National Parma Audioconference

Pharmaceutical Drug Pricing and Reporting Issues

A Brief Overview of Government Drug Price Reporting Requirements

July 28, 2005

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

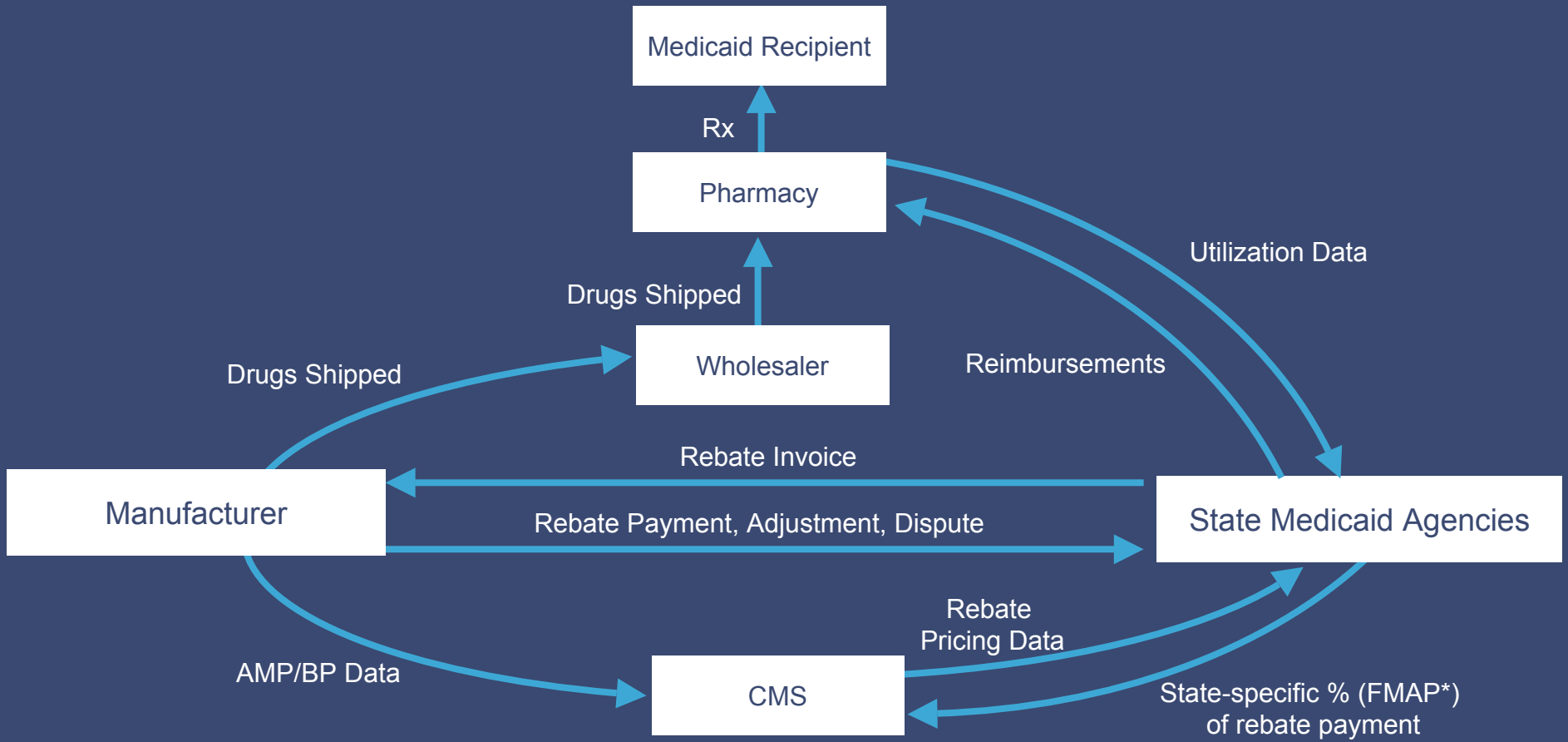
• - Will be covered as part of Medicaid

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.

