



**Government Price Reporting
Obligations
“A Compliance Discussion”**



Discussion Agenda

- **Compliance Requirements Relating to Government Price Reporting Obligations**
- **Introduction to Managed Care Rebates**
- **Introduction to Prime Vendor Chargebacks**

Compliance Requirements Relating to Government Price Reporting Obligations



The primary goal of this section of the break-out session is to introduce the concepts, methodologies, and challenges surrounding government price reporting obligations within the pharmaceutical industry



Reasons for the Increased Government Price Reporting Obligation Focus

- Increased Governmental scrutiny concerning Government Price Reporting
- Continues to be investigated by the OIG
 - ❑ Recent negotiated CIA agreements and their increased reporting obligations
 - ❑ Increased investigation of industry practices and their effect on government price reporting
 - ❑ A significant part of the OIG Workplan
 - Medicare Benefit (Anticipated Legislation)
 - ❑ Additional reporting obligations
 - ❑ May require Average Selling Price (“ASP”) reporting requirements for Part B reimbursement

The Federal Programs

There are currently three types of government pricing programs, with a fourth on the horizon.

**Medicaid Drug
Rebate Program**

**Federal Supply
Schedule Program**

Public Health Service *

Medicare Reform?

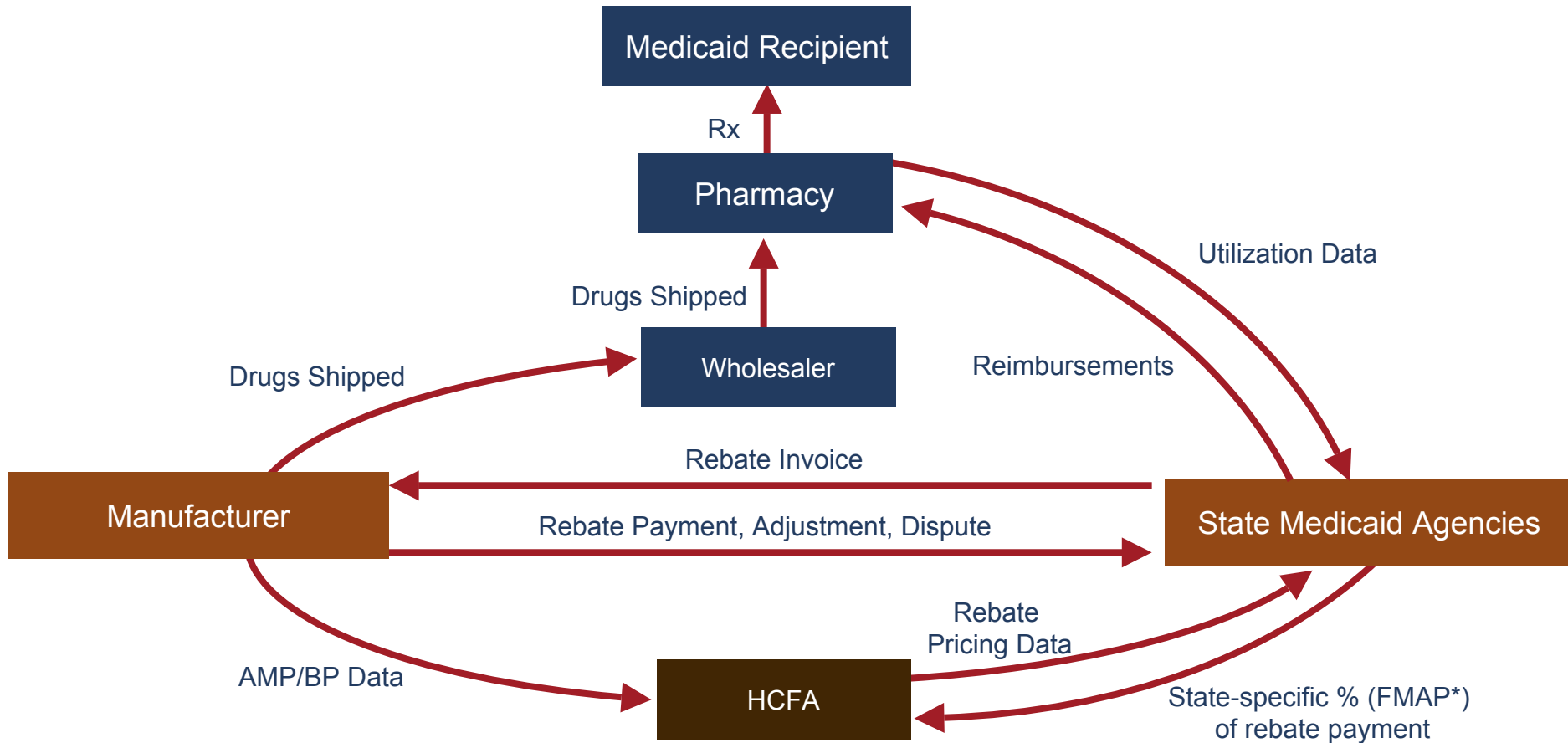
* Will be covered as part of Medicaid

Medicaid Rebate Program Overview

Medicaid, Title XIX of the Social Security Act, is a jointly-funded, Federal-State entitlement program designed to assist States in the provision of adequate medical care to vulnerable and needy individuals and families.

- Program eligibility basis includes certain individuals and families with low incomes, the indigent, the aged, the blind and/or disabled.
- Medicaid became law in 1965 under the administration of the Health Care Financing Administration (HCFA).
- Within broad national guidelines established by Federal statutes, regulations and policies, States have a wide degree of flexibility to design their program, including:
 - establish eligibility standards;
 - determine what benefits and services to cover;
 - set payment rates.

Medicaid Drug Rebate Program Cycle



*FMAP, the Federal Medical Assistance Percentages are used in determining the amount of Federal matching in State medical and medical insurance expenditures.



How do you calculate the Medicaid Rebate?

The Medicaid Rebate calculation is composed of three steps. The first is to calculate the Basic Rebate.

