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# 340B Program Overview

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# Agenda

- 340B 101
- The Value of 340B
- 340B Contract Pharmacy
- 340B and Medicaid
- 340B Manufacturer Actions
- 340B What Now??

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POLL

# What is your familiarity with 340B?

A. What is 340B?
B. 340B Confused
C. 340B Novice
D. 340B Expert

SECTION 1

# 340B 101

# What is 340B?

**The 340B Drug Discount Program is an extension of the Medicaid rebate program**

Congress enacted 340B in 1992, extending the same relief from high drug costs to safety-net providers that was previously provided to the Medicaid program

The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

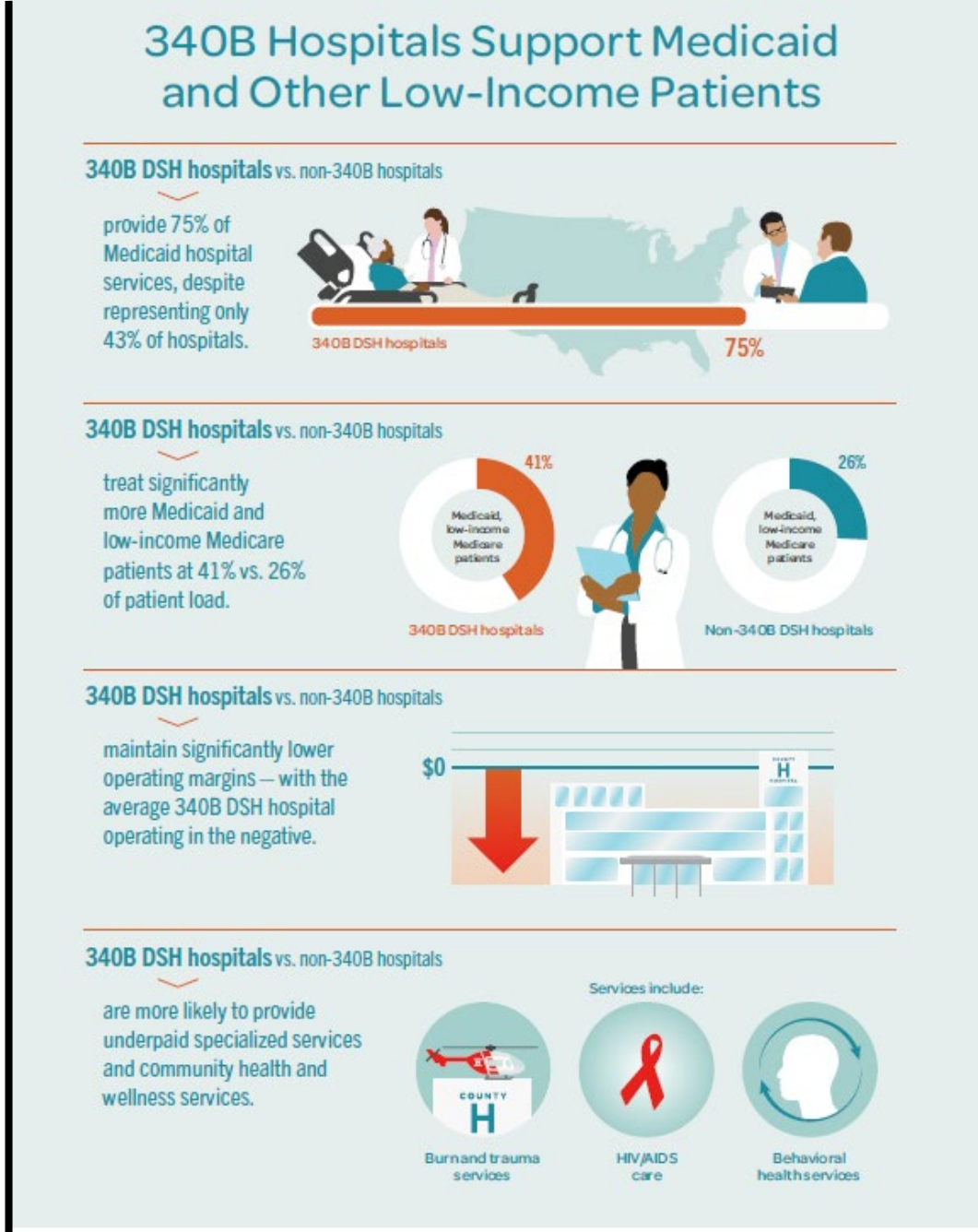
Manufacturers participating in Medicaid agree to provide outpatient drugs to covered entities at significantly reduced prices.

