

# 340B Under Attack – A Look at Recent Developments

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October 21, 2020



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Community Health Centers®

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# DISCLAIMER

- › Information in this presentation is as of October 21<sup>st</sup>
- › NACHC and others are reviewing current activities & looking to provide further guidance & insight as new information is released
- › Stay tuned for further developments



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# Strategic Planning Considering 340B Uncertainties

# Introduction

- › New 340B rules, regulations, strategies are being considered frequently
- › What will the 340B program look like in future years?
- › How can health centers plan for the future with so much uncertainty?
- › Is it possible that the potential changes in the 340B pharmacy program will not come to fruition, but today we would like to explain why hoping for that outcome & doing nothing to plan may not be the best course of action



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# Why Health Centers Don't Financially Plan?



# 4 Keys to Financial Success

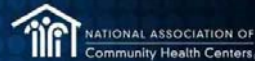
1. Having an accurate picture of where you are financially at an given moment.
2. Knowing your market.
3. Understanding what the main financial drivers of your health center are.
4. Having a financial planning process in place.

# 4 Keys (with 340B Focus)

1. Having an accurate picture of where you are financially at an given moment. (How much money are you making from contract pharmacy, in-house, etc., site specific information, etc.)
2. Knowing your market (where does the community get their meds, what is your pharmacy use rate, any gaps)
3. Understanding what the main financial drivers of your health center are. (340B savings and the overall bottom line)
4. Having a financial planning process in place. (what do you do if contract pharmacy goes away, etc.)

# FOM/IT

Financial, Operations Management / Information Technology  
2020 Virtual Conference & Expo  
October 20-21, 2020



Resiliency, Innovation and Transformation:  
Community Health Re-Imagined

## 340B Under Attack: A Look at Recent Developments

Sue Veer, MBA  
President and CEO  
Carolina Health Centers, Inc.



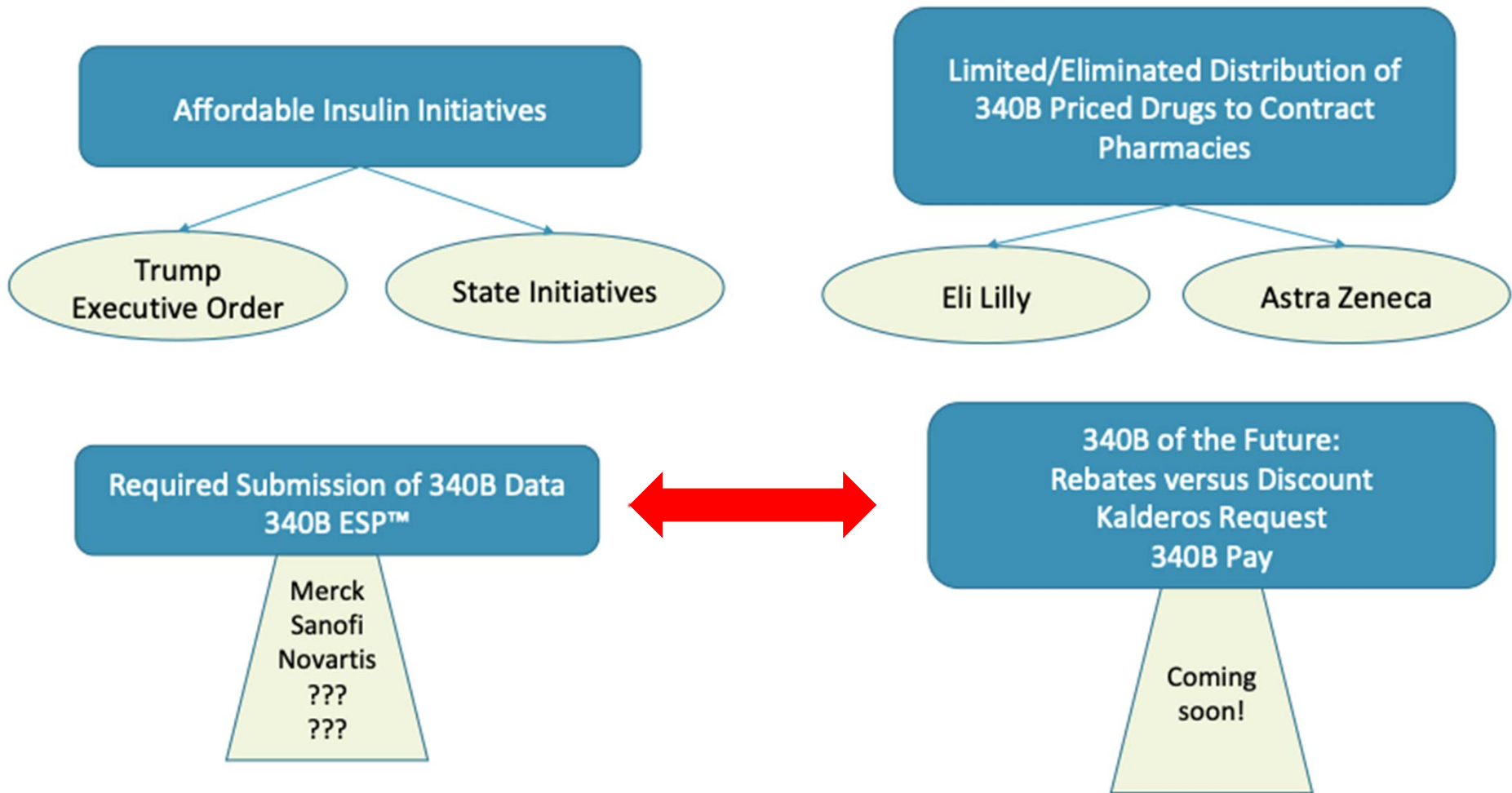
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# As if 2020 wasn't interesting enough...

