



Demystifying Pharmaceutical Class of Trade

A presentation for HealthTrust Members
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Learning Objectives

Pharmacists and Supply Chain Professionals

Recall the different pharmaceutical Class of Trade (COT) designations

Identify the pros and cons of pharmaceutical COT

Recognize the impact of COT on health-systems and Group Purchasing Organizations (GPOs)



Learning Objectives

Pharmacy Technicians

Recall the different pharmaceutical Class of Trade (COT) designations

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Definitions

Name	Abbreviation	Definition
Average Manufacturer Price	AMP	Average price paid to manufacturer
Average Sales Price	ASP	Average price sold by manufacturers to direct purchasers
Class of Trade	COT	Categorization of drug purchaser based on their business type
Diagnosis Related Group	DRG	A system used in healthcare reimbursement to classify patients into groups based on their diagnosis, treatment, age, sex, and other relevant factors
Drug Enforcement Agency	DEA	Federal law enforcement agency within the United States Department of Justice. Responsible for enforcing the controlled substances laws and regulations of the United States
Heath Industry Number	HIN	A unique and standardized identifier enumerating hospitals, providers, suppliers, and all other partners doing business in the supply chain
Group Purchasing Organization	GPO	An entity that helps healthcare providers, such as hospital and clinics leverage their collective purchasing power to negotiate discounts and obtain favorable pricing on medical supplies, equipment, and services from vendors and manufacturers
Wholesale Acquisition Cost	WAC	The price at which a manufacturer sells its drugs or medical products to wholesalers or direct purchaser. It is the list price before any discounts, rebates, or other price concessions are applied
New Technology Add on Payment	NTAP	Provides additional payment to hospitals for cases involving eligible new and innovative medical technologies that substantially improve patient care and outcomes
Outpatient Prospective Payment System	OPPS	Reimbursement system used by the Centers for Medicare & Medicaid Services (CMS) in the United States to reimburse hospitals and certain outpatient facilities for services provided to Medicare beneficiaries on an outpatient basis
Integrated Delivery Network	IDN	An organization that owns and operates a network of one or more healthcare facilities



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Introduction

Definition of Pharmaceutical Class of Trade

- Pharmaceutical COT refers to the various channels involved in the dispensing or administering a pharmaceutical product
- COT designations are **assigned by drug manufacturers** to each purchaser
- If a potential purchaser is not correctly classified, they may be restricted from acquiring the medication, or receive disadvantageous pricing

