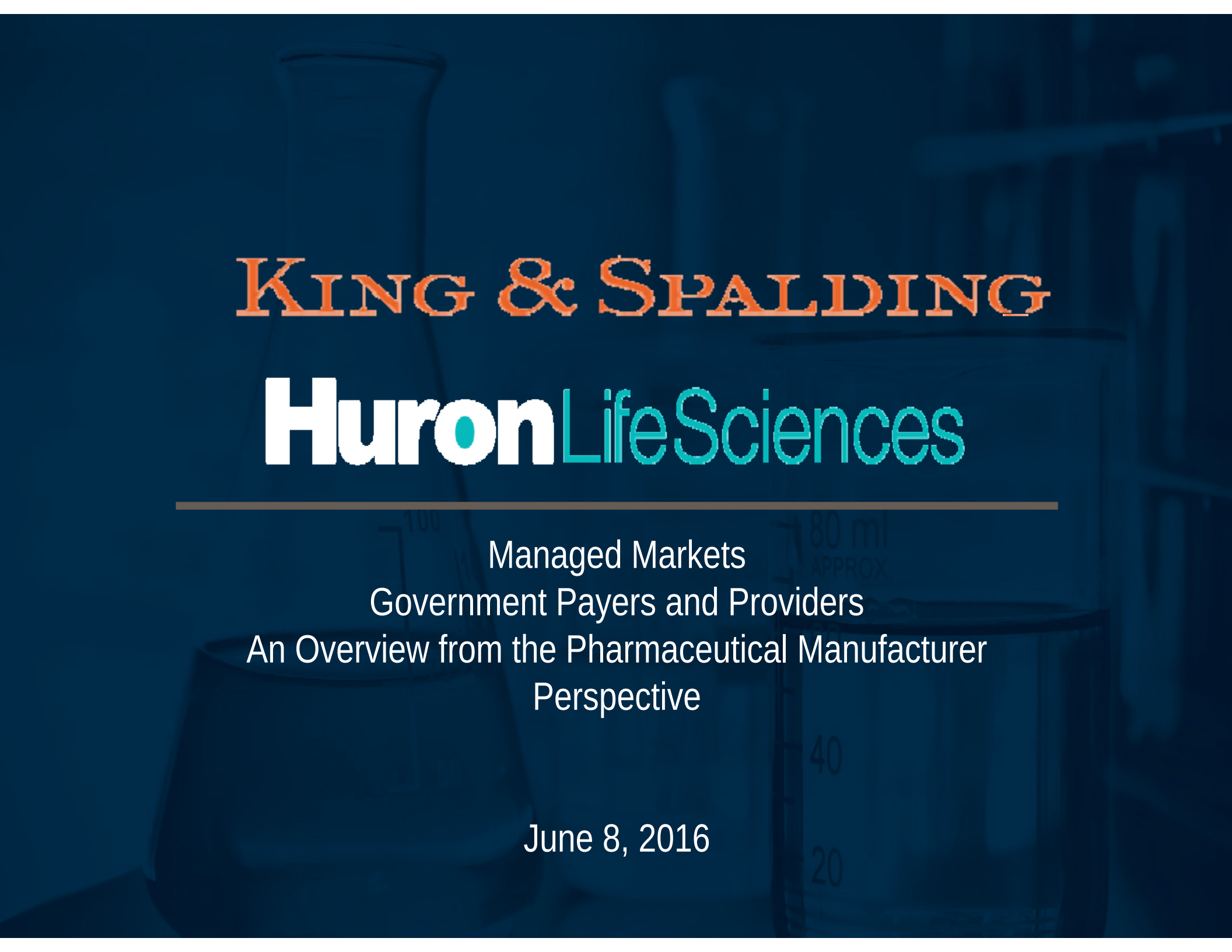

KING & SPALDING

Huron Life Sciences

Managed Markets
Government Payers and Providers
An Overview from the Pharmaceutical Manufacturer Perspective