- Currently, the Basic Rebate is equal to the greater of AMP x 15.1% or AMP minus Best Price.
 - Average Manufacturer Price (AMP) - the average price paid to the manufacturer for a covered drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. Calculation of AMP for any given quarter should be adjusted for all returns, rebates, chargebacks and other adjustments affecting actual price relating to sales in that quarter, although in practice CMS (formerly HCFA) may permit certain adjustments to be made in the quarter in which they are realized
 - Best Price (BP) - defined as the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser (nominal sales¹ are excluded) in the United States, inclusive of cash discounts, free goods, volume discounts, and rebates. The BP provision of the calculation in essence ensures the government is being provided the lowest price

Therefore, the Basic Rebate provides a 15.1% discount off AMP unless the manufacturer has given a customer a larger discount in which case the government would receive the same larger discount

1 Nominal sales are sales to customers for a price that is less than 10% of the calculated AMP in the prior quarter

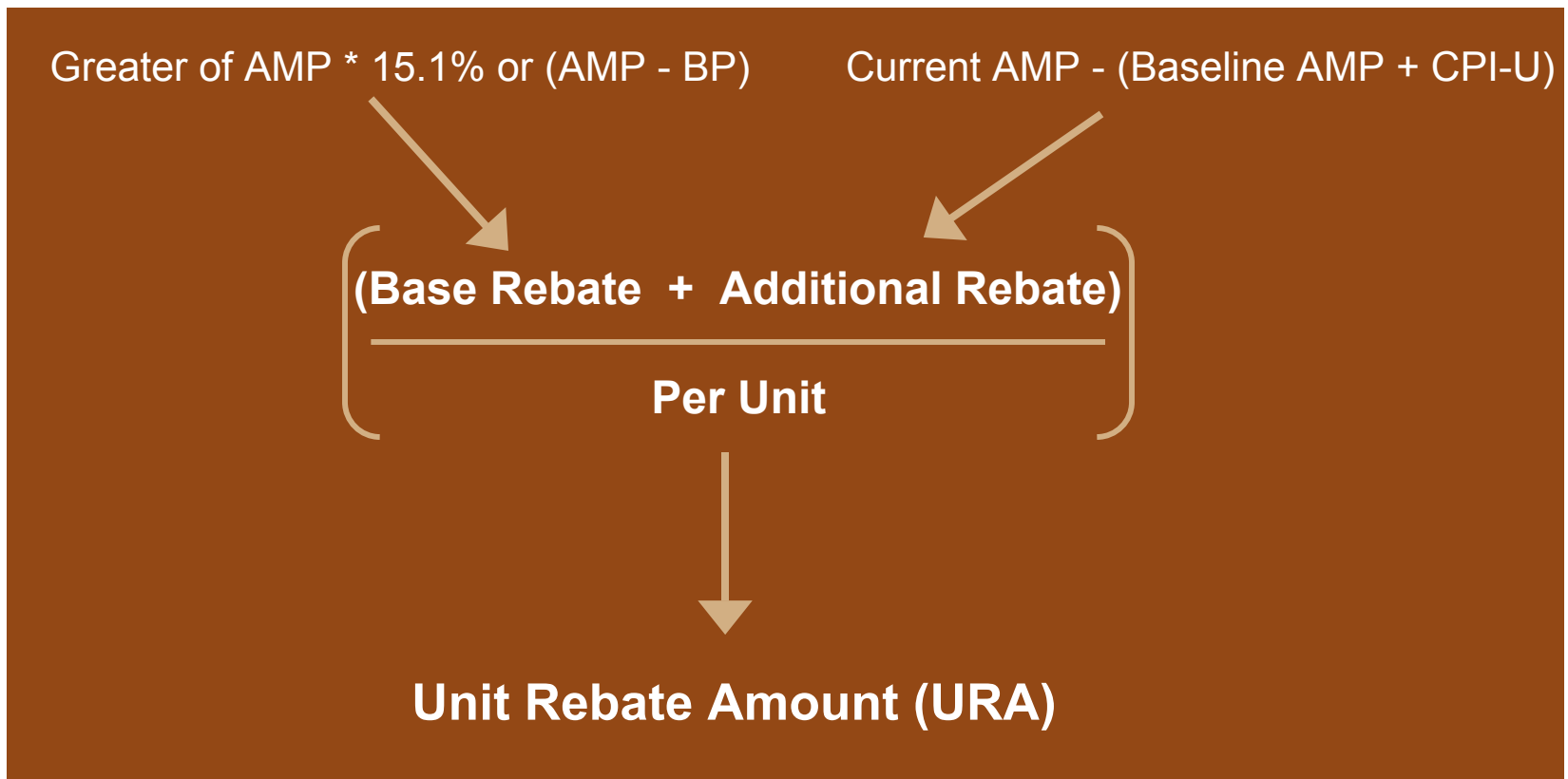
How do you calculate the Medicaid Rebate?

The second is to calculate any Additional Rebate through the CPI-U limitation.

- The Additional Rebate is derived by comparing the current quarter AMP to the Baseline AMP, adjusted for the CPI-U.
 - Baseline AMP is defined as 3rd Qtr, 1990 for most products, time of launch for newer products
 - If the current quarter AMP exceeds the Baseline AMP plus the CPI-U, the excess amount becomes the Additional Rebate.
 - If the current quarter AMP is equal to or lower than the Baseline AMP plus the CPI-U, there is no Additional Rebate.

How do you calculate the Medicaid Rebate?

The URA calculation is performed on a quarterly basis for each NDC of a Covered Drug (branded pharmaceutical marketed under a NDA).



How do you calculate the Medicaid Rebate?

The third is to extend the URA by the number of units dispensed to Medicaid recipients under each participating state program.

