

# A Contract Pharmacy's Guide to Navigating 340B Manufacturer Restrictions

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# Disclosure Statement

- Jason Martinez has no relevant financial relationship(s) with ineligible companies to disclose.  
*and*
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

# Learning Objectives

At the completion of this activity, the participant will be able to:

1. Review the current landscape regarding restrictions on 340B pricing under contract pharmacy arrangements and limited exceptions
2. Describe strategies covered entities use to reduce the negative impact of manufacturers' restrictions on contract pharmacy
3. Review the process for designation of contract pharmacies.

# 340B Program Intent

"To permit covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"

-H.R. Rep. No. 102-384 (II), at 12 (1992)

# Community Health & Wellness

## Partners

- Federally Qualified Health Center
- Serve ~12,000 unique patients annually
- 4 medical centers, 1 mobile health center, and 4 school based health centers

## Services:

- Primary Care
- Behavioral Health
- Population Health
  - Clinical pharmacy, Nursing, Dietary

# 340B Pricing Overview

- Federal program requiring manufacturers to provide discounted prices on medications to certain health care providers
  - Manufacturers that participate in the Medicaid Drug Rebate Program must also offer their drugs through the 340B Program
  - 340B covered outpatient drugs are defined in Section 1927(k)(2) of the Social Security Act
  - Eligible providers must comply with program requirements

# Covered Outpatient Drugs

- Section 1927(k)(2) of the Social Security Act
  - Outpatient drugs
  - Over-the-counter drugs (with prescription)
  - Clinic-administered drugs
  - Biologics/insulin

# 340B Entity Eligibility

- Hospitals
  - Disproportionate Share Hospitals (DSHs)
  - Children's Hospitals
  - Cancer Hospitals
  - Sole Community Hospitals
  - Rural Referral Centers
  - Critical Access Hospitals



# 340B Entity Eligibility

- Non-Hospital Entities
  - Federally Qualified Health Centers (FQHCs)
  - FQHC “look-alikes”
  - State-operated AIDS drug assistance programs
  - Ryan White clinics, tuberculosis clinics
  - Black lung clinics
  - Title X family planning clinics
  - Sexually transmitted disease clinics
  - Hemophilia treatment centers
  - Urban Indian/Native Hawaiian clinics

# 340B Savings

- Entities save on drug costs by purchasing 340B drugs at a reduced price for eligible patients
  - Example: physician administers drug to 340B eligible patient at an outpatient clinic

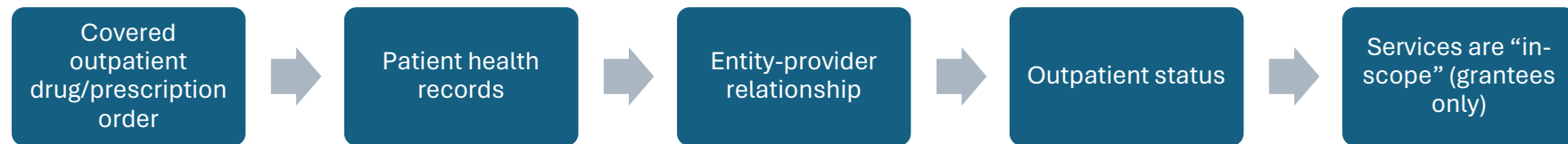
$$\begin{array}{r} \text{Non-340B cost: } \$100 \\ \text{-340B cost: } \quad \underline{\$50} \\ \text{\$50 savings} \end{array}$$

- Best practice: \$50 is reinvested into entity services

# 340B Compliance

- Prevent diversion to ineligible patients
  - To be an eligible patient, the entity must have records of that individual's care delivered by a health care professional and maintain responsibility of that care
  - Services must be more than dispensing
- Medicaid duplicate discount prohibition
  - 340B statute defines that an entity cannot bill Medicaid for a 340B drug that Medicaid also requests a rebate from the manufacturer

# 340B Patient Definition



# Case Study

- Audit Checklist
  - Eligible patient of covered entity
    - Documented in health record
    - Confirmed health care service and provider
    - Outpatient Status
    - Consistent with scope of grant
- Patient: Jane Doe
- Rx: Amoxicillin 500mg TID
- Quantity: 21
- Date: 1/5/24
- Physician: Jim Johnson, MD