Examples of Pharmaceutical COT



Acute Care



Ambulatory Care



Retail



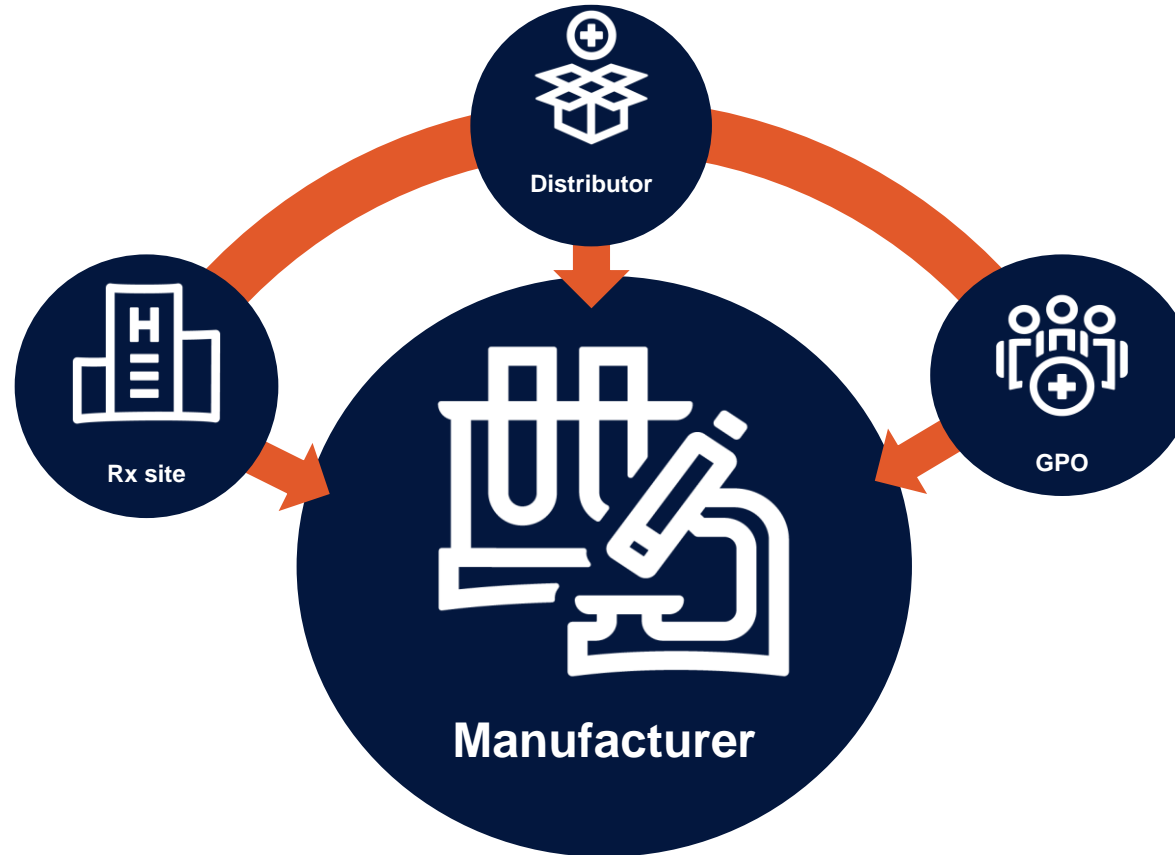
Home Health



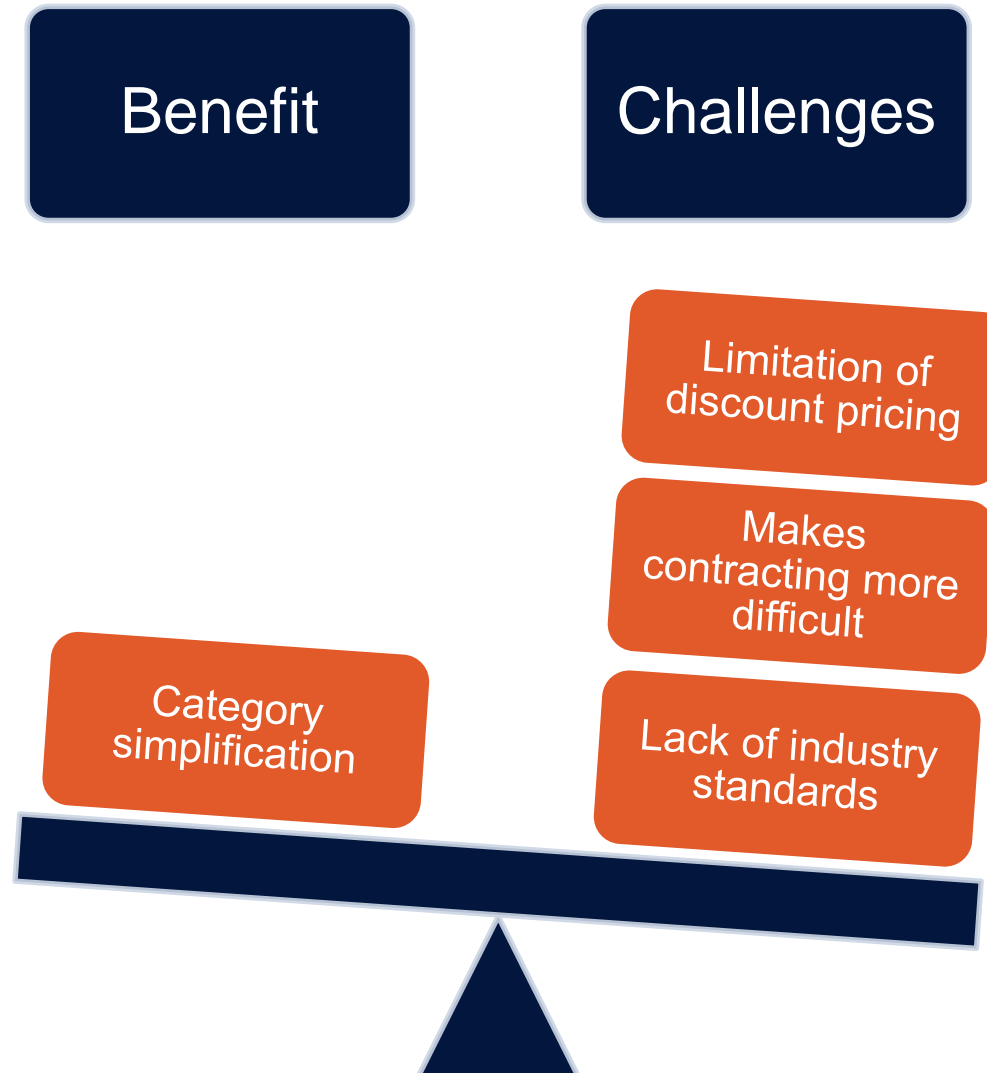
Long Term Care

Class of Trade Purpose and Influence

- COT Purpose – Categorize the general business intent of the purchaser



Class of Trade Benefit and Challenges



Class of Trade Determinations

Location

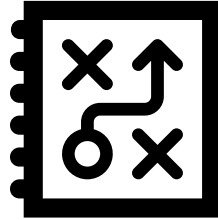
Therapy
Provided

Reimbursement
Strategy

Prescriber
Ownership

Closed Door
Status

Government
Program
Involvement



Assessment



Question #1

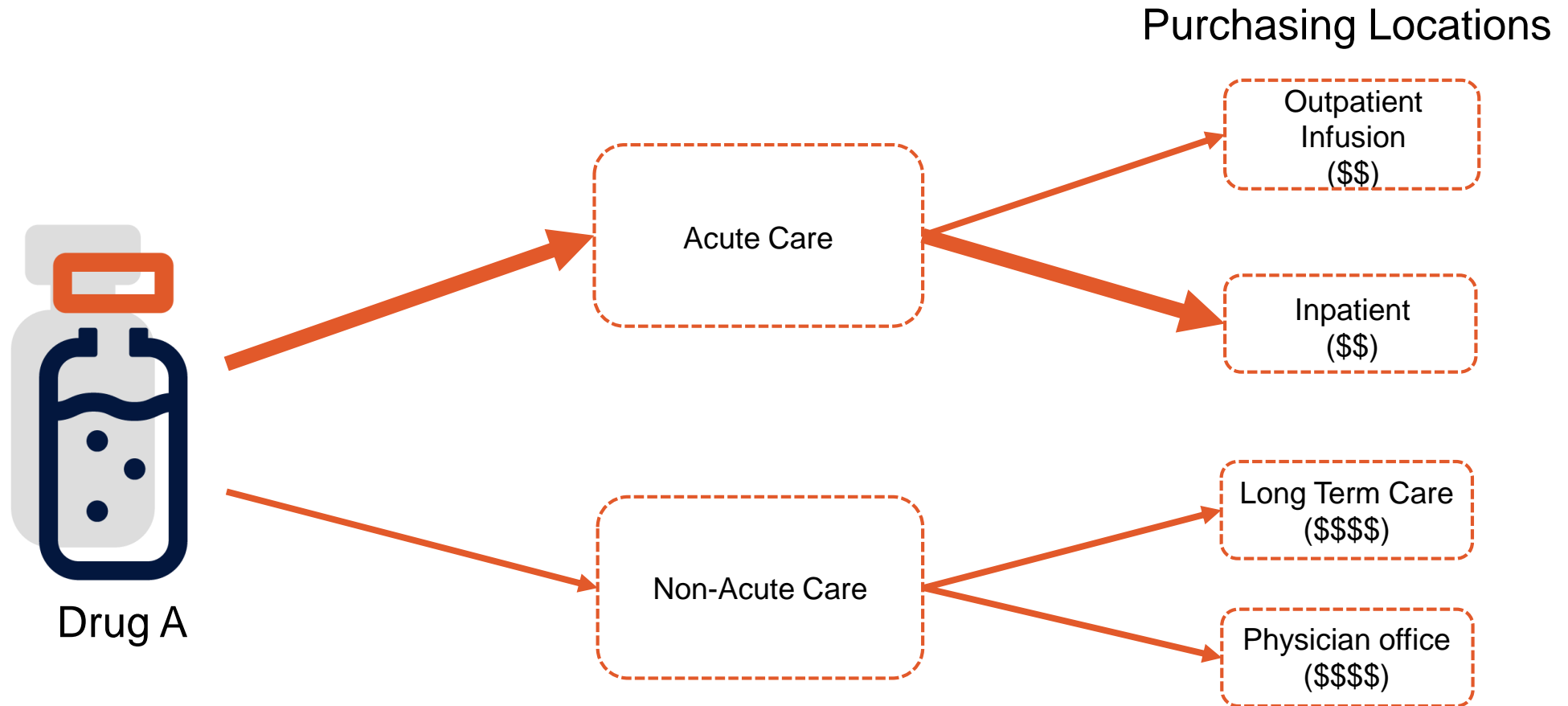
- Which of following may be a drawback of pharmaceutical Class of Trade?
 - A. Limiting access to discount pricing
 - B. Lack of industry standards
 - C. Class of Trade assignment process
 - D. All the above

