Navigating 340B

Paul Schiferl Pharm D., BCPS, 340B Coordinator

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Meet the presenter

CITIZENS HEALTH

Paul Schiferl

- From: Colby, KS
- Education: Graduated from KU School of Pharmacy with PharmD in 2018 and became Board Certified in Pharmacotherapy in 2021.
- Employer: Citizens Health since 2018
- 340B Consultant for 4 years and contracted with over 55 CAHs in 7 states

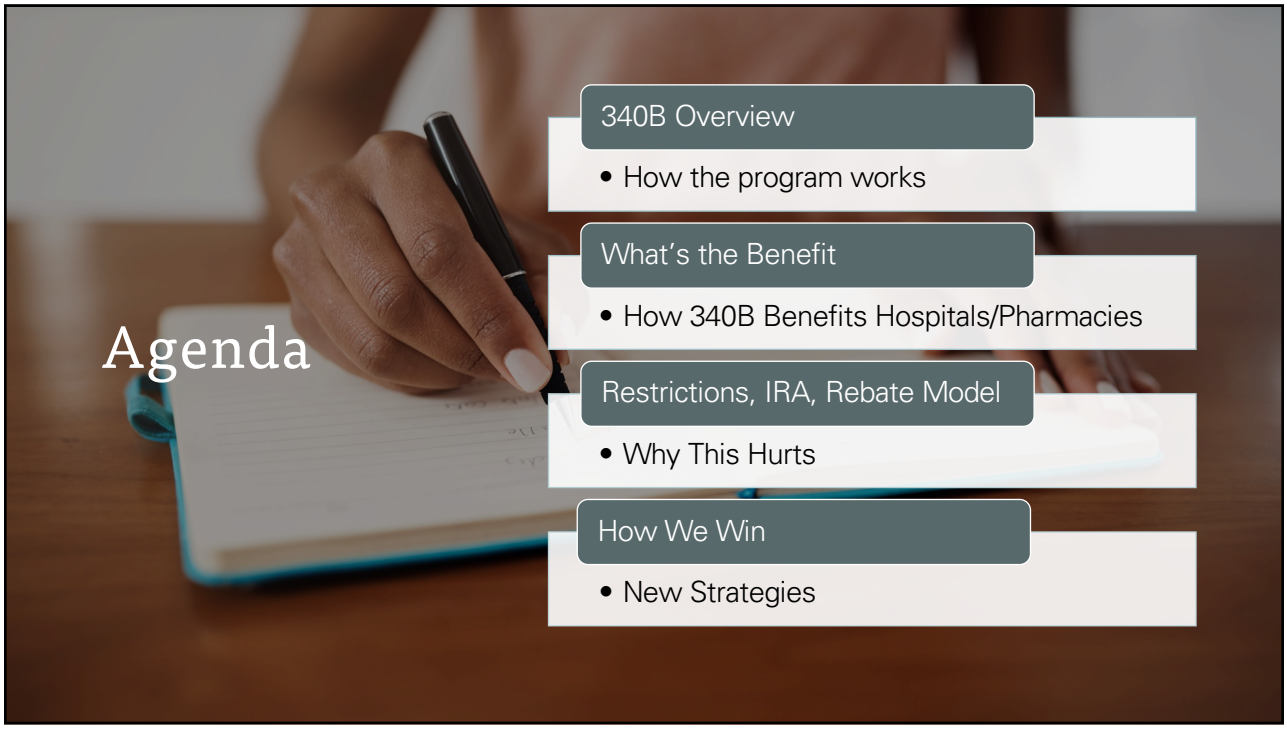
Disclosures

Faculty

Paul Schiferl, faculty for this activity, has no relevant financial relationships with ineligible companies to disclose.

Planners

None of the planners for this activity have other relevant financial relationships with ineligible companies to disclose.



