2021

Policy & Issues Forum

NATIONAL ASSOCIATION OF Community Health Centers®

SESSION PTUB2:

340B:

DEVELOPMENTS IN POLICY AND REIMBURSEMENT

TUESDAY, MARCH 16, 2021

11:30 – 12:30 PM

MODERATOR:

MATT HUNTER

PANELISTS:

SUE VEER, MBA, PRESIDENT AND CEO, CAROLINA HEALTH CENTERS

TIM MALLETT, RPH, 340B ACE, VP OF PHARMACY SERVICES, 340BASICS

Introduction: What we plan to cover in the next hour

- Quick snapshot of the 340B Program
- Pharmacy as a core component of our health center model and a high priority for NACHC and its members:
- Threats to the program that have emerged over the last 7-8 months and their potential impact
- Strategies and tools for adapting and ultimately eliminating the threats

340B Program Snapshot

Enacted in 1992, the 340B Drug Discount Program is a **federal program** that requires **pharmaceutical manufacturers** to sell drugs to **eligible providers** at a **discount**, for **outpatient** use.

"To permit eligible 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)

Take-away #1: The 340B Program is not federally funded. It is a public/private partnership.

Take-away # 2: Congress intended for the program to benefit covered entities and the patients they serve.

340B Program Snapshot

Basic implementation models:

- In-house
  - 340B only or open retail
- Contract
- Dispensary
- Open or closed formulary

Rule # 1: No drug diversion

- 340B purchased drugs may only be dispensed to patients that meet HRSA's definition of a "patient".
- 340B purchased drugs may only be dispensed to fill prescriptions that emanate from health center medical site that is registered on the OPA database.

Participation Requirements:

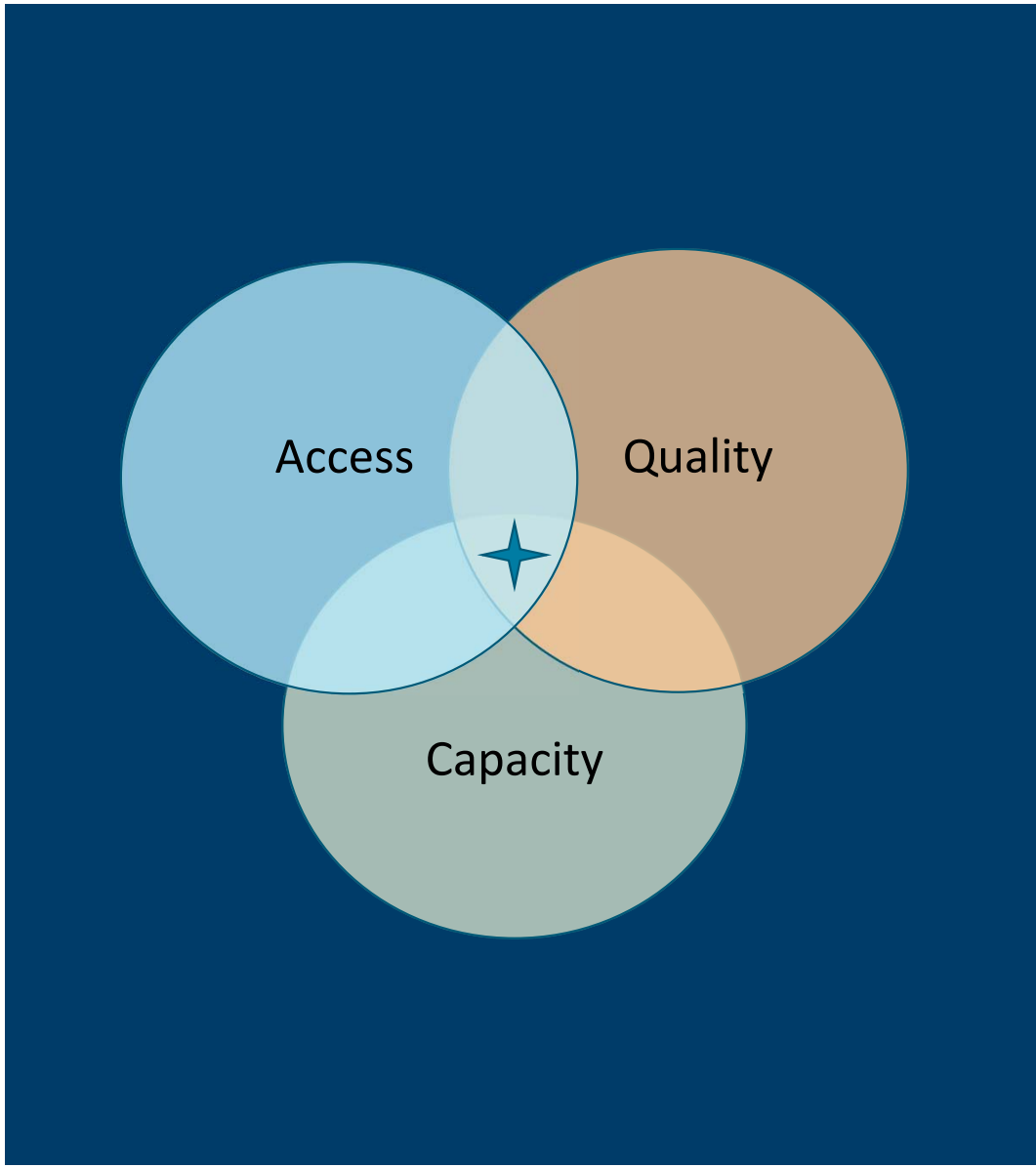
- Maintain auditable records documenting compliance with program rules:
- Register on the HRSA Office of Pharmacy Affairs Information System (OPAIS); and
- Recertify with HRSA annually.