Question #1, Correct Response

- Which of following may be a drawback of pharmaceutical Class of Trade?
 - A. Limiting access to discount pricing
 - B. Lack of industry standards
 - C. Class of Trade assignment process
 - D. **All the above**

Medications and Relation to Class of Trade

- Medications are routinely used in multiple COT



Manufacturer Imposed Reporting Requirements

Average Manufacturer Price

- Retail pharmacy direct sale or wholesalers
- **Retail pharmacy COT**
- AMP – Used to calculate drug rebates under Medicaid programs

Average Sales Price

- **Includes sales for all classes of trade***
- ASP is used by Medicare in the Medicare Part B program

*Sales to the US government and non-US entities are excluded

Manufacturer Imposed Pricing Requirements



Tracking

- Drug manufacturers must track and report all discounts provided



Best Price Policy

- State Medicaid programs must receive the lowest price



Other

- Antitrust laws



Baldwin, Paul. Don't Fall Asleep on Your COT (Class of Trade). 2023

Dolan R, Tian M. Pricing and Payment for Medicaid Prescription Drugs. KFF. 2020

Baghdadi R. Medicaid Best Price. HealthAffairs. 2017

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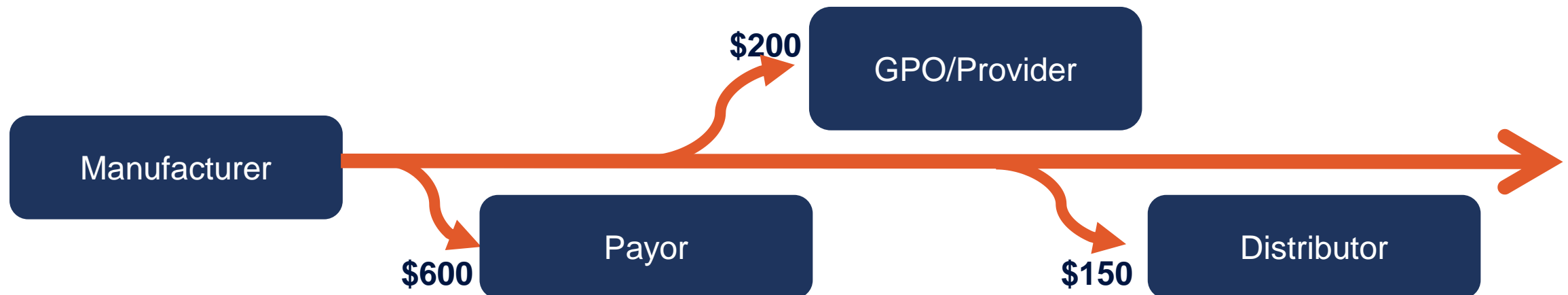
Peter RM, ed. Big pharma monopolies: major antitrust cases over the past decade. Labiotech. 2023

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Drug Manufacturers Discount Allocation

- Manufacturers strategically allocate discounts depending on where the drug is being purchased
 - In situations where drugs are reimbursed, payors tend to receive most of the discounts
 - In scenarios where providers control prescribing and administering, they can often receive the largest discounts
 - Distributor discounts may vary based on the difficulty of stocking and distributing the drug and other factors

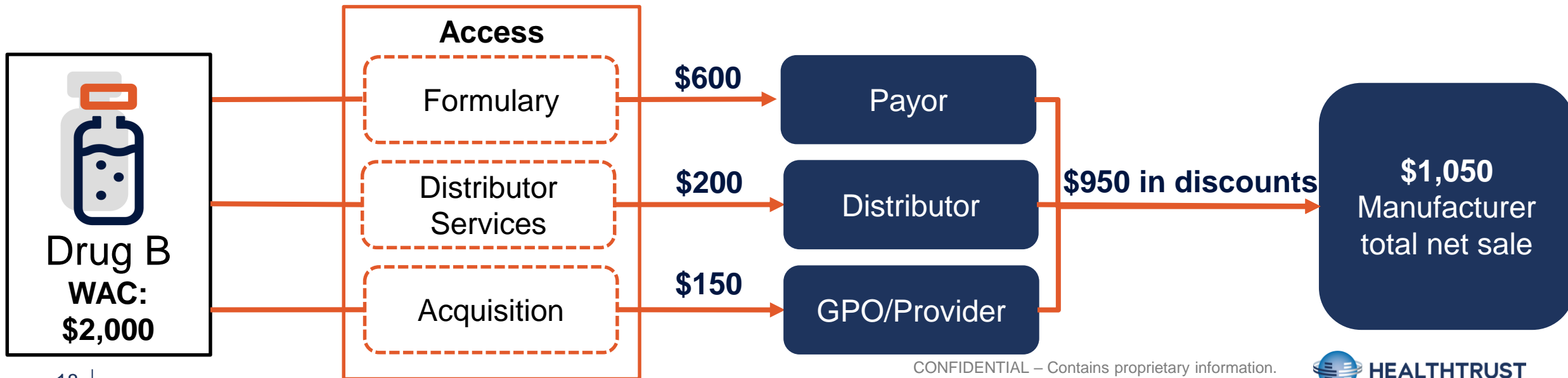


Drug Manufacturer Discount Strategy



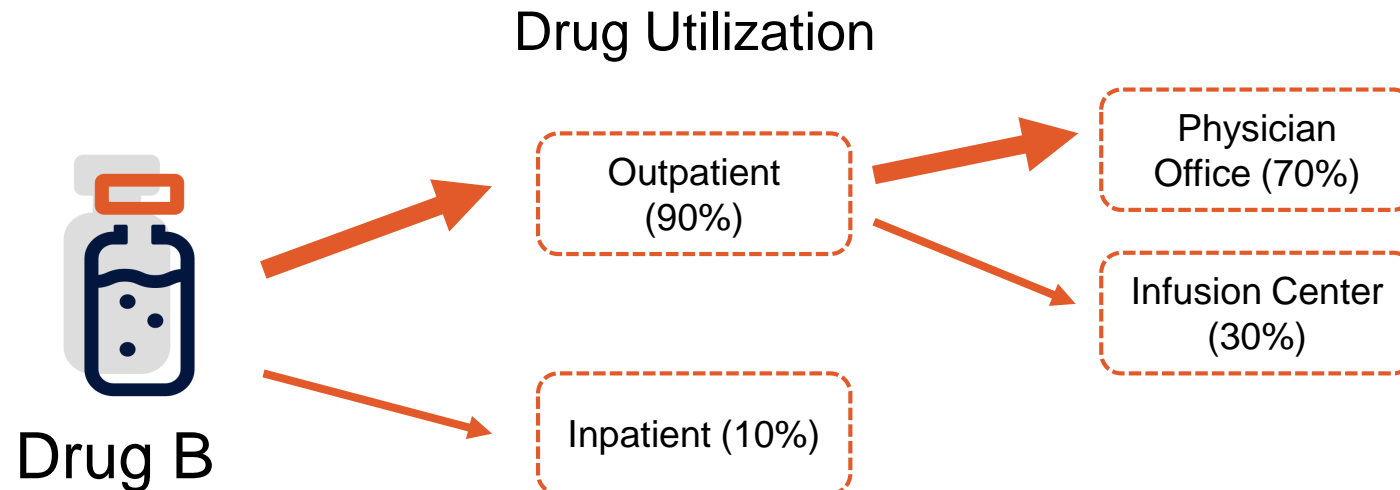
- Outpatient oncology medication
- Recently launched on the market
- **The manufacturer sets the medication price at \$2,000**