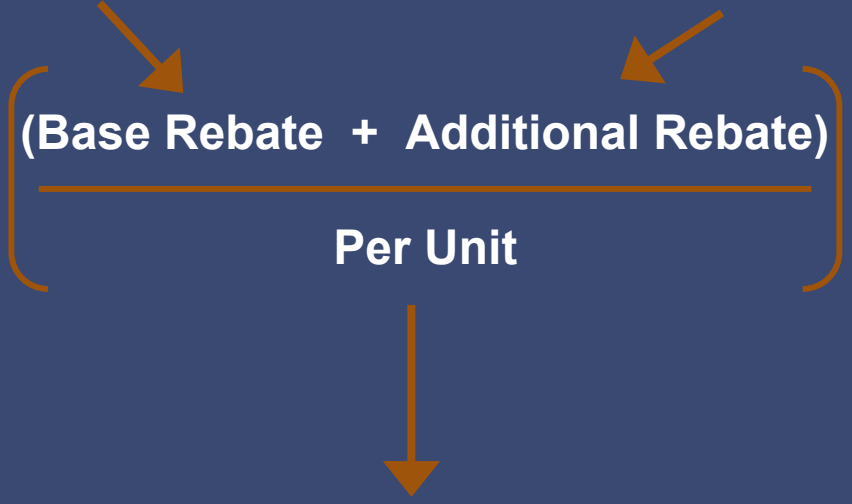
How do you calculate the Medicaid Rebate?

The URA calculation is performed on a quarterly basis for each NDC (9-digit level) of a Medicaid covered drug for pharmaceutical products considered to be Innovator and Non-Innovator products

Greater of AMP * 15.1% or (AMP - BP) for Innovator products

AMP * 11% for Non-Innovator products

Current AMP - (Baseline AMP + CPI-U)

