The 340B Program

Overview and Developments

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What is 340B?

“The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices.”

“340B entities realize significant savings by purchasing outpatient drugs through this program. Entities use the savings to provide additional services that benefit the populations they serve.”

Why does the 340B Program Exist?

Program Intent

- To permit 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)

How the Program Works

Manufacturers that participate in Medicaid and Medicare Part B are required to provide discounts on covered outpatient drugs to 340B covered entities

Hospitals that meet statutorily defined criteria can enroll with the government to receive discounts from manufacturers for covered outpatient drugs

Insurers reimburse the healthcare entity at their normal payment, which translates to savings for hospitals (Medicaid being an exception)

Hospitals use the savings to fund and sustain services, including to offset the costs of providing care to uninsured and underinsured patients

Adapted from a slide by 340B Health, 340Bootcamp Series 1, What is 340B? May 11, 2022

Today's Topics

- Introduction to the 340B Drug Pricing Program
- Eligibility for 340B Pricing
- Program Compliance Requirements
- Contract Pharmacy
- The State of 340B

340B Statute

- Resulted from a 1992 federal statute, administered by the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA)
  - P.L. 102-585, the Veterans Care Act of 1992, codified as Section 340B of the Public Health Services Act
- Manufacturers participating in Medicaid Drug Rebate Program must sign a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services
  - 340B Program creates a "ceiling pricing" to be charged by manufacturers to providers when dispensing certain drugs to their patients.