The Office of Pharmacy Affairs (OPA) within Health Resources and Services (HRSA) is responsible for administering the 340B program.

# The 340B Program's Intent

- Allow covered 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)
- Law does not offer clarity regarding what to do with "savings". Savings can go directly to the patient or may go into operations to expand services:
  - Drug Discount Cards
  - Uncompensated care
  - Expanded non or under reimbursed clinical services
  - New outpatient clinic and/or staffing
- Policies and procedures should discuss use of the savings and how such use supports intent of Program.

**340B patient eligibility criteria does not require that the patient is indigent or qualifies for a sliding fee scale discount*




*Infographic courtesy of 340B Health*

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# 340B Covered Entity Types

| HOSPITAL TYPES |
| --- |
| Disproportionate Share Hospitals (DSH) (11.75%) |
| Critical Access Hospitals (No minimum DSH rate) |
| Rural Referral Centers (8%) |
| Sole Community Hospitals (8%) |
| Children's Hospitals (11.75%) |
| Free Standing Cancer Hospitals (11.75%) |

| FEDERAL GRANTEES |
| --- |
| Community Health Centers "FQHC Look-alike" |
| State-operated AIDS drug assistance programs |
| Comprehensive Hemophilia Treatment Centers |
| Black Lung Clinics |
| Ryan White Programs |
| Sexually Transmitted Disease/Tuberculosis |
| Title X Family Planning |
| Urban 638 Health Center |
| Federally Qualified Health Centers (FQHC) |
| Native Hawaiian Health Centers |

# Who is Eligible to Participate?

Only nonprofit health care organizations that have certain Federal designations or receive funding from specific Federal programs are eligible to register.

To participate in the 340B Program, eligible organizations / covered entities (CE) must register and be enrolled with the 340B program and comply with all 340B Program requirements.

CE's must recertify eligibility for 340B drug discounts every year.

# 340B Registration

- Eligible entities are not automatically enrolled in the 340B Program.
- Entities must go through an online enrollment process.
- After OPA receives the enrollment request, the eligibility of the entity is verified. Once approved, the entity will be added to the official OPA 340B database for the next quarterly database update.

| REGISTRATION PERIOD | START DATE |
|---|---|
| Oct 1 - Oct 15 | January 1 |
| Jan 1 - Jan 15 | April 1 |
| April 1- April 15 | July 1 |
| July 1 - July 15 | October 1 |

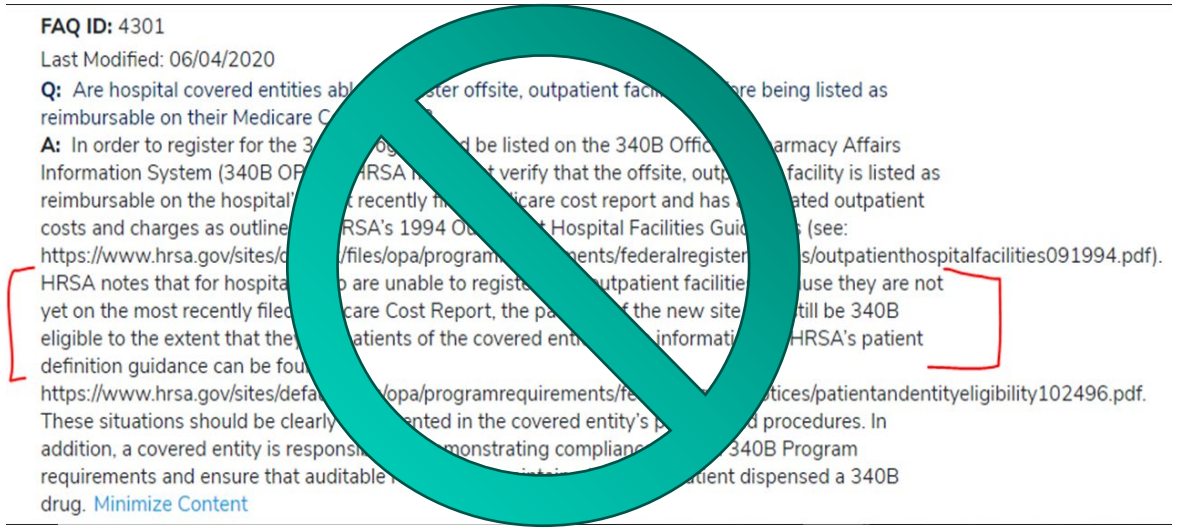
* If the last date falls on a Saturday, Sunday, or Holiday, the following Monday will be the deadline.