# Case Study

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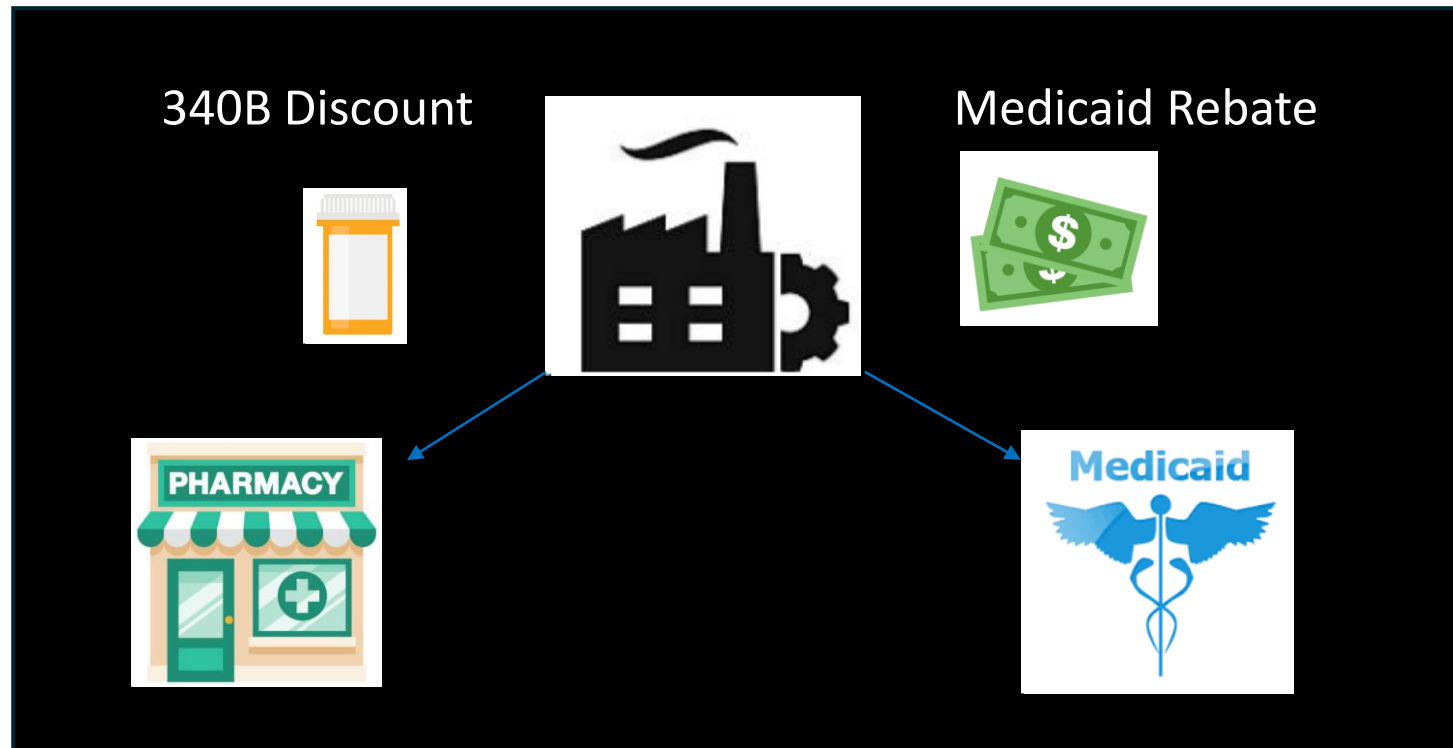
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- Quantity: 21
- Date: 1/5/24
- Physician: Jim Johnson, MD

## Health Record Information

Jane Doe ✓  
Rx: Amoxicillin 500mg TID ✓  
Date: 1/5/24 ✓  
Physician: Jim Johnson, MD ✓  
Encounter: FQHC Clinic ✓