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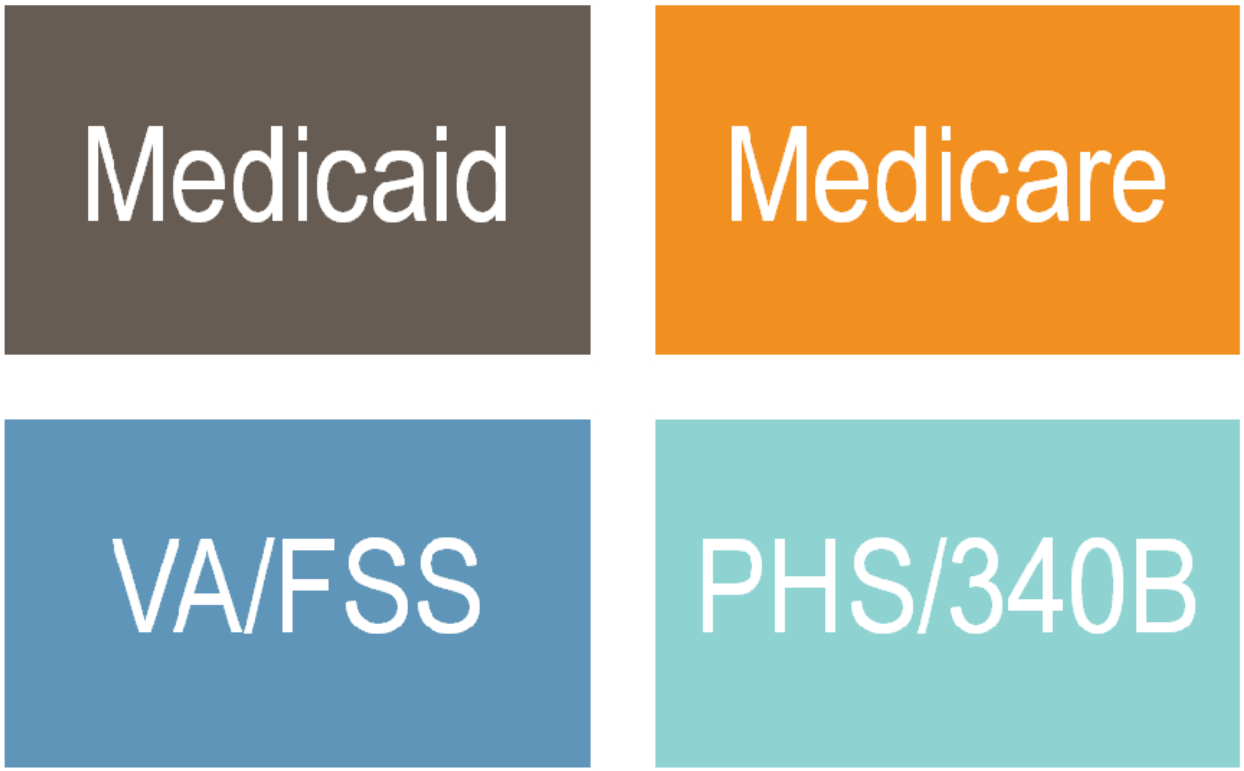
The Programs and the Populations they Serve

The “Government Customer”

- The government pays for or reimburses providers for drugs distributed to American beneficiaries based on beneficiaries’ eligibility for various Government Programs
- Nearly 50% of Americans receive some benefit through a Government Program



As Gov't Programs Grow and Increase Their Buying Power, Compliance is Becoming a Major Focus

Growth in Gov't Healthcare Programs

- Government healthcare programs, such as Medicaid and Medicare continue to grow
- Over 50% of Americans are expected to receive some benefit from a publicly funded program

Manufacturer Compliance with Gov't Programs

- As a result of increasing drug spend, federal and state governments are focusing more on manufacturer compliance
- The Office of Inspector General (OIG) oversees the federal programs with the mandate to "protect the integrity of the programs"
  - Can apply the False Claims Act if data (statutory pricing calculations) reported to the government causes the government to pay more than they should for a manufacturers products
  - Manufacturers are expected to have processes, systems and controls in place to ensure the accuracy of their calculations
  - The calculations are very complex, and in many cases guidance is insufficient and/or unclear, and manufactures must make reasonable assumptions

Overview of Agencies and Oversight

Federal Administration:

CMS	VA	OPA	DoD
Medicaid (AMP,BP) Medicare B (ASP) Medicare D (CGDP)	Federal Supply Schedule (FSS) (NonFAMP, FCP)	340B (PHS Price PHS & DSH Eligibility)	Tricare

State Administration:

State Medicaid Agencies
Medicaid (State eligibility and membership, Pharmaceutical Mfg Rebates)
State Pharmaceutical Assistance Programs,
Supplemental Programs

Investigation / Enforcement:

Office of Inspector General (OIG)
Audit and Investigation, Compliance with Programs
(OIG Work Plan, response to Whistleblower cases)

