Pharmaceutical Compliance Congress and Best Practices Forum

Preconference Symposia

Government Price Reporting – Staying Ahead of the Curve on Problems and Solutions

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The Federal Programs

There are currently four types of government pricing programs

Medicaid Drug Rebate Program

Federal Supply Schedule Program

Public Health Service *

Medicare Program

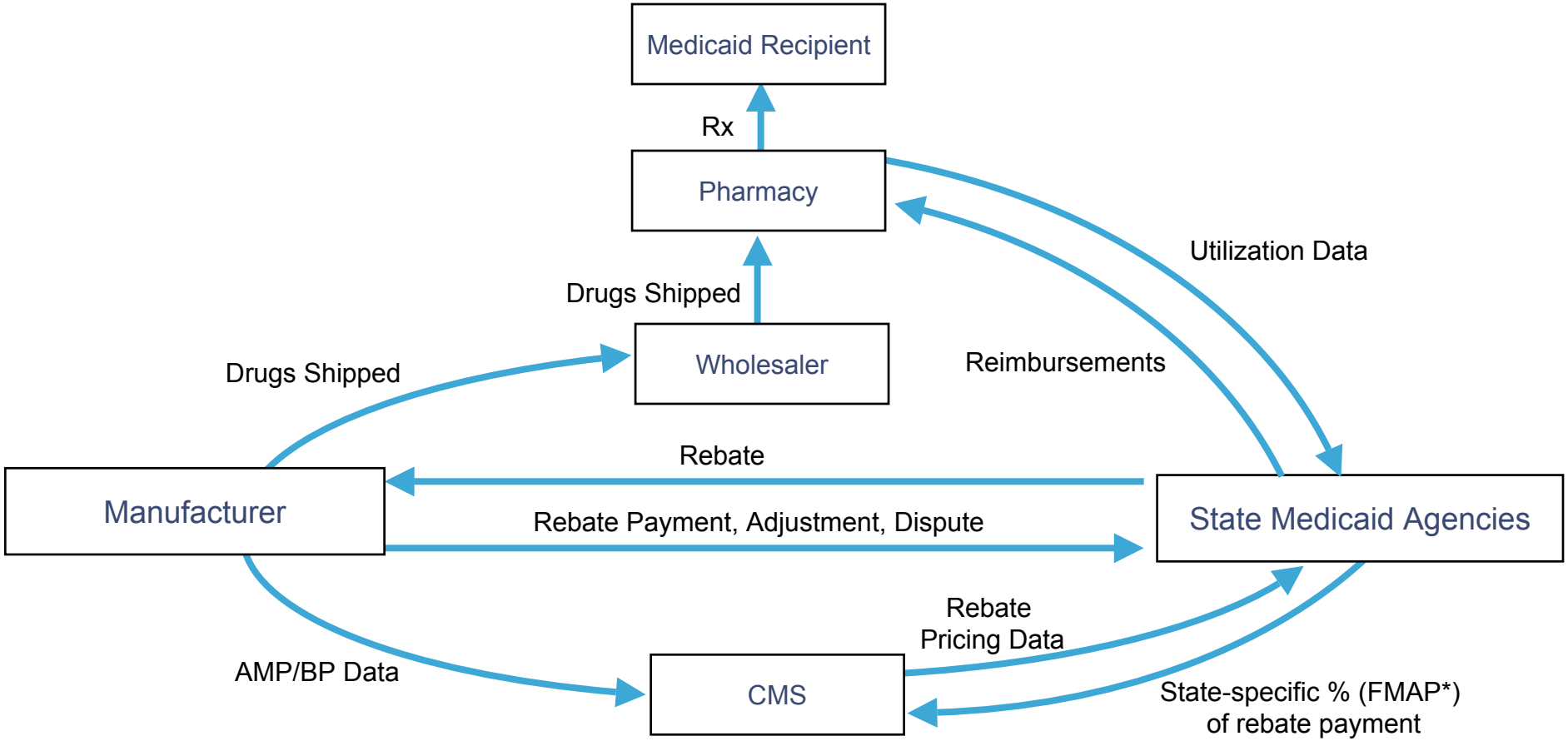
- - Will be covered as part of Medicaid

Medicaid 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 and is under the administration of the Center for Medicare and Medicaid Services ("CMS"), formerly 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.

What is the Medicaid Drug Rebate Program?

The Omnibus Budget Reconciliation Act of 1990 (OBRA'90) created the Medicaid Drug Rebate Program with pharmaceutical manufacturers. The Program is administered by the Centers for Medicare and Medicaid Services (CMS) and the key objectives of the program are to:

- Obtain a minimum discount of 15.1% on each branded pharmaceutical and 11% on generic pharmaceutical products dispensed to Medicaid recipients
- Obtain the Best Price paid in the commercial market for each branded NDC in cases where the Best Price is lower than the imputed price level at the minimum discount level;
- Limit price growth on drugs dispensed to Medicaid recipients to the Consumer Price Index for Urban areas (CPI-U).

These objectives are achieved through a quarterly rebate paid on each drug dispensed to Medicaid recipients.