*Beginning in July the 340B Program erupted with the source of the eruption coming from an unanticipated direction and having the potential to end the program as we know it.*



# A View of the Landscape:



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## Trump Executive Order

- Conditions HRSA 330 grant funding on the provision of insulin and epi-pens at the 340B price plus a reasonable administrative and dispensing fee
- Proposed to be applicable to patients at or below 350% FPL
- Unnecessary and inflammatory
- Potential and significant administrative and operational burden
- Potential confusion for patients

## Limited/Eliminated Distribution to Contract Pharmacies

- **The obvious:**
  - Loss of access for patients
  - Loss of revenue for the health center = reduced services for the in the community
- **The not so obvious:**
  - Deterioration in clinical outcomes
  - Deteriorating performance on HEDIS measures and MLR
  - Negative impact on the delivery system
- **The dominos are lined up to fall**

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## “Required” Submission of 340B Claims Data

- Stated purpose is so they can **prevent ineligible rebates** - not just under Medicaid , but also Medicare and private insurance
- 340B ESP™ trainer: *“You have to remember that the manufacturer’s view of duplicate discount is different than that of a Covered Entity”*
  - Intent is not to harm CEs but to prevent ineligible rebates to 3<sup>rd</sup> party payers
  - That premise only works if coupled with statutory protection against discriminatory reimbursement practices
- Concerns about Terms of Use
- Interesting question: Is it extortion?

*The 2020 Great Data Heist*



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## The New Model – Kalderos Request/340B Pay

- Purchase at WAC and request a rebate following the sale
- Claims to “streamline the way 340B covered entities **request** and receive their discounts and eliminates the risk of supplicate discounts”
- Manufacturers signing up for Kalderos Request/340B Pay (to be announced after go-live on September 8<sup>th</sup>) WILL NOT offer any up front discounts on their products in ANY pharmacy model
  - Entity owned in-house pharmacies
  - Clinic administered drugs and devices
  - Contract pharmacies
- Three pronged risk to health center viability:
  - Dual inventory
  - Negative impact on cash flow
  - Positioning health centers to be in competition with PBMs and payers for rebates
- And, as a bonus they get all your point-of-sale data!