Agenda

- **340B Overview**
  - How the program works
- **What's the Benefit**
  - How 340B Benefits Hospitals/Pharmacies
- **Restrictions, IRA, Rebate Model**
  - Why This Hurts
- **How We Win**
  - New Strategies

HISTORY OF 340B, BENEFIT

1990

Medicaid rebate program required drug companies to enter into rebate agreement with HHS as precondition for coverage of their drugs

1992

Passed pharmaceutical pricing agreement (PPA) extending discounts to some covered entities

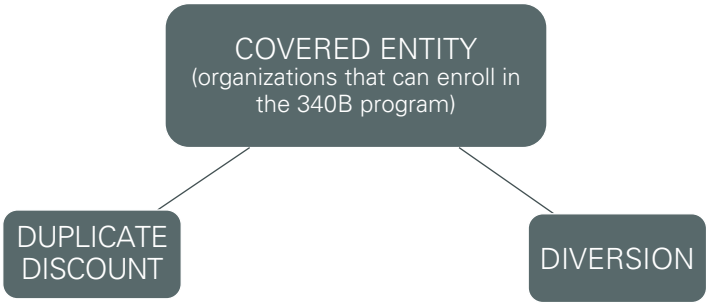
2010

ACA extended safety net providers to include Critical Access Hospitals

History of 340B, Benefit

- Drug manufacturers are subject to ceiling prices on 340B medications
  - Often 30-50% cheaper than normal pricing
- 340B Program enables covered entities to stretch scarce federal resources reaching more eligible patients and providing more comprehensive services

Program Requirements



Duplicate Discount

- When a covered entity obtains a 340B discount on a medication and a Medicaid agency obtains a discount in the form of a rebate from the manufacturer for the same medication.
- Results in an audit finding and possible repayments.
- Covered entity must decide to either carve 'in' or carve 'out' Medicaid.
- HRSAs Duplicate discount is different than manufacturers

Diversion

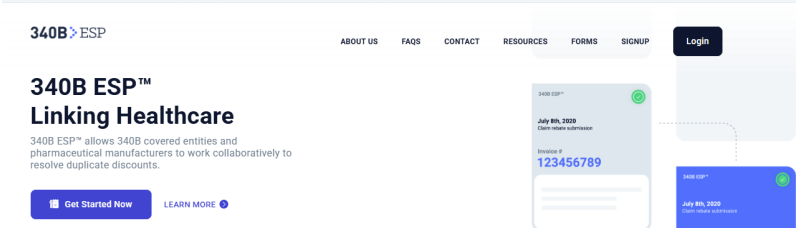
- Dispensation of a 340B drug to an individual who is not an eligible patient of the covered entity
- Results in an audit finding and possible repayments.

Patient Definition

- An individual is a patient of a 340B covered entity only if:
  - The covered entity has **established a relationship** with the individual such that the covered **entity maintains records** of the individual's health care.
  - The individual receives health care services from a health care professional who is:
    - Employed by the covered entity
    - Provides health care under contractual or other arrangements (referral for consultation)
  - The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally qualified health center look-alike status has been provided to the entity

340B ESP

- Website that drug manufacturers and covered entities use
  - Submit claims data
  - Designate Contract Pharmacies to receive 340B pricing
  - Get the latest manufacturer policies



Contract Pharmacies

- Locations that dispense medications to 340B eligible patients.
  - Pharmacy dispenses their stock of medication and then are replenished by the covered entity who gets to purchase the medication at 340B price.
- Covered Entities can contract with an unlimited number of contract pharmacies
  - The pharmacy must be registered on the HRSA OPAIS website
  - Entities may use the pharmacies they own

Third Party Administrators (TPAs)

- Pharmacy inputs information to fill a prescription such as patient name, drug, prescriber, insurance information etc.
- Information goes through a pharmacy 'switch' and gets sent to TPA.
- TPAs determine if the patient is 340B, orders 340B medications to be sent to contract pharmacies, and does the billing work.
- Examples included Macro Helix, PharmaForce, PDMI, SunRX, and many more

What's the Benefit

How 340B Benefits Hospitals and Pharmacies

Why go to the Trouble?