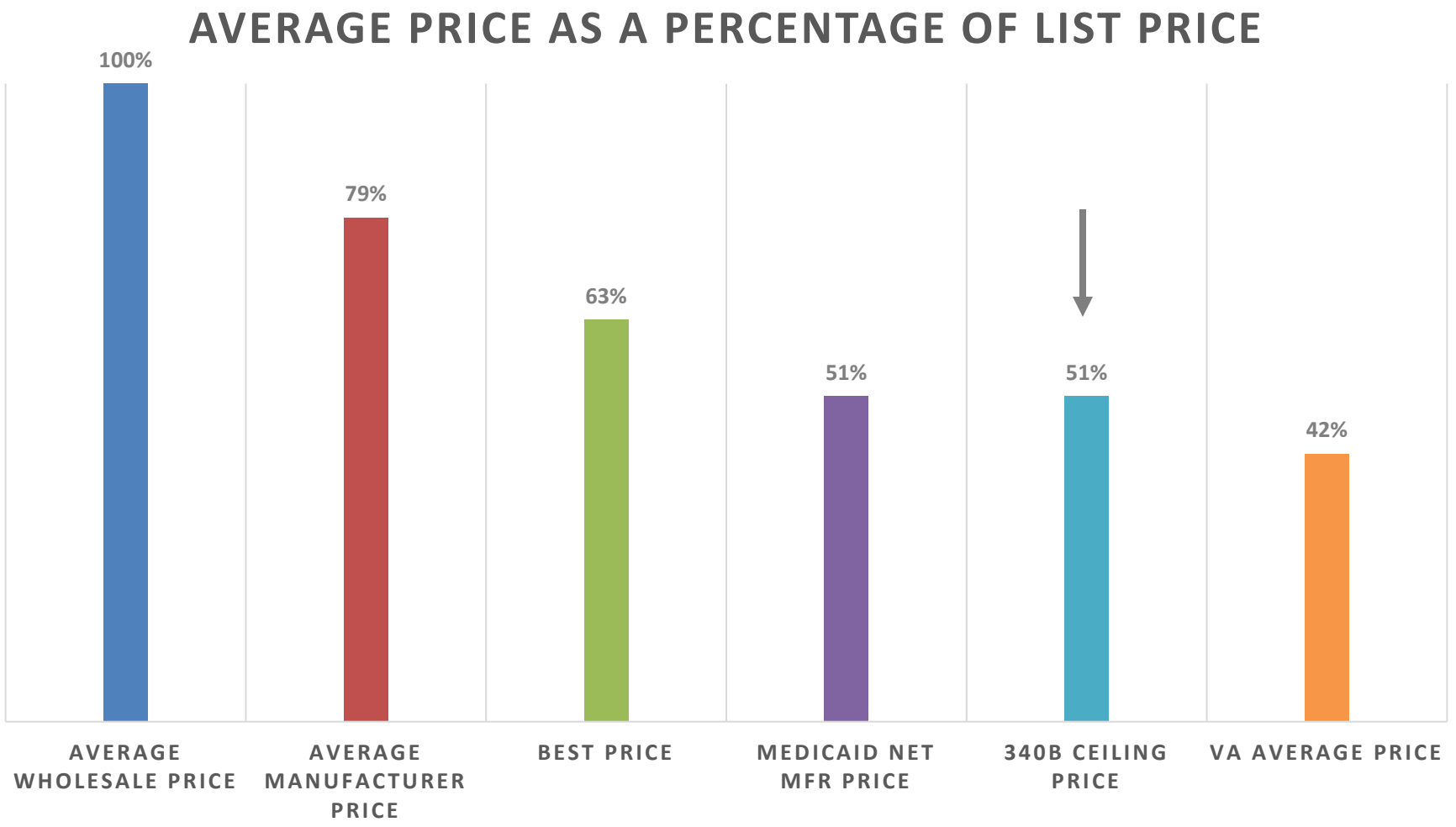
340B Price

- Calculated quarterly

  340B price = (Average manufacturer price – Medicaid unit rebate amount) / 340B ceiling price

- Manufacturer submits data to CMS
- 340B ceiling price:

Relative Pricing



Source: Data derived from Prices for Brand-Name Drugs Under Selected Federal Programs, Congressional Budget Office (June 2005)

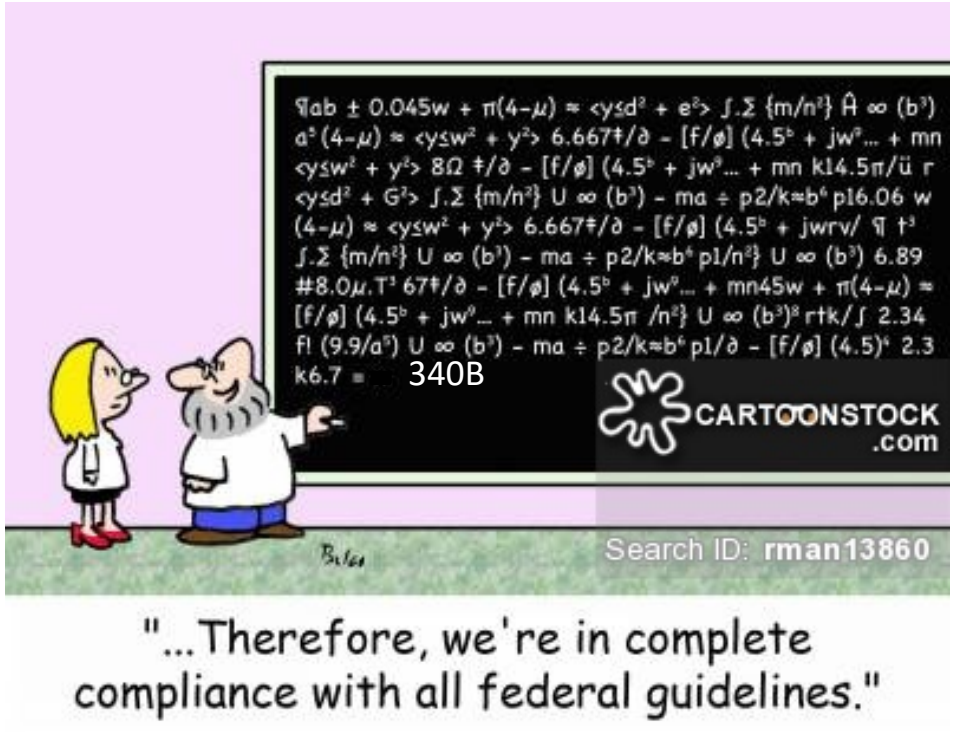
Oversight

- The 340B program is managed by the Health Resources and Services Administration (HRSA), which is an agency of the Department of Health and Human Services.
- HRSA is charged with ensuring compliance of both covered entity providers and participating manufacturers.