# 340B Eligible Locations

To use 340B purchased drugs of the covered entity, the clinic or child site must:

- Be an outpatient location of the covered entity
- Appear on the most recently filed hospital cost report
  - This requires the location to be a provider-based location of the covered entity (hospital)
  - Revenue and expense should be identified for each clinic

- Child Sites not on the most recently filed Medicare Cost Report:



# 340B Patient Eligibility



Covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's healthcare.

Individual receives healthcare services from a healthcare professional who is either employed by the CE or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the CE.

Individual receives a health care service or range of services from the CE with the service or range of services for which the FQHC look-alike status has been provided to the entity. Disproportionate Share Hospitals are exempt from this requirement.

An individual will NOT be considered a patient of the CE if the only healthcare service received by the individual from the CE is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

# 340B Restrictions



**GPO (Group Purchasing) Prohibition**

- Applies to DSH, Cancer, and Children's hospitals

**Orphan Drug Exclusion**

- Orphan drugs are used to treat rare diseases
- Allows manufacturers to qualify for development incentives, including tax credits
- Applies to RRC, SCH, and CAH facilities only

**Medicaid**

- Applies to all CE types

SECTION 2

# The Value of 340B

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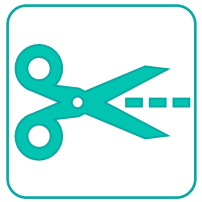
# 340B Pricing Calculation



Drug companies must sell their medicines to 340B outpatient pharmacies at 25% to 50% discounts if they want to sell to state Medicaid programs

- 340B represents 2-6% of US drug spend

The 340B cost for a drug paid by CE—sometimes referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities.

Occasionally, the formula results in a negative price for a 340B drug

- In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—a directive known as HRSA's *penny pricing* policy.

Covered Entities may negotiate discounts lower than the 340B ceiling price.

# How are 340B drugs dispensed to eligible patients?

## Contract Pharmacies

CVS caremark®

Walmart Pharmacy

accredo®

Kroger SPECIALTY PHARMACY

US Bioservices AmerisourceBergen Specialty Group

Good Neighbor Pharmacy — Get to know your neighbor.

allianceRx Walgreens + PRIME

## Hospital/Clinic Administered

## Poll Question

Do you currently have a contract pharmacy program?

A. Yes
B. No
C. Not sure

SECTION 3

# 340B Contract Pharmacy

# Sample Contract Pharmacy Revenue Flow

## Value to Covered Entity

- Generate income by purchasing the drug at the discounted 340B price while collecting the pharmacy's reimbursement or reference price value (e.g. WAC-3%)

## Value to Contract Pharmacy

- Generate incremental revenue through additional dispense fees
- Increased patient traffic and new referrals as a result of the relationship with the Covered Entity.

| +$140 | Reference Price | Paid by Contract Pharmacy |
|---|---|---|
| – $10 | Dispensing Fee | Paid to Contract Pharmacy |
| – $4 | Admin Fee | Paid to 340B Administrator |
| – $70 | 340B Drug Cost | CE pays to Wholesaler |
| +$56 | Net Proceeds | Retained by Covered Entity |