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WORST CASE  
SCENARIO



Elimination of the 340B Contract  
Pharmacy Model

Loss of all savings on Medicare  
and commercial 3<sup>rd</sup> party  
covered prescriptions

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# Responses and New Developments

- PhRMA letter to Rep. Katie Porter
  - No big surprise



Executive Order

Attack on Contract Pharmacy

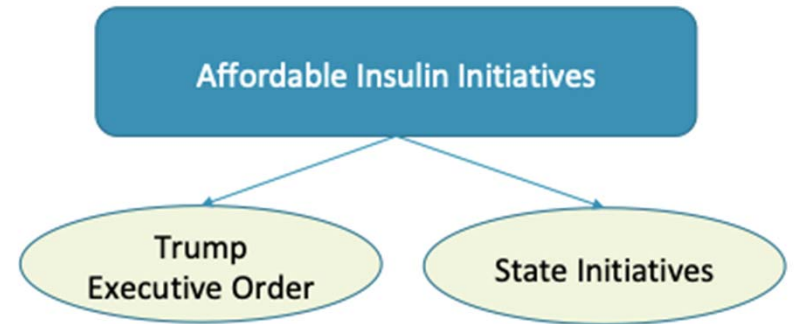
The Great Data Heist

The Rebate Model

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# New developments

- Friday, September 17<sup>th</sup>: publication of Interim Final Rule was imminent
- Monday, September 20<sup>th</sup> OMB suddenly cancelled all meetings scheduled to get input on this issue – assumption that Interim Final Rule would be announced
  - In effect immediately upon publication
- Wednesday, September 23<sup>rd</sup> OMB shifts to a Proposed Rule (aka NPRM)
  - HHS proposal with opportunity for public comment
- We were heard!
- NACHC draft comments are underway

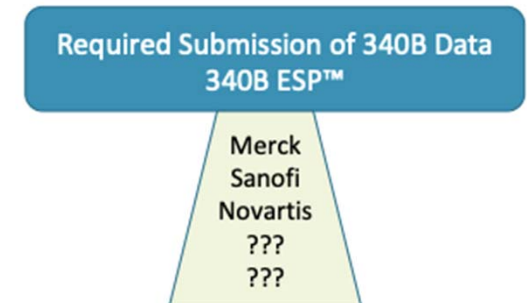
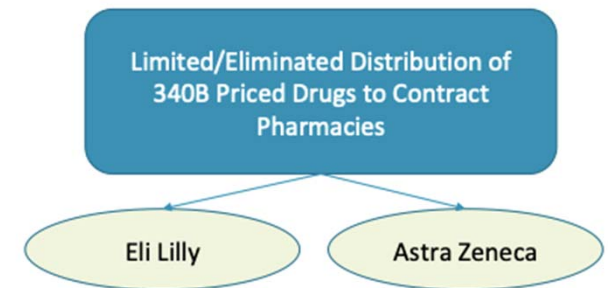




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# New developments

- Last week: Eli Lilly contract pharmacy restrictions in effect and waiting for the other dominos to fall
- Tuesday, September 21<sup>st</sup> General Counsel for HHS issues letter to Eli Lilly
  - Presumptive
  - Insensitive and rapacious
  - Incorrect about FOIA protection
  - Potential consequence of knowingly violating a material condition of the program
- Not a definitive statement that Lilly's actions to be illegal, but a "shot across the bow" that may act as a warning to those manufacturers waiting in the wings
- Astra Zeneca expanded carve-in allowance: a concession or an administrative nightmare
- Others standing firm with scattered rumors of sudden price changes – some are taking liberties with the door left open



Let's talk about  
CRITICAL MASS...



