

A Complete Guide
to Overcoming the
Most Common
**340B Challenges with
Manufacturer Restrictions**

**Learn how to navigate the complexities
of 340B manufacturer restrictions to
optimize your program**



The 340B drug pricing program helps Covered Entities (CEs) offer medications to underserved patients at a reduced cost. It allows 340B hospitals to stretch limited federal resources to support patients and expand health services in the communities they serve. But over the last few years, a growing list of drug manufacturers have implemented policies that limit contract pharmacies' access to 340B pricing. The varied requirements and processes for reinstating 340B pricing have become complex, and are difficult for CEs to navigate.

As a result, the process to submit claims and monitor pricing restoration is an administrative burden. At Visante, we have worked with dozens of CEs to help them navigate the 340B ESP™ process and regain lost revenue quickly and efficiently.

If you are struggling to manage the complexities of pricing restoration, this guide will help you overcome the most common challenges.



Which manufacturers have pricing restrictions in place?

In 2020, drug manufacturers began implementing policies that limit the purchase of 340B-priced drugs for CEs through contract pharmacies.

Today, a total of 21 manufacturers have some type of restrictions in place for CEs. You can review the policies for participating manufacturers on the 340B ESP™ Resources page. Note that some manufacturers are partnering with 340B ESP™, and others are not.



[View manufacturer policies](#)

340B ESP™ data requirements

When you are ready to upload data in the 340B ESP™ platform, we recommend only providing the minimum information that is required. You should develop a reliable data scrubbing process with your Third-Party Administrators (TPAs), and include only data for the relevant National Drug Codes (NDCs). You can download a restricted NDC list from the 340B ESP™ portal.



[Restricted NDC List](#)

During the 340B ESP™ data submission process, you will be required to provide the following information:

Contracted Entity ID: the 340B ID of the covered entity where the prescription originated.

Date of Service (Fill Date): date the patient filled their prescription.

Date Prescribed: date the prescriber wrote the prescription.

NDC: the 11-digit National Drug Code (NDC)

Quantity: the number of units in the prescription.

Rx Number: the native prescription number generated by the pharmacy.

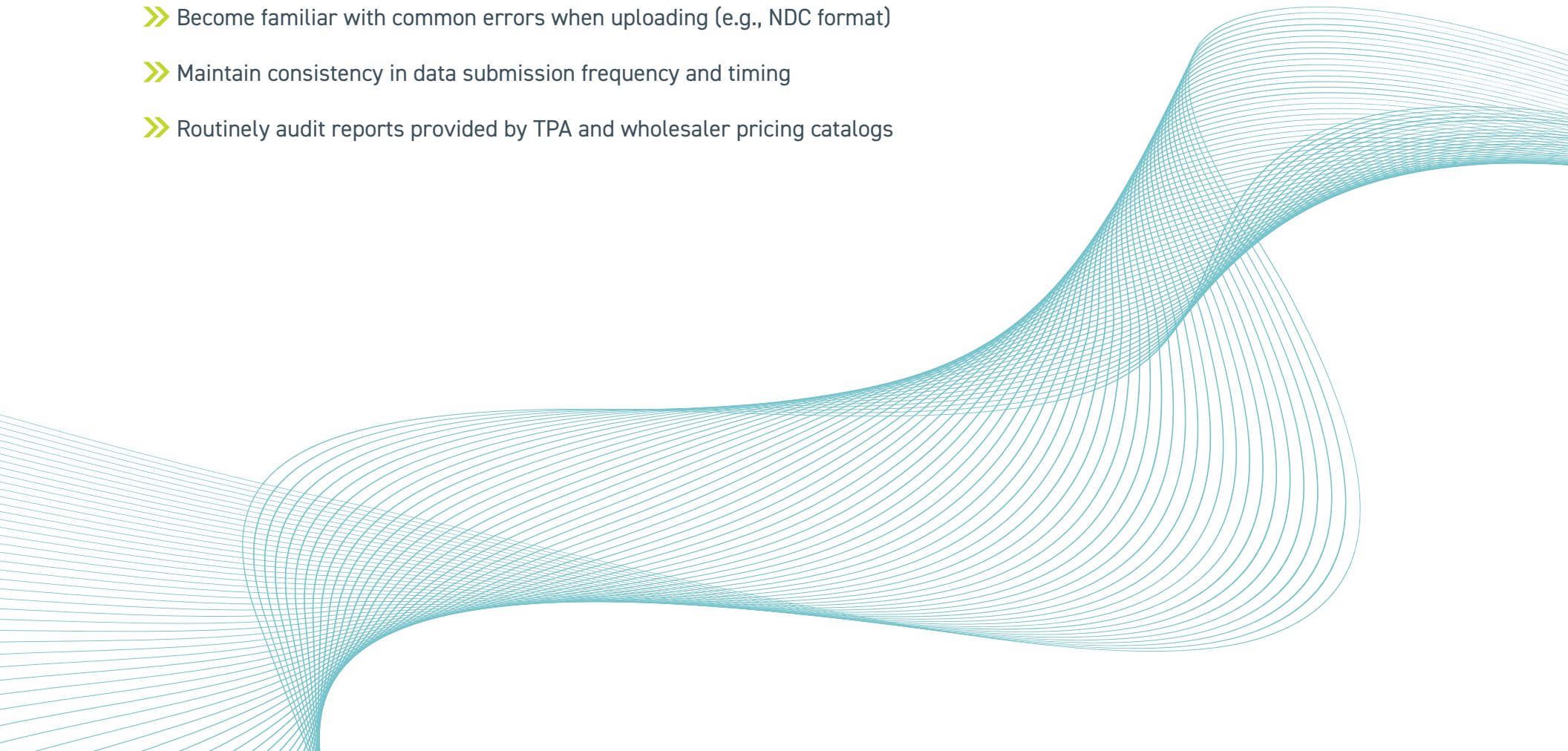
Service Provider ID: a unique ID for the dispensing pharmacy.