# Contract Pharmacy Process

| +$140 | Reference Price | Paid by Contract Pharmacy |
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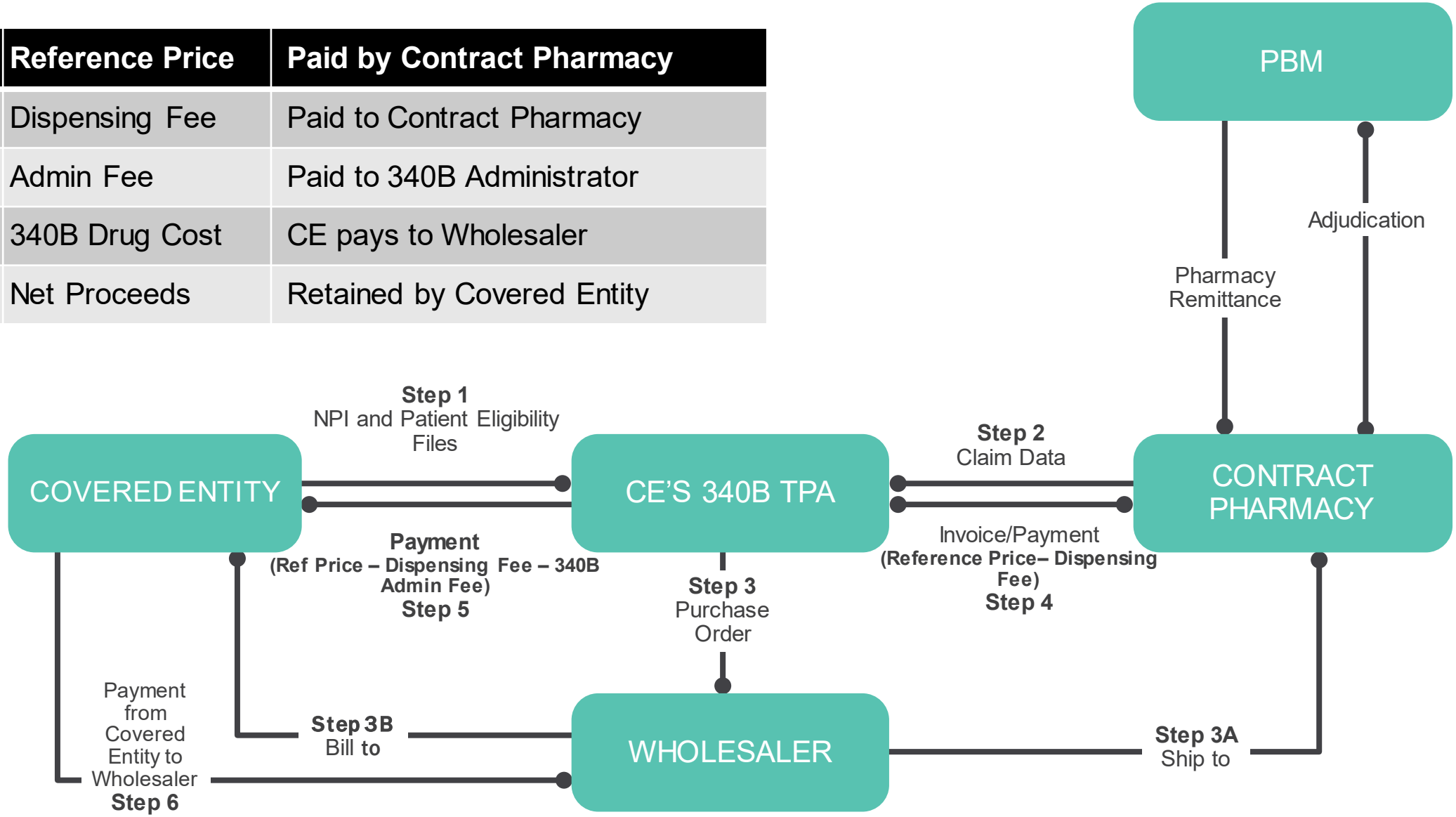


# Pharmacy Services Agreement Fees

## Flat

- Pharmacy paid fee for brand and or generic
- Cost or reimbursement of medication is not a factor

## Percentage

- Pharmacy is paid a percentage of the reimbursement or reference price
- Typically, works better for the pharmacy especially with higher cost medications

## Reference

- Remittance to the CE is based upon a pharmacy's acquisition
- Pharmacy keeps spread, plus a dispensing fee
- Helps to keep Direct and Indirect Remuneration (DIR) fees out of the negotiation process

# Third Party Administration Fees

| | |
|---|---|
| Percentage of revenue | • Gross or net? |
| Flat Fee | • One size fits all<br>• Easy to budget |
| Match / Transactional | • Fee charged for “matched” claim<br>• Variable |
| Switch | • Includes all patients of the pharmacy<br>• Can be very costly if a high volume pharmacy |
| Replenishment | • TPA only gets paid when the CE wins |

# Pros/Cons of Contract Pharmacies

## Pros:

- Increases access to 340B medications
- Becomes an income source for the CE
- Opportunity to offer indigent patients low cost or free drugs