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# Response Strategies:

- Administrative
- Legislative “fix”
- Legal Action
- Adaptation
- Contingency Planning



- Compile the data to evaluate the impact
  - Patient impact
  - Financial/service impact
  - Remember the price tag argument?
- Consider changes in prescribing patterns
  - Brief your providers
  - Switch patients as possible to drugs that are affordable AND accessible
  - Consider standing orders and automatic substitutions
- In the case of no in-house pharmacy:
  - Select single contract pharmacy options strategically
  - Evaluate feasibility of launching an **entity owned\*** pharmacy
- If you have in-house/entity owned pharmacy:
  - Develop strategies for increasing in-house capture rate
  - Consider delivery options to expand your pharmacy's reach
- Contingency planning
  - Have a clear understanding of the services and programs supported by your pharmacy contribution margin
  - Identify alternate sources of funding and/or necessary operational adjustments

## Considerations for Adaptation and Contingency Planning

# Looking for Details on Recent Developments?

- Do you need a quick reference for the various threats now facing 340B? E.g., which manufacturers are making data demands? What the status of the Executive Order?
- A chart is included as Tab 3 in the “mega-spreadsheet” of Federal funding sources for COVID-19
- Important updates are highlighted in bright green for at least 14 days

<https://docs.google.com/spreadsheets/d/1DfM-aU42TMaByT5YPOo0DAVWgT6CyIAo67j4FWj9dho/edit#gid=1029484203>

	#1. Exec Order	#2. Demands for Extensive Data	#3. Refusal to Ship 340B Rx to Contract Pharmacies (CPs)	#4. Moving from Discounted Price												
<b>Summary</b>	Requires FQHCs to sell insulin and EpiPens to low-income uninsured patients at the 340B price	Requires FQHCs to submit data on all of the manufacturer's drugs that were purchased at 340B price and dispensed via contract pharmacies	Manufacturers refusing to ship any of their drugs purchased at the 340B price to contract pharmacies. (CHCs without an in-house pharmacy may be permitted one CP)	Currently CHCs to purchase discounted price. Under full price upon request to a third party send them a rebate + discount												
<b>Impact on Discriminatory Contracting</b>	No direct impact	MAJOR - FQHCs will likely lose the ability to retain 340B savings on all Rx dispensed to insured patients (Medicaid, Medicare and privately-insured)	No direct impact	MAJOR - FQHCs will likely lose 340B savings on insured patients (Medicaid, Medicare and privately-insured)												
<b>Other Major Concerns (beyond discriminatory contracting)</b>	Hassle due to need to: 1. track changing prices to ensure patient charged the correct amount., 2. switch patients among various Rx to maintain affordability.	1. Burdensome to collect & submit data. 2. Several legal risks to providing the requested data.	1. Loss of patient access to Rx at CPs. 2. Loss of savings from Rx dispensed at CPs.	1. Cash flow issues due to full cost of Rx. 2. Will lose 340B savings by giving power to decide if any savings												
<b>Affects Contract Pharmacies (CPs)?</b>	Yes	Yes	Yes	Yes												
<b>Affects In-House Pharmacies?</b>	Yes	Not yet, but could easily be extended to in-house	No	Yes												
<b>Applies to other types of 340B providers?</b>	No - limited to FQHCs	Yes - applies to all 340B providers	Yes - applies to all 340B providers	Yes - applies to all												
<b>Status</b>	Not yet in effect; awaiting reg or guidance from HHS	CHCs are being pressured by manufacturers to sign up	Currently in effect for Eli Lilly; Oct. 1 effective date for other manufacturers	Scheduled to go into effect												
		<table border="1"> <thead> <tr> <th>Name</th> <th>Effective Date</th> <th>Consequences for Non-Compliance</th> </tr> </thead> <tbody> <tr> <td>Metformin</td> <td>Aug 14</td> <td>Not specified, but will be...</td> </tr> </tbody> </table>	Name	Effective Date	Consequences for Non-Compliance	Metformin	Aug 14	Not specified, but will be...	<table border="1"> <thead> <tr> <th>Name</th> <th>Which Rx</th> <th>Effective Date</th> </tr> </thead> <tbody> <tr> <td>Metformin</td> <td>Cialis</td> <td>July 1</td> </tr> </tbody> </table>	Name	Which Rx	Effective Date	Metformin	Cialis	July 1	Unknown as of 8/27; K...
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Categories Tags