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 manufacturers for sales to the retail class of trade
  - Best Price (BP) - the lowest price at which the manufacturer sells a drug to any purchaser in any pricing structure

Medicaid AMP Calculation

AMP is defined as 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 may permit certain adjustments to be made in the quarter in which they are realized

Description	**Dollars**	**Units**
Direct AMP Eligible Sales	$ X	X
Adjustments:		
Returns	(X)	(X)
Direct Sales that resulted in a chargeback sale to an AMP ineligible customer	(X)	(X)
Subtotal	**X**	**X**
Prompt Pay Discount	(X)	
Wholesaler/Trade Rebates	(X)	
AMP Eligible Chargeback Adjustments	(X)	
Net AMP	**X**	**X**

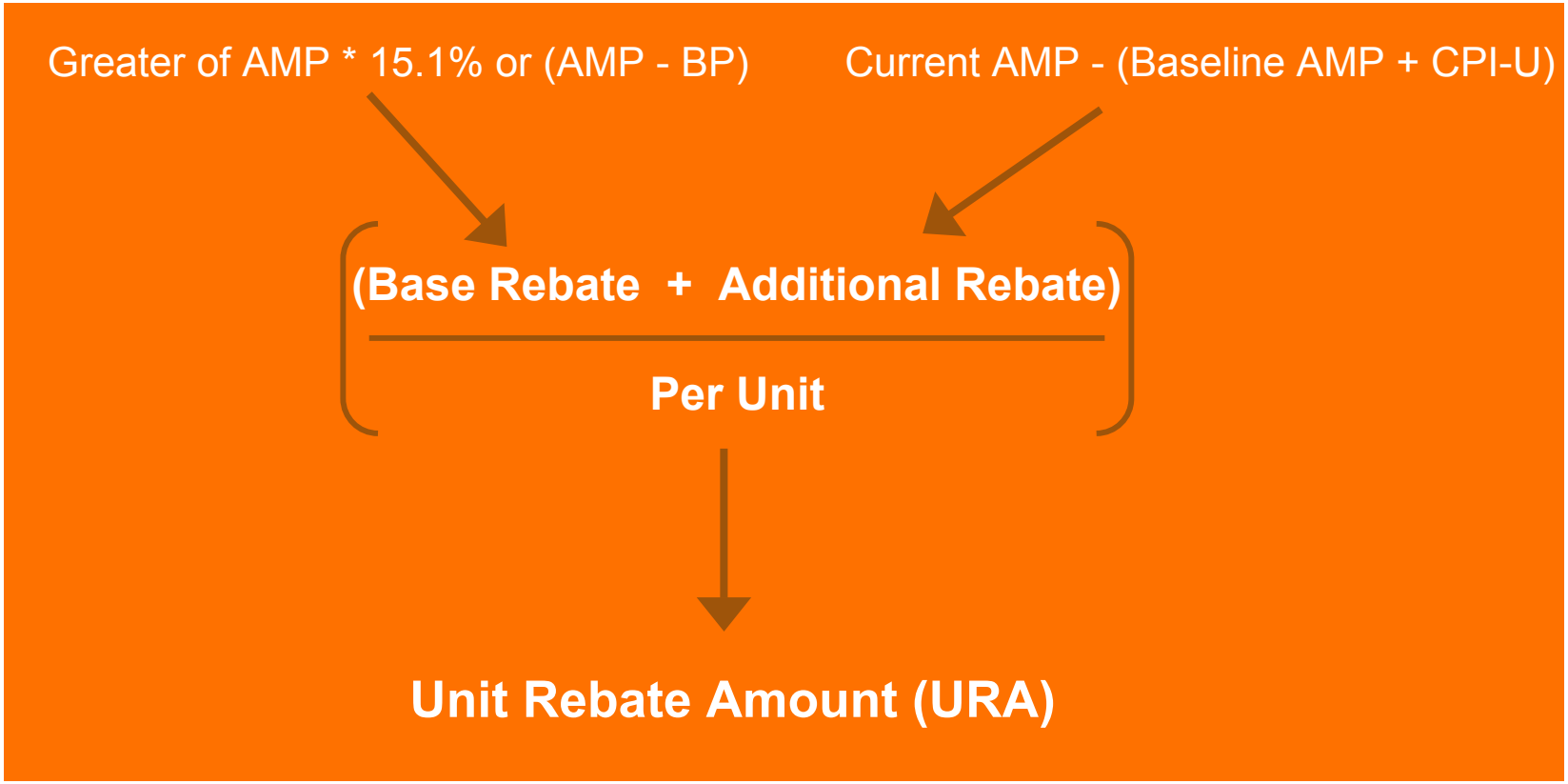
How do you calculate the Medicaid Rebate?

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).

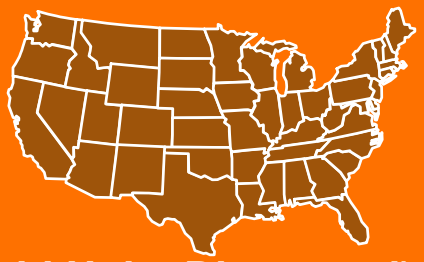


How do you calculate the Medicaid Rebate?