- Allows the covered entity to increase profits and savings which are used to benefit the patient
- Benefits the pharmacy which in turn can be used to help the patient
  - Manufacturers argue program should not be used at for profit pharmacies, but I disagree. There should be some benefit to the program because it is MORE work for the pharmacy.
  - We need pharmacies in our communities to serve patients. The Pharmacy's success is very important to patient healthcare access.

Contract Pharmacy Example

- Normal Jardiance Claim:
  - Pharmacy is paid $600 from insurance and patient copay
  - Jardiance costs pharmacy $575 to buy
  - $600 (paid) - $575 (cost) = $25 net profit for pharmacy
  - No covered entity benefit

Contract Pharmacy Example

- 340B Eligible Claim
  - Pharmacy is paid $600 from insurance and patient copay
  - Pharmacy dispensing fee is 25% = $150
  - Covered Entity buys and replaces Jardiance for $0.29
  - $600 (paid) - $150 (dispensing fee) = $450 owed to Covered Entity
  - $450 - $0.29 = $449.71 Covered Entity Net Profit

Pharmacy prefers to pay the covered entity $450 vs paying wholesaler $575

What is this Revenue Used For?

- Bad Debt/Charity Care
- Savings passed on to patients through cash card program
- Increased wage/compensation pressure
- Increased drug and medical supplies costs

Manufacturer Restrictions, IRA, Rebate Model

Why this hurts

Contract Pharmacy Restrictions

- Since 2010 HRSA issued guidance that Covered Entities can utilize an unlimited number of contract pharmacies.
- In 2020, manufactures challenged this "guidance" and said since it was not statute or law they did not have to honor this arrangement.
- Since that time, nearly all major manufactures only allow one contract pharmacy to get 340B pricing. This has substantially impacted the revenue generated for Covered Entities.

Inflation Reduction Act, Manufacturer Fair Pricing

- Reduced reimbursement: As Medicare negotiates lower prices, reimbursement amounts tied to Average Sales Price (ASP) may decrease.
- 340B program tensions: Lower ceiling prices may further reduce the 340B margin, potentially affecting program sustainability.
- Increased compliance and tracking: Covered entities must monitor MFP-eligible drugs and reporting requirements closely.
- Operational strain: More complexity in managing inventory, pricing tiers (negotiated vs. non-negotiated), and patient eligibility for savings.

Affected Drugs

2026

- **Eliquis ($231)**
- **Jardiance ($197)**
- **Xarelto ($197)**
- **Januvia ($113)**
- **Farxiga ($178)**
- **Entresto ($295)**
- **Enbrel ($2,355)**
- **Imbruvica ($9,319)**
- **Stelara ($4,695)**
- **NovoLog / Fiasp ($119)**

2027

- **Ozempic**
- **Rybelsus**
- **Wegovy**
- **Trelegy Ellipta**
- **Xtandi**
- **Pomalyst**
- **Ibrance**
- **Ofev**
- **Linzess**
- **Calquence**
- **Austedo / Austedo XR**
- **Breo Ellipta**
- **Tradjenta**
- **Xifaxan**
- **Vraylar**
- **Janumet / Janumet XR**
- **Otezla**

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Contract Pharmacy Example

- 340B Eligible Claim
  - Pharmacy is paid $197 from insurance and patient copay
  - Pharmacy dispensing fee is 25% = $49.25
  - Covered Entity buys and replaces Jardiance for $0.29
  - $197 (paid) - $49.25 (dispensing fee) = $147.75 owed to Covered Entity
  - $147.75 - $0.29 = $147.46 Covered Entity Net Profit

  - Pharmacy Loses $100.75
  - Covered Entity Loses $302.25

Potential Shift to Rebate Model

- Some drug manufacturers are pushing for the 340B program to be turned into a rebate model
  - Instead of purchasing drugs at the **340B ceiling price up front**, covered entities **purchase drugs at wholesale or market price**, and **receive a post-sale rebate** from the manufacturer to reflect the 340B discount they would have received.
- Potential Issues:
  - Cash Flow Strain
  - Increased Administrative Burden
  - Risk of Denied or Delayed Rebates
  - Interruptions to Patient Assistance Programs