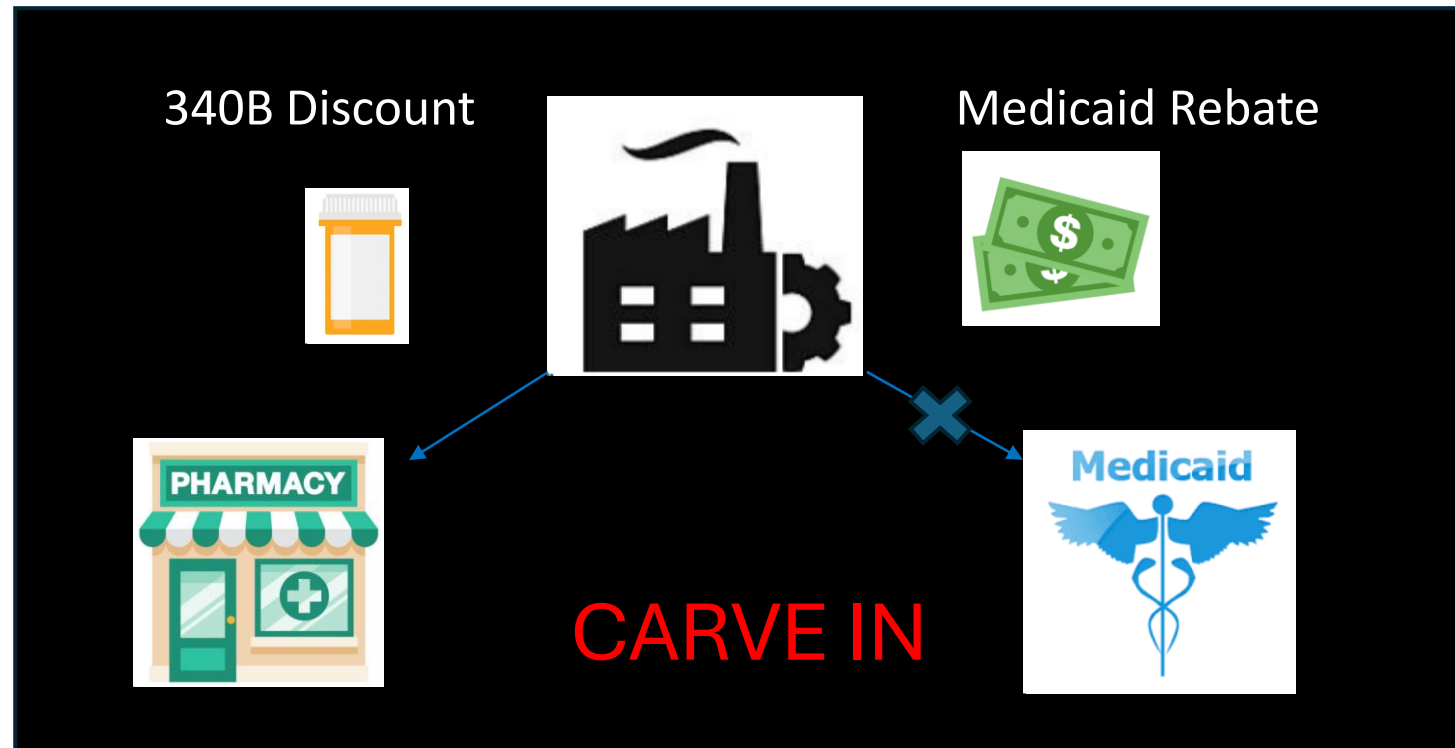
# 340B Duplicate Discounts

- A duplicate discount occurs when a manufacturer sells a product to a covered entity at a 340B discount, but then pays a rebate to Medicaid for that same specific product