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

Calculated by CMS with data provided by manufacturers

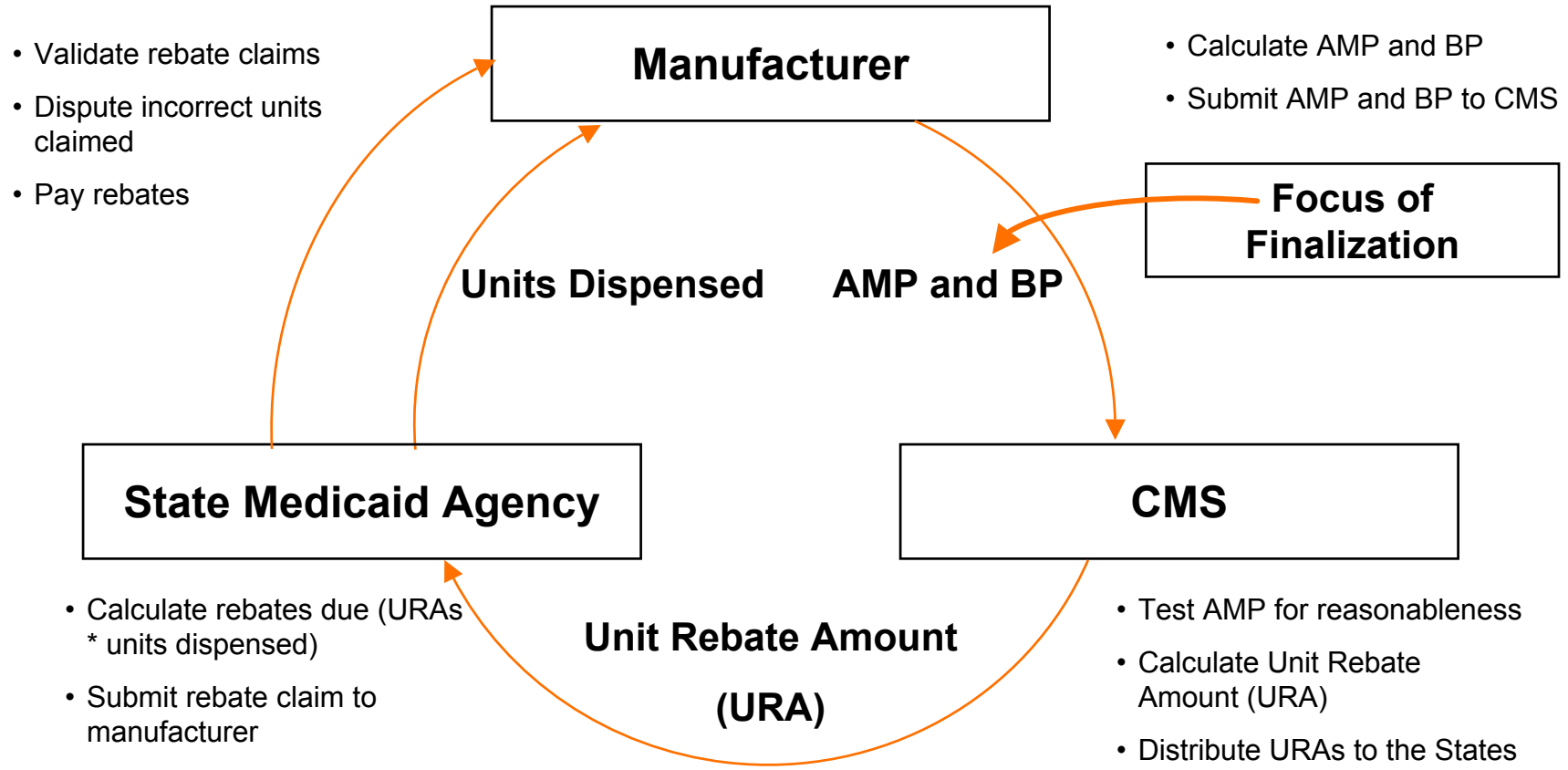
Collected from retail pharmacies and submitted to manufacturers by the Medicaid State Agencies



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, CMS, and the Medicaid state agencies.



Rebate Agreement Finalization Clause

The Finalization clause in the Medicaid Rebate Agreement states that Average Manufacturer Price (AMP) and Best Price (BP) "…must be adjusted if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized."

An Approach

Collect Required Documentation

- Relevant Contracts
- Sales and rebate Data
- Contract and NDC Control Reports
- General Ledger Reports
- Policy Documentation

Validate and Reconcile Data

- Reconcile contract terms with sales and rebate data
- Verify rebate data with rebate payment documentation
- Apply bundling reallocation technique (if applicable)
- Data enter hard copy rebate data (if necessary)
- Perform G/L reconciliation

Finalize AMP

- Compile chargebacks and rebates in a summary report
- Recalculate AMP using new data
- Perform analysis