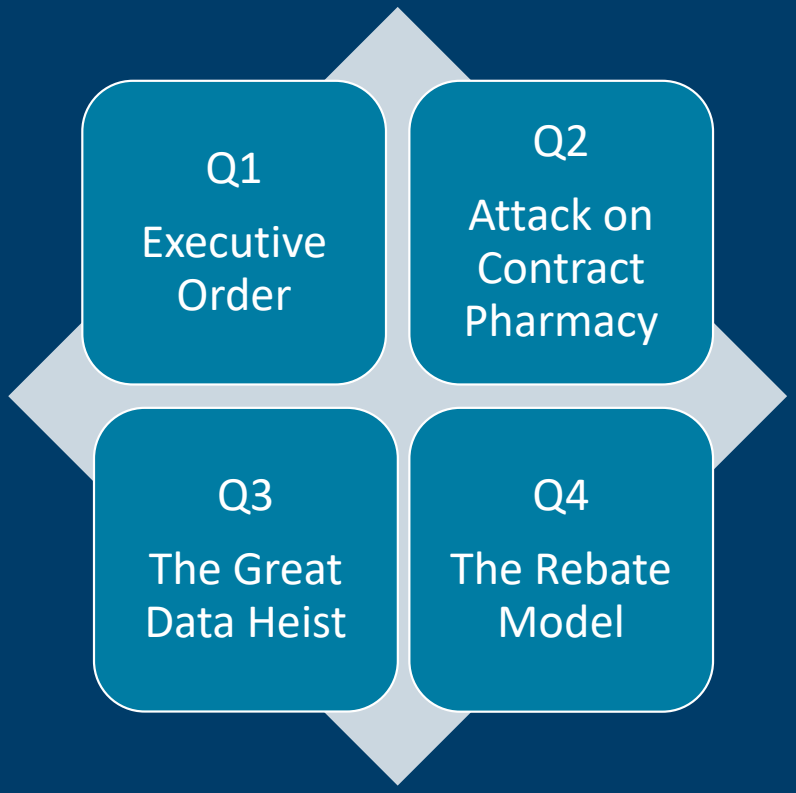
Rule # 2: No duplicate discount

- A duplicate discount occurs when manufacturers provides a 340 discount on the purchase of a drug and then pays a Medicaid rebate to the state on the same drug.
- The eligible entity is responsible for preventing duplicate discounts by carving in or carving out using the Medicaid Exclusion File.