- When a new drug is launched, a drug manufacturer will attempt to incentivize use by providing various discounts



Discounts to GPO/Provider

- Manufacturers know where the medication is being purchased from COT



- Utilize market insight from COT to provide and allocate discounts
- Manufacturers can control cost by restricting discount eligibility from COT

Class of Trade Used as a Price Control Mechanism

Manufacturer Goal

- Ensure a sustainable discount strategy

Control

- Discounts allocated to the various COT
- Drug ASP

What happens when a drug manufacturer fails to control their drug price?

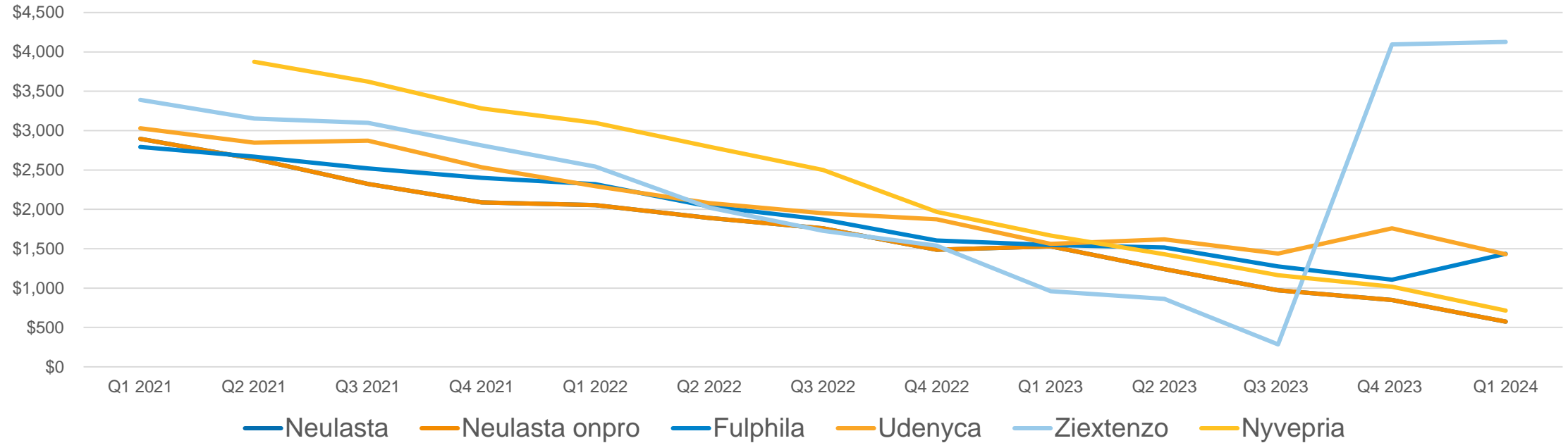
ASP goes into rapid decline

Manufacturer must eliminate discount

Reset ASP

Lost of Price Control - Ziextenzo

Pegfilgrastim ASP Trend (per 6 mg dose)

