The 340B Program

Overview and Compliance

Jake Simons, MHA, MSHI, 340B ACE

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
- Inventory Management
- 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.

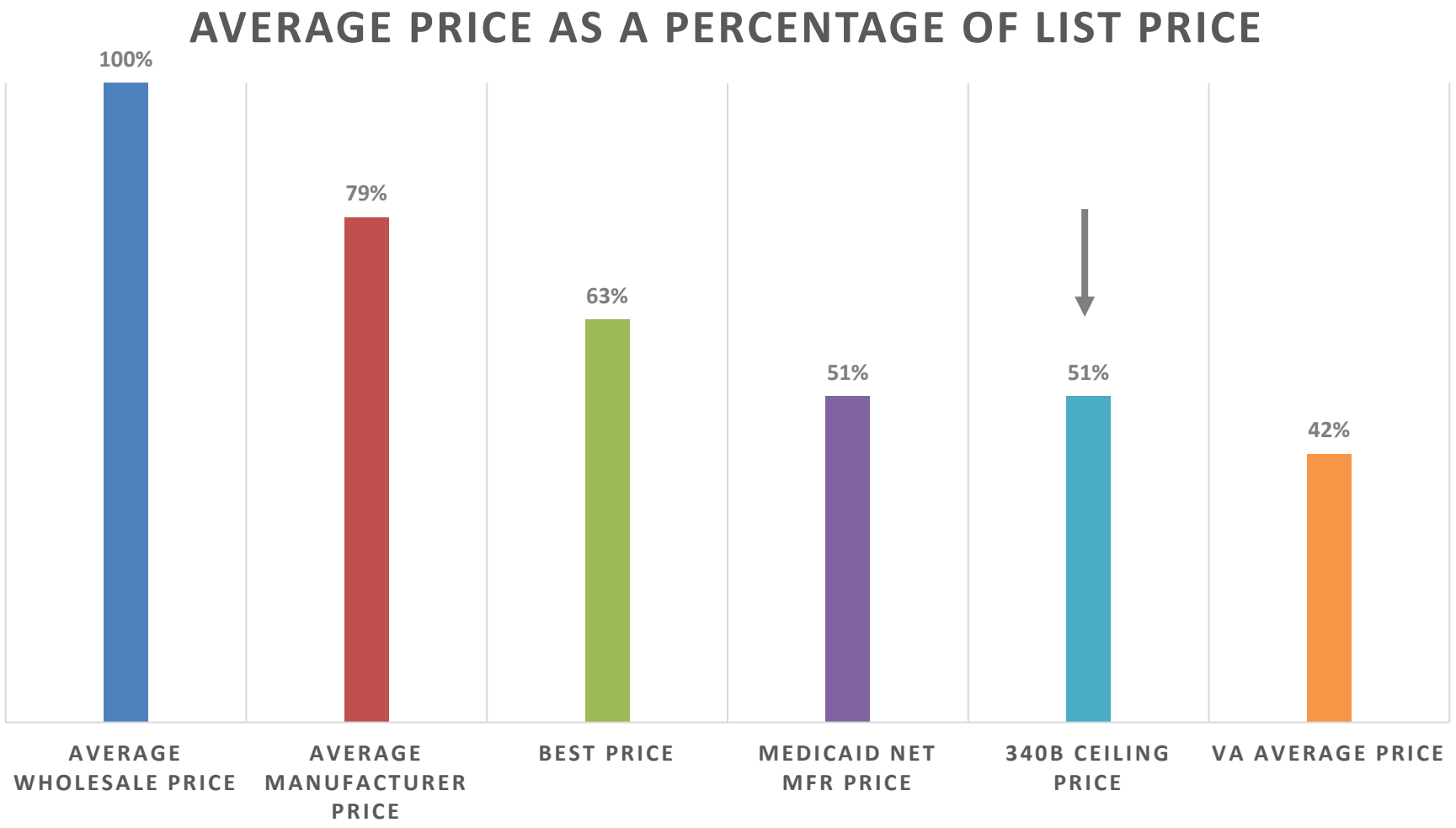
340B Price

- 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)