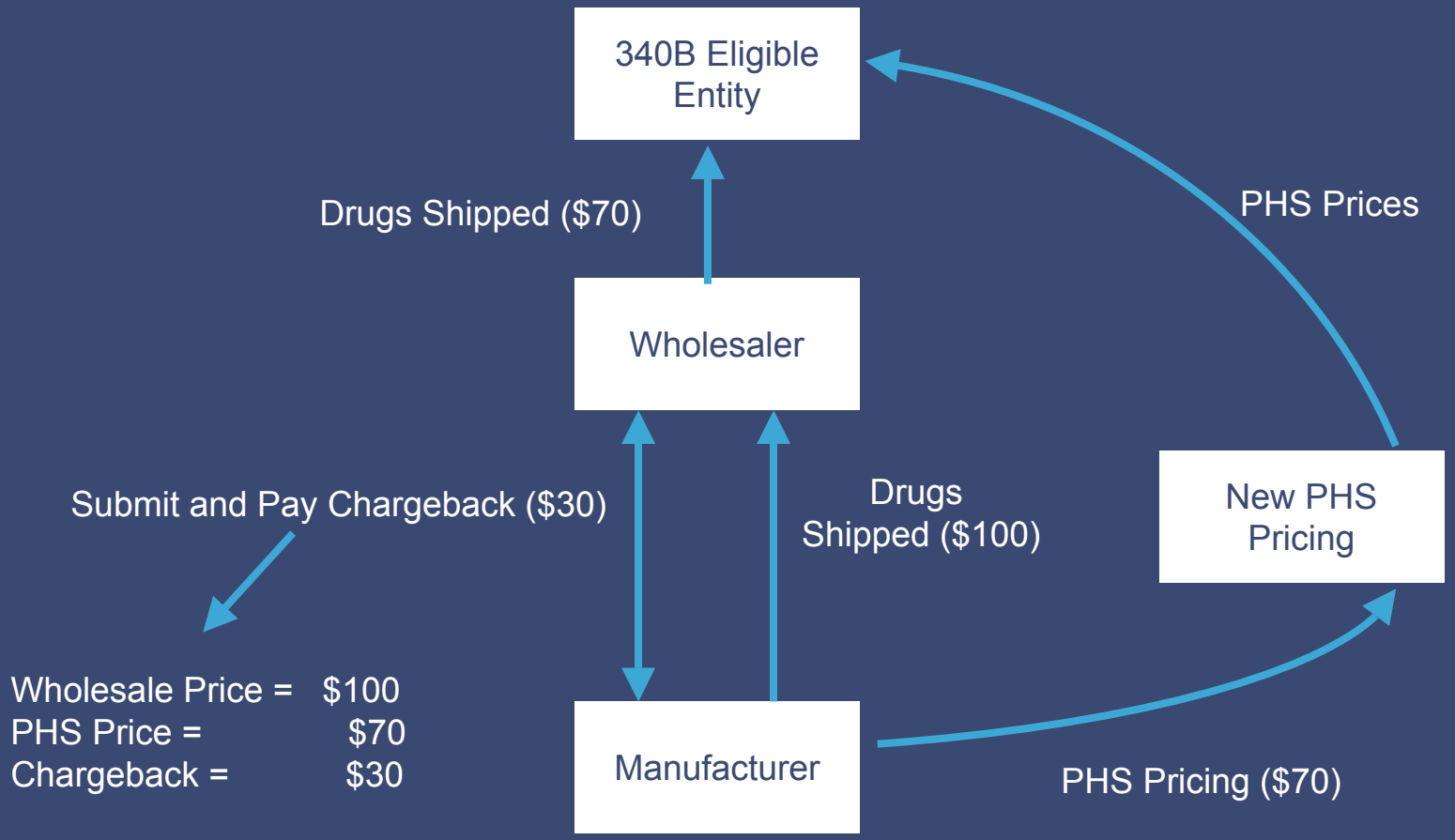


Public Health Services Program Overview

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



How do you calculate PHS pricing

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