## Cons:

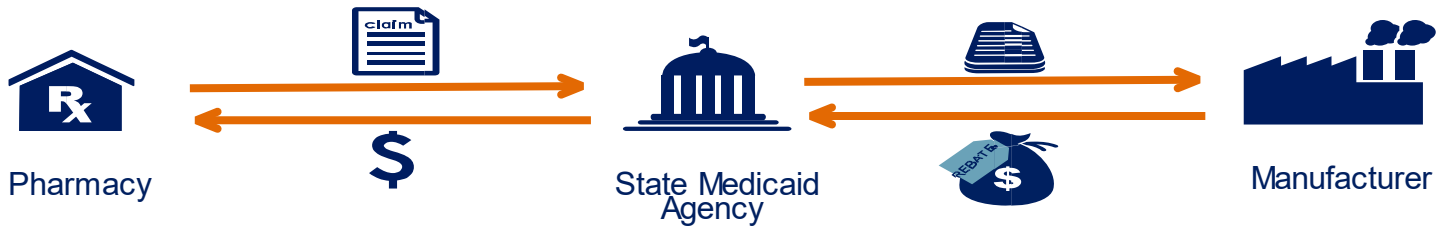
- Fees paid to TPA
- Fees paid to contract pharmacies
- Increased compliance risks
  - Mandates independent audit

SECTION 4

# 340B and Medicaid

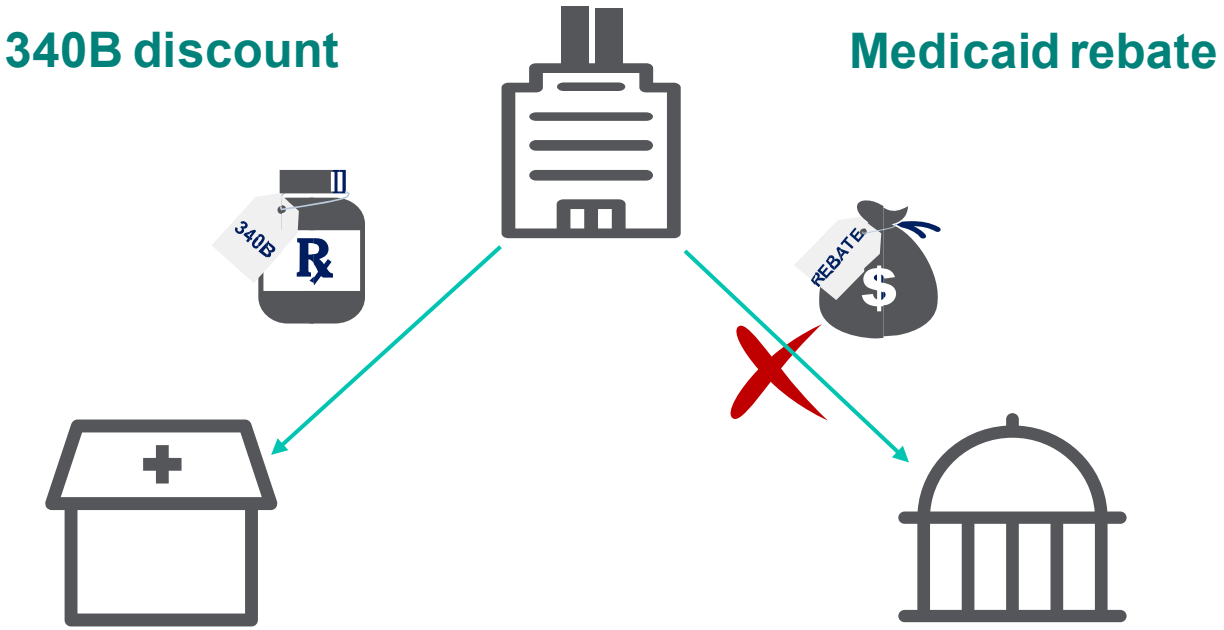
# Medicaid Drug Rebate Program

- The Medicaid Drug Rebate Program is a program that includes the Centers for Medicare and Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers and helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients (authorized by Section 1927 of the Social Security Act).
- The program requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs.
- Manufacturers are required to report all covered outpatient drugs under their labeler codes to the Medicaid Drug Rebate Program. Manufacturers may not be selective in reporting their NDCs to the program.
- As a part of this program, the manufacturer is required to sign a pharmaceutical pricing agreement (PPA) that requires the manufacturer to offer 340B pricing to covered entities. In other words, if a drug manufacturer wants their drug on a state Medicaid list, the drug must also have 340B pricing.



# The Issue: Duplicate Discounts

- One of the major tenants of 340B Compliance is avoiding Duplicate Discounts. How do they occur?