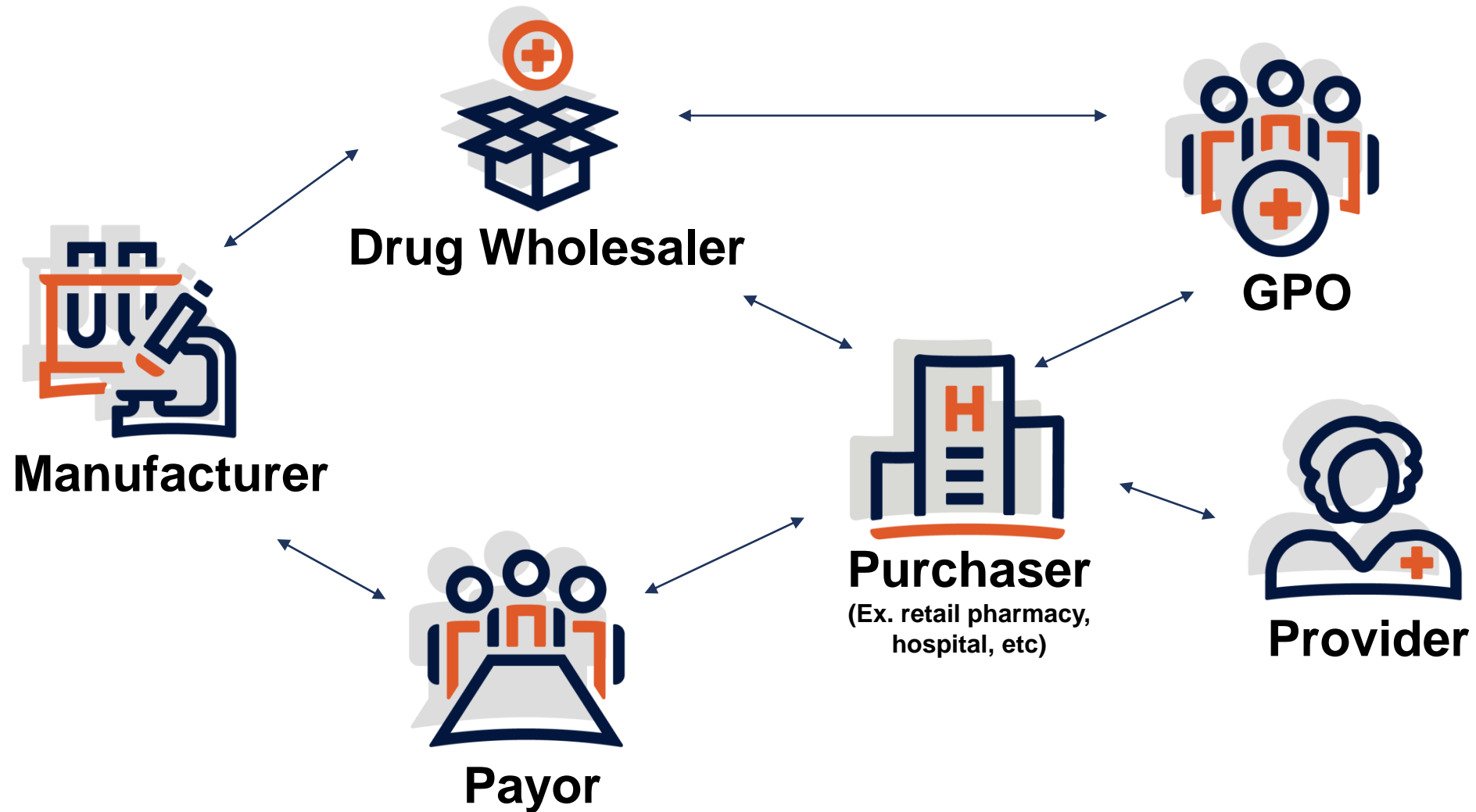




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The Class of Trade Landscape

Healthcare Landscape Diagram



Retail Class of Trade




Retail Pharmacy



Payor



Provider

 Entity with the most leverage

- Main roles
 - Retail Pharmacy – Dispense medication
 - Payor – Negotiate with drug manufacturers to develop health insurance formulary
 - Provider – Prescribe medications and treatments to patients
- Payor controls the formulary and can control the site of care
- Manufacturers offer discounts to the payor in order to gain a preferred placement on the formulary

Specialty Pharmacy Class of Trade

Provisions

- High cost medications
- Special handling procedure
- Complex patient care

Goals

- Manage access and handling of specialty drug
- Provide clinical management services

Licenses

- Multiple accreditation bodies
- Not every state recognizes specialty COT

Specialty Pharmacy Programs

Created to meet requirements for delivery of costly, limited distribution drugs to hospitals

Potential new hospital revenue stream

Multitude of challenges including payor denial and varying accreditation requirements

Acute Care – Inpatient Class of Trade




Pharmacy



Payor

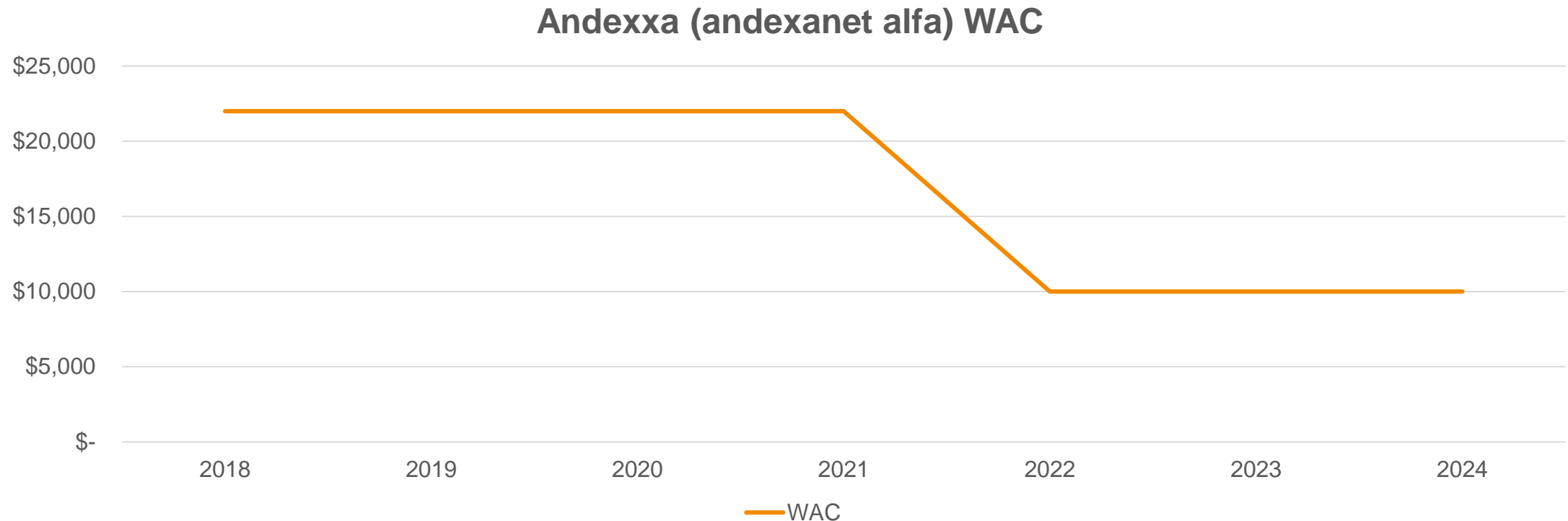


Provider

 Entity with the most leverage

- Payors have low leverage
 - Majority of billing is bundled under the diagnosis related group payment system
- Pharmacy and Providers have more leverage
 - Pharmacy and Therapeutic Committees determine what drugs are on formulary
 - When efficacy and safety are equal, cost is the major driver of selection
- Manufacturers are motivated to offer discounts in order to gain formulary status

Acute Care – Inpatient Class of Trade



- Launch – WAC was \$22,000, low utilization because of minimal separate reimbursement incentives and clinical alternatives such as Kcentra
- In 2022, WAC was reduced by 54%, started seeing increased utilization

Acute Care – Inpatient Class of Trade

New Technology Add on Payment (NTAP)

- Benefit
 - Helps offset the high cost of a new drug
- Negative
 - Increased administrative burden
 - Capped reimbursement
 - Limited selection of drugs available for NTAP
 - Strict time frames for reimbursement allowance
- Payment amount
 - The lower of either 65% of the drug costs or 65% of the difference between the case costs and the standard DRG payment
 - For certain eligible antimicrobial agents, payment is increased to 75%