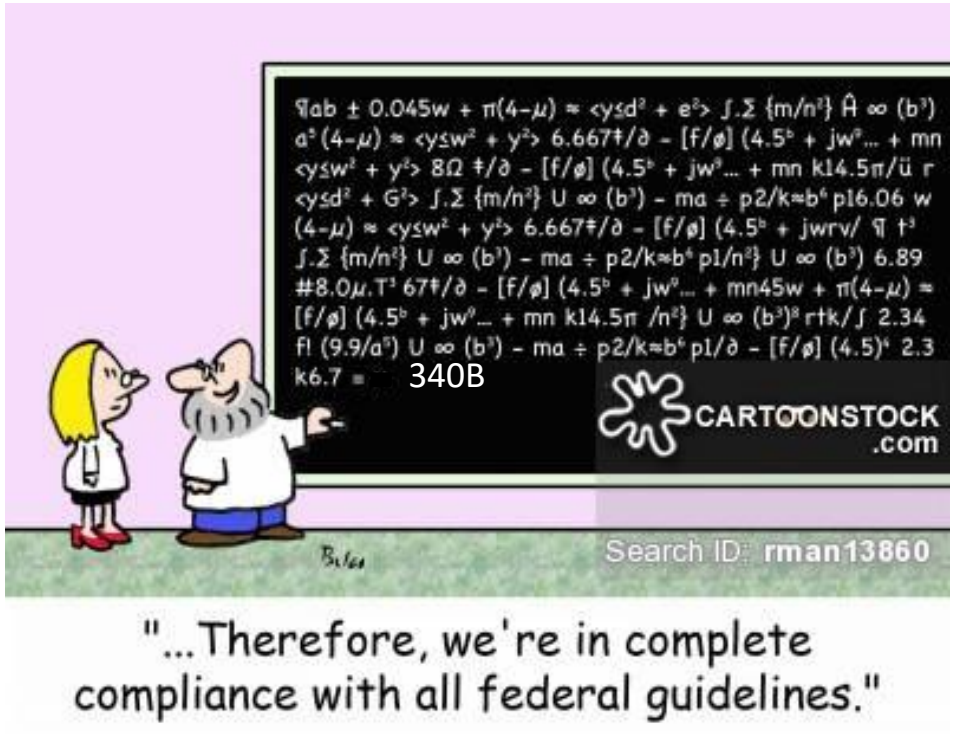
Oversight

- 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 most recently filed 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.*
  - *New locations that are not yet registered with OPA, but that are either (i) listed on the CE's most recently-filed Medicare cost report with reimbursable outpatient costs and charges or (ii) will be listed with such on the next filed MCR, are 340B Eligible Locations where 340B drugs can be purchased and/or used.*