Finalize Best Price

- Calculate final retail BPs
- Determine final non-retail BPs
- Perform analysis

Finalize Medicaid Rebate Liability

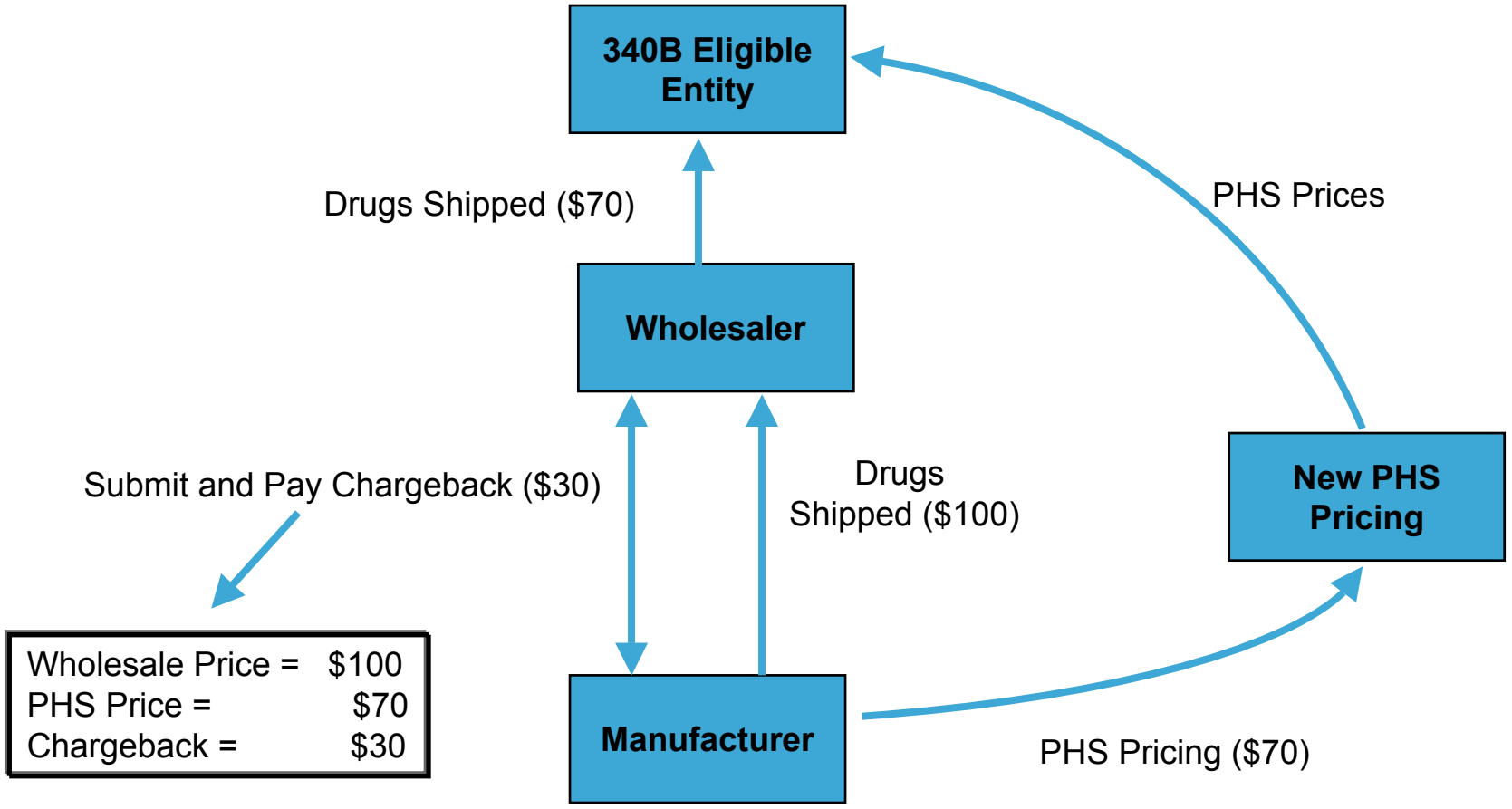
- Calculate final URAs
- Calculate variance between old and new URAs and extend for units claimed
- Perform analysis

Public Health Services Program Overview

The Public Health Services Program is the program through which the manufacturer agrees to charge eligible entities a price for covered outpatient drugs that will not exceed the amount determined under a statutory formula .

- The relevant law related to the PHS pricing is the Veterans Healthcare Act of 1992.
- Eligible entities are 340B entities including outpatient disproportionate share hospital (DSH) facilities
- 340B eligible entities can be located on Health Resources and Services Administration (HRSA) website: http://bphc.hrsa.gov/opa/downld.htm

PHS Program Cycle



What is the Public Health Service Program?

The Veterans Health Care Act of 1992 enacted section 340B of the Public Health Service Act ("PHS Act"), which created the "Limitation of Prices of Drugs Purchased by Covered Entities". Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities agrees to charge a price for covered outpatient drugs that will not exceed that determined under a statutory formula

How do you calculate PHS pricing

Statutory Formula for prices charged to 340B (Disproportionate Share Hospitals (DSH)) eligible entities :