# 340B Duplicate Discounts

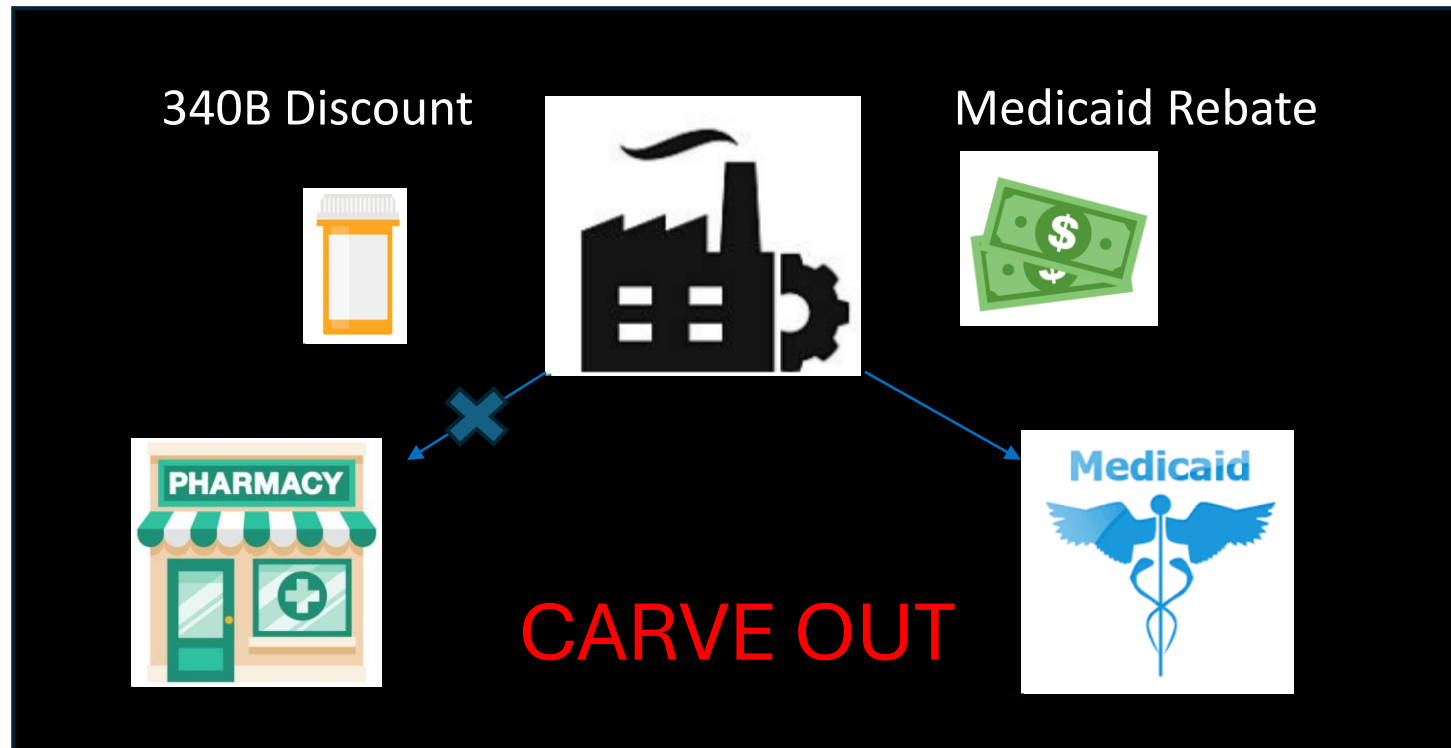
- Covered entity has purchased drugs for Medicaid patients at upfront 340B Discount = Medicaid cannot seek rebate





# 340B Duplicate Discounts – Contract Pharmacies

- Covered entity has purchased drugs for Medicaid patients without an upfront 340B discount (non-340B account) = Medicaid seeks rebate from manufacturer



# Contract Pharmacy Arrangements

- 1996: Health Resources and Services Administration (HRSA) issues guidance that authorized covered entities to enter into a contract pharmacy arrangement with a single third-party contract pharmacy
  - Utilize a Ship-To/Bill-To arrangement
- 2010: HRSA issues revised guidance permitting unlimited contract pharmacy arrangements

**Third Party\*  
Insured  
Rx Claims**

Total Rx Claim Reimbursement (third party rate + patient copay)  
- Fees (Pharmacy dispense fees, TPA admin fees, etc.)  
- 340B *discounted* drug ingredient cost  
= Savings for entity



**340B  
Savings**



**Rx Cash Discount Program**  
1. "Pass Through" Cash Discount  
2. Subsidizing



**ENTITY**

- Reach more patients
- Existing service expansion
- New service initiatives

# 340B Savings - Contract Pharmacy

- Entities save on drug costs by purchasing 340B drugs at a reduced price for eligible patients
  - Example: physician prescribes Drug A to a 340B eligible patient at an outpatient clinic

Non-340B cost: \$100

-340B cost: \$50

\$50 savings

Insurance reimbursement: \$110

# 340B Savings - Contract Pharmacy

- Contract pharmacy agreement states that covered entity will keep 75% of revenue

$$\begin{array}{r} \text{Non-340B cost: } \$100 \\ \text{-340B cost: } \underline{\quad \$50 \quad} \\ \text{\$50 savings} \end{array}$$

Insurance reimbursement: \$110

- Contract pharmacy normal profit would have been \$10
- **340B profit to Contract pharmacy through covered entity: \$15**