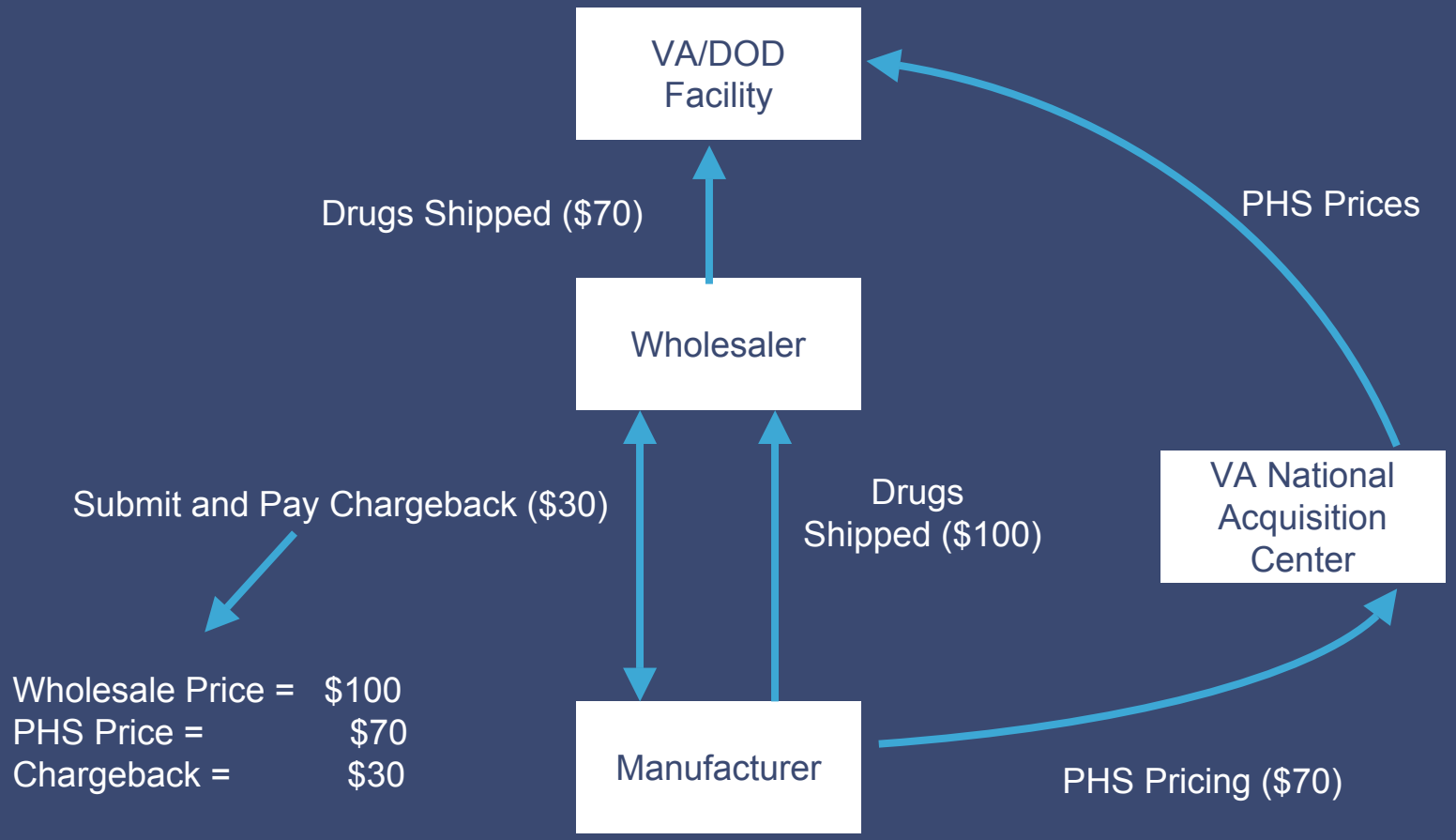
- Based on the availability of data, the PHS price is calculated based on one or two quarters prior AMP less the corresponding Medicaid Rebate Per Unit (“RPU”) calculated for the respective quarter