HRSA
Health Resources & Services Administration

Regulatory Framework

- While HRSA's Office of Pharmacy Affairs (OPA) is charged with enforcing the program requirements of 340B, unlike many familiar regulatory structures, OPA lacks clear statutory rulemaking authority.
- Consequently, the 340B Program requirements are in large part described in terms of *guidance* rather than traditional *regulation*.



Prime Vendor Program (PVP) - Apexus

- Further, much of the communication of such guidance has been delegated to the 340B “prime vendor program” (PVP).
- Apexus, a non-governmental private corporation is the current PVP and much of the guidance to date is published in the form of FAQs.
  - HRSA relies on Apexus to communicate policy and provide education, training, and support to all 340B stakeholders.

Apexus | 340B Prime Vendor PROGRAM™

https://www.340bpvp.com/controller.html

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Eligibility for 340B Pricing

Generally, 340B covered entities are able to purchase 340B discounted drugs for their patients receiving outpatient services.

- Eligible Organizations / Covered Entities
- Patient Definition
- Covered Outpatient Drugs

Eligible Organizations

The types of organizations that are eligible to participate in the 340B program include qualifying hospitals, Federal grantees from HRSA, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service.

- The eligible hospital organizations include:

Disproportionate Share Hospitals	Free Standing Cancer Hospitals
Children's Hospitals	Rural Referral Centers
Critical Access Hospitals	Sole Community Hospitals

- Importantly, each type of organization has its own corresponding qualification and compliance requirements.

Other Hospital Requirements

All of the Hospital-type covered entities must be one of the following:

1. Owned or operated by a State or Local government
2. A private, non-profit hospital with a valid contract with a State or Local government to provide health care services to low-income individuals who are not entitled to benefits under Medicare or eligible for State Medicaid
3. A public or private non-profit hospital that has been formally granted governmental powers.

Eligibility Limited by Medicare Cost Report

- In order to be eligible to dispense 340B-purchased drugs, all outpatient clinics and services must be reimbursable sites on the hospital's Medicare cost report.
  - Typically located on lines 50 to 118. Must be able to demonstrate outpatient costs on Worksheet A. Reimbursable clinics must also show outpatient charges on Worksheet C.
  - All off-site outpatient clinics and services located outside the four walls of the hospital that intend to use or purchase 340B drugs for its patients must register as *Child Sites.*

HRSA Policy on Off Campus Outpatient Facilities

- Pre-COVID PHE
  - 340B cannot be used until the new outpatient location appears on a filed Medicare cost report with associated costs and charges and is registered with HRSA.
- COVID PHE
  - FAQ on HRSA OPA COVID-19 said that patients not yet registered locations may be eligible for 340B to the extent that they are patients of the CE.
- Ending of PHE
  - HRSA initially shared language with 340B Health stating that it would stop permitting use of 340B in unregistered child sites – Not released. Later published “the specific COVID-19 PHE flexibilities allowed under the 340B Program will expire on May 11, 2023.” Did not specify that HRSA intended to revert back to Pre-COVID policy.

Patient Definition

An individual is a patient of a 340B covered entity only if:

1. Establish a relationship with the individual
   - Maintain records of the individuals care
2. Health care professional employed by the hospital or under contractual or other arrangements (e.g., referral for consultation) provides health care to the individual
   - Hospital remains responsible for the care provided
3. Services must be more than dispensing. An individual will not be considered a patient if the only health care service received is the dispensing of a drug(s) for subsequent self-administration or administration in a home setting

Adapted from a slide by 340B Health, HRSA Audit Trends: Findings and Focus Points, April 9, 2019

340B Covered Outpatient Drugs

- **Eligible Drugs:**
  - FDA-approved prescription drugs
  - Over-the-counter drugs (with a prescription)
  - Clinic administered drugs
  - Biologics and insulin
- **Drugs not covered include:**
  - Vaccines
  - Inpatient drugs
  - Drugs not directly reimbursed
  - FDA doesn’t require NDC

Locations a Patient Receives 340B Drug

Source: 340B Health, 340Bootcamp Series 1, What is 340B? May 11, 2022

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340B Program Compliance Requirements

- Prevent Diversion of 340B discounted drugs to ineligible patients.
- Prevent Duplicate Discount.
- Comply with Group Purchasing Organization (GPO) Prohibition.
- Comply with Orphan Drug Exclusion.
- Recertify eligibility annually.
- Maintain auditable records in preparation for HRSA audit.