# Manufacturer Restrictions

- Starting in 2020, the first drug manufacturer announced restrictions on access to 340B pricing in the contract pharmacy setting
- AstraZeneca dictated that 340B pricing would not apply at contract pharmacy unless covered entity did not have their own pharmacy
- Sanofi and Novo Nordisk imposed similar rules unless the covered entity furnished pharmacy claims data
- May 2021: HRSA sent warning letters to AstraZeneca, Sanofi, and Novo Nordisk, forcing them to resume shipping to all pharmacies which resulted in a suit filed on behalf of the manufacturers.
  - District courts ruled that HRSA could not enforce its 2010 contract pharmacy policy

# Manufacturer Restrictions

- Now, more than 20 drug companies – AbbVie, Amgen, AstraZeneca, Bausch Health, Bayer, Biogen, Boehringer Ingelheim, Bristol Meyers Squibb, Eli Lilly, EMD Serono, Exelixis, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Sanofi, UCB, and United Therapeutics

# Manufacturer Restrictions

- Types of restrictions
  - Refusing 340B pricing for drugs dispensed at contract pharmacies
  - Allow pricing if entity submits contract pharmacy claims data
  - Some manufacturers are refusing to ship 340B-priced drugs to contract pharmacies regardless of data submission
    - Sometimes this is limited to a certain type of entity
  - Some are putting limits on where contract pharmacy can be located (i.e. within 40 miles of parent site)



# Manufacturer Restrictions

- Patients lose access to preferred pricing and may need to utilize a different medication
- Pharmacists can create charts and tables to highlight which options may be available for patients
  - Offer clinically therapeutic options
  - Maximize use of other savings options for patients
    - \$4 lists, manufacturer assistance programs, other cash programs

# Lost 340B Savings Hurts Patients

- A 340B Health report found the following:
  - Safety-net hospitals lost \$1.1 billion in 340B savings in 2021 alone
  - 1/3 of critical access hospitals have been forced to cut services
  - 2/3 of hospitals with impacted drug assistance programs report delayed access to medications
  - 90% of hospitals expect to have to cut services

# Contract Pharmacy Strategies

- Ensure that your covered entity is taking advantage of options available to them
  - Single contract pharmacy
  - Data submission through 340B ESP Platform

# Contract Pharmacy Strategies

- 340B ESP Platform
  - Online portal operated by Second Sight Solutions (private company)
  - June 2020: Merck becomes first manufacturer to utilize
- Reporting requirements
  - Covered entity uploads prescription data twice monthly
  - Some entities do not have access to all information needed to upload or the resources to complete
- 340B ESP Registration
  - [340besp.com/register](https://340besp.com/register)
- Work with Third Party Administrator (TPA) to gather data
  - Rx Number, Date of Service, Prescribed Date, NDC, Quantity, Covered Entity ID
- Monitor process

## Legislation – SB 263

- Passed in 2020 – prohibits insurance companies and pharmacy benefit managers from imposing discriminatory pricing or other contract terms
  - Discriminatory contract absorbs all or a part of the savings generated by 340B entity
  - One example was a PBM that wanted to reimburse at 30 times less for the same exact brand name drug because it was a 340B pharmacy

## Legislation – PROTECT 340B Act (HR 2534)

- Similar to SB 263 and has been introduced in the House of Representatives by Reps. Johnson and Spanberger
- Adds language about patient freedom of choice
- Require HRSA to codify their 2010 contract pharmacy guidance into regulation
- Would apply to all states

# Summary

- The 340B Drug Pricing Program is a federal program that requires participating manufacturers to provide discounted prices on medications to certain healthcare providers
- Eligibility of covered entities is defined in statute
- Entities save on drug costs by purchasing 340B drugs at a reduced price for eligible patients
- Contract pharmacies are a vital part of the program but are having more restrictions placed from manufacturers
- Compliance is a cornerstone of the program

# Where to Find Help - 340Bpvp.com





# References

- Apexus ([340Bpvp.com](http://340Bpvp.com))
- Office of Pharmacy Affairs ([340bopais.hrsa.gov/home](http://340bopais.hrsa.gov/home))
- 340B Health ([340bhealth.org](http://340bhealth.org))
- 340B ESP ([340besp.com](http://340besp.com))
- SB 263 ([legislature.ohio.gov/legislation/133/sb263](http://legislature.ohio.gov/legislation/133/sb263))
- PROTECT 340B Act ([congress.gov/bill/118th-congress/house-bill/2534](http://congress.gov/bill/118th-congress/house-bill/2534))

# Need More Information?

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