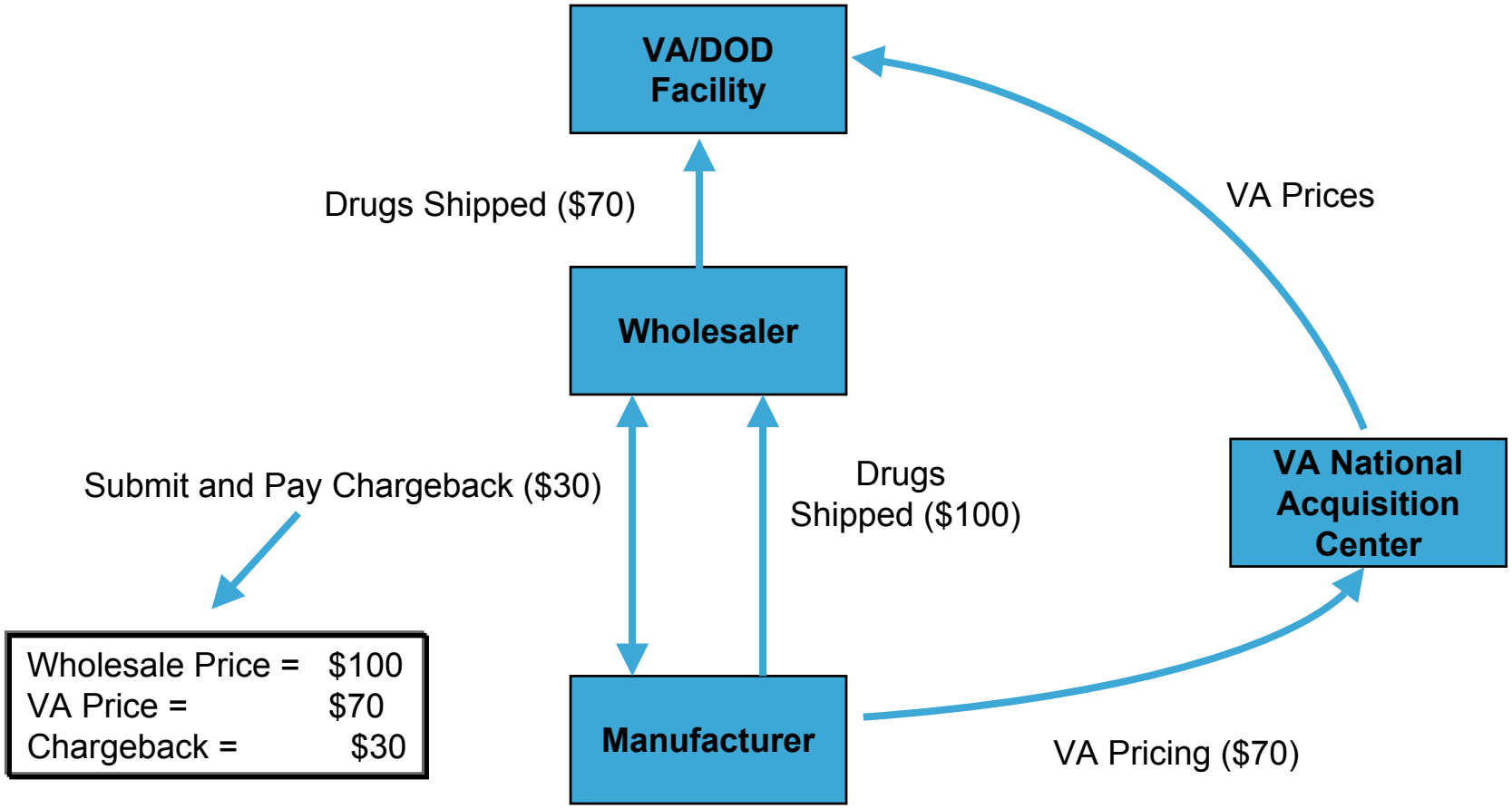
- Based on the availability of data, the PHS price is calculated based on one or two quarters prior AMP less the corresponding Medicaid Rebate Per Unit (“RPU”) calculated for the respective quarter

Federal Supply Schedule Program Overview

The Federal Supply Schedule (FSS) is the program through which the federal government purchases various products for its own use, including pharmaceuticals and other healthcare products.

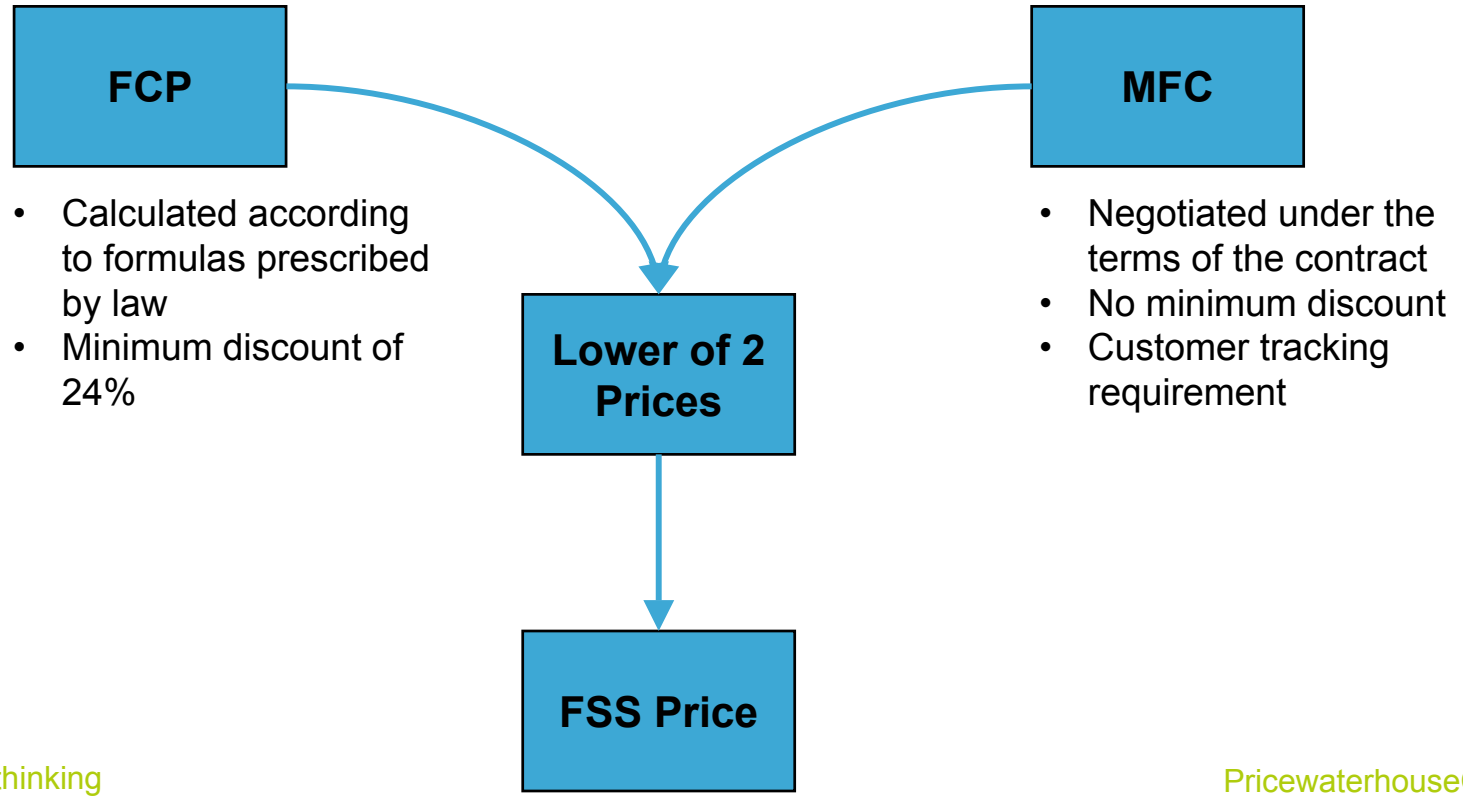
- The U.S. Congress has delegated responsibility for administering the FSS to the Veterans Administration (VA).
- The relevant law related to the FSS contract is the Veterans Healthcare Act of 1992.
- The largest purchasers of pharmaceuticals within the federal government are the VA, DoD, Indian Health 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.