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.

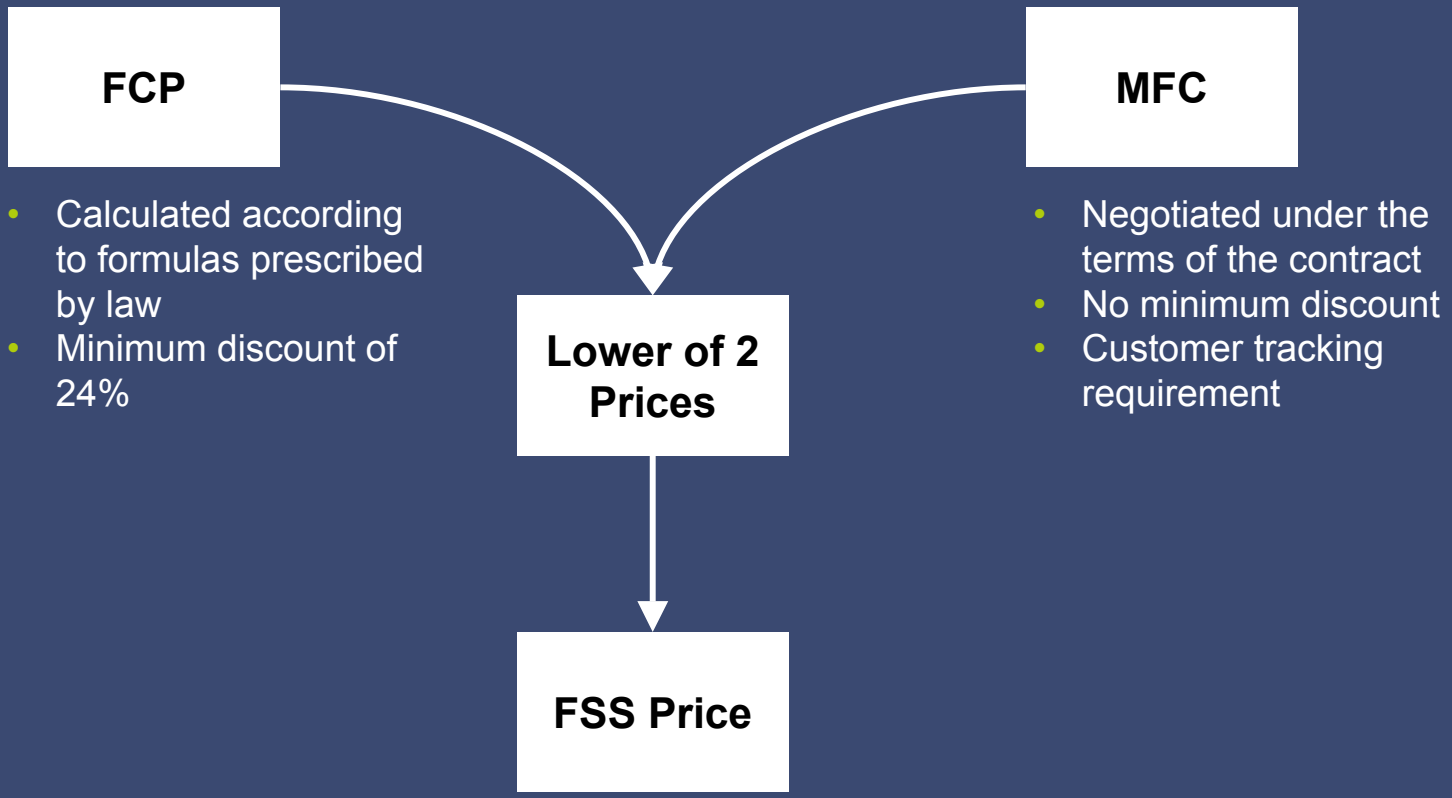
- The U.S. Congress has delegated responsibility for administering the FSS to the Veterans Administration (VA).
- The relevant law related to the FSS contract is the Veterans Healthcare Act of 1992.
- The largest purchasers of pharmaceuticals within the federal government are the VA, DoD, Indian Health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