Acute Care – Outpatient Class of Trade




Outpatient



Payor



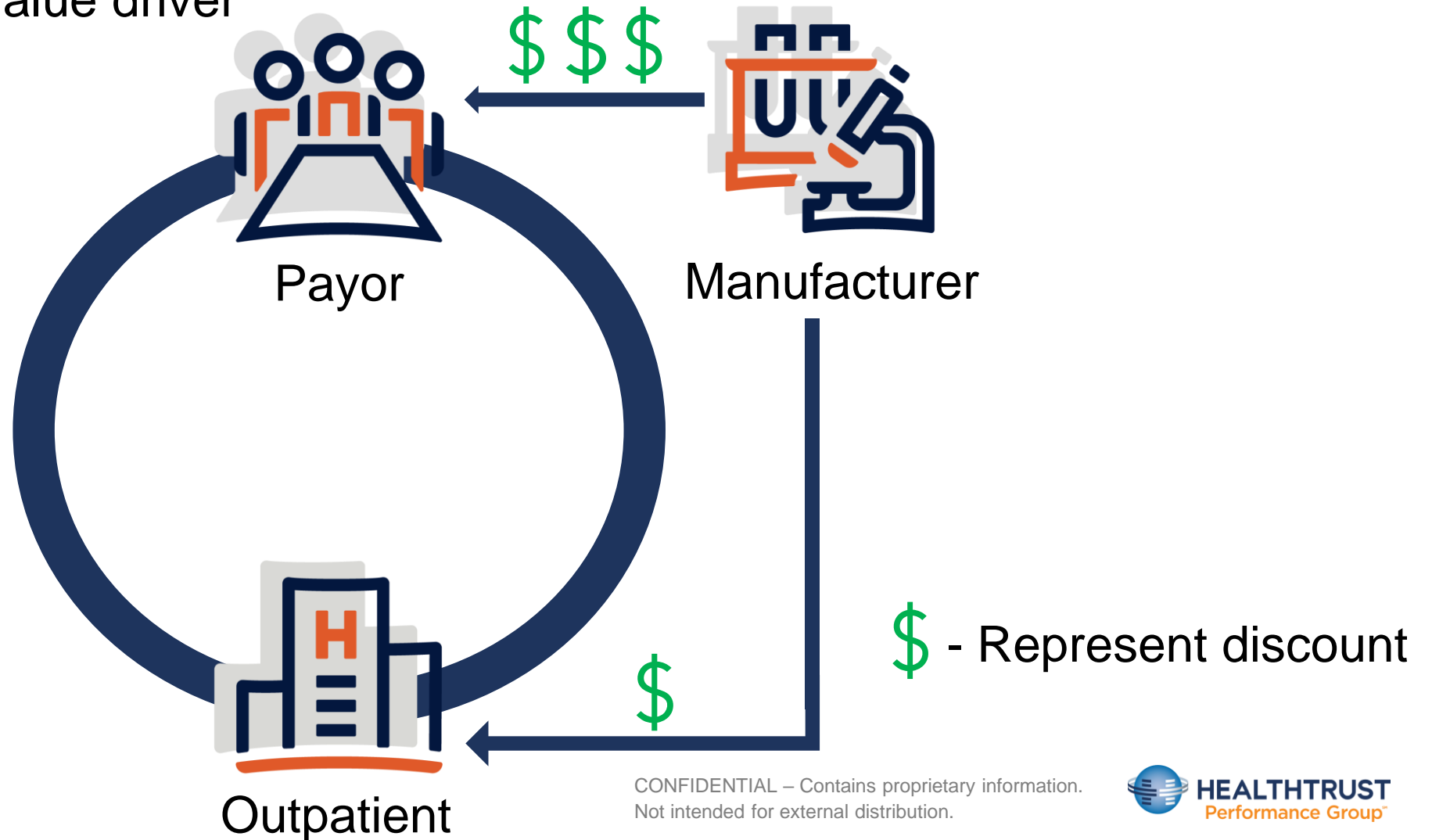
Provider

 Entity with the most leverage

- Medications are separately reimbursed most often through commercial payors or Medicare
- Payors have significant leverage
 - Have control in setting formulary, ultimately driving utilization
- Manufacturer viewpoint
 - Offers the most discount to the payor in order to gain preferred placement on the payors' formulary