Applicability of Requirements

Covered Entity Type	Non Profit or Government Contract	DSH %	Prevent Diversion	Prevent Duplicate Discount	GPO Prohibition	Orphan Drug Exclusion
DSH Hospital	Yes	>11.75%	Yes	Yes	Yes	No
Children's Hospital	Yes	>11.75%	Yes	Yes	Yes	No
Free-Standing Cancer Hospital	Yes	>11.75%	Yes	Yes	Yes	Yes
Rural Referral Center	Yes	>8%	Yes	Yes	No	Yes
Sole Community Hospital	Yes	>8%	Yes	Yes	No	Yes
Critical Access Hospital	Yes	N/A	Yes	Yes	No	Yes

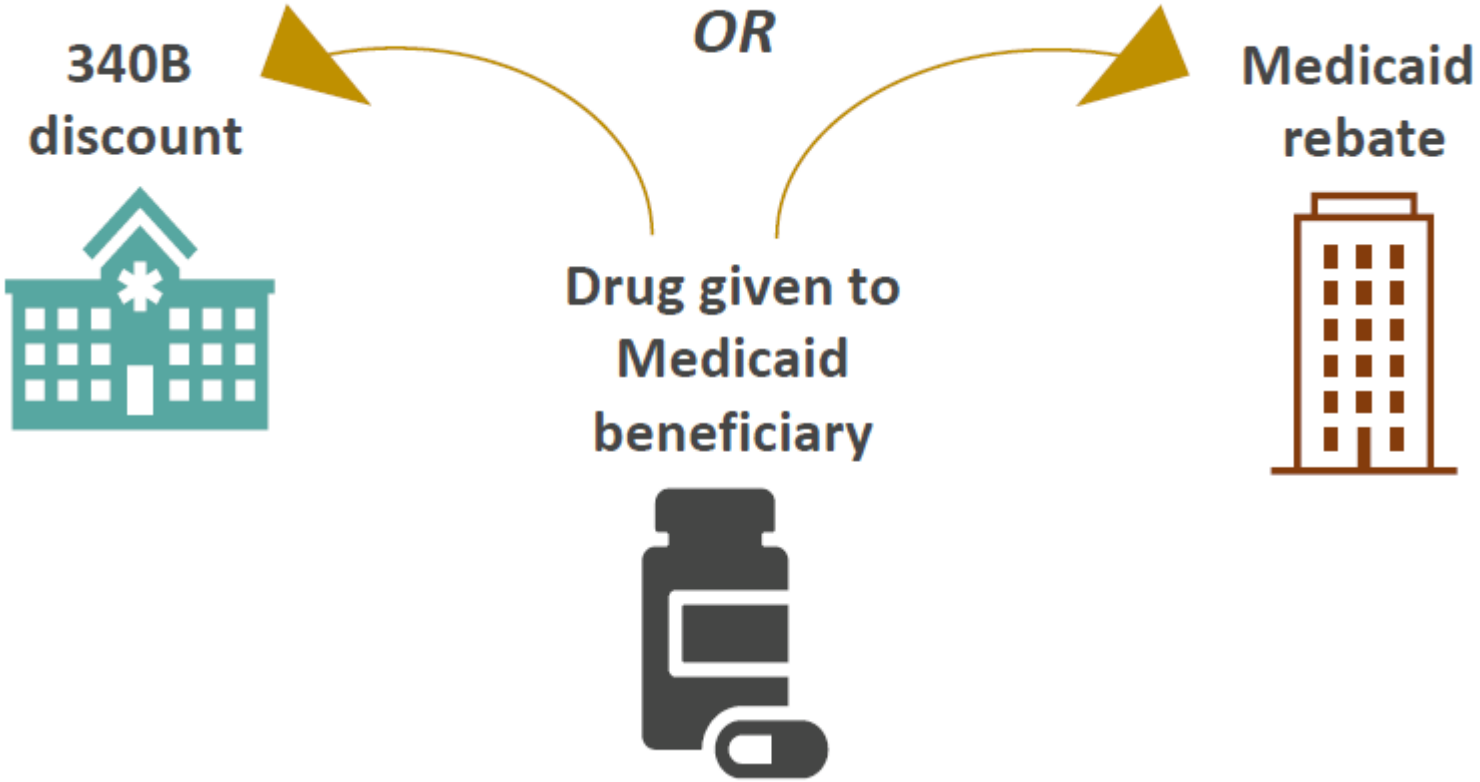
Diversion

- Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients.
- Risk areas:
  - Inpatients
  - Location(s) not reimbursable on the most recently filed Medicare Cost Report
  - Non-exclusive providers (provider has privileges but also works at a private practice)
  - Infusion only services: order written by a provider that has no relationship to the covered entity. Eligible if there is documentation of health services provided by the covered entity in connection with the infusion; this will usually be the administration of the infusion and monitoring

Duplicate Discounts

- Manufacturers are not required to provide discounted 340B price and Medicaid drug rebate for the same drug.
- Covered entities must choose whether they will use 340B drugs for their Medicaid patients (carve-in) or procure drugs for Medicaid patients from other sources (carve-out).
- Carve-in covered entities must assist in preventing state Medicaid programs from additionally taking Medicaid drug rebate by listing hospital Medicaid provider number or NPI on Medicaid exclusion list.
- Risk Areas:
  - Multiple Medicaid Provider Numbers
  - State billing requirements
  - Out-of-state Medicaid billing

Duplicate Discounts (Cont.)



Adapted from a slide by 340B Health, 340Bootcamp, Part 2: Diversion, Duplicate Discounts and 340B Audits. May 18, 2022

GPO Prohibition

- Covered entities subject to the GPO Prohibition must not obtain covered outpatient drugs through a GPO.
- Current guidance gives covered entities the discretion to develop internal policies to determine inpatient vs. outpatient status.
- Risk Areas:
  - Mixed-use areas
  - Direct from manufacturer purchases
  - Consignment

Orphan Drug Exclusion

- For Covered Entities subject to the Orphan Drug Exclusion, “covered outpatient drug” does not include any drug designated by the FDA for the treatment of a rare disease or condition.
- Covered entities may not purchase designated orphan drugs at 340B discounted pricing

Billing and Reimbursement

- Billing: Claim Identification
  - Medicare
    - Claims paid under the Outpatient Prospective Payment System (OPPS) must have 340B claim modifiers: JG or TB.
  - Medicaid
    - Many states require use of a modifier to identify 340B claims.
    - Hospital – MO: JG or TB
    - Retail – MO: Submission Clarification Code 20, and Actual Acquisition Cost (AAC)
  - Commercial
    - Some payers are introducing 340B claim identifier requirements into payer agreements. This has primarily impacted pharmacy benefit manager (PMB) agreements that impact retail and specialty pharmacy.

Billing and Reimbursement (Cont.)

- Reimbursement
  - Medicare
    - Claims paid under the Outpatient Prospective Payment System (OPPS) must have 340B claim modifiers
  - Medicaid
    - Reimbursement for Medicaid FFS retail drugs, including 340B, must be based on actual acquisition cost (AAC) plus a professional dispensing fee.
  - Commercial
    - Some commercial payers lower reimbursement for 340B. This is seen as a discriminatory practice.
    - Currently there is no federal protection, but some states are enacting laws to protect hospitals from 340B discriminatory reimbursement.

HRSA Program Integrity Audits

- Covered entities are subject to audit by the federal government (HRSA) or manufacturers
- Covered entities will be audited for all 340B Program requirements
  - Focus on Eligibility, Diversion, Duplicate Discount, and 340B OPAIS accuracy
- Bizzell Group – HRSA's subcontractor, performing all integrity audits
- Any covered entity that fails to comply with 340B Drug Pricing Program (340B Program) requirements may be liable to manufacturers for refunds of the discounts obtained or removed from the 340B Program.