# Medicaid Exclusion File (MEF)

- The MEF is published on HRSA's OPAIS database and is available for states and manufacturers to access and validate how each 340B entity bills Medicaid.
  - ***Carve-In:*** Entities that use 340B purchased-drugs for Medicaid patients and bill Medicaid
  - ***Carve-Out:*** Entities that will not bill Medicaid for 340B drugs and state Medicaid will apply for the rebate
- The Carve-In versus Carve-Out decision is rarely mandated (New Hampshire). Most often the decision is based on financial and/or management analysis to decide the best option for an entity.
- Covered entities that carve-in must list their Medicaid Provider Number and/or hospital and other areas NPI number(s) on the MEF with HRSA
- Federally used for Fee-For-Service (FFS) Medicaid only
  - Pennsylvania utilizes for both FFS and Managed Medicaid

# Retail Pharmacy Implications

Most states require that all contract pharmacy relationships ***Carve-out*** Medicaid

- Including Pennsylvania

Entity-Owned retail pharmacies can be handled differently and maybe allowed to carve-in Medicaid, but the CE must follow both the HRSA and state requirements appropriately

- State requirements are often difficult to ascertain
- Can have a significant financial impact if you have a solid process in place for retaining outpatient prescription volume, especially in the specialty medication market.

## Poll Question

340B Covered Entities can take 340B savings and State Medicaid agencies can collect a rebate on the same transaction

- True
- False

SECTION 5

# 340B Manufacturer Actions

# Manufacturers Actions to Date (Happened Fast, then slowed down, picking back up…)

| 2020 | 2021 | 2022 | 2023 | 2024 |
|---|---|---|---|---|
| AstraZeneca | Boehringer Ingelheim | AbbVie | Abbvie* | Takeda* |
| Eli Lilly | Merck | Amgen | Amgen* | Gilead* |
| Novartis | Novo Nordisk | Bausch Health | Astellas | Amgen* |
| Sanofi | UCB | Bristol Myers Squibb | Bausch Health* | |
| United Therapeutics | | Exelixis | Bayer | |
| | | Gilead | Biogen | |
| | | GlaxoSmithKline | Boehringer Ingelheim* | |
| | | Johnson & Johnson | Bristol Myers Squibb* | |
| | | Pfizer | Eisai | |
| | | | Eli Lilly* | |
| | | | EMD Serono | |
| | | | Exelixis* | |
| | | | GlaxoSmithKline* | |
| | | | Incyte Corp. | |
| | | | Jazz Pharmaceuticals | |
| | | | Johnson & Johnson* | |
| | | | Merck* | |
| | | | Novartis* | |
| | | | Novo Nordisk* | |
| | | | Organon | |
| | | | Pfizer* | |
| | | | Sandoz | |
| | | | Sanofi* | |
| | | | Teva | |
| | | | UCB* | |

# Manufacturer Contract Pharmacy Restriction Lawsuits

## HHS Challenges to Manufacturer Restrictions

| Case | Federal Court | Status |
|---|---|---|
| Novartis v. Johnson | 3rd Circuit Court of Appeals | **Judge upheld** manufacturer policy restrictions January 2023 |
| Eli Lilly v. Becerra | 7th Circuit Court of Appeals | **Decision pending** (court heard oral arguments October 2022) |
| Sanofi v. HHS | D.C. Circuit Court of Appeals | **Decision pending** (court heard oral arguments October 2022) |