Calculated by HCFA with data provided by manufacturers



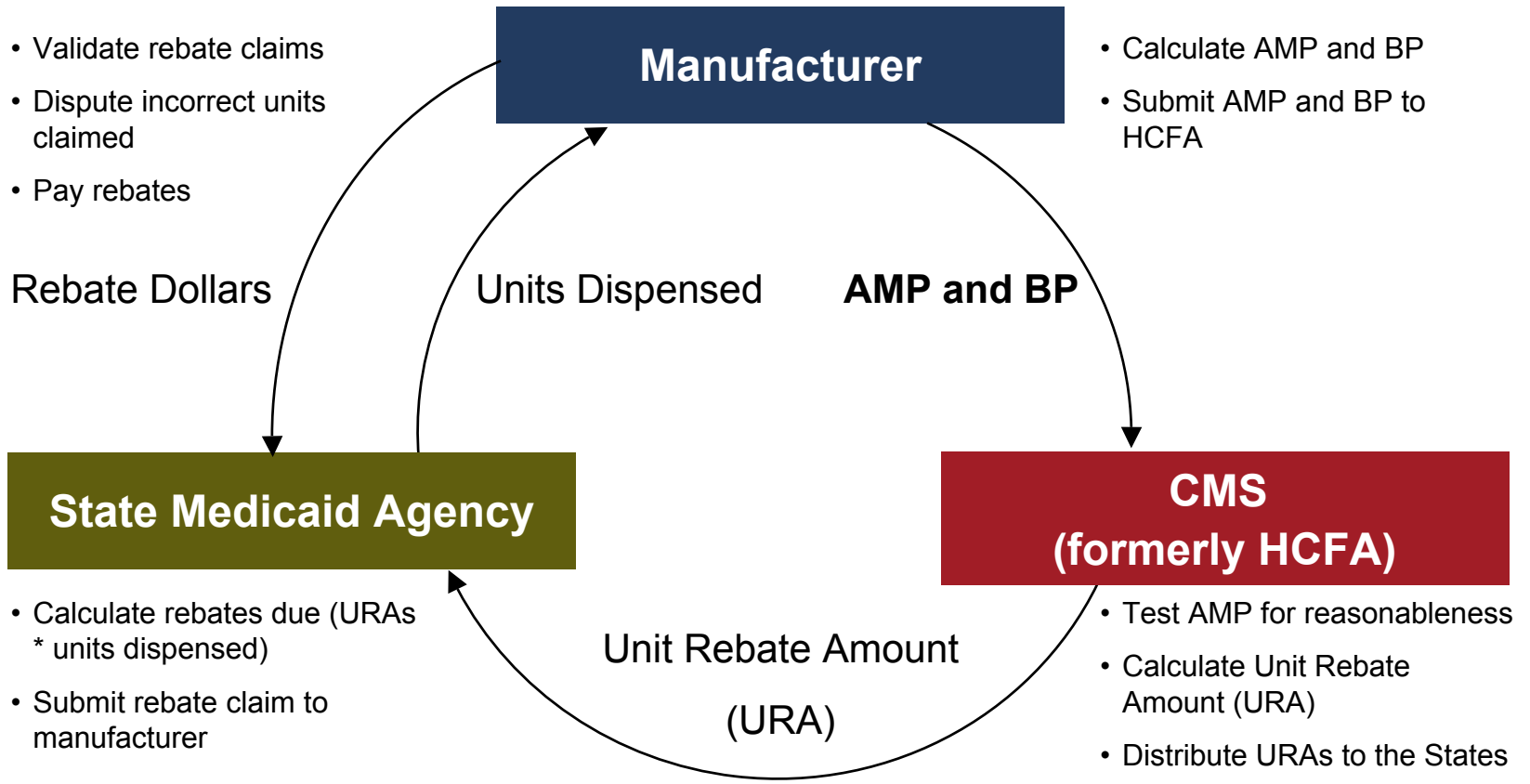
Collected from retail pharmacies and submitted to manufacturers by the Medicaid State Agencies



Medicaid Rebate = (Unit Rebate Amount x Number of Medicaid Units Dispensed)

The Manufacturer - State - Federal Medicaid Program Relationship

The Medicaid process is a three-way interaction between manufacturers, HCFA, and the Medicaid state agencies



VA and Other Government Agency Pricing

The U.S. Congress has delegated responsibility for administering the FSS to the Veterans Administration (VA).

The relevant law related to the FSS contract is the Veterans Healthcare Act of 1992.

The largest purchasers of pharmaceuticals within the federal government are the VA, DoD, Indian Health Service, and Coast Guard.

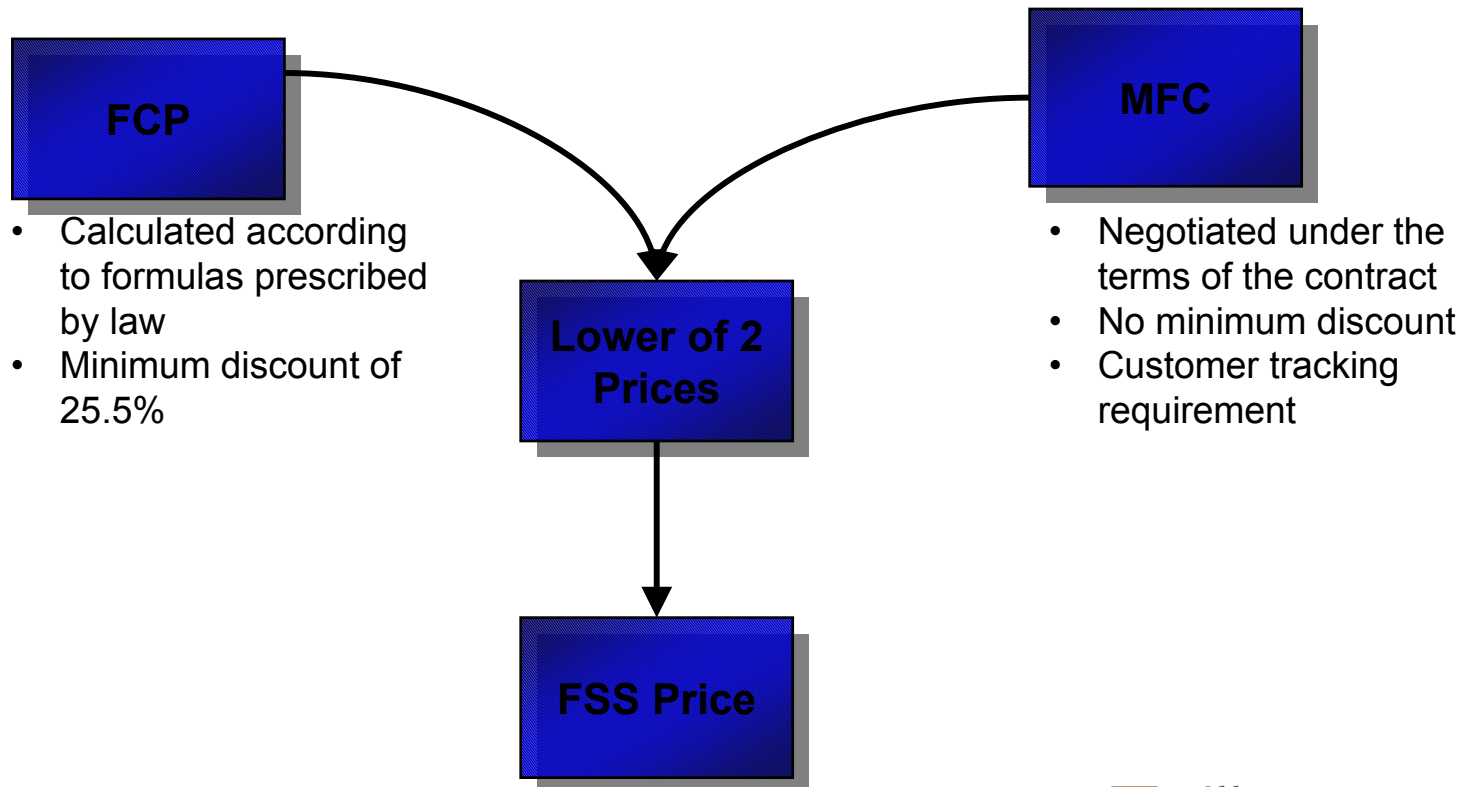
These entities (a.k.a. The Big Four) purchase over \$2 billion in pharmaceuticals each year.