All categories  
Uncategorised

- Welcome and Introduction
  - NoddlePod Guide
- CURRENT OPPORTUNITIES for advocacy
  - Congress
    - Dear Colleague sign-on opportunities
    - Draft letters to send to lawmakers
    - Legislative Changes
    - Letters sent
  - Contract Pharmacy Restrictions
  - Exec Order/ IFR on Insulin
    - OMB Meetings on Exec Order
  - HHS Outreach
  - Legal Action
  - Media
    - Op-Eds
    - Articles by outside groups
    - Press releases
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    - Merck
  - Presentations

## Viewing posts in all categories

Add a new post

Enter search term... Search

### Filters

- No filter
- Official content
- Files
- Comments



Colleen M new

Congress 17 Sep

### House member drafting legislation to address our 3 big 340B concerns

Hi all -- I am thrilled to report that a Republican House member is currently drafting legislative language to address three of our biggest 340B challenges:

- To stop "pick-pocketing" (aka discriminatory contracting) by PBMs and private insurers.
- Make clear that manufacturers must offer 340B discounts up front, as opposed to forcing us to pay full price up front, and then apply for and wait for a rebate check to come months later.
- Make clear that manufacturers must allow 340B-priced drugs to be shipped to all pharmacies with this health centers (and other CEs) contract.

This is the first time that any Member of Congress has ever drafted legislation to address these issues, so it's an important step forward. It's too soon to start looking for legislative champions/ supporters for this language, but hopefully we'll be at that point soon. We'll keep you informed here.

14 likes 4 / 4



Harvey L new

18 Sep

Bill number and author?



