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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*:
 - **3/4th** 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
 - Manufactures 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 Manufactures: 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



Take full advantage of your 340B opportunity!

Let us help you optimize your 340B Program.

The 340B Drug Discount Program requires drug manufacturers to provide outpatient medications to eligible healthcare organizations at significantly reduced prices, allowing you to stretch scarce resources and reach more patients.

PHV has been educating and helping Critical Access Hospitals leverage the 340B Program for over five years.

By enrolling in the 340B Program you gain:

- Significant savings on outpatient medications
- New revenue from contract pharmacies
- Expanded opportunities for patient care

We help members succeed through collaboration. Prairie Health Ventures (PHV) is a leading alliance of hospitals and non-acute healthcare organizations in the Midwest. Member owned and directed, we have a growing membership of 34 hospitals and over 500 healthcare and business entities across the region. We are actively engaged in a variety of business activities aimed at providing solutions to improve access, quality and business performance.

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

- Facilitating contract pharmacy negotiations
- Providing financial and compliance analytics
- Registration on the OIRA website
- Setting up software for virtual inventory management
- Providing ongoing educational opportunities
- Establishing policies and procedures
- Building strong, long-term relationships with 340B vendors
- Providing one-on-one continued compliance support
- Maximizing 340B program opportunities

Contact us to expand patient care with 340B savings!

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Questions?



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