



## **340B Price Restatement and Refund Service**

Supporting efficient, pragmatic, and compliant 340B operations

The 340B Drug Pricing Program is growing in complexity, as are your responsibilities regarding 340B price restatements and refunds to customers. Deloitte Risk and Financial Advisory and Apexus have simplified the process so that when you need to prepare restatements and provide refunds, you have experienced advisors who can help save time, money, and resources.

**Why comply?**

Manufacturers are required to comply with the 340B statute and the Pharmaceutical Pricing Agreement, including the obligation to charge 340B covered entities no more than the 340B ceiling price for covered outpatient drugs. The Patient Protection and Affordable Care Act includes an expectation that manufacturers restate and issue refunds or credits for overcharges to covered entities, in both routine (e.g., Best Price true-up) and exceptional (e.g., error) instances.

In addition, the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Final Rule, with an effective date of July 1, 2019, requires manufacturers to true-up Provisional 340B Ceiling Prices for new products and refund overcharges to covered entities within 120 days of overcharge determination. These regulations address civil monetary penalties that can be imposed on manufacturers for "knowingly and intentionally" overcharging 340B covered entities at a price above the 340B ceiling price. (83 FR 25943, (June 5, 2018))

Manufacturers face compliance risk as well as reputational risk with their 340B customers and within the industry if they do not adhere to 340B Program requirements. Manufacturers should take precaution to mitigate such risk and prepare for HRSA auditing of manufacturers, which is part of HRSA's 340B Program integrity priorities. (Public Health Service Act, section 340B(d)(1)(B)(v))

**A tested, integrated approach to address covered entity overcharges**

To help you address these challenges and support your 340B compliance, Deloitte and Apexus offer complementary services to restate 340B prices and return overcharges to your covered entity customers.

**How our complementary strengths help you**



**Compliant**

Supports 340B Program integrity by restating prices, identifying refund amounts, and processing credits within 90 days.



**Efficient**

Advisory services and operations related to restatements, refunds, and communications with covered entities and distributors so your staff can focus on more strategic business priorities.



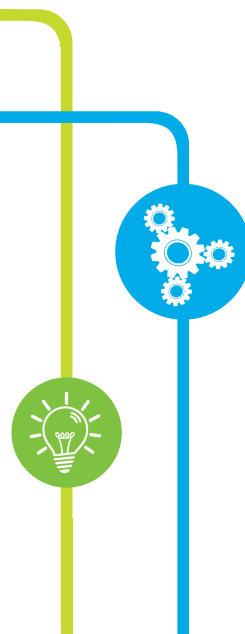
**Correct**

Restated prices and refunds are provided through a centralized approach that leverages Apexus' proprietary database that matches covered entities to their current distributors.



**Due diligent**

Restatement assessments, communications, research, and processes are documented to meet government guidance and provide peace of mind.

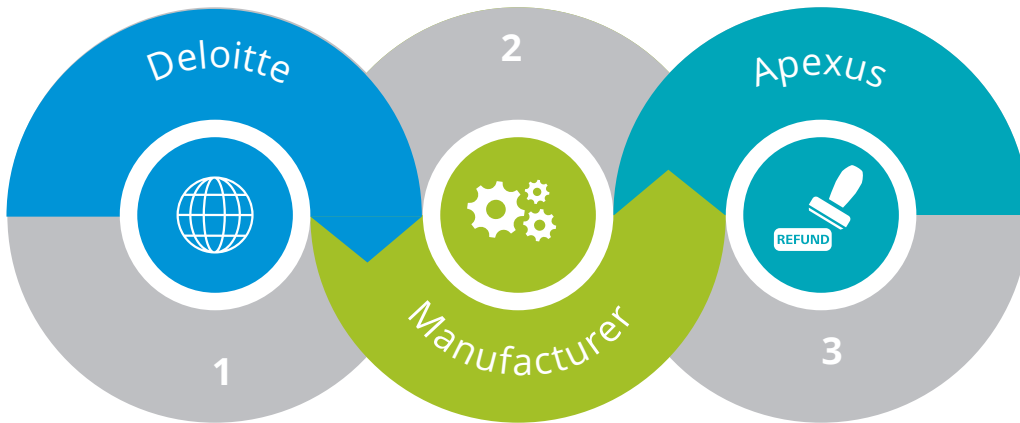
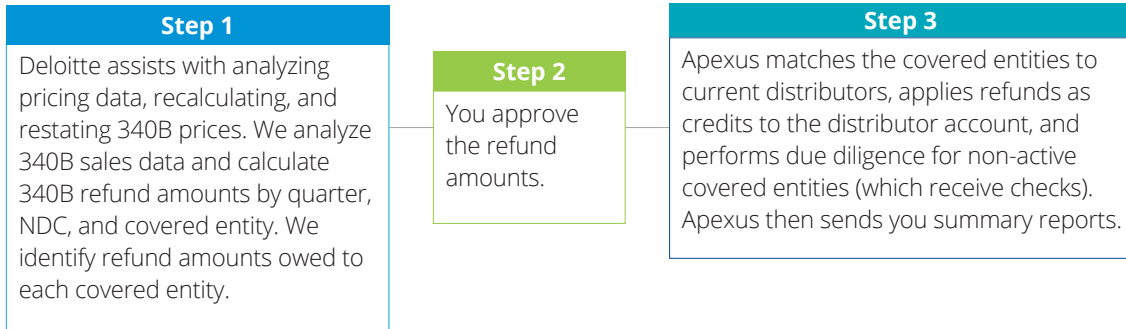




## How it works: easy as 1-2-3

### From start-to-finish within 90 days, we assist you with your 340B reconciliations

First, Deloitte works closely with you to gather pricing data and assess whether adjustments should be made based on 340B ceiling prices. We recalculate and help you restate 340B prices, as well as identify 340B refund amounts by quarter, by National Drug Code (NDC), and by covered entity. After you approve, Apexus leverages the time-saving and cost-efficient approach of processing overcharge refunds as credits and applying the credits directly to your covered entity's distributor account.



### Why Deloitte and Apexus?

By leveraging our established processes and knowledgeable team, we have supported the return of hundreds of millions of dollars in refunds for more than five years.

#### Deloitte

##### Recognized for our deep government programs knowledge and high-quality work

Our 340B regulatory compliance specialists and former industry professionals understand the challenges of complying with the 340B Program and the uncertainty and pressure that come with implementing new government regulations. We recognize that experience counts, and we support you with broad restatement services that set the standard for government programs integrity and risk management.

#### Apexus

##### The government's designated Prime Vendor for the 340B Drug Pricing Program

Manufacturers trust Apexus in its role as the single 340B Prime Vendor managing program discounts and serving as a business partner to 340B stakeholders to help improve the program's overall integrity. Over 100 manufacturers have engaged Apexus as the 340B Prime Vendor to voluntarily extend additional discounts on their drugs within the program. In addition, Apexus provides award-winning education and compliance tools and manufacturer refund services to nearly 40,000 health care facilities serving vulnerable populations. More information about the Prime Vendor Program is available at [www.340BPVP.com](http://www.340BPVP.com).

# Learn more

If you'd like to learn more about how we can support your 340B compliance, please contact:

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