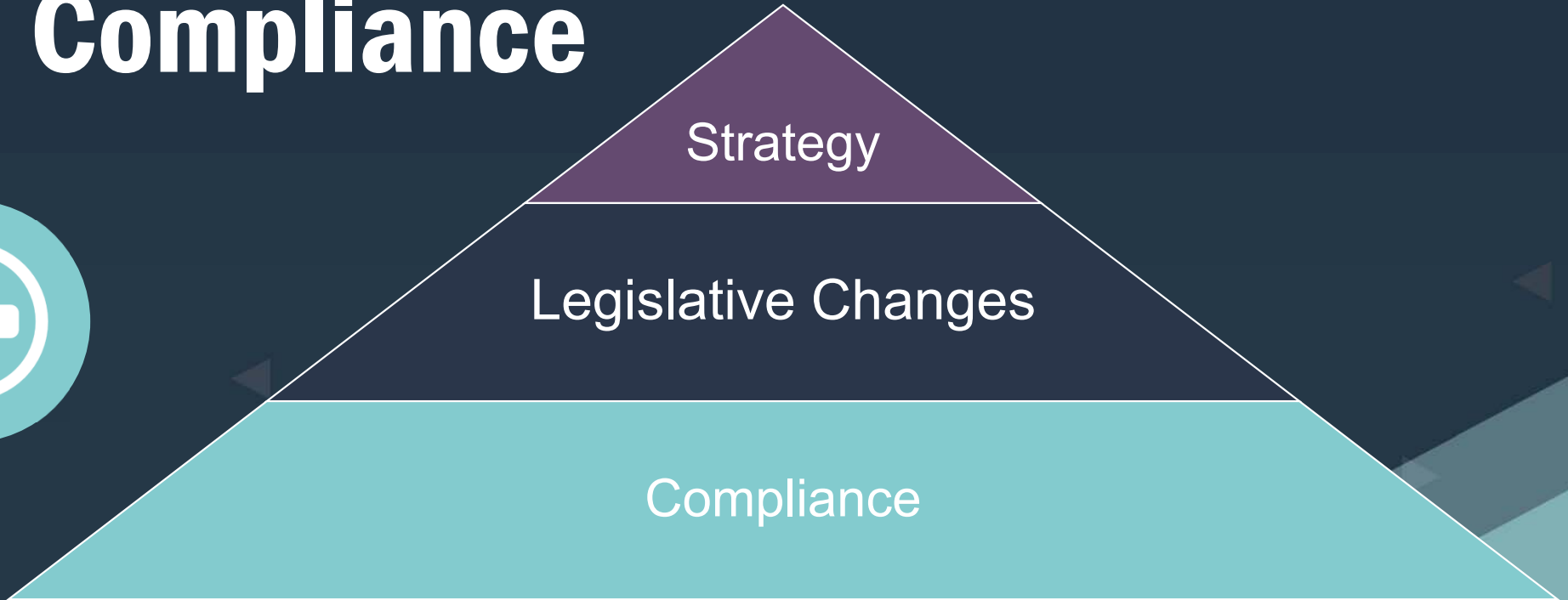
Kimberly C new

18 Sep

This is FANTASTIC news and I am hopeful that all our efforts to rally support around these major issues are reaching a culmination of some supportive legislation! The NACHC press conference this week seemed to be successful and spurred some great discussion! Thank you for your continued efforts!



# 340B Strategy and Compliance



# Diversions

## Diversions

- Drugs can only be used on an outpatient basis for covered entity's patients as defined by HRSA
- Use for other individuals constitutes prohibited diversion
- Focus on defining **"patient"** & **"covered entity"**

## What is **"covered entity"**?

- Where services are provided
- Physicians must be employed or under a contractual or other arrangement
- Entity should maintain a listing of approved 340B physicians



# Medicaid Duplicate Discounts

- › 340B laws prohibit application of both 340B price discount on front end and payment of pharmacy rebate to state Medicaid on back end for same drug claim
- › General options for covered entities
  - **Carve-out** Medicaid - from 340B drug purchases
  - **Carve-in** Medicaid - requires verifying Medicaid exclusion file is accurate in 340B OPAIS
- › Some states have been slow to establish and communicate Medicaid billing requirements and potential modifiers
- › Transition to Medicaid managed care has created confusion
  - Covered entities should have mechanisms in place to identify Medicaid MCO
  - Contract pharmacies should not “Carve-in” Medicaid FFS and should review state guidance and consult with legal on Medicaid MCO

**The responsibility for avoiding duplicate discount is on the covered entity**

# Contract Pharmacy

- › HRSA allows providers to enter into arrangements with multiple contract pharmacies to dispense 340B drugs to qualifying patients of providers
- › Covered entity is responsible for compliance and must monitor contract pharmacies
- › HRSA recommends independent audits
- › Child sites, outpatient clinics
- › Retail pharmacy split-billing software
- › Brand vs. generic
- › Do you periodically review your contract pharmacy arrangements?

# 340B Software



- › Virtual Inventory
- › Receive discounts based on the drug utilization by covered outpatients
- › Retrospective procurement is used to realize the discounts based on utilization
- › Can be used for Mixed Use and Contract Pharmacy

# 340B Software

## › Accumulator maintenance

- Crosswalk
- Utilization data sources and queries
- Purchasing trends
- Rules and filters
- Reports
- Multiple contract pharmacy split-billing vendors
- EHR billing conversions



# 340B Strategy - Approach

- › 340B Team
- › Policies and procedures
- › Documented use of savings
- › Internal monitoring
  - Medicaid BIN/PCN/Groups
  - Eligible locations
  - Contract pharmacy qualification parameters
- › Internal audit
  - Mock audit procedures
  - Frequency and sample
- › Independent external reviews
  - Operational
  - Compliance



# 340B Strategy - Opportunities

- › Contract pharmacy arrangements
- › Medicaid Carve-In
- › Clinic conversions / Child sites
- › Legislative changes
- › Registration type
- › Direct vendors
- › Biosimilars



# 340B & Telehealth

- › Covered entities seeing a rise in telehealth encounters
- › HRSA recognizes telehealth as a mode by which healthcare services are delivered
- › If a telehealth encounter meets 340B patient definition, a prescription resulting from that encounter may be 340B eligible
- › Could expand reach of covered entities and contract pharmacy arrangements
- › Recommendations
  - Outline use of telehealth within 340B policies and procedures
  - Check data feed and vendor settings for appropriate inclusion and qualification of telehealth encounters



# Recommendations/Actions

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# Action Steps



-  **Contact your Congress Person**
-  **Work with NACHC Advocacy**
-  **Monitor FAQs**
-  **Educate your Board**
-  **AICPA - Healthcare Entities Expert Panel**



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# Q&A

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# Thank You!

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