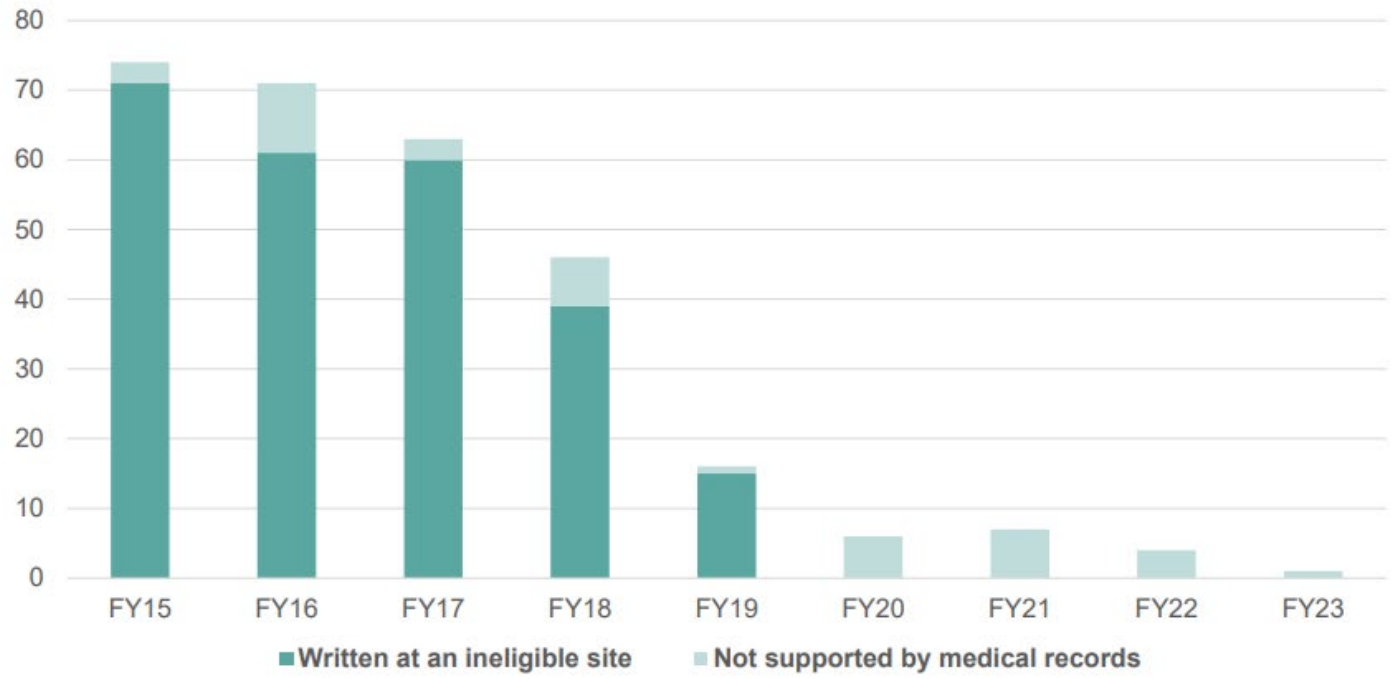
2023 HRSA Audit Trends

- Most Common Finding issued for FY23 audits – Database Errors
  - Incomplete, inaccurate or missing entity and/or individual information (i.e. incorrect address or phone number)
  - Contract pharmacy registered without a written contract in place
  - Duplicate registrations

Adapted from a slide by 340B Health, Year in Review: 340B Developments. December 13, 2023

2023 HRSA Audit Trends (Cont.)

Changes in Diversion Findings for Hospitals, FY 2015-2023: Ineligible Site v. Not Supported by Medical Records



340B HEALTH

Source: 340B Health: Implication of Genesis Decision on 340B Patient Definition. November 30, 2023

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What is a Contract Pharmacy?