The VA and DoD alone operate over five hundred hospitals, medical centers, and clinics.



Federal Supply Schedule Pricing Process

Pricing on the FSS is determined by taking the lower of the Federal Ceiling Price as calculated under the Veterans Health Care Act and the negotiated price (based on Most Favored Customer) under the terms of the contract.



Non-FAMP Calculation

The Non-Federal Average Manufacturer Price (Non-FAMP) is calculated on both a quarterly and annual basis.

$$\frac{((\text{Gross Sales} - \text{Federal Sales}) * .98) - (\text{Gross Chargebacks} - \text{Federal Chargebacks}) - \text{Trade Discounts}}{(\text{Gross Units} - \text{Federal Units})}$$

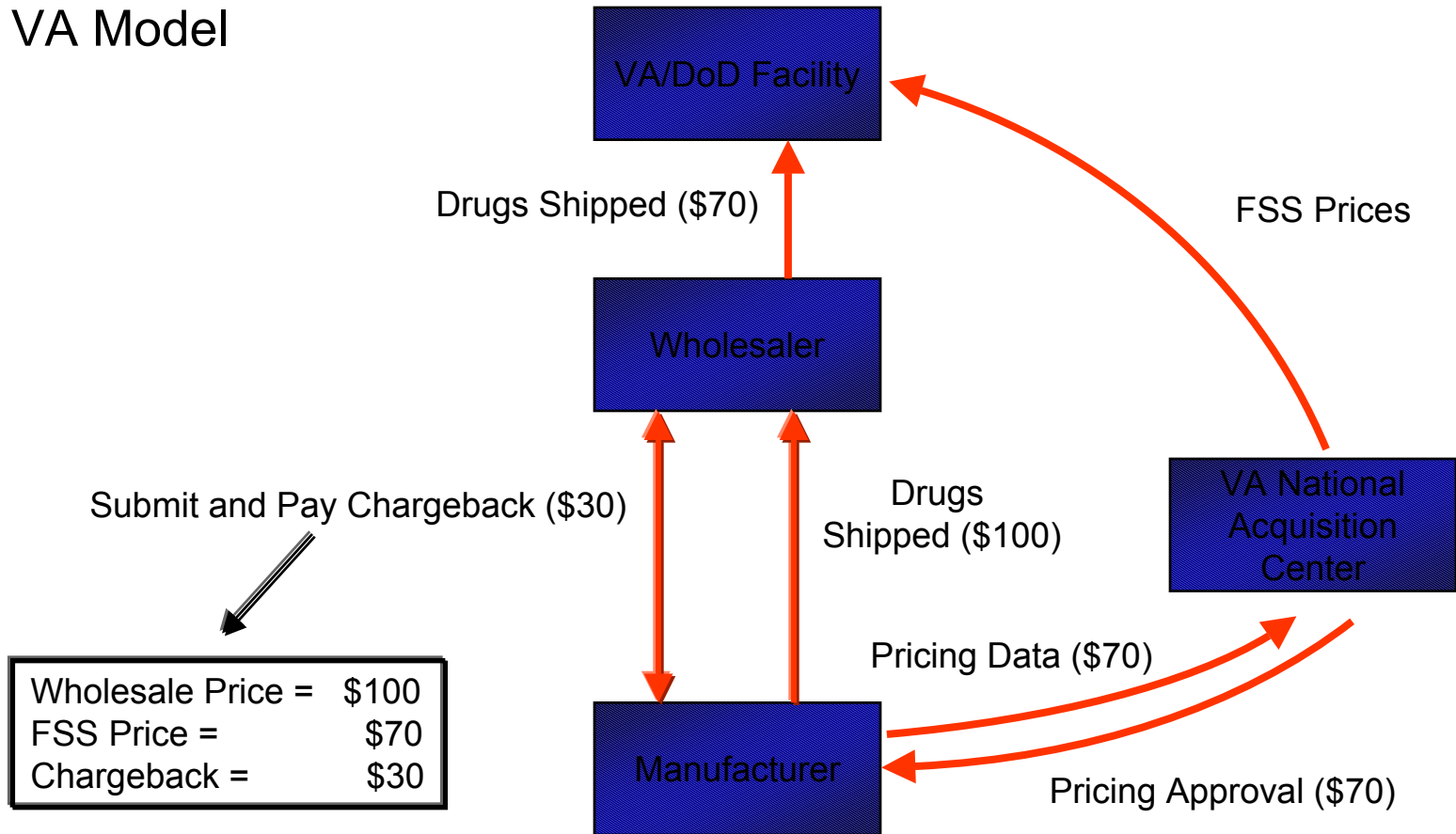
Gross Sales include sales to wholesalers, distributors, and other “merchant middlemen” only