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

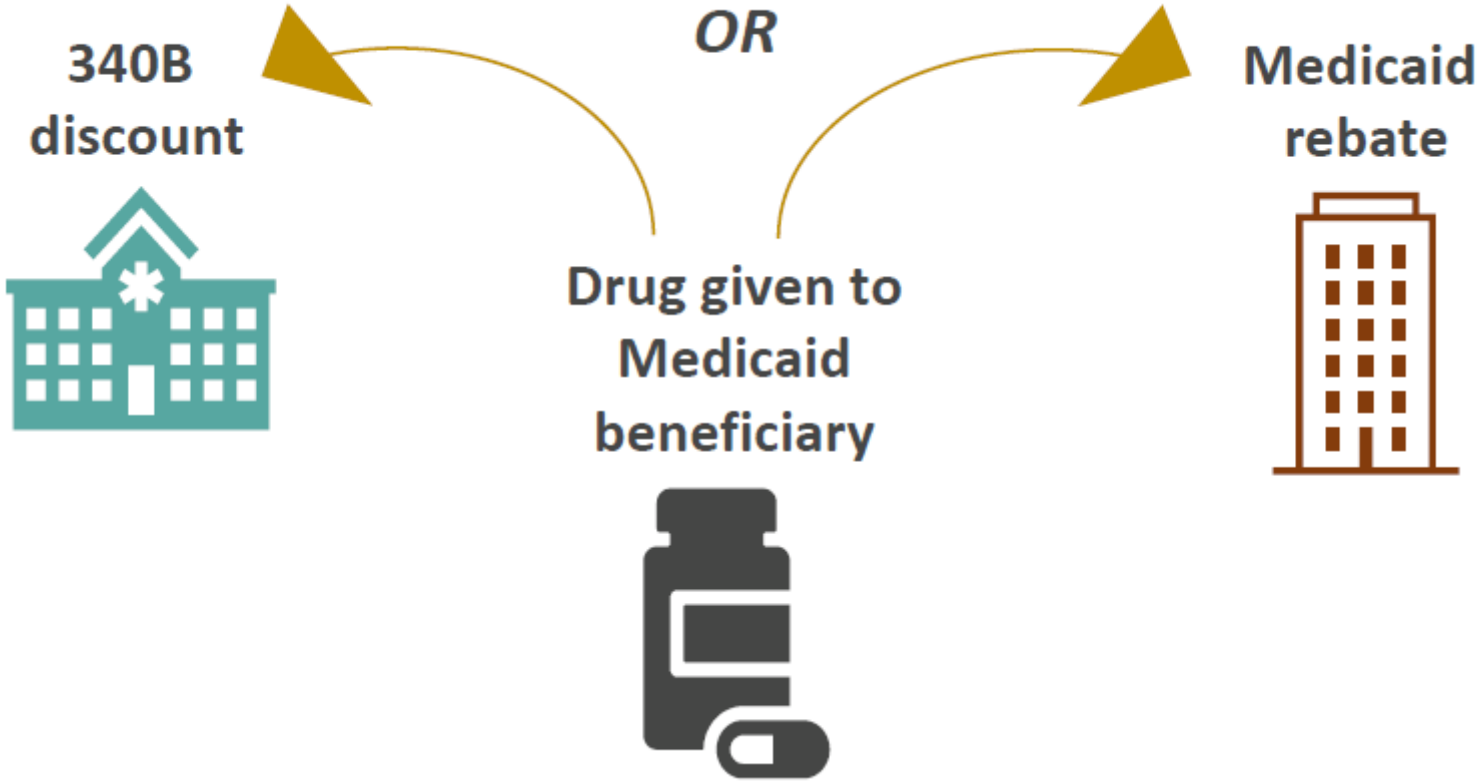
Diversion

- 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

Compliance Considerations

- 340B Oversight Committees
- Dedicated 340B resources
- Leadership Commitment*
- Comprehensive Policies and Procedures*
- Rigorous self-audits*
- 340B Compliance Solutions Vendors
  - Split-billing
  - Third Party Administrator (TPA)
- Independent Audits*
- Education and Training*
- Prepare for program audits*
- Keep 340B OPA Information System (OPAIS) information accurate and up-to-date*

*HRSA Expectations

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.

HRSA Program Integrity Audits (Cont.)

More than 1,600 covered entity audits since 2012

- 78% are of Hospitals

FY21 Hospital Audit Findings

- Diversion: 9%
- Duplicate discount: 16%
- Inaccurate Medicaid exclusion file: 8%
- Inaccurate database: 49%
- GPO exclusion: 2%

200 covered entity audits annually

Adapted from a slide by 340B Health, HRSA Audit Trends, Part 2: Diversion and Duplicate Discount Policy Update. May 4, 2022

HRSA Audit Trends

	FY15	FY16	FY17	FY18	FY19*	FY20	FY21**
Diversion	54%	54%	52%	40%	16%	6%	9%
FFS Duplicate Discount	20%	22%	24%	29%	26%	17%	16%
Inaccurate Medicaid Exclusion File	6%	5%	5%	8%	3%	6%	8%
Inaccurate Database	48%	28%	29%	31%	25%	21%	49%
GPO Exclusion	11%	6%	4%	1%	3%	<1%	2%

Source: 340B Health, HRSA Audit Trends, Part 2: Diversion and Duplicate Discount Policy Update. May 4, 2022