FSS Program Cycle



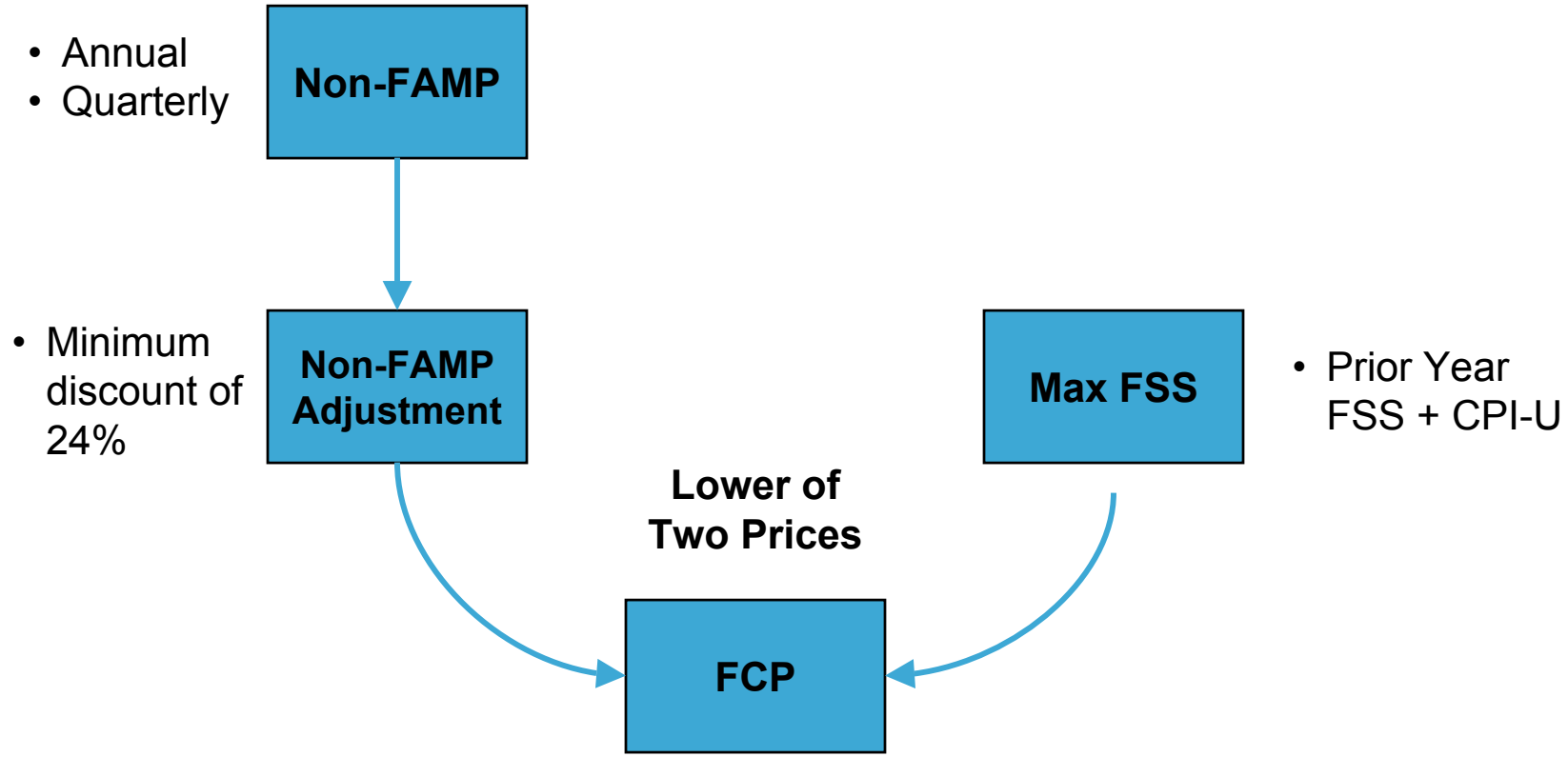
Federal Supply Schedule Pricing Process

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.



Federal Ceiling Price Process

The FCP is a calculated value that is derived through a three step process.



Non-FAMP Calculation

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

((Non-Government Sales through Wholesaler Middleman- Nominal Sales) * .98) - (Non-Government Chargeback Adjustments - Trade Discounts – Financial Adjustments)

(Total Non-Government Units – Nominal Units)

- Sales to wholesalers, distributors, and other “merchant middlemen” only
- Nominal Sales are valued at wholesale list price
- Trade Discounts and Financial Adjustments represent any other discounts, allowances, or incentives given to the wholesale trade other than the 2% prompt pay discount

Calculated Ceiling

The second step calculates the Calculated Ceiling Price by discounting the non-FAMP and reducing the resulting price by an inflationary penalty.