Acute Care – Outpatient Class of Trade

- Payors are the value driver



Ambulatory Care Class of Trade




Manufacturer



Payor



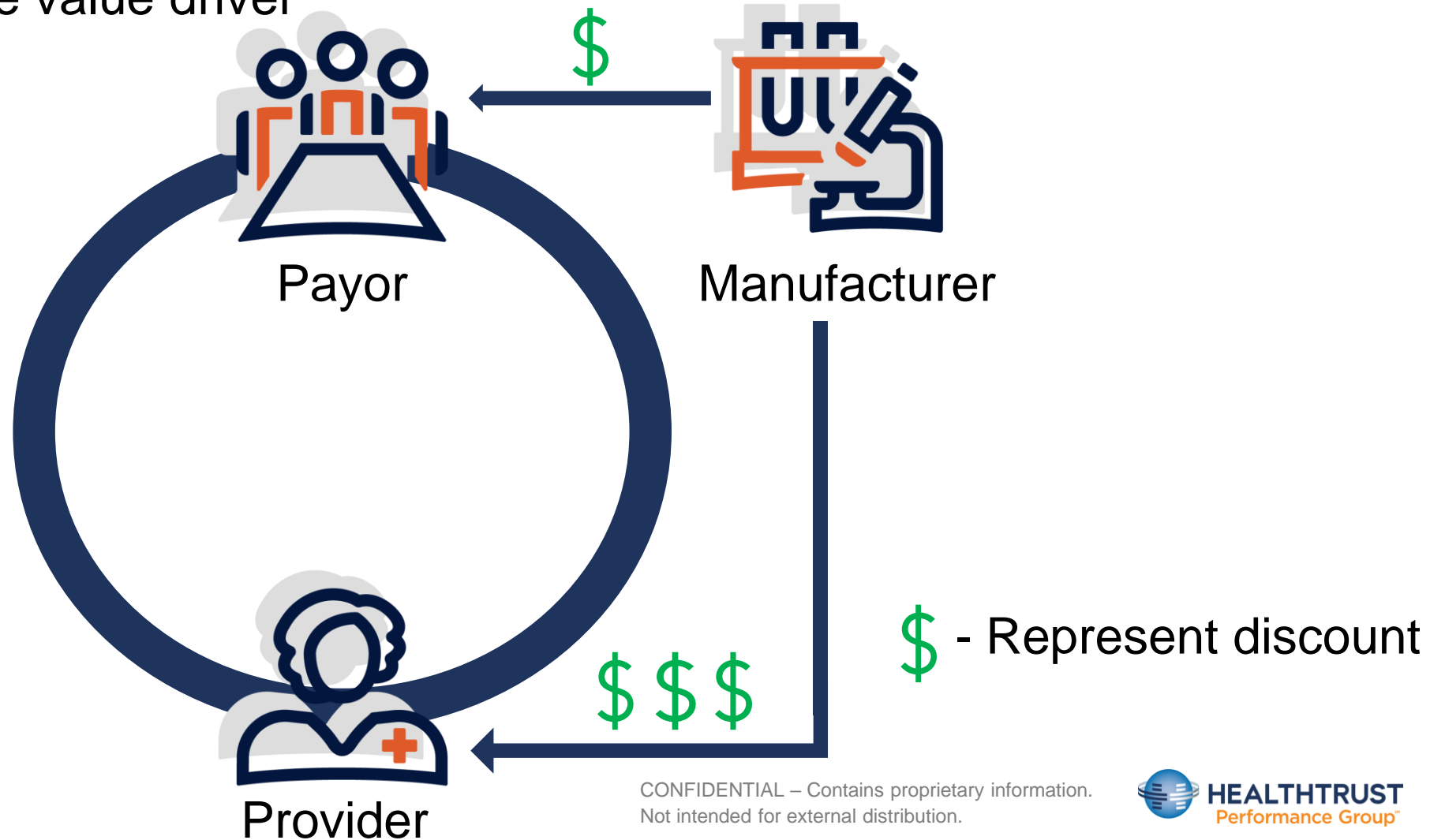
Provider

 Entity with the most leverage

- Buy and Bill model – Providers purchase the drug upfront and then bill the payor for the cost
- Clinical control and financial incentives
 - Formulary
 - Reimbursement
- Manufacturer viewpoint
 - Buy and bill physician clinics are viewed as more aligned providers

Ambulatory Care Class of Trade

- Providers are the value driver



Home and Long Term Care Class of Trade




Pharmacy



Payor



Provider

 Entity with the most leverage

Reimbursement plays a major role

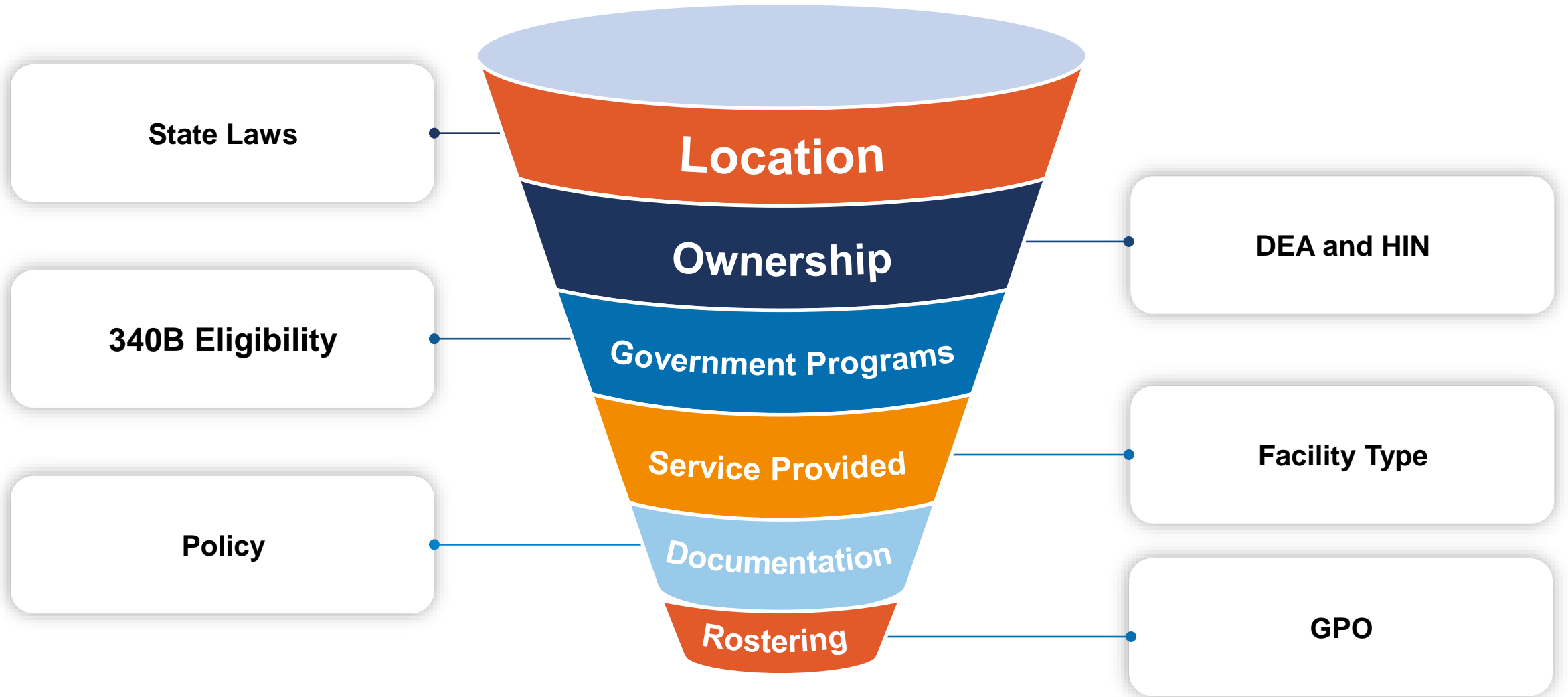
- High reimbursement rate
 - Reimbursement drives pricing in this area
- Low reimbursement rate
 - Manufacturer price of the medication is more of a factor



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Class of Trade Considerations

Class of Trade Check List



Key Pharmacy Considerations for Class of Trade

Important considerations when setting up a new clinic or acquiring a new site

- State laws
- DEA number
- HIN

DEA Activity Codes Examples		
Business Activity code	Business Activity sub code	Description
A	0	Retail Pharmacy
A	1	Central Fill Pharmacy
A	3	Chain Pharmacy
A	5	Online Retail Pharmacy
B	0	Hospital/Clinic
B	3	Hospital/Clinic-Federal

HIN Class of Trade Codes	
Codes	Description
CL	Clinic
DC	Dialysis Centers
DS	Distributor or Wholesaler
GV	Government Agency
HH	Home Health Corporation
HO	Hospital
NH	Nursing Home
OS	Outpatient Surgery Center
PH	Pharmacy
PS	Psychiatric Health Facility
SY	Hospital System