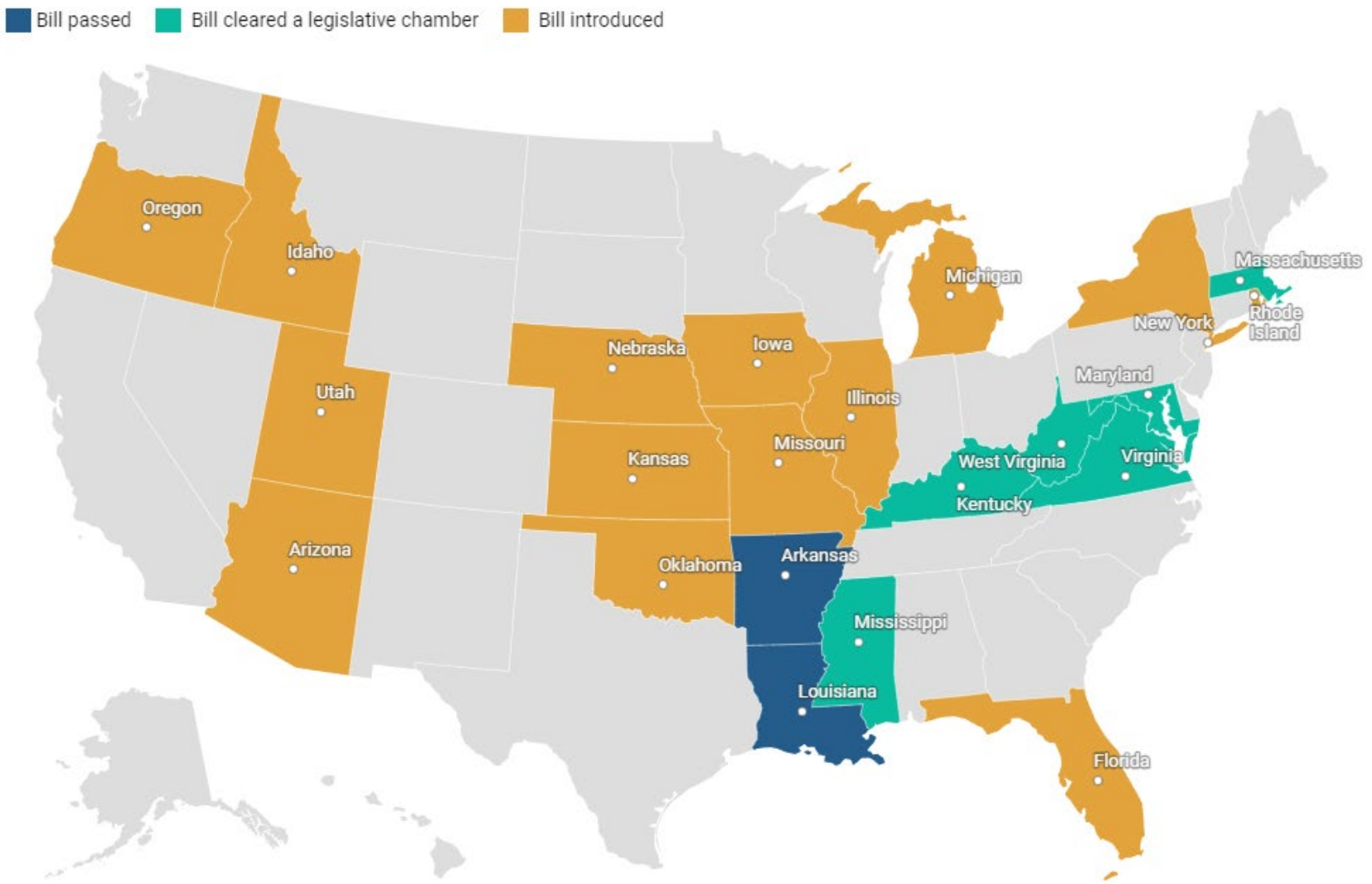
## Manufacturer Challenges to State 340B Contract Pharmacy Laws

| Case | Federal Court | Status |
|---|---|---|
| PhRMA v. McClain (Arkansas) | 8th Circuit Court of Appeals | **Court upheld legality of Arkansas law** (March 12, 2024) |
| PhRMA v. Murrill (Louisiana) | Western District of Louisiana | **Decision pending** (initial complaint filed in July 2023) |
| AstraZeneca v. Murrill (Louisiana) | Western District of Louisiana | **Decision pending** (initial complaint filed in August 2023) |
| AbbVie v. Murrill (Louisiana) | Western District of Louisiana | **Decision pending** (initial complaint filed in September 2023) |