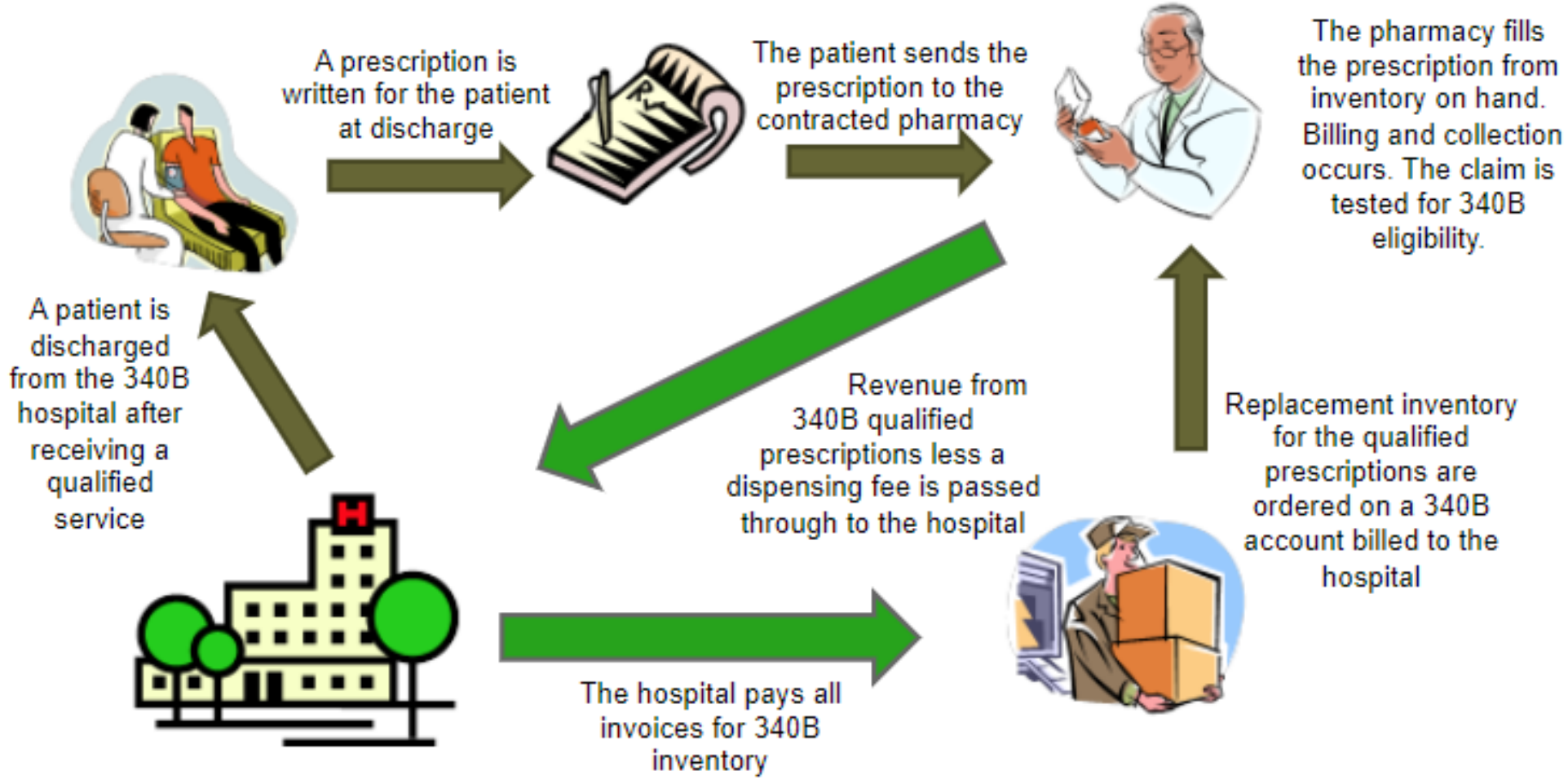
A contract pharmacy:

- Contracts with covered entity to dispense 340B drugs to its patients
- Helps facilitate/expand program participation for those covered entities that
  - Do not have access to available or appropriate ‘‘in-house’’ pharmacy services
  - Have access to ‘‘in-house’’ pharmacy services but wish to supplement these services
  - Wish to utilize multiple contract pharmacies to increase patient access to 340B drugs

Contract Pharmacy Requirements

- Covered Entity must have written contract with a pharmacy to provide pharmacy services. The written contract must include and comply with HRSA's 12 contract pharmacy essential compliance elements.
  - Fee structure
  - Data: Reporting/Auditing
  - Supports program integrity and aligns with program intent
- Bill to/ship to arrangement typically used
- Registered on HRSA 340B OPA Information System (OPAIS)
- Must carve-out Medicaid*
- Covered entities are responsible for ensuring compliance of their contract pharmacy

Contract Pharmacy Model



WIPFLi (2015). 2015 HFMA Annual Update: 340B Drug Pricing Program [PowerPoint Slides].