340B Introduction

Purpose

- Qualified organizations gain access to discounted prices on outpatient drugs

Inpatient Influence

- For profit hospital – Not a factor
- Nonprofit – Significant factor

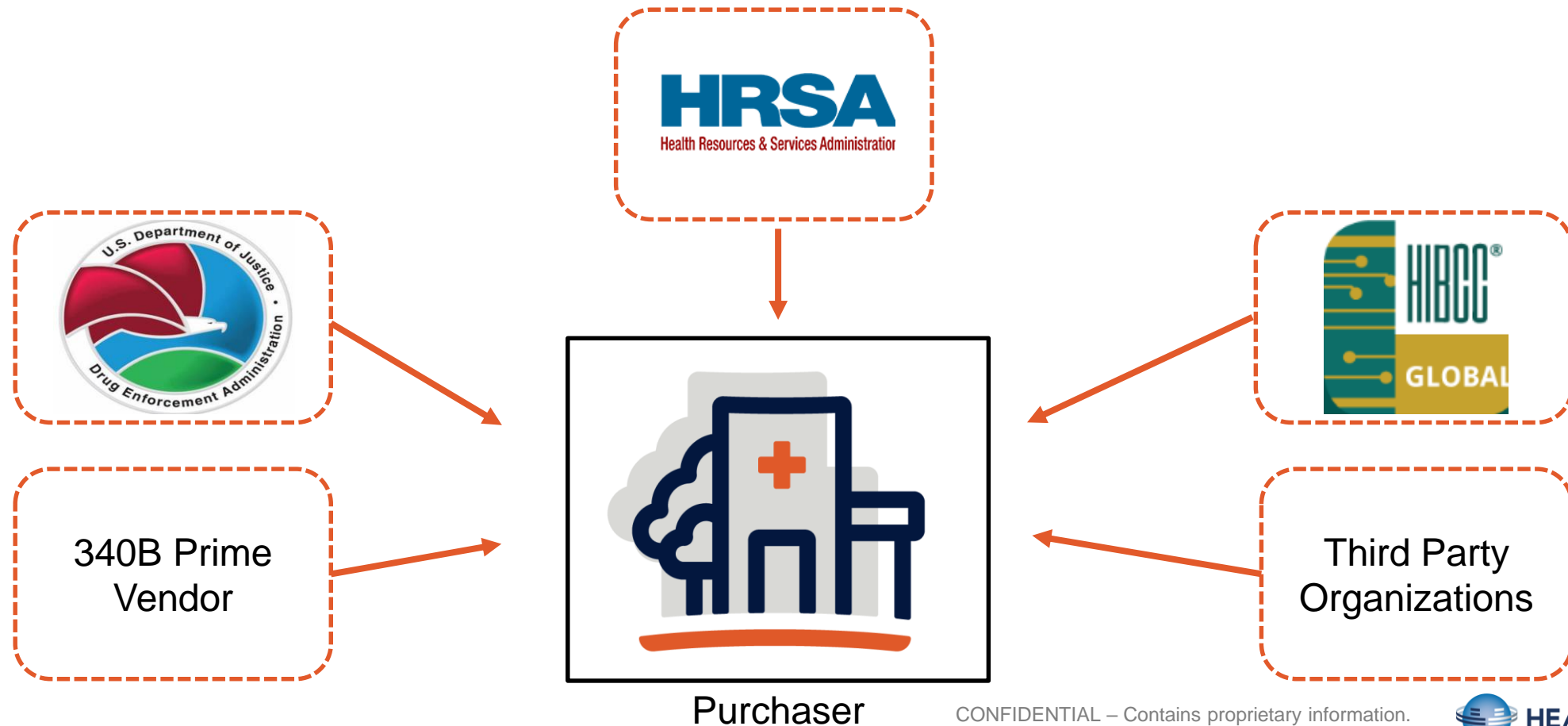
Class of Trade Status

- 340B is not a COT

How a 340B qualifying health system sets up their outpatient services has an indirect impact to COT designations.

Manufacturer Implementation

- Manufacturers utilize data sources from various avenues but do not have a standardized process for COT designation



Group Purchasing Organization Roster

Class of Trade	Facility Type	Class of Trade	Facility Type	Class of Trade	Facility Type
Acute	General Acute Care Hospital	Ambulatory Care	Hospital Out-Patient Oncology Center	Home Health	Home Health Care
	Rehabilitation Hospital		Hospital Outpatient Care Center		Home Infusion (Home Infusion Closed Door)
	Psychiatric/Behavioral Hospital		Surgery Center		Hospice Home Care (Hospice Closed Door)
	Long Term Acute Care Hospital (LTACH)		Physician Office/Clinic		Long Term Care Pharmacy (LTC Pharmacy)
	Hospital Teaching Institution		Community Based Outpatient Care Center	Long-Term Care	Nursing home
	Disproportionate Share Hospital (DSH)		Immediate/Urgent Care Center		Correctional Facility
	Critical Access Hospital		Rheumatology Center		Hospice Inpatient Services
	Central Supply Center (CSC) and Central Distribution Center (CDC)		Dialysis Center	Retail Pharmacy	Hospital Out-Patient Retail Pharmacy
	Hospital Out-Patient Pharmacy (Hosp OP Pharm)				Community Retail Pharmacy

- Best practice is to utilize the GPO for membership guidelines
- Rostering
 - One class of trade per facility

Class of Trade Optimization Overview

Research

- Internal review of sites rostered
- Analyze drug purchases
- Identify COT assignment gaps

Optimize

- Modify operations to obtain most optimal allowable COT

Audit

- Perform continuous audits
- Utilize resources from the GPO

Facility Class of Trade Analysis

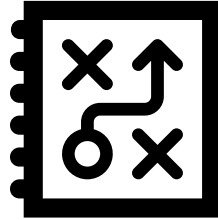


Ambulatory care
center

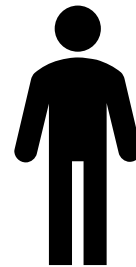
- A facility pharmacy is assigned an acute care COT
- The pharmacy purchases medication for an outpatient ambulatory care center

Considerations

- Perform an internal review of the operations, clinical needs, site of care, and rostering of the facilities pharmacy
- Review impact from modify operations and services to optimize COT
- Collaborate with GPO to obtain desired COT



Assessment



Question #2

- Which of the following is not a Class of Trade designation?
 - A. Acute care
 - B. Ambulatory care
 - C. Home Health
 - D. 340B

Question #2, Correct Response

- Which of the following is not a Class of Trade designation?
 - A. Acute care
 - B. Ambulatory care
 - C. Home Health
 - D. **340B**

Question #3

- Which impact does Class of Trade have on health systems and group purchasing organizations?
 - A. Class of Trade has an indirect impact on drug purchases
 - B. Class of Trade has a direct impact on drug purchases
 - C. Class of Trade impact is limited to the inpatient acute care setting
 - D. Class of Trade impact is limited to the outpatient and retail pharmacy

Question #3, Correct Response

- Which impact does Class of Trade have on health systems and group purchasing organizations?
 - A. Class of Trade has an indirect impact on drug purchases
 - B. Class of Trade has a direct impact on drug purchases**
 - C. Class of Trade impact is limited to the inpatient acute care setting
 - D. Class of Trade impact is limited to the outpatient and retail pharmacy

Presentation Key Takeaways

- COT refers to the various areas that a drug is purchased
- Manufacturers utilize COT as a method to control drug prices
- COT designation is ultimately assigned by the manufacturer
- Within the different COT, the manufacturer will provide discounts to the value driving force
- Manufacturers view, monitor, and assign COT inconsistently
- It is important for IDNs and facilities to be aware and try to optimize their COT designation

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