Referral Capture

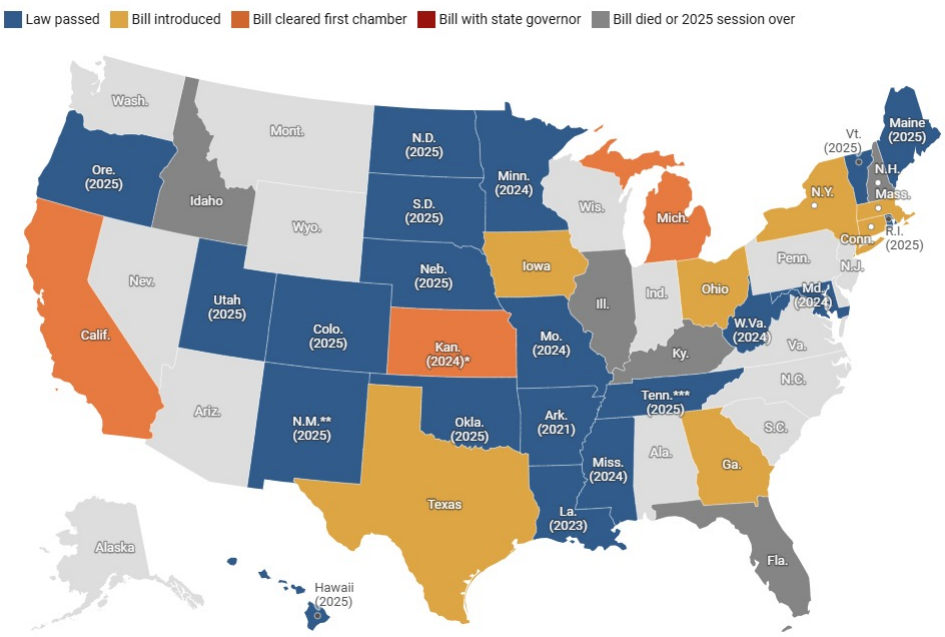
- Maximizes the amount of eligible 340B prescriptions by capturing eligible specialty doctors.
  - Often these doctors write for high-cost brands.
- On average increases program profitability by 25%
- Polices and procedures are very important. Remember the patient definition is very vague. The covered entity has a big say in how they determine responsibility of care.
- Do you need a referral and consult notes??
  - All depends on CE's Policies and Procedures

Patient Assistance Programs

- Evaluate ways to provide assistance to patients
  - Manufacturer Cards – E Vouchers (make sure switch is getting data)
  - Established Charity Care Programs
  - CE funded opportunities
- Is the Cash Card program being over utilized?
  - Recommended to have strong policies and procedures in place

Advocacy

- State-Level Advocacy is Critical
- Federal policy is uncertain; state protections can secure 340B access now.
- Kansas legislators must understand how 340B directly impacts community health and safety-net providers.
- 2026 changes in leadership positions within Kansas government may increase the chance of bill passage.



CE Question

Which of the following options are covered entities responsible for to maintain 340B compliance. (select all that apply)?

A. Covered entities must prevent duplicate discount by ensuring that Medicaid FFS claims are not qualified as 340B at contract pharmacies.

B. Covered entities must prevent diversion and ensure that 340B claims are only qualified for patients in which the covered entity has documented responsibility of care.

C. Covered entities must ensure that the drug manufacturers do not have to pay rebates on any drugs that were qualified as 340B on commercial insurance plans.

CE Question

Which of the following options are solutions to optimize 340B programs?

A. Covered entities can operate referral capture programs to capture all possible claims.

B. Covered entities can explore patient assistance programs which may allow patients to access medications more affordably and increase revenue.

C. Stake holders can participate in advocacy efforts to allow unimitated contract pharmacy access like many of Kansas neighboring states.

D. All the above.

Questions?

pschiferl@cmciks.com

(785) 460 4846

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