Federal Sales are valued at wholesale list price

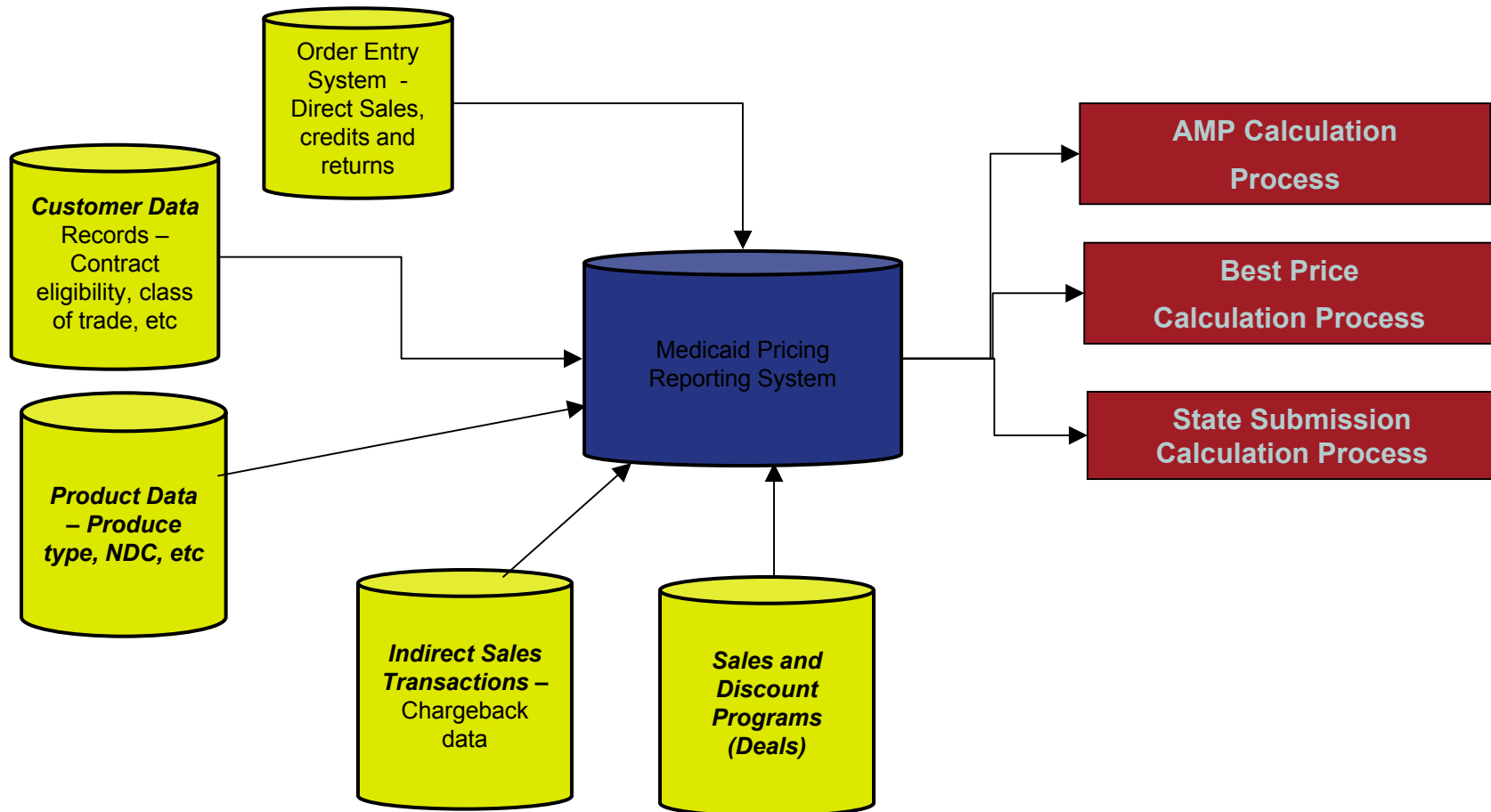
Trade Discounts represent any other discounts, allowances, or incentives given to the wholesale trade other than the 2% prompt pay discount

FSS Program Cycle

VA Model



Understanding Your Data Interfaces



Where to begin?

- Manufacturers should understand the data and process flow of all information being interfaced into the government pricing system. This should include discussion with users and IT personnel to map out the following:
 - All data sources used
 - All transactions included/excluded during the interface, as well as, within the government pricing system
 - Understanding of system edit checks and reports generated by the interface system, as well as, the government pricing system
 - What is being done with each of these reports and errors discovered during the edit checks
- Manufacturers should develop and maintain well documented policies and procedures around all of the data interfaces, which take into consideration the use of the data when performing the Medicaid Government Price calculations

Common Concerns Around Data Interfaces

The following outlines questions to be considered when reviewing the data interfaces:

- What formal written policies and procedures exist, when were they developed and have they been reviewed by counsel and management, as it relates to the government price reporting
- Has a risk assessment been performed to ensure the policies and procedures that are in place are actually being followed
- What controls exist to ensure the information is accurate
- Does proper supervision and training exist

Common Concerns Around Data Interfaces (cont'd)

- How can information be overridden and who has the ability to perform overrides
- How are transactions being valued and what is the effect on the government pricing (AMP and BP)
- When was the system reviewed to evaluate if all relevant customer information and transaction data is being extracted properly
- Assess whether appropriate data retention and audit trails exist

Are We Communicating?

Establish ongoing communication between sales and marketing, finance, legal, information technology and the government pricing administrators to ensure the following:

- Timely communication of new promotion programs
- Complex promotion programs are evaluated in the context of government pricing regulations and are incorporated into existing government pricing models
- Capabilities and limitations of IT systems are considered. “One-off” contracts or programs that cannot be captured by systems are included in the pricing calculations

What Is In Our AMP and Best Price?