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OPPS Remedy

- Centers for Medicare & Medicaid Services (CMS) issued final rule (CMS 1793-F) remedy for repaying 340B hospitals for unlawful Medicare cuts from 2018-2022
  - Repayment will be be lump sum amounts to impacted hospitals.
  - CMS requires that Medicare Administrative Contractors (MACs) issue the one-time lump sum payments to affected 340B hospitals within 60 calendar days of receiving the payment instruction from CMS. Estimated that CMS will likely make the lump sum payments at the beginning of CY 2024.
  - Link to Addendum A: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1793-f
- CMS issued the final rule before the final rule on November 2, 2023. The final rule went into effect on January 8, 2024.
- CMS does not anticipate cutting reimbursement only for 340B drugs again in the near future.

340B Restrictions on Contract Pharmacy

- In September 2020, Eli Lilly imposed the first 340B restrictions on contract pharmacies. The current list is up to 29 manufacturers.
- Restrictions impose a significant reduction in contract pharmacy benefit.

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

*further restricted from original policy

HRSA Notice and Other Updates

October 27, 2023:

- HRSA filed notice that they would be reverting to its earlier policy that requires offsite, provider-based hospital outpatient locations to appear on a filed MCR with associated costs and charges and be registered in the HRSA Office of Pharmacy Affairs Information System (OPAIS) before hospitals can use 340B drugs at those locations.

October 31, 2023:

- 40+ hospitals and health systems have sued HRSA to block the agency from implementing a notice requiring offsite, provider-based outpatient locations of a hospital to appear on a filed Medicare cost report (MCR) before those sites can use 340B drugs.

December 15, 2023

- HRSA added a compilation of 340B patient definition compliance resources to its website.
  - Multiple references to requirements that do not appear in HRSA's patient definition guidelines but that link 340B drug eligibility to health services furnished in provider-based locations of the hospital that are reimbursable on the hospital's Medicare cost report.
  - Employees
  - Self-audit practices

Genesis

On November 3, 2023 a federal judge in South Carolina filed a decision for a lawsuit filed by Genesis Health Care challenging a diversion finding issued by HRSA.

- The federal court filed a ruling that HRSA cannot require covered entities to have initiated the health care service resulting in a prescription as a condition of using 340B for that prescription.
- Congress intended for 340B to have a “broad application” to protect covered entities from prescription drug price increases by helping them “increase their profit margins” through access to drug discounts. “It is not the role of HRSA to legislate and limit the 340B program by restricting the definition of the term ‘patient,’ thereby frustrating the ability of the 340B statute to accomplish its purpose,” the decision states.
- Potential for significant impact on HRSA’s authority to implement its interpretation of the statutory term “patient.”
- Breaking news on January 4, 2024:

Genesis (Cont.)

Considerations:

- Statute requires that patient relationship be “ongoing.”
- Court also said there was no specific time limit in the statute.
- Relevance of script being written by a provider credentialed by the hospital?
- Importance of referral documentation?
- Do outside prescriptions have to tie to the diagnosis treated by the CE hospital?
- Dispensing for self-administration – additional services provided?
- Application to physician administered drugs
- Hospital in-house retail and contract pharmacies
- Inadvertent duplicate accumulation if individuals are patients of multiple CEs
  - Many TPAs and contract pharmacy chains use software that already prohibit duplicate accumulation
- Medication therapy management

2023 Notable Developments

- **Medicare Part B Remedy and 2024 OPPS Rule**
- **Contract Pharmacy**
  - Tighter restrictions
  - Less 340B benefit
- **HRSA Developments**
  - Compliance Letters
  - Genesis Lawsuit
  - Audit Findings
- **State Actions**
  - Reporting requirements (Maine, Minnesota, Washington)
  - Laws to protect 340B CEs – 29 states

Adapted from a slide by 340B Health, Year in Review: 340B Developments. December 13, 2023

MO Legislation

- **2024 Legislation**
  - MHA Bill: SB 751 (Sen. Brown)
    - White-bagging
    - 340B discriminatory reimbursement
    - Biosimilars
  - FQHC only bills: SB 978 (Trent) SB 1035 (Beck), HB 1977 (Stinnett)
  - PBM with 340B: SB 1213 (Moon)
  - PBM sans 340B: HB 1627 (Wright), SB 834 (Bernskoetter), SB 1105 (Fitzwater)

Questions???