many 340B-eligible prescriptions as possible — in part, to ensure that savings stay within the system, thereby enabling them to pass-along those savings to patients.

ProxsysRx manages and/or owns retail outpatient pharmacies located on hospital campuses nationwide. At select 340B-eligible locations, our pharmacists make themselves available to system physicians and providers — serving as a resource to help them determine the best medications, for patients in need, which also qualify for 340B savings. When necessary, our pharmacists can consult with ProxsysRx's team of 340B experts for additional guidance.

At the same time, our 340B team is available to help guide clinical-practice decisions for all the hospitals whose 340B programs we manage. We're always there to help physicians select the best medications in any class that are 340B-savings eligible — so they can pass-along those savings to patients in need. It's a critically-important service for those patients, given the research (and our first-hand experience) indicating that when prescriptions are prohibitively expensive, patients simply won't get them filled.

Uploading only the 340B Data required, and NO MORE

As with every aspect of our program, we learned this lesson through experience: When working in the 340B ESP platform, you should never upload any data that isn't absolutely required by the platform.

We know how complicated 340B ESP's requirements are, and how difficult it is to determine the necessary minimum information required — particularly when you consider how difficult it is to find a complete, up-to-date list of impacted National Drug Codes (NDCs, which are identifier codes for drugs used by the FDA) required for reporting inclusion. Which is why we've developed a reliable process for scrubbing reports — from the TPAs used by the health systems we serve — before they're submitted.

We submit the NDCs only from manufacturers that impose 340B pricing restrictions that are contingent on data reporting, and here's why: As we mentioned earlier, the 340B ESP website is owned by a man with a long history of drug-industry advocacy — and under the website's [Terms Of Use](#), his corporation (Second Site) uses the non-required data you submit to influence even *more* manufacturers to require data submission through its website.

Never trusting 340B ESP to restore prices on its promised scheduling

340B ESP says health systems should expect a period of 10 days, post-submission, for 340B prices to be restored in their contract pharmacies' 340B wholesaler accounts. In reality, that rarely ever happens within 10 days — if at all.

Which is why ProxsysRx has implemented a system for checking all NDCs, in all of our health systems contract pharmacies' 340B accounts, before instructing their TPAs to restart processing on any restricted NDCs. Since there are times when Wholesale Acquisition Costs (WACs) are loaded, instead of 340B pricing (which leads to covered entities overpaying), TPAs began blocking processing when notice of NDC restrictions was introduced.

There are more than 1400 restricted NDCs, and for every contract pharmacy a covered entity has, each and every one of those 1400 NDCs must be checked. Needless to say, it's a process that would be impossible without proprietary software to do just that. ProxsysRx's 340B Pro platform displays all the information from your EHR, and from all of your TPAs, in a very easily-understood dashboard — offering you actionable information for compliance, audits, missed auditing data and referrals. We rolled-out the first version of 340B Pro in 2021, and we are constantly updating and adjusting it to deal with the ever-evolving challenges manufacturers introduce in their 340B pricing restrictions.

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Never trusting 340B ESP price restoration, period

When dealing with 340B ESP, we've learned that health systems cannot assume that any 340B price restorations they *have* will actually be honored. Manufacturers working with 340B ESP routinely, and unilaterally, decide that the purchases made for arbitrarily-selected contract pharmacies are more than the dispenses. When that happens, they refuse to pay the wholesaler's chargeback — resulting in a credit-rebill. And when that happens, covered entities pay WAC — which is a much higher price.

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Never assuming that submitted eligible dispenses result in 340B price access

Some manufacturers now require you to submit 340B purchase data reports within ~~past~~ 45 or 60 days from dispense — or they disallow those submissions. Because, of course, that policy means that — in these instances — covered entities will never be able to get many of the 340B prices they are entitled to.

Although ProxsysRx mines clients' 340B-submission records for eligible prescriptions missed by their TPAs, the time frame is tight with these arbitrary, fraudulent manufacturer requirements — and thus far, we've yet to develop a workaround for dealing with them.

Never assuming that 340B ESP will be compatible with your TPAs' reports

If you're thinking you can simply pull reports from your TPAs and upload them, when submitting your own reporting to 340B ESP, think again. Most TPAs' reports require significant modifications first. Your own uploads have to be submitted in 340B ESP's exactly-specified format, and every upload has the potential for reporting errors that can cause failures.

It's impossible to pull submission-data from some TPAs' systems, because their systems require 340B prices to be available before they'll even consider dispenses for matching. And without 340B pricing, reports from those TPAs won't produce data you can submit to 340B ESP.

It's an absolutely infuriating dilemma: No price means no data. Which means no price. All of which adds-up — morally, ethically and legally — to No Excuse for the crimes 340B ESP and the manufacturers are committing against the 340B law, not to mention the struggling entities that law was created to serve.

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Never wasting time asking 340B ESP for help

On the 340B ESP home page, in the top left corner, you'll find an email address — support@340besp.com. Don't waste your time.

Nobody working with 340B ESP — or the manufacturers — has ever helped our team when our clients didn't receive the 340B prices to which they're entitled, even when months have passed since we made data submission.

There's still hope for covered entities dealing with 340B ESP.

Despite all the barriers the manufacturers have thrown our way over the past two years, ProxsysRx's 340B team has generated tens of millions in 340B savings and revenue for the hospitals we serve. And yes, we'd like to think, with our experience, we're well-positioned to handle whatever new challenges they throw our way.

ProxsysRx is here to help, if you have questions.

There are so many ways to optimize your 340B drug program savings and benefits, while minimizing the likelihood of noncompliance. For more information, contact Howard Hall. C: 205.588.0946 | howard.hall@proxsysrx.com