Inclusion of Discounts in AMP and Best Price

- Work with legal counsel and marketing to ensure the policies and procedures consider the more complex discounts and promotions including chargebacks, tiered rebates, administrative fees, etc.
 - Develop a policy on whether multiple discounts given for products sold through wholesalers should be aggregated in the calculations.
- Develop policies and procedures around the promotions/discounts earned in one period which are paid in another.
 - Estimating techniques
 - Retroactively adjusting prices (finalization)

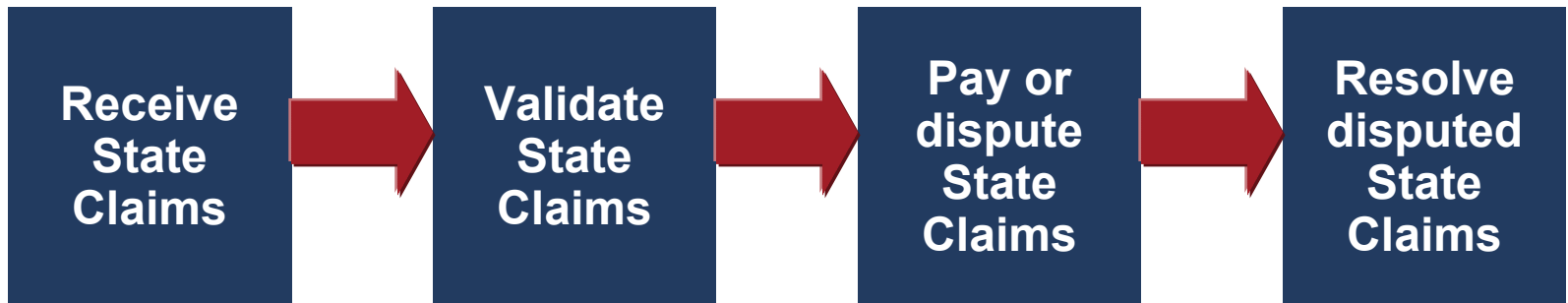
Who's Product is it?

Products Sold to Other Manufacturers

- Contracts to sell products should include specific provisions to address which party will be responsible for government pricing administration as well as paying rebate claims.
- Manufacturers should make an assessment as to whether there is an impact on any products which have been sold to other manufacturers in the past.

Medicaid rebate payment process Overview

The Medicaid rebate payment process is executed in four steps.



Medicaid rebate payment process

First Step

The First Step is to receive state claims.

Most states submit invoices at the NDC level, either electronically or on paper.

Invoices will include the number of units dispensed, the related number of scripts, the amount reimbursed to the pharmacy for the script, and the Medicaid AMP, BP, and URA for each NDC.

Some states submit script level data to Data Niche Associates (DNA) who scrub the data prior to sending to manufacturers.

Electronic data is uploaded and hard copy is manually entered into Medicaid Administrator or a similar system used to pay Medicaid rebates.

Medicaid rebate payment process

Second Step

The Second Step is to validate the state claims.

Most manufacturers will attempt to validate the number of units claimed for rebate by performing one or more analytical edits.

A common validation tactic is a unit trend analysis, which is done by comparing current period utilization to the average over a recent historical period and disputing units in excess of a pre-determined threshold (e.g. 20%).

Some manufacturers will purchase third-party data at the script level to compare to the State-submitted data and dispute discrepancies.

In cases where DNA script-level data is available, additional tests such as calculating average units per script can be performed and units in excess of a pre-determined threshold can be disputed.

Medicaid rebate payment process

Third Step

The Third Step is to pay and dispute the state claims.

Within 38 days of receiving the state invoice, manufacturers will typically pay some portion of the rebate claim and dispute the rest based on the results of the validation tests.

Manufacturers will send the states documentation supporting the amount of units in dispute.

All disputed units (that are ultimately paid) and all late payments will incur interest at the 90 day T-Bill rate.

Many disputes today are based on a unit of measure issue with non-standard packages or delivery systems such as inhalers, vials, patches, etc.

Disputes are not nearly as significant as in the past as many of the startup problems of the Medicaid program have been worked out.

Medicaid rebate payment process

Fourth Step

The Fourth Step is to resolve the disputed claims.

Once the manufacturer disputes all or part of the claim, the onus is on the State(s) to send to the manufacturer supporting documentation for the amount claimed.

If the manufacturer is satisfied with the additional documentation, all legitimate units must be rebated with interest from the day the unit was disputed.

If the manufacturer disagrees with the State, the process continues and the units remain in suspense.

The relevant legislation is completely silent on dispute resolution, leaving regulators, manufacturers, and States to develop policy and procedures.