Pharmacy services are a core component of the primary care medical home model.

The value proposition for the 340B program lies at the intersection of access, quality, and the capacity of our health care delivery system.





The 340B program has been and continues to be under attack on 4-fronts since July 1, 2020 with the potential harm largely falling into two categories:

1. Elimination of the contract pharmacy option; and
2. Increased potential for disparate treatment of 340B eligible entities.

Outlier: Trump Administration Executive Order Re: Insulin and Injectable Epinephrine

The Rule:

- Final Rule published on December 23, 2020 with original effective date of January 22, 2021.
- President Biden "froze" the rule delaying its effective date for 60 days.
- Proposed additional delay pending 5-day comment period (closed March 15th)
- Conditions HRSA health center grants on providing drugs @ 340B cost for all patients at or below 350% of FPL if:
  - Uninsured
  - Insured with high deductible balance
  - Insured with high cost sharing requirement

Setting the Record Straight:

1. As of 2018 there were 26.8 million Americans with diabetes and only 2,709,755 of them were patients of community health centers. Trump's EO applied ONLY to health centers, meaning it did ABSOLUTELY NOTHING to effect lower insulin costs for the vast majority of people with diabetes.
2. ***The EO was a completely unnecessary measure to solve a problem that doesn't exist for the patients it impacts***. By mission and mandate we offer an income based sliding fee discount to all patient at or below 200% of poverty. Our patients are not the ones being denied access to live saving medications.
3. The implementation of this unnecessary EO will result in an unwieldy administrative burden that adds to the operating cost of health centers already operating on thin margins. In addition, it eliminates savings that are essential to keeping the community health center program whole.

https://blog.nachc.org/setting-the-record-straight-on-the-340b-drug-discount-program

The Assault on the Contract Pharmacy Model:
Limiting or eliminating shipping 340B priced drugs to contract pharmacies

- **Eli Lilly** – effective as of September 1st
  - Applies to all CEs
  - 1 pharmacy if CE lacks in-house pharmacy
- **Astra Zeneca** – effective as of October 1st
  - Applies to all CEs
  - 1 pharmacy if CE lacks in-house pharmacy
  - Lack of clarity re: 1 RX per site
- **Sanofi** – originally effective as of October 1st but position shifted effective March 1, 2021
  - Applies to all CEs
  - Can name 1 pharmacy if CE lacks in-house pharmacy
  - Requires registration with Second Sight Solutions, but is not contingent upon submission of data
- Merck – Appears to be in a holding pattern but still aligned with Second Sight Solutions
- Novartis – effective November 16th
  - Hospital contract pharmacies more than 40 miles from parent
  - Can name 1 pharmacy if CE lacks in-house pharmacy
- Novo Nordisk – effective January 1st
  - Hospitals only
  - Can name 1 pharmacy
- United Therapeutics – effective November 20th (unless current purchaser) and May 31, 2021 unless submitting claims data
  - Applies to all CEs
  - Can name one contract pharmacy
- Gilead
  - Required single mail-order pharmacy for PrEP now optional

Status of NACHC Legal Action and Overcharge Claim under the ADR Process

- NACHC sued HHS demanding implementation of ADR process and immediate relief.
- The position shifted when the ADR rule was implemented: legal action **STAYED** pending ADR ruling.
- Administrative Dispute Resolution (ADR) is an adversarial process wherein covered entities can bring claims that manufactures are overcharging for 340B drugs directly to an HHS panel
  - Discovery available
  - Panel can issue binding orders
  - Decisions have precedential value
- Finalized Jan. 13
  - NACHC filed same day and filed request the next day for immediate injunction against manufacturers

Newest Development: Express Scripts' New 340B Rules

- About Express Scripts:
  - Owned by Cigna as of December 2018
  - 22nd largest company in the U.S
  - Revenue > $100 billion (2017)
  - One of 4 PBMs that account for 70% of claims volume - tied with OptumRX for # 2 with 23% in 2018
  - 2.3% growth in 2019
- New rules effective today March 1, 2021
- Requires POS or post-adjudication notification of all claims identified as 340B eligible regardless of payer
- Impact in both threat categories:
  - Further limiting access to contract pharmacy
  - A new player in the great data heist = increased risk of discriminatory reimbursement; and

What do We Mean by “the Great Data Heist”?

