

# 340B Drug Discount Program Fact Sheet

An overview of the 340B Program's origin, evolution, and growing impact on manufacturers



## 340B Timeline

**1992:** Congress creates the 340B Program

**2010:** HRSA allows unlimited CPs for each CE, effectively expanding the reach of 340B

**2020:** First MFR-led 340B policy changes implemented to limit CP utilization<sup>5</sup>

**2021:** States begin banning MFR CP restrictions<sup>6</sup>

**2022:** IRA passes, exempting brands up for Medicare price negotiation (MFP) from 340B discounts

**2023:** 3<sup>rd</sup> Circuit rules MFRs are not required to provide 340B discounted drug to unlimited number of CPs (Sanofi v. HHS)

**2024:** First MFRs announce plans for a 340B rebate model to address program misuse<sup>7</sup>



## 340B Background & Context

The 340B Program was established to **improve access** for uninsured, Medicaid, and other vulnerable patient populations. A primary goal was for manufacturers (MFRs) to provide designated safety-net providers with discounts so that the resulting savings could be **reinvested to improve patient care**.<sup>1</sup>

As written in Section 340B of the Public Health Service Act, 340B **participation is mandatory to be covered by both Medicaid and Medicare Part B**<sup>2</sup>:



## How 340B Works

340B covered entities (CEs) are HRSA-specified hospitals or federal grantees that predominantly serve vulnerable patients.<sup>3</sup> MFRs work with wholesalers to provide discounts of 23.1% or more on brand-name products shipped to CEs.<sup>\*\*</sup><sup>2</sup>



**Wholesalers** buy product from MFRs and sell it at 340B pricing to CEs; wholesalers also collect the difference between their purchase price and 340B price (i.e., chargebacks) from MFRs.

Other entities can also be involved in the selling and purchasing of 340B product:



**Contract Pharmacies (CPs)** have arrangements with CEs to help dispense their 340B product.



**Third-Party Administrators (TPAs)** have arrangements with CEs (and are often PBM-owned). They flag pharmacy claims as 340B if prescribed by CE-affiliated HCPs. The TPA then requests product replenishment and 340B chargeback with the wholesaler for flagged 340B claims.

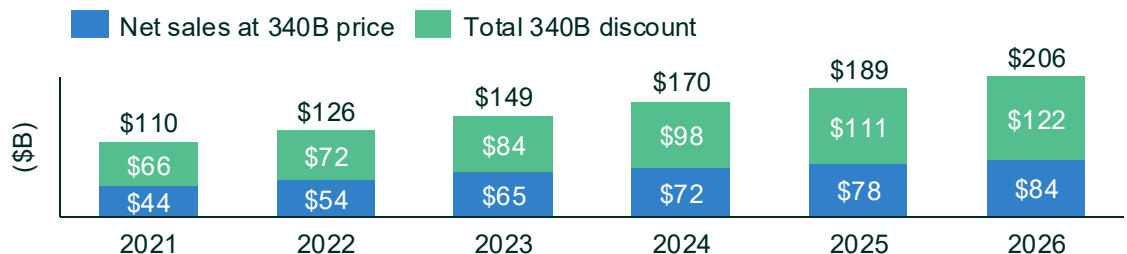


## 340B Growth & Impact

340B has become the **second largest federal prescription drug program** due to<sup>1</sup>:

1. Rampant rise in CP utilization
2. Program misuse; this includes PBMs invoicing MFRs for additional rebates on 340B claims and CEs illegitimately expanding their 340B footprint for greater savings<sup>\*\*\*</sup>

### Forecasted Growth of Gross and Net 340B Sales<sup>4</sup>



In recent years, manufacturers have taken various approaches to manage rising 340B exposure, such as **policy changes** restricting CP utilization, **data scrubbing** for duplicate discounts, and **legal/judicial action** calling for more explicit government protections against program misuse.

<sup>\*</sup>340B eligibility is updated annually <sup>\*\*</sup>340B ceiling price is AMP minus URA, URA is  $\geq 23.1\%$  for most brands <sup>\*\*\*</sup>Program misuse includes 340B chargebacks on claims the manufacturer is paying rebates on (duplicate discounting), multiple chargebacks for the same 340B claim, and 340B chargeback volume inflation through M&As or dispensing at non-compliant child sites Sources: <sup>1</sup>"The 340B Program" Janssen, 2022, <sup>2</sup>"340B Drug Pricing Program Overview", 340B Health, 2024, <sup>3</sup>"340B Eligibility" HRSA, 2024, <sup>4</sup>"340B Program at a Glance" BRG, 2024, <sup>5</sup>"340B Manufacturer Updates" AmerisourceBergen, 2025, <sup>6</sup>"Exploring the evolution of 340B contract pharmacy policies" ZS, 2024, <sup>7</sup>"J&J gives up controversial plan for 340B rebates..." Fierce Healthcare, 2024