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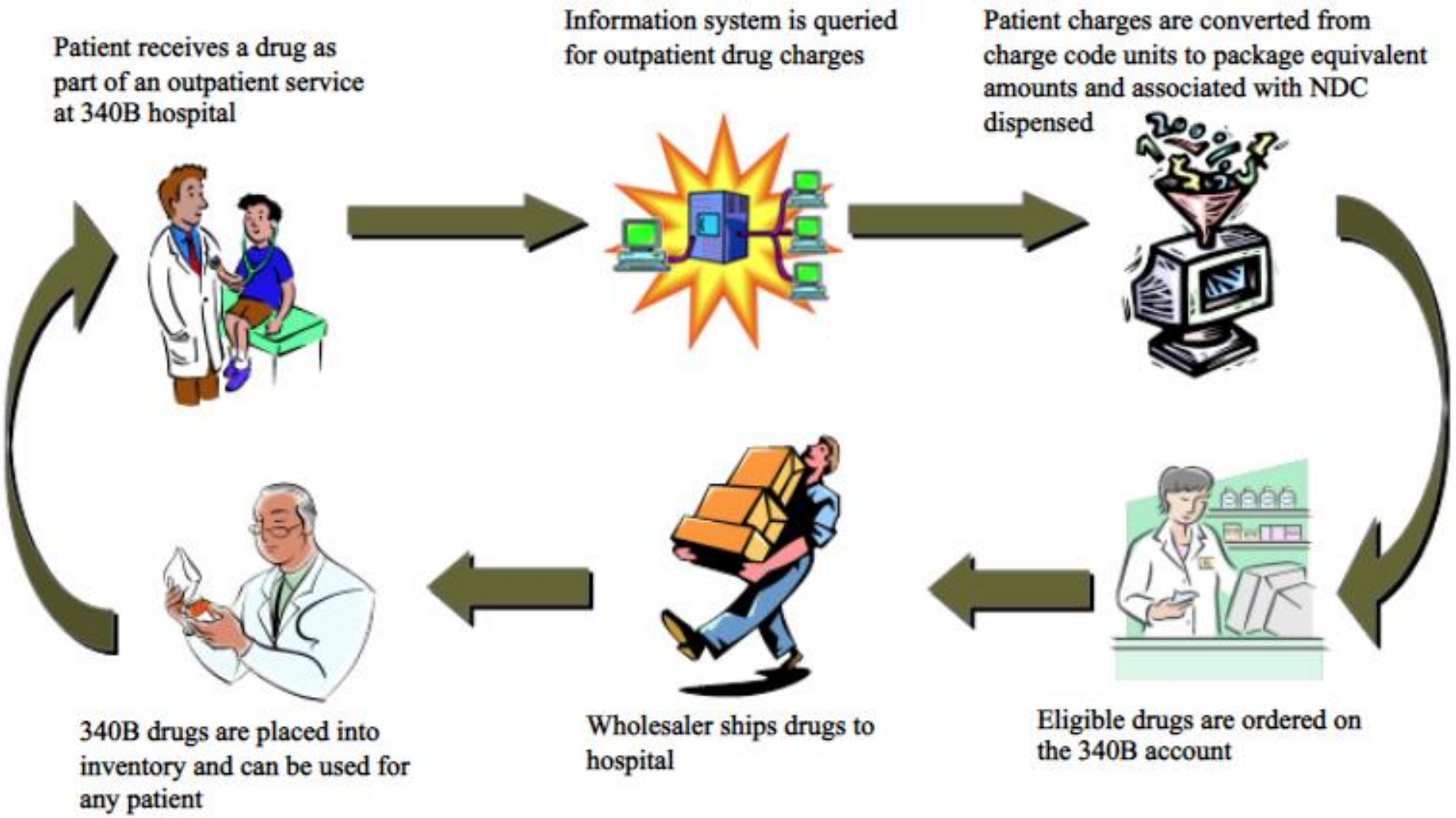
Inventory Management Methods

The three common inventory models used most often by 340B entities include:

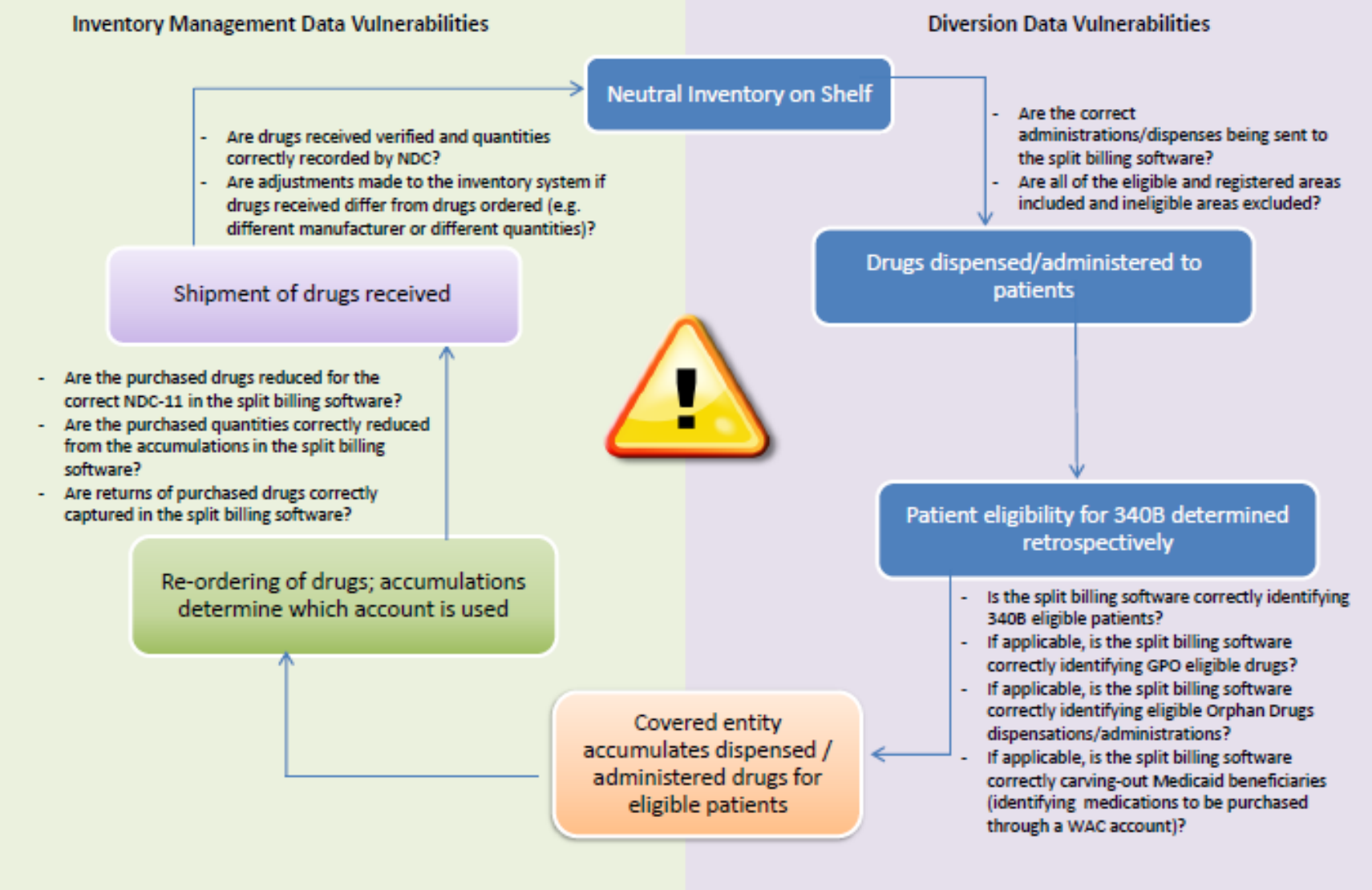
- **Separate physical inventory** – entity maintains physically separate inventory for products purchased on different wholesaler accounts.
- **Replenishment inventory model** – 340B drug replenishment occurs when a non-340B drug is dispensed to a 340B-eligible patient, and the entity later replaces the non-340B dispensed drug with a 340B purchased drug because of patient eligibility.
  - Neutral Inventory
- **Hybrid inventory model**

Virtual Inventory



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

Virtual Inventory Complexities



HRSA 340B Peer-to-Peer Resource Network, Managing 340B Inventory and Associated Data Vulnerabilities in a Virtual System. April 8, 2015

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What is a Contract Pharmacy?