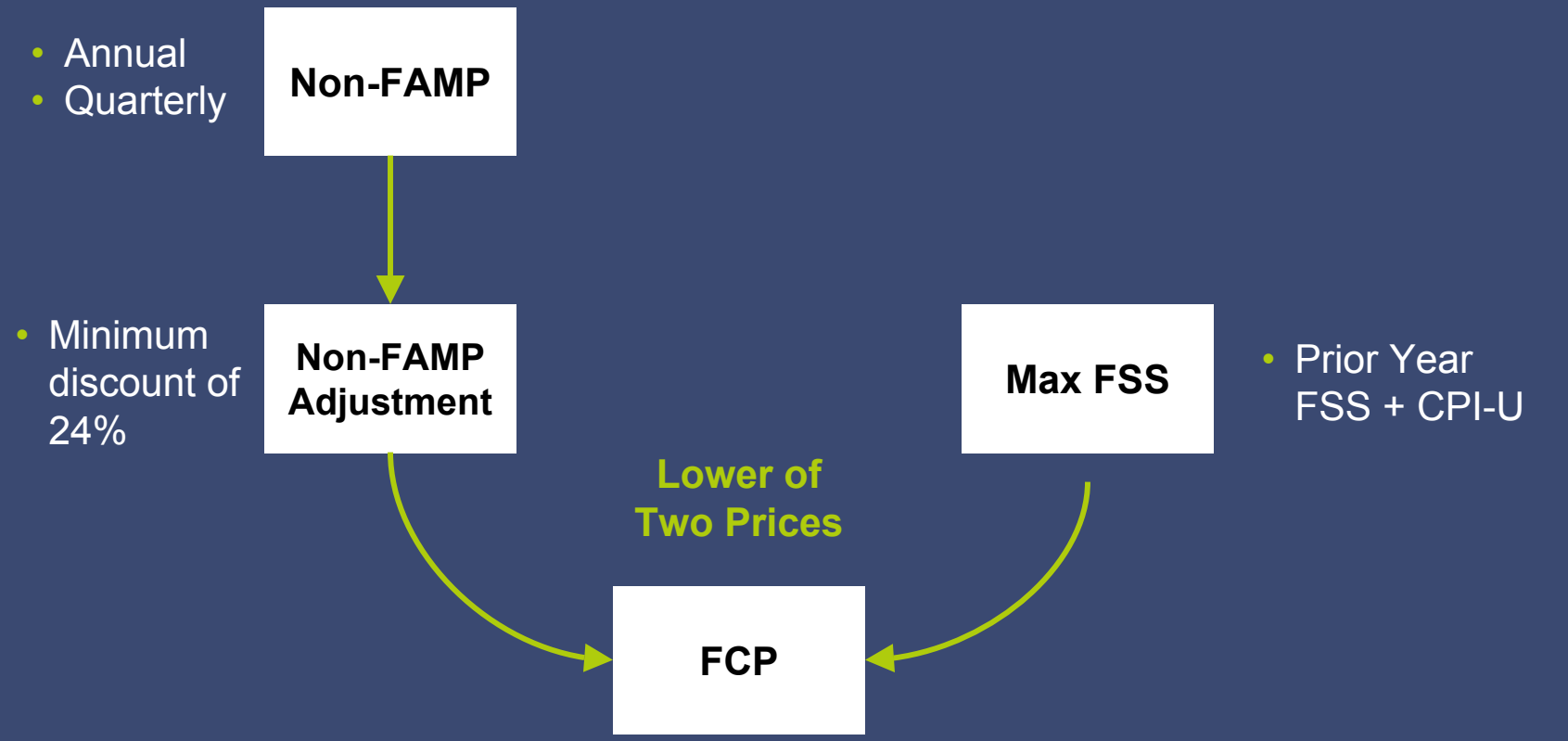
Federal Supply Schedule Pricing Process

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.