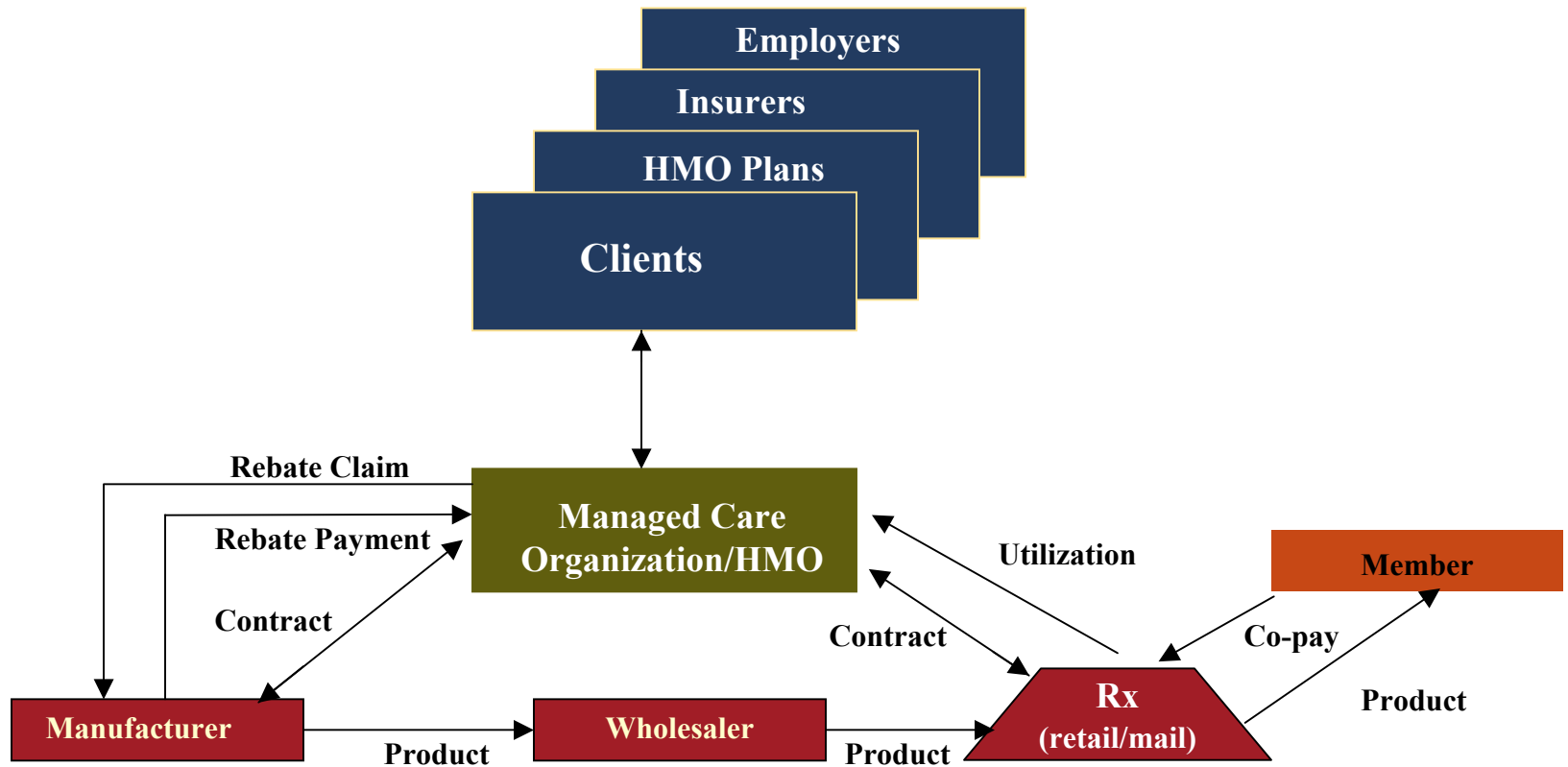
Introduction To Managed Care Rebates



The primary goal of this section of the break-out session is to introduce the concepts, methodologies, and challenges surrounding Managed Care rebates in the pharmaceutical industry



Rebate Process Overview



Types of Managed Care Organizations (MCOs)

Pharmaceutical Benefits Manager (PBM) - Third-party administrator of pharmacy benefit plans

- Merck-Medco Managed Care
 - Rite Aid / PCS Health Systems
 - Express Scripts / Diversified Pharmaceutical Services
- In early 1990's, pharmaceutical companies feared that PBMs could block access to customers / formularies
 - Currently the manufacturers are much more selective in who they contract with based on understanding of the PBMs capabilities to influence product selection and are much more rigorous in development of contract requirements to demonstrate performance

Types of Managed Care Organizations (MCOs), continued

Health Maintenance Organization (HMO)

- A prepaid system where the organization assumes financial risk for the care provided to its enrolled members. Therefore, the HMO may carve in/manage its own pharmaceutical benefit for its members, like a PBM, and earn rebates
- Different Types of HMOs
 - Staff Model
 - Group Model
 - Network Model / Independent Practice Association (IPA) model

Types of Managed Care Contracts

Most contracts pay rebates on a product by product basis. Contract terms could offer rebates in the form of Access, Administrative and Market Share rebates

- Access and Administrative Fees are either on a product by product or on a contract basis. These rebates could range from 1% - 9% and 1% - 2% of wholesale acquisition price (WAC) or Average Wholesale Price (AWP) for Access and Administrative fees, respectively
- In addition, access rebates may have differing rebate levels based on the MCO's level of control (open, closed or 3-tier plan design) or product formulary positioning (on formulary, one of several products within the defined therapeutic class on formulary, contracted product as a preferred or exclusive formulary status)

Example of Access and Administrative Fee Rebates Calculation:

WAC or AWP Price = \$75

Access or Administrative Fee Rebate Percentage = 8%

Units in reporting period = 10,000

Rebate to MCO

= $\$75 * 10,000 * 8\% = \$60,000$

Types of Managed Care Contracts, Cont.

- Market Share or Performance based rebates - are on a product by product. Market share definitions (the products within the therapeutic class which define the market basket) are outlined within the contract. The rebate percentages offered to the MCO will be based on the market share achieved by the MCO. The rebate paid to the MCO is usually a percentage of wholesale acquisition price (WAC) or Average Wholesale Price (AWP) during the reporting period
- In addition, market share rebates may have differing rebate levels based on the MCO's level of control (open, closed or 3-tier plan design) or product formulary positioning (on formulary, one of several products within the defined therapeutic class on formulary, contracted product as a preferred or exclusive formulary status)

Example of Market Share Rebate Calculation:

List Price = \$75

Units=10,000

Rebate Percentages Based on Contract Terms

<50%	2%
51% to 75%	3%
75% to 80%	3.5%
80% to 85%	4.0%
> 85%	5.0%

Actual Market Share Achieved by the MCO = 82.5%

Rebate Paid to the MCO = \$75 * 10,000 * 4.0% = \$30,000



Manufacturers and the PBM Contractual Relationships

- Manufacturers should continually review the PBM contractual relationship for two objectives
 - Compliance
 - Manufacturer has stringent contractual requirements, such as product positioning, interchange programs or has questions about positioning of their contracted products vs. competitor's products
 - Products drive significant rebate
 - Data integrity issues (unusual fluctuations in rebates or lives between quarters, delay in reporting from PBM, etc.)
 - Strategic
 - Manufacturer is evaluating a change in contracting strategy or entering into new contracts with the PBMs
 - Assess capabilities of PBM with structuring new contracts or strategy - do they have the administrative capabilities to comply with the new contract
 - Evaluate positioning of their products vs. competitor products when structuring new agreements
- Due to the complexities of the industry, manufacturers should seek industry experts when performing these reviews
 - In-house or external resource team with expertise in Managed Care Rebate contracting
 - Management should focus on the issues rather than the process to perform the reviews

Introduction to Prime Vendor Chargebacks



The primary goal of this section of the break-out session is to introduce the concepts, methodologies, and challenges surrounding Prime Vendor chargebacks in the pharmaceutical industry