Calculated Ceiling = (Annual Non-FAMP * .76) - Additional Discount (Inflation Penalty)

- The Annual non-FAMP is based on the prior year's third quarter, back four quarters
- The Additional Discount is designed to 'limit' any increases in Non-FAMP to the CPI-U, and penalize any increases over and above that benchmark, and is determined by:
  - Calculating the prior year's third quarter non-FAMP (New non-FAMP) and the third quarter non-FAMP from the year before last (Old non-FAMP)
  - Comparing the Old non-FAMP plus the CPI-U to the New non-FAMP
  - Price difference becomes the Additional Discount

FSS Price Comparison

The final step is the comparison between the Max. FSS and the Calculated Ceiling, to determine the FCP.

- Compare the current FSS plus the CPI-U, the Max. FSS, with the Calculated Ceiling price
- The lower of the two prices becomes the new FCP

FSS Price Comparison

Once the FCP is determined, it is compared with the Most Favored Customer (MFC) price.

- The MFC price is a negotiated price disclosed to the VA, independent of the calculation of FCP
- The VA is not entitled to most favored customer (MFC) prices under the law, but is charged with negotiating the best prices possible
- MFC prices are calculated as the lowest achievable price after maximum possible chargebacks and rebates, excluding administrative fees.
- MFC prices are disclosed according to VA guidelines
- The current commercial strategy is to increase Most Favored Customer prices to reduce the level of discounts and rebates in the commercial and Medicaid markets
- Typically most Federal Ceiling Prices range from far below to slightly higher than Most Favored Customer prices

Most Favored Customer Price

Two conditions could drive the Most Favored Customer price below the Federal Ceiling Price.

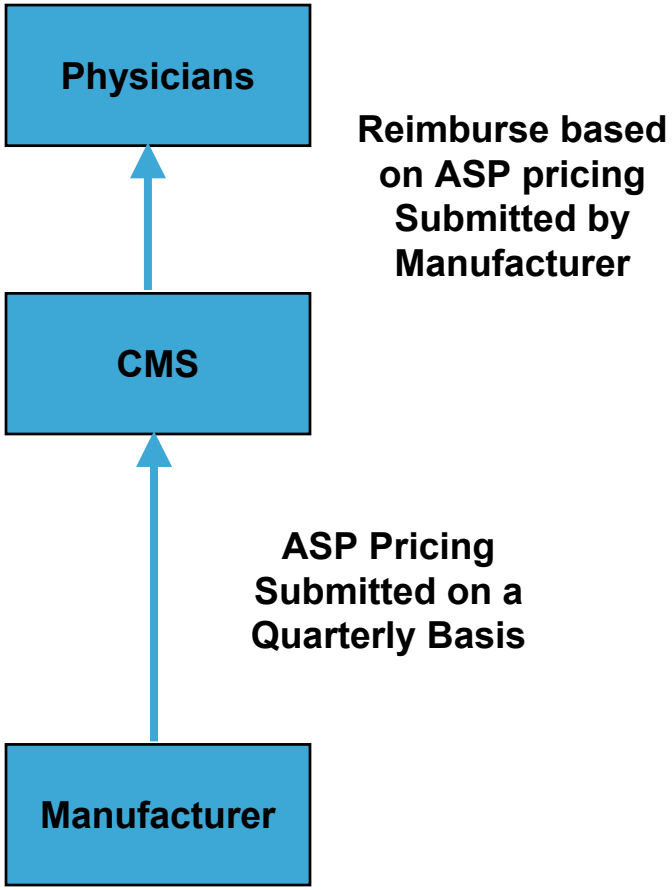
- All or most of the Most Favored Customer Price is attributable to a rebate that is not incorporated into the Federal Ceiling Price calculation
- The best discount level (chargeback) is substantially deeper than the average discount level across all customers

Medicare Part B Overview

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required manufacturers to submit on a quarterly basis to CMS the "Manufacturer's Average Sale Price" (ASP) based on a statutory formula and guidance provided by CMS

- ASP pricing data is submitted quarterly for Medicare Part B reimbursable products
- 1Q04 was the first quarter ASP pricing was required to be submitted to CMS by April 30, 2004
- Beginning January 1, 2005, CMS started using the reported ASP prices to reimburse physicians for Part B drugs not paid on a cost or prospective payment basis
- Because the reported ASP pricing is used for reimbursement purposes, there is no re-filing mechanism available to the manufacturer (unlike the re-filing mechanism available for Medicaid Rebate Reporting)
- The manufacturer's CEO, CFO or an individual who has delegated authority to sign for, and who reports directly to the CEO or CFO needs to certify to the accuracy of the calculations

Medicare ASP Pricing Cycle



What is Medicare ASP Price Reporting

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 created the ASP price reporting requirement for the pharmaceutical manufacturers. The Program is administered by the Centers for Medicare and Medicaid Services (CMS) and the key objectives of the program are to:

- Obtain the average selling price to purchasers in the United States for a drug or biological reimbursed under Medicare Part B
- Purchases excluded under Medicaid best price calculation under section 1827(c)(1)(C)(i) are excluded from the ASP calculation
- Beginning January 1, 2005, CMS started using the reported ASP prices to reimburse physicians for Part B drugs not paid on a cost or prospective payment basis
- First quarter ASP reporting was 1Q04, however, finalization of the calculation requirements was provided by CMS to the manufacturers in April 2004 and September 2004
- The manufacturer's CEO, CFO or an individual who has delegated authority to sign for, and who reports directly to the CEO or CFO needs to certify to the accuracy of the calculations