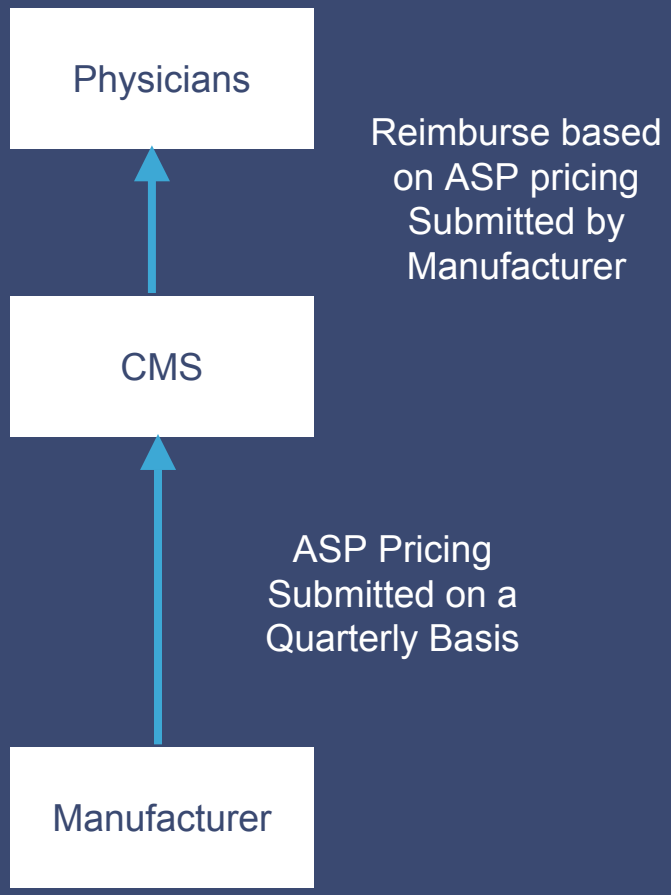


Medicare Part B Overview

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

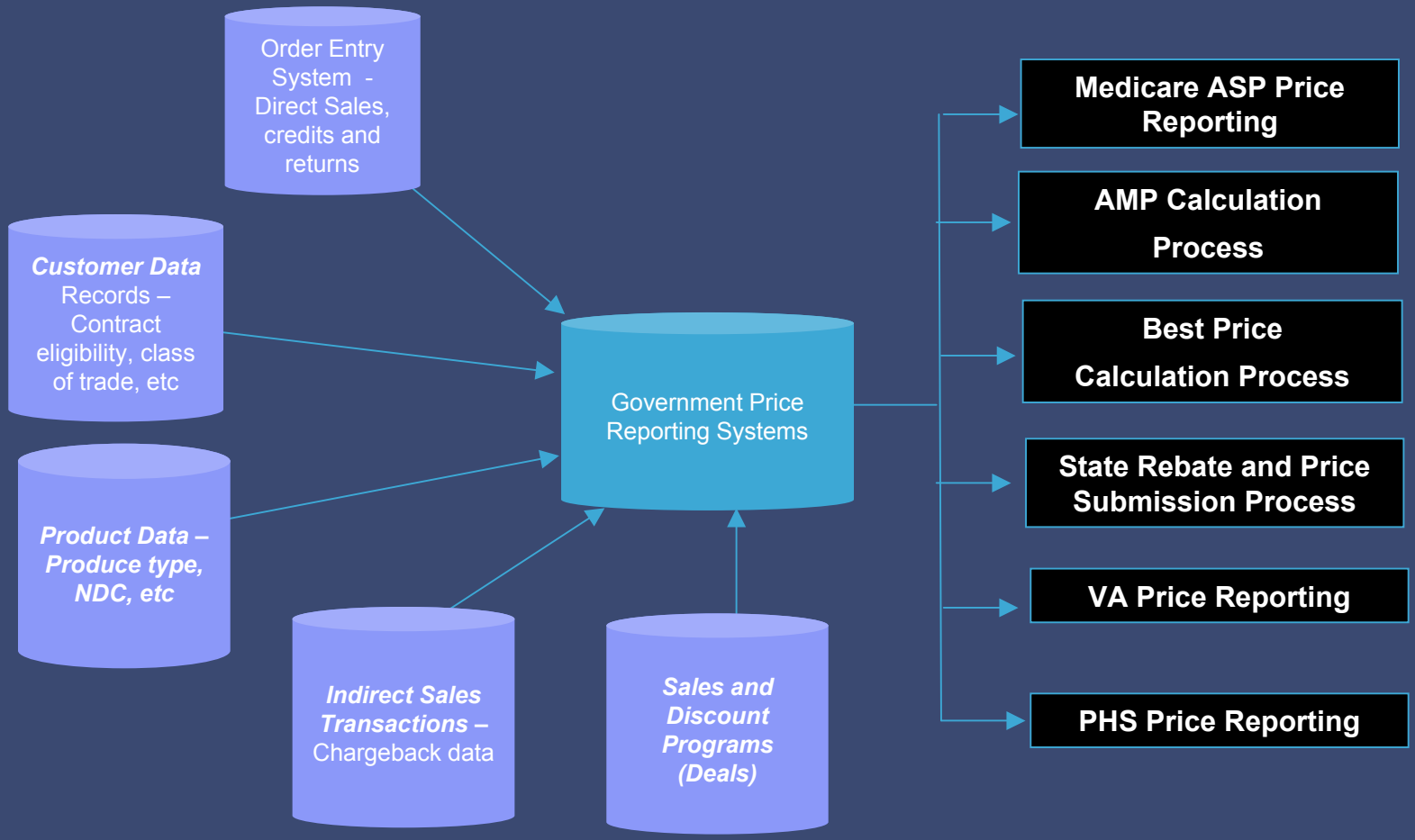


Data Integrity

- 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

- ✓ Understanding your systems and data interfaces



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