- Manufacturers, PBMs, and others requiring identification of prescriptions filled with 340B inventory regardless of payer.
- Stated purposes include *in the interest of transparency* and is so they can **prevent ineligible rebates.**
- 340B ESP™ trainer: “*You have to remember that the manufacturer’s view of duplicate discount is different than that of a Covered Entity*”
- Manufacturer’s interest is to prevent any rebates being paid on 340B drugs including those voluntary rebates they have voluntarily negotiated for marketing purposes
- The 340B obligation of CEs to prevent duplicate discount is limited to those situations in which a rebate is statutorily established
- Game over if they reach critical mass!

It’s all about “pick-pocketing”

- The predatory business strategy formerly called discriminatory contracting
- A fundamental flaw in the statutory and regulatory framework of the 340B Program with the current 340B
- At present, not prohibited by federal statute (limited success at state level)
- Not new, the 2020 great data heist paves the way for it to become the norm!

Two Paths We Are Following: Adaptation and Advocacy

Adaptation re: Manufacturer Issues at Contract Pharmacies (CPs)

- Note: This issue only impact your CPs, not your in house pharmacy
- Ensure that your TPA has blocked the NDCs for Lilly, AZ and Sanofi at your CPs
- **Be sure that your medical staff has been briefed on this issue**
  - Patients coming in saying they cannot get their medications due to an increase in price at CP
  - Providers need to be included in a plan to convert patients from excluded meds to covered therapeutic equivalent meds (example on next slides Courtesy of Jangus Whitner Primary One Health)
- Promote your in-house pharmacy
- Utilize patient assistance programs to help patients obtain the excluded meds

Drug Manufacturer Changes to 340B		Current Medications Affected			Updated 340B options patients can be transitioned to in order to get discounted price	
		"If the patient is on _____" *(from this column)*			Then "switch them to this alternative" *(from this column)*	
		Lilly	AstraZeneca	Sanofi		
Diabetes						
Diabetes	GLP-1 Agonists	Trulicity	Bydureon Byetta	Adlyxin	Victoza [Novo] Ozempic [Novo]	Rybelsus [Novo]
	GLP-1 + Long-acting insulin (COMBO)			Soliqua	*Xultophy*	*[Novo - but not very cost effective on 340B]*
	DPP-IV inhibitors		Onglyza		Tradjenta [BI] Nesina [Takeda]	Januvia [Merck]
	DPP-IV Inh + Metformin (COMBO)		Kombiglyze (+XR)		Jentadueto (+ XR) [BI] Kazano [Takeda]	Janumet (+XR) [Merck]
	SGLT-2 Inhibitors		Farxiga		Jardiance [BI] Invokana [Janssen]	Steglatro [Merck]
	SGLT-2 Inh + Metformin (COMBO)		Xigduo		Invokamet (+ XR) [Janssen] Synjardy [BI]	Segluromet [Merck]
	SGLT-2 Inh + DPP-IV (COMBO)	Glyxambi	Qtern		Steglujan [Merck]	
	Long-acting Insulin	Basaglar		Lantus Toujeo	Levemir [Novo] Tresiba [Novo]	Semglee [Mylan]
	Rapid-acting Insulin	Humalog Insulin Lispro		Admelog Apidra	Novolog [Novo]	
	Intermediate-acting Insulin	Humulin N			Novolin N [Novo]	
	Short-acting Insulin	Humulin-R			Novolin R (Vial &Flexpen) [Novo]	
	Combo Insulin: Intermediate + Short-acting	Humulin 70/30			Novolin 70/30 (Vial & Flexpen) [Novo]	
	Concentrated Short-acting insulin	Humulin-R U-500 Kwikpen & vial			*No alternatives for U-500 concentration available*	
	Glucose Evelating Agents	Glucagon 1mg Emergency Kit (NDC: 00002-8031-01)			Glucagen 1mg Hypokit (NDC: 00169-7065-15)	