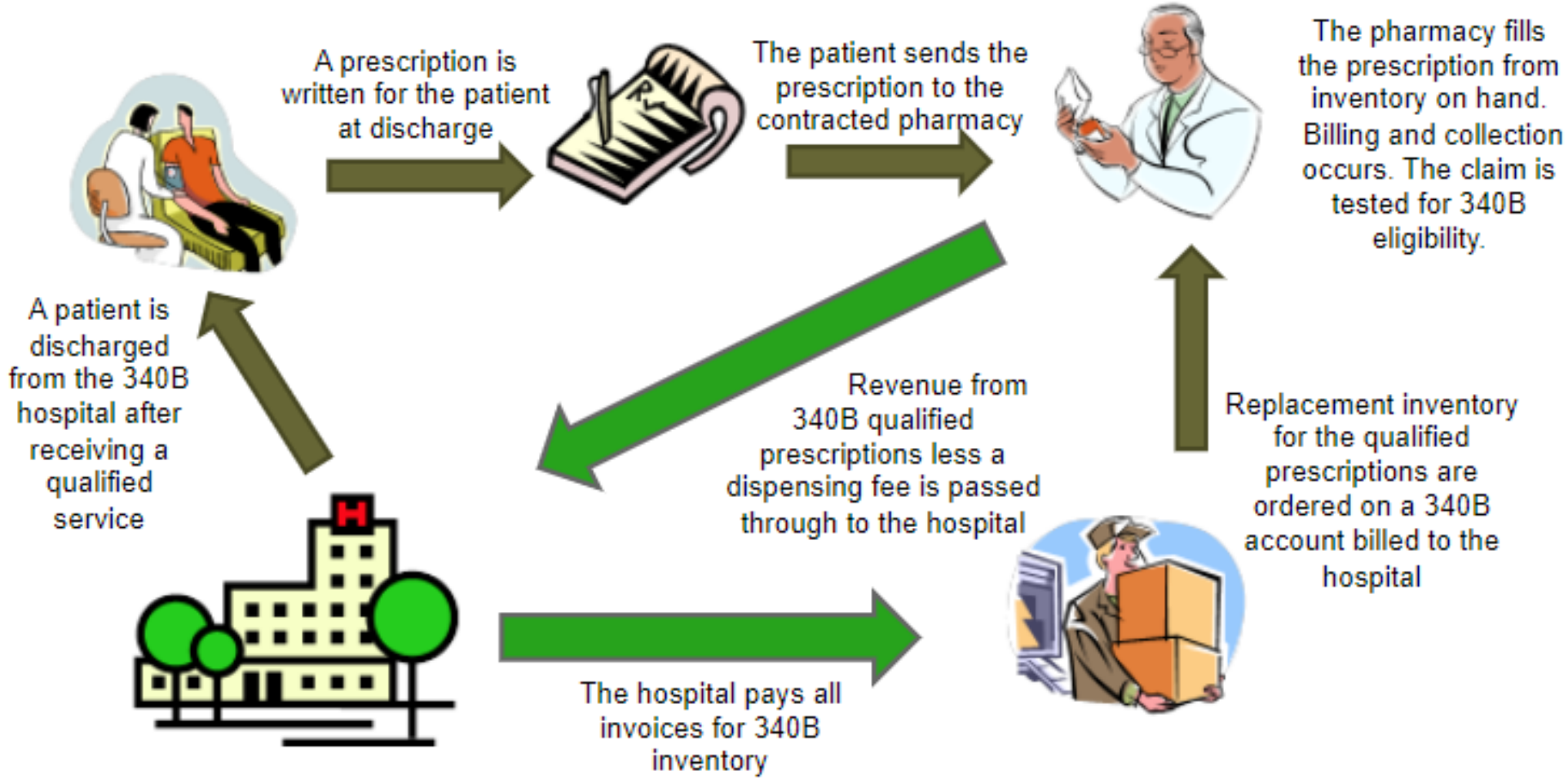
A contract pharmacy:

- 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



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Regulation Changes Impacting 340B Entities

- **CY 2018 OPPS Final Rule**
  - Payment reduction to certain 340B hospitals for Part B drugs: ASP + 6% to ASP – 22.5% for status indicator “K” drugs
  - JG & TB Modifier Requirements
- **CY 2023 OPPS Final Rule**
  - What changes are in store??
- **Site-neutral Payment Rule** - Section 603 of the Bipartisan Budget Act of 2015
- **JW Modifier Policy (Waste)**
- **State Medicaid Trends**
  - State Plan Amendments
  - 340B Actual Acquisition Cost (AAC)
  - Claim modifiers (i.e. UD)
  - NDC requirements
  - Mandatory carve out/carve in
  - Resources
    - https://dss.mo.gov/mhd/providers/pdf/bulletin39-52_2017april14.pdf
    - http://manuals.momed.com/edb_pdf/D.0%20Companion%20Guide.pdf
    - https://dss.mo.gov/mhd/providers/pdf/bulletin41-42_2-19.pdf

Regulation Changes Impacting 340B Entities (Cont.)