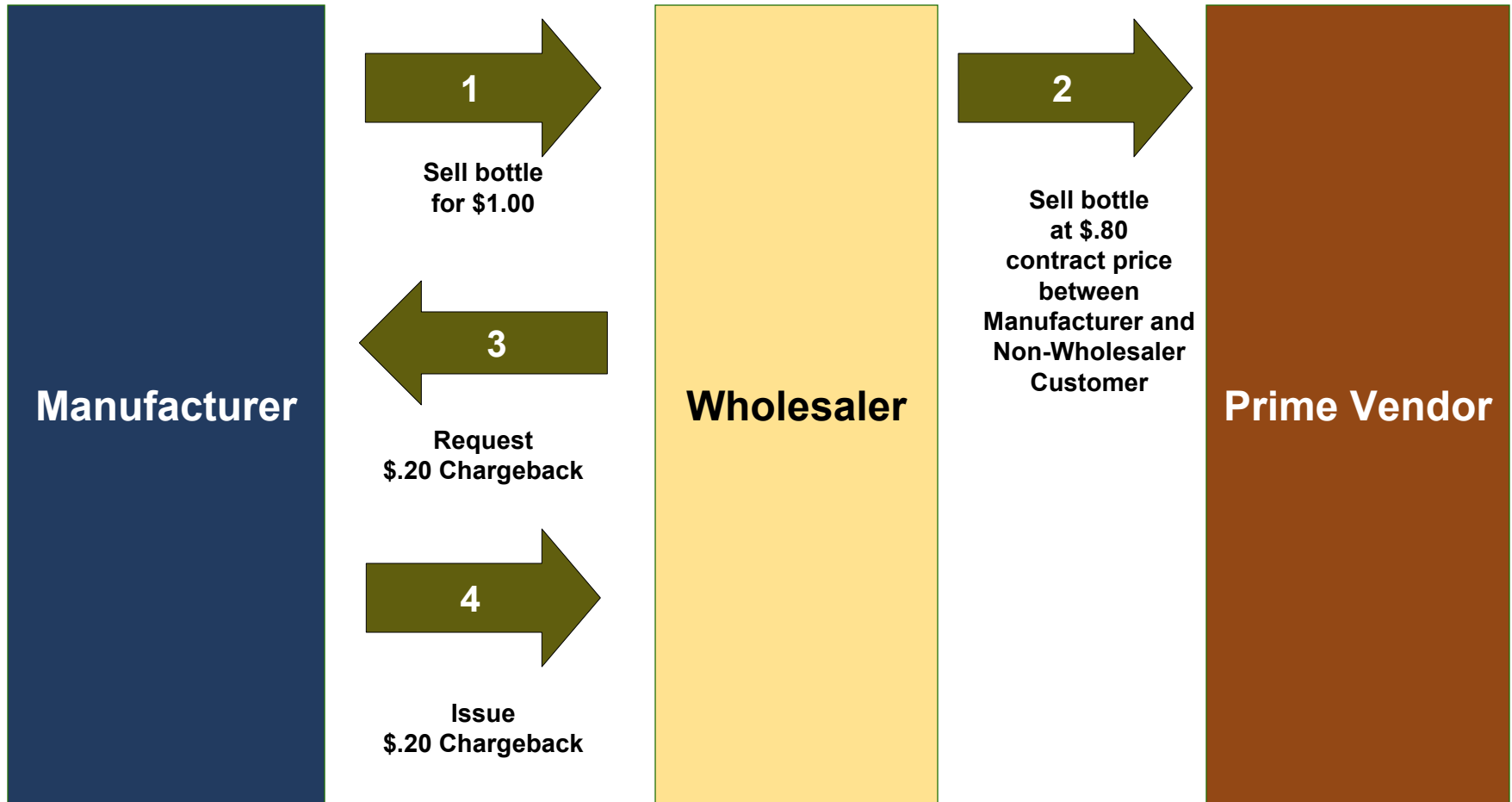


Overview of Contracting

Prime vendor (chargeback) contracting

- Contract Administration group negotiates a contract price with non-wholesaler customers
- Prime Vendor customers include:
 - Hospital buying groups (e.g. GPOs)
 - Staff model HMOs (e.g., CIGNA, Kaiser)
 - HMO/PBM Mail Facilities (e.g. Medco, CIGNA (Tel-Drugs))
 - Government (e.g. VA, DoD)
 - Retail Pharmacies (Walgreens, Eckerd)
- Manufacturer sells product to wholesalers at WAC or list price
- Wholesalers sell products to Prime Vendors at the negotiated contract price
- Wholesalers and manufacturers have a well defined process to share contract pricing and eligibility data to allow wholesalers to appropriately invoice Prime Vendors
- Wholesalers request chargeback credit from manufacturer for difference between WAC/list price and Prime Vendor contract price

Overview of Chargeback Cycle



Chargeback Processing

Wholesaler submits chargeback request to manufacturer

- Primarily electronic (EDI Submission)
- Submitted on periodic basis (weekly, bi-weekly)

Manufacturer receives chargeback

Manufacturer validates and processes electronically (typically w/in a week). This is performed by the manufacturer by reviewing the wholesaler submitted chargeback data to the manufacturer's contract terms, prices and and customer eligibility

Key information in chargeback request

- Wholesaler DEA#
- Customer #
- Contract #
- NDC #
- Quantity purchased
- Contract price
- Invoice #
- WAC

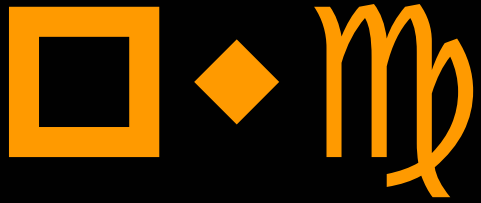
Typical Chargeback issues

Chargebacks can be misstated for a number of reasons. Those include situations such as:

- **Returns to wholesalers** – wholesaler issues a credit to the Prime Vendor without issuing a corresponding negative chargeback to the pharmaceutical company.
- **Resales of returned products** – wholesaler claims a second chargeback upon the resale of product previously returned
- **Sales by wholesalers of alternative sourced product** – wholesaler inappropriately claims a chargeback when it sells a product not acquired directly from the pharmaceutical company.
- **Chargeback processing errors** – for example, claiming a chargeback at rates different than the contract or for: products that were not shipped to the claimed customer

Typical Chargeback issues (cont.)

- **Prime Vendor not a member of buying group** – chargeback customer is not eligible to purchase off of the buying group contract
- **Contract invalid or expired** – contract assigned to chargeback is not valid or has expired
- **Incorrect contract pricing** – chargeback price does not agree to contract
- **Duplicate chargeback request** – chargeback included in current submission twice
- **Incorrect WAC Incorrect Pricing** – wholesaler purchase price included in chargeback is not the original price the wholesaler paid



Your worlds



Our people