



The Dangers Facing 340B

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Legal

- ❖ This presentation should not be considered as legal advice.
- ❖ PHV strongly recommends contacting your legal team for advice on how to proceed



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Prairie Health Ventures

- ❖ Healthcare Alliance of 56 hospital/owners
- ❖ Owned/Directed by hospitals since 1975
- ❖ Our vision is to **sustain the independence** of hospitals in our region through an alliance which improves costs and business performance



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Agenda

- ❖ 340B Overview
- ❖ 340B: By The Numbers
- ❖ The Issue: Manufacturer Restrictions
- ❖ Manufacturer Restrictions: By The Numbers
- ❖ Designations/Submitting Data Considerations
- ❖ Retail Pharmacy Considerations
- ❖ Predictions
- ❖ Other 340B Considerations



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340B: Overview

- ❖ Started in 1992 allowing Covered Entities (CE) to obtain outpatient drugs at significantly reduced prices
 - Later expanded to more Entity Types, such as Critical Access Hospitals (CAH), under the ACA
 - Manufacturers participating in Medicaid must provide 340B pricing to CE's
- ❖ **Goal:** Enable CE's to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services
 - No Requirements on how a Hospital can use 340B Savings
- ❖ The 340B Program costs taxpayers **\$0**
- ❖ Contract Pharmacy: CE's can expand their 340B network to retail pharmacies (independent, chain, specialty, owned, etc.)
 - Written as guidance and **not** under statute



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340B: By the Numbers

- ❖ 340B Health's 2020 Survey*:
 - **3/4ths** of 340B CAHs rely on 340B savings to keep doors open
 - **9/10** CAH's use savings to increase access for patients with low incomes or live in rural areas
 - **8/10** CAH's use savings to improve medication adherence

https://www.340bhealth.org/files/340B_Health_Survey_Report_2020_FINAL.pdf

- ❖ Air 340B Report 2020:
 - From 2010-2020, CP participation grew 4,228%
 - 8,000+ CE's have 112,000 CP agreements (75% stemming from Disproportionate Share or Children's Hospitals)
 - 75% of CPs are larger retail chains (CVS, Walgreens, Walmart, etc.)

<https://340breport.com/wp-content/uploads/2020/12/AIR340B-Report-on-the-Impact-of-Growth-in-340B-Contract-Pharmacy-Arrangements.pdf>



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The Issue: Manufacturer Restrictions

- ❖ **What:** 14 Manufacturers pulled 340B pricing for Contract Pharmacy Relationships
- ❖ **WHO:** Eli Lilly, Sanofi, AstraZeneca, Novartis, Novo Nordisk, United Therapeutics, Boehringer Ingelheim, Merck, UCB, Amgen AbbVie, Bristol Myers Squibb, Pfizer, Johnson & Johnson
- ❖ **When:** Eli Lilly became the first in September 2020 with J&J being the latest to join in starting May 3rd 2022.
- ❖ **Where:** All non-owned contract pharmacies
- ❖ **How:** Contract Pharmacy language written as guidance which HRSA cannot enforce
 - Manufacturers send “eligibility files” to wholesalers who either removes product from drug catalog entirely OR puts in WAC pricing
- ❖ **Why:** Manufacturers pay rebates to PBMs except for 340B claims. Currently, no way to prove which claims are 340B eligible, so PBMs charge rebates on all claims
 - Manufacturers call this a “duplicate discount”



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Manufacturer Restrictions: By the Numbers

Manufacturer	% of CP Monies
Eli Lilly	8%
Sanofi	6%
AstraZeneca	8%
Novo Nordisk	19%
Boehringer Ingelheim	10%
Merck	6%
UCB	1%
Amgen	1%
AbbVie	2%
BMS	14%
J&J	6%
Total	81%

*Novartis not included due to distance restrictions (40 Miles)

**United Therapeutics & Pfizer not included due to no-impact



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Manufacturer Restrictions: By the Numbers Cont.