Respiratory						
Respiratory	ICS		Pulmicort Flexhaler		Flovent (HFA & Diskus) [GSK] Asmanex (HFA & Twisthaler) [Merck]	Arnuity Ellipta [GSK] QVAR Redihaler [Teva]
	ICS/LABA (combo)		Symbicort		Advair (HFA & Diskus) [GSK] Breo Ellipta [GSK]	Dulera [Merck]
	ICS/LABA/LAMA (combo)				Trelegy Ellipta [GSK]	
	SABA				ProAir(HFA, Respiclick, & Digihaler) [Teva] Albuterol HFA [generic]	Ventolin HFA [GSK] Proventil HFA [Merck]
	SAMA				Atrovent HFA [BI]	
	LAMA				Spiriva Handihaler [BI] Spiriva Respimat [BI]	Incruse Ellipta [GSK] Seebri Neohaler [Novartis]
	LABA				Serevent Diskus [GSK] Strivedi Respimat [BI]	Arcapta Neohaler [Novartis]
	LAMA/LABA (combo)		Bevespi Aerosphere		Anoro Ellipta [GSK] Stiolto Respimat [BI]	Utibron Neohaler [Novartis]

Adaptation re: Manufacturer Issues at CPs

(continued)

- If you are contract pharmacy only
  - Work with your TPA to select the pharmacy(s) that uses the most Lilly and Sanofi products.
  - Utilize the manufacturers process for identifying the pharmacy(s)
  - Direct patients on your SFS/EPPAP program to those pharmacies
- CHCs with CP, In-house or both
  - For AZ products, chose one CP for each registered site on OPAIS that does not have an in-house pharmacy and follow the AZ's process
- Utilize patient assistance programs to help patients with medications that cannot be obtained at CPs
- NACHC has a toolkit that expands on these available options and ideas

Responding to Kalderos data requests and status of proposed rebate model

- No recent developments regarding implementation of the proposed rebate model
  - Watch Noddlepod for updates
- Recent inquiries to CHCs requesting a description of the process for identifying Medicaid FFS and MCO claims
  - Recommend holding off until more is known about their true intent
- Recommendation remains that we respond in good faith to Kalderos requests clarifying if specific claims dispensed for Medicaid FFS and MCO were filled with 340B meds

A word about Express Scripts

- Express Scripts (ESI) recently announced requirements for CPs to utilize a special form to identify 340B claims
  - To date there is no indication that any of the chains have agreed to do this
- Per ESI's pharmacy manual, in-house pharmacies are to identify all ESI claims as well (July 2020)
  - Some in-house pharmacies have complied, and others have not
- NACHC in discussions with ESI regarding this issue and will continue to advocate on our behalf
  - We agree that Medicaid FFS and MCO rxs need to be identified
  - All other claims identification is not required statutorily

Advocacy!

Advocacy is the path that has the potential to achieve lasting results by:

- Preserving the contract pharmacy model
- Protecting against pickpocketing

Advocacy initiatives among the States

- 7 states have signed bills protecting 340B savings from PBMs
- Many others are in the process
- Utah bill had language to protect against actions like ESI
- Stay tuned to NACHC's Advocacy Noddlepod site for opportunities to support 304B

Let’s talk about the elephant in the room…

The “silver bullet” is statutory protection at the federal level; however

Our strongest protection = Our greatest risk

- A legislative “fix” remains on the table with the risk being continually assessed.
- Other channels for federal advocacy include:
  - Congressional influence on regulatory process;
  - Executive actions; and
  - Appeals to the court of public opinion.

Let’s talk about what all is in play and where we go from here …

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