Submitting data to 340B ESP™

The 340B ESP™ platform requires CEs to submit data twice per month or face risks for losses and lag time in 340B price restoration. CEs should make submissions on the 1st and 16th days of the month for the prior period.

Data submission tips

- » Have a standardized reporting and upload process to reduce errors during data upload to 340B ESP™
- » Create a column mapping in 340B ESP™ for each TPA file format to ensure the data imports appropriately
- » Become familiar with common errors when uploading (e.g., NDC format)
- » Maintain consistency in data submission frequency and timing
- » Routinely audit reports provided by TPA and wholesaler pricing catalogs



Tracking pricing restoration

After data submission, the 340B ESP™ portal will display the status of pricing eligibility by pharmacy location for most manufacturers. 340B ESP™ indicates that pricing is typically restored with the wholesaler within 10 business days of submitting data to the 340B ESP™ portal. You should work with your TPA to identify what method was utilized to block restricted NDCs, how those blocks will be removed and the timing for claims to be reprocessed. Note that your TPA should be able to provide you with a report listing the block status for all restricted NDCs.

- » **If the TPA has an automated review process**, they can unblock NDCs with restored pricing.
- » **If the TPA does NOT have an automated review process**, price restoration must be identified through the wholesaler catalog and communicated to the TPA.

These are the most common issues we see with price restoration, and how to solve them:

The “chicken or the egg” scenario

Data submissions must include all 340B eligible claims, whether pricing has been restored or not.

Solution

Upload a claim with that NDC to 340B ESP™

Tracking pricing restoration across multiple TPA systems

Many CEs find it difficult to keep up with the volume and complexities.

Solution

CEs should develop a tracking solution that includes claims from all TPAs

Different price loading policies

Manufacturers have varied policies for how pricing gets restored (i.e., store-by-store vs. all locations).

Solution

Review each policy so you know what to expect

Auditing ineligible claims

For CEs with a contract pharmacy program, it is critical to review carve-out/ineligible claims data from your TPA system(s) to understand why claims are not qualifying in your 340B program. Carve-out/ineligible claim data can reveal potential configuration issues or limitations within the TPA system.

Examples include the following:

- » Entity-owned pharmacies that have had manufacturer restrictions applied in error.
- » Prescribers or locations that are 340B eligible but are not configured correctly.
- » Excluded payers that should be eligible.
- » Claims that were not reprocessed after manufacturer pricing was restored.

Keeping the pricing turned on

Once pricing is restored, it will be necessary to continue to monitor the process. Several manufacturers will initially restore pricing for all pharmacy locations, even if claims were not submitted for those locations initially. As a result, manufacturers may then change a pharmacy location status to “at-risk”.

If claims are not submitted for that pharmacy location in a timely manner, the status will change back to “ineligible” and pricing will be lost. In addition, a pharmacy location may have the status changed to “at-risk” if the purchase data and submitted claims do not reconcile. 340B ESP™ is working with the manufacturers to complete this analysis each month.

Manufacturer inquiries

Manufacturers are utilizing data submitted to 340B ESP™ to conduct inquiries of purchasing habits. The CE should ensure those that are registered with 340B ESP™ are monitoring their emails regularly.



340B price restoration can be a convoluted and lengthy process. And as more manufacturers continue to implement pricing restrictions, the process is unlikely to get easier in the future. Many CEs find that they simply do not have adequate time and resources to manage the process.

At Visante, we can help you remove the guess-work and the administrative burden behind managing this critical avenue to revenue restoration. Our 340B ACE certified consultants are experts on 340B ESP™ processes, and we can help you make the most of 340B to optimize your savings. Contact us to learn more about how we can support all aspects of your 340B program. Email solutions@visanteinc.com or call (866) 388-7583 to speak to one of our team members.