340B REPORT

Courtesy of 340B REPORT

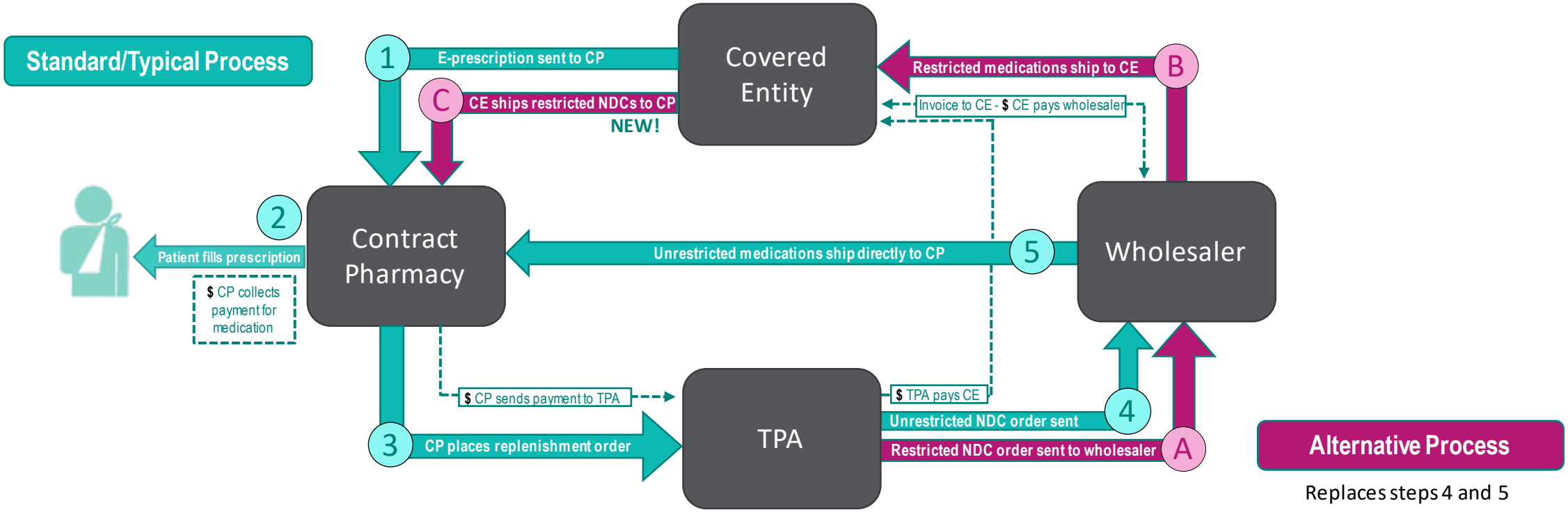
# State Legislative Activity



SECTION 6

# 340B – What now??

# A new path forward….Direct Replenishment



# Best Price Optimization

- With over 100,000 NDC's, it is nearly impossible for Covered Entities to do an analysis on their best blended price
  - Work with your TPA partner to help with this analysis
- 340B Prices change every quarter, therefore any analysis is quickly out of date. Without an automated solution, Covered Entities miss 66.5% of savings opportunities
- There are roughly 32,000 items in the 340B price file for a given quarter

  All of the distributors ordering systems have the ability to find the lowest priced item within a drug class, but this does not prioritize the changes based on utilization
- Factors to Analyze:
  - GPO, WAC, and 340B Pricing
  - Utilization by Purchase Category
  - Wholesaler Availability of Stock

| Statistic | GPO | 340 B | WAC | Blended Price |
|---|---|---|---|---|
| Utilization | 20% | 70% | 10% | |
| Drug Cost A | $100 | $90 | $101 | $93 |
| Drug Cost B | $95 | $80 | $110 | $86 |
| Drug Cost C | $97 | $60 | $116 | $73 |

**RESULT:**
Based only on GPO price, you would pick **Drug B.**
Based on price and utilization, you would pick **Drug C.**

**Without an automated solution, hospitals are leaving 3-5% of their drug spend on the table.**

# Keep an eye out for the Inflation Reduction Act

- Maximum Fair Price ("MFP")
  - For each drug selected for negotiation, the manufacturer and CMS will "negotiate" a "maximum fair price."
    - The MFP is subject to a ceiling, and will be at least 25% lower than the "non-federal average manufacturer price" (increasing to 60% for drugs that have been on the market 16+ years)
  - The MFP is the maximum price that a **drug manufacturer can charge** for a drug that will be dispensed to a Part D beneficiary
  - The MFP is the maximum price that a **pharmacy will be paid** when a selected drug is dispensed to a Part D beneficiary
  - CMS has proposed using a "Medicare Transaction Facilitator" (MTF) to ensure that pharmacies promptly receive a credit for the difference between the non-MFP price and the MFP price of a drug

# Inflation Reduction Act continued

- 340B Impact
  - Manufacturers are protected from providing the MFP and 340B price on the same drug (i.e., a “duplicate discount”)
  - Covered entities can access one price or the other (whichever is lower), but recall that reimbursement will be at MFP level
    - If MFP > 340B price, covered entity benefits
    - If MFP < 340B price, covered entity buys at MFP and has no margin
  - CMS is proposing that MTF will prevent duplicate discounts
  - **Could MTF be used for identifying 340B drugs in context of inflationary penalty? Could it be used for Medicaid duplicate discount prevention?**

# What can you do?

- **Actively** participate in your health system's 340B steering committee.
- Get involved with advocacy at the state and federal level
- Spread the word on how 340B helps the community, most don't know the impact it has on their care!

*Community Voices for 340B* is a great group to help you with getting started
CV340B.org

# Questions?

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