- Inflation Reduction Act
  - In 2026, Medicare can begin to negotiate prices for 10 drugs in Part D. In 2027, an additional 15 Part D drugs will be added, and in 2028 another 15 Part D or Part B drugs will be negotiated. In 2029 and in each subsequent year, an additional 20 Part D or B drugs will be added;
  - Prices for selected drugs will be reduced by a projected 25% to 60%, with higher price reductions for drugs that have been on the market longer;
  - Medicare reimbursement and cost-sharing will be based on these lower prices;
    - Lower Medicare reimbursements for negotiated drugs will reduce the total amount of 340B savings that covered entities realize from purchasing them for Medicare patients
  - In 2023, manufacturers that increase a drug's price faster than inflation must provide rebates to the government for the above-inflation amount of their price increase; and
  - In 2025, Medicare beneficiaries' out-of-pocket costs for Part D drugs will be capped at $2,000 per year.

Advocacy and the Politics

- U.S. Supreme Court Strikes Down Medicare Part B Drug Payment Cuts for 340B Hospitals in 2018 and 2019
  - Part B payment cuts for 340B hospitals in 2020, 2021, and this year, are unaffected by the decision.
- CMS proposing a payment rate of ASP minus 22.5% for drugs an biologics acquired through the 340B Program, but anticipates applying a rate of ASP plus 6% in the final rule, in light of the Supreme Court's decision.
- 14+ state legislatures enact legislation addressing third part payer discriminatory reimbursement and billing practices
  - West Virginia, Vermont, Utah, Tennessee, South Dakota, Oregon, Ohio, North Dakota, North Carolina, Montana, Minnesota, Indiana, Georgia, and Arkansas
- Legislation in Missouri?
  - **HB 1677 (MO Pharmacist Association)**
  - **HB 2305 (MHA)**
  - **SB 1129 (MHA)**
  - ***Session ended and no proposals made it to the finish line. Gear up for 2023!!***

340B Restrictions on Contract Pharmacy

- In September 2020, Eli Lilly imposed 340B restrictions on contract pharmacies.
- Manufacturer justification is to resolve duplicate discount issues
- To date, 17 additional manufacturers have followed suit
- Restrictions impose a significant reduction in contract pharmacy revenue
- 14 manufacturers will restore 340B pricing, if the covered entity shares claims data with a vendor called 340B ESP
- Data use and future risk unknown – potential impact on PBM reimbursement due to reduction in rebates
- HRSA ordered 8 companies to reinstate 340B discounts; 7 sued in 4 federal district courts; decisions have been mixed

Manufacturer Restrictions

	Lilly	AstraZeneca	Sanofi	Novartis	United Therapeutics	Novo Nordisk	Boehringer Ingelheim	Merck	UCB Pharma	Amgen	Abbvie	Bristol Myers Squibb	Pfizer	GlaxoSmithKline	Gilead	Janssen	Exelixis	Bausch Health
Effective Date	Sep 1, 2020	Oct 1, 2020	Oct 1, 2020	Nov 16, 2020	Nov 20, 2020	Jan 1, 2021	Aug 1, 2021	Sep 1, 2021	Dec 13, 2021	Jan 3, 2022	Feb 1, 2022	Mar 1, 2022	Mar 1, 2022	Apr 1, 2022	May 2, 2022	May 2, 2022	Jul 2, 2022	Aug 2, 2022
Other Conditions		CP's with the existing AZ Sx Network		40-mile radius	CEs + CPs w/ 340B purchase Q1 - Q3 '20													
CP Exceptions	1 CP for CEs w/o pharmacy, Wholly owned CPs subject to conditions	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy , Wholly owned CPs	1 CP for IMiDs, and 1 for non-IMiDs for CEs w/o pharmacy, Wholly owned CP	Grantee, 1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs	1 CP for CEs w/o pharmacy, Wholly owned CPs
340B ESP	**Data Required** *Effective 10/29/2021	**No Data Option**	**Data Required**	Voluntary Data Sharing	**Data Required**	**No Data Option**	**No Data Option**	**Data Required**	**No Data Option**	**Data Required**	**Data Required**	**Data Required**	**Data Required**	**Data Required**	**Data Required**	**Data Required**	**Data Required**	**Data Required**
Products Included	All Products	All Products	All Products	All Products	Adcirca, licensed w/ Lilly	All Products	All Products	All Products	All Products	Aimovig, Enbrel, Otezla, Repatha	24 products	All Products	Xeljanz and Oral Oncolytics	9 Inhaled Drugs	Epclusa, Harvoni, Sovaldi, and Vosevi	29 Products	Cometriq and Cabometyx	All Products

Questions???