- ❖ 68% of Nebraska CAH's 340B Monies come from Contract Pharmacy
- ❖ 340B Health March 2022 Report (data from December 2021):
 - **\$448,000** median annualized loss of CP Savings
 - **1/3rd** of CAHs report the loss of CP monies puts their hospital at risk of closure
 - Reported cuts CE's would make due to restrictions:
 - **80%** cuts to patient care services
 - **74%** cuts to services in underserved areas
 - **72%** cuts to targeted programs to serve patients with low incomes that live in vulnerable or rural areas
 - **50%** cuts to staff in terms of layoffs

https://www.340bhealth.org/files/340B_Health_Survey_Report_2021_FINAL.pdf



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Designations/Data Submissions

- ❖ Eli Lilly, Novo Nordisk, and AstraZeneca have Designation Form (can designate 1 pharmacy if CE doesn't own retail pharmacy)
 - May need to "renew" annually
- ❖ 340B ESP:
 - Other Manufacturers: Can designate 1 Pharmacy w/o the need to submit data (if CE doesn't own Retail Pharmacy)
 - Can update Designations 1 time annually
 - Submitting Data:
 - Upload 2x a month
 - Data must be from a "Relevant Time Period"
 - ESP wants corrections if made on already submitted claims



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Designations/Data Submissions continued

❖ 340B ESP cont.:

- Sanofi & Merck added additional rules around “eligibility timeframe” where a drug would become ineligible to purchase after X days of submitting data.
- Data Submissions Concerns:
 - HIPPA concerns
 - Eventual PBM Reimbursement Reduction
 - Burdensome
 - Other Uses for Data/Manufacturer Audit Risk

❖ Healthcare Industry Number (HIN) required to designate Retail Pharmacy



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Retail Pharmacy Implications

❖ For Non-Designated Pharmacies:

- Dispense Fees should be reviewed
 - Especially those with Flat Fees
- Rebates:
 - Retail Pharmacy's rebates are determined by the Brand/total spend
 - Exclusion of high dollar brand NDCs will cause retail pharmacy rebates to decrease
 - PSA's must be reviewed to ensure Pharmacies are not under water due to 340B program.
 - Switching to Brand Only may mitigate these impacts

❖ For Designated Pharmacies:

- Chain Pharmacies: Could go back and requalify historical claims to capture lost revenue, but not more than a few months
- Non-Chain Pharmacies: Recommend qualifying going forwards (not historically)
 - Going back could cause influx in unwanted product and cashflow



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What Will the Future Hold?

1. Additional Manufacturers will restrict program forcing CE's to commit to one pharmacy or submit data
 1. Pharmacy hour reduction/closures?
 2. Hospitals open their own retail pharmacy
2. Near Future: 340B Stakeholders will discover true value of Manufacturer/PBM rebates
 1. As PBM's try to recoup rebates, will they raise premiums or reduce reimbursement?
3. 1+ Years: Congressional acts to reform 340B:
 1. Transparency
 2. Patient definition
 3. Orphan Drugs?
4. 2+ Years: If no legislation, Supreme Court Ruling on issue



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Other 340B Considerations

- ❖ Resolution to Manufacturer Restrictions:
 - Unblocking of restrictions could cause massive supply chains disruptions of life saving drugs
 - Manufacturer repayments may be impossible to untangle:
 - Penny Pricing forever?
 - Massive Credit Rebills? (how does this work with the new DSCSA rules)
 - CE/CP Cash-flow resolutions
- ❖ Fight for Orphan Drug 340B Pricing for all
 - 48% of CAH drug spend solely from orphan drugs
 - Removal of Amgen and J&J orphan "340B-Like" prices cause 11% increase in annual drug spend at CAH's
- ❖ 340B Medicare Reimbursement Reductions
 - Supreme Court Case Pending
- ❖ 340B "Clearing House" Debate
 - Creation of a central clearing house to decide eligibility of claims. Change 340B to rebate model



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Prairie Health Ventures-- 340B Management

- ❖ TPA Agnostic
- ❖ No Requirement to be a PHV Member
- ❖ 1 on 1 Assistance
- ❖ Personalized program to meet your hospital's needs
- ❖ Increase in 340B Network
- ❖ Increase in Compliance Rates



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We make it easy for you to take full advantage of our 340B managed services program. We assist with:

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- Providing financial and compliance analytics
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Questions?

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