ASP Calculation

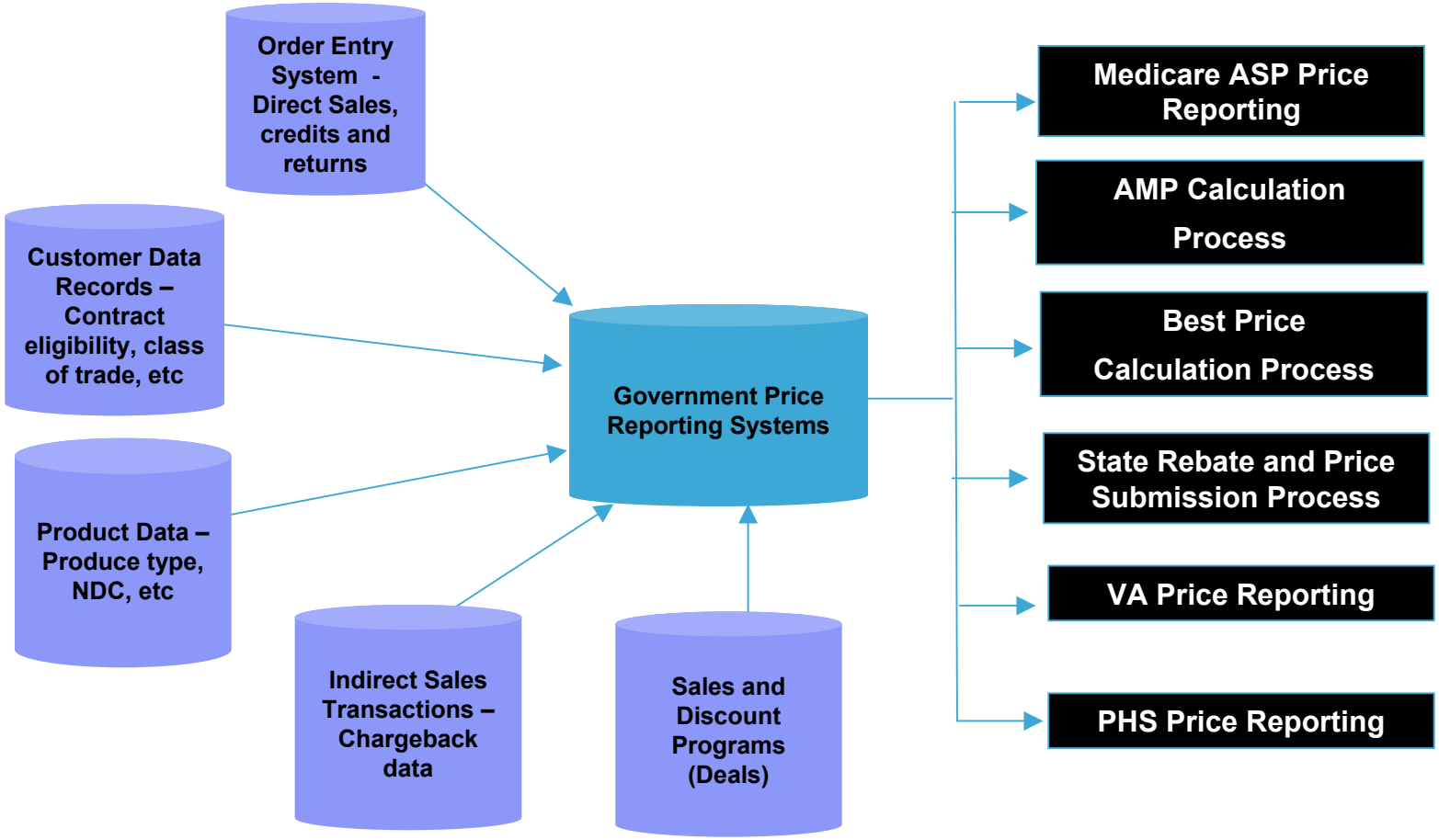
Description	$ Amount	Unit Amount
ASP Eligible Direct Sales	$ X	X
Adjustments		
1 Direct Sales that resulted in a chargeback sale to an ASP ineligible customer	- X	- X
2 Nominal Sales	- X	- X
Adjusted ASP Eligible Sales	- X	- X
Prompt Pay Discounts	- X	
Non-Lagged Price Concessions	- X	
12 Month Rolling Average Price Concession Percentage	X	
Multiplied by the Adjusted ASP Eligible Sales		
ASP pricing to be Reported on CMS	$ X	X

- Calculations are performed at the 11-digit NDC Level
- ASP Nominal Sales is identical to the Medicaid Nominal Sales definition
- A 12-month rolling average methodology is to be applied to any price concessions that requires an estimation. This rolling average is based on calculating the prior twelve months of price concessions paid compared to total ASP eligible sales for the prior twelve months and applying that percentage to the current filing quarters ASP eligible sales

Data Integrity

- ✓ Manufacturers should understand the data and process flow of all information being interfaced into the government price reporting 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 Government Price calculations

Data Integrity, cont'd



Data Integrity, cont'd

- The following outlines questions to be considered when reviewing the data interfaces:
  - What are the data interfaces into the government price reporting system
  - What formal written policies and procedures exist, when were they developed and have they been reviewed by counsel and management
  - Has a risk assessment been performed to ensure the policies and procedures that are in place are actually being followed
  - What controls exist around this data within the interfacing systems, as well as, once the data is gathered and implemented in the government price reporting calculations
  - What is being done with the data once it is gathered into the government price reporting system
  - Does proper supervision and training exist
  - 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 calculations
  - 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

Question and Answer

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