Department of Justice (DOJ)
Investigation, violations of law, prosecution

States
State Attorneys General, NAMFCU, Medicaid Integrity

Impact of Commercial Activity on Government Pricing

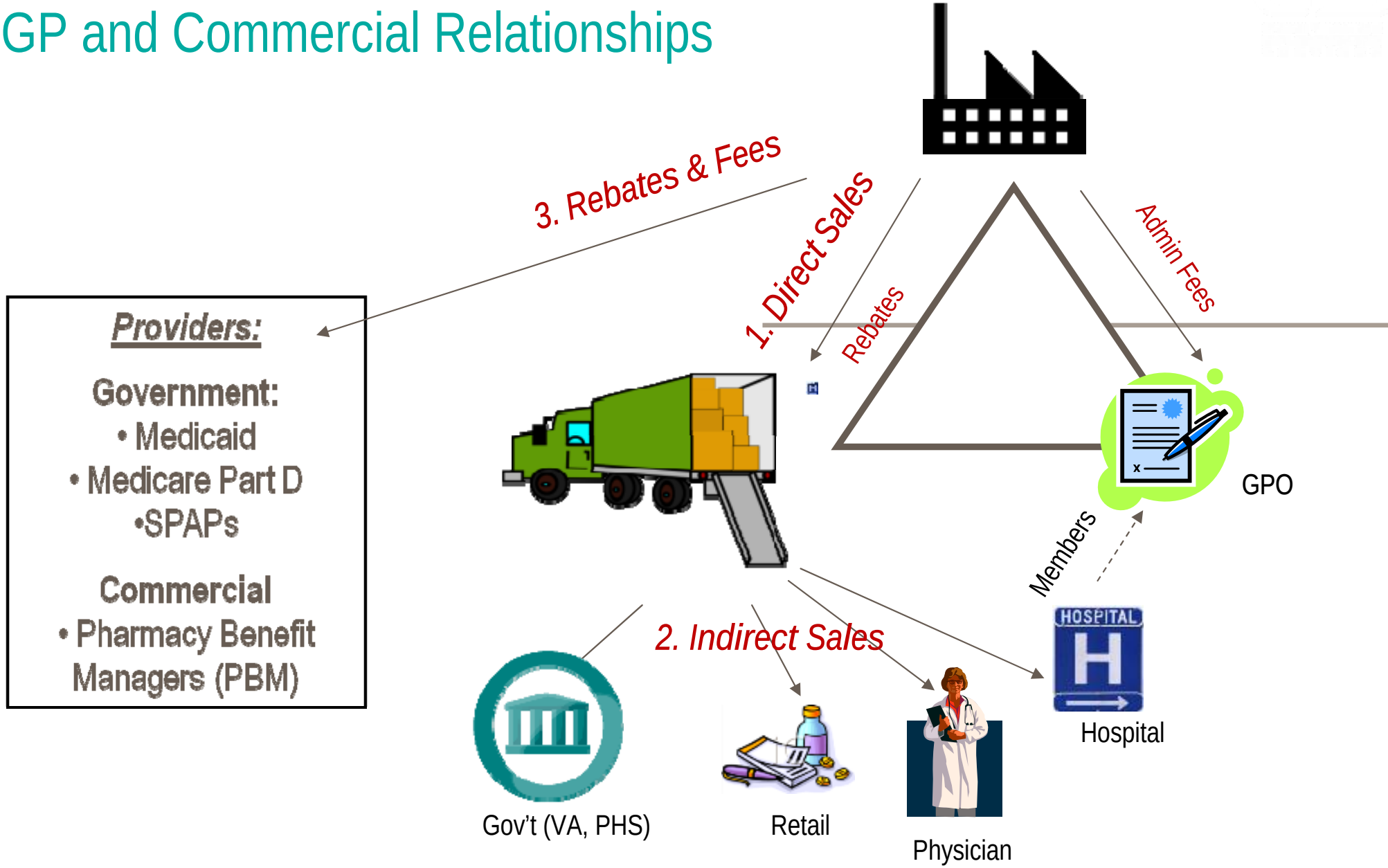
Government Pricing Calculations are based upon Commercial Activity.

The calculations are based upon net prices to certain Classes of Trade and discounts to those customers.

•Classes of Trade that are included and excluded from a specific type of calculation

•Determination of fees paid, and whether they constitute a Bona Fide Service Fee and may be excluded from a calculation (or Service Fee for VA), or treated as a discount.

GP and Commercial Relationships



Providers vs Payers/Purchasers

Providers

(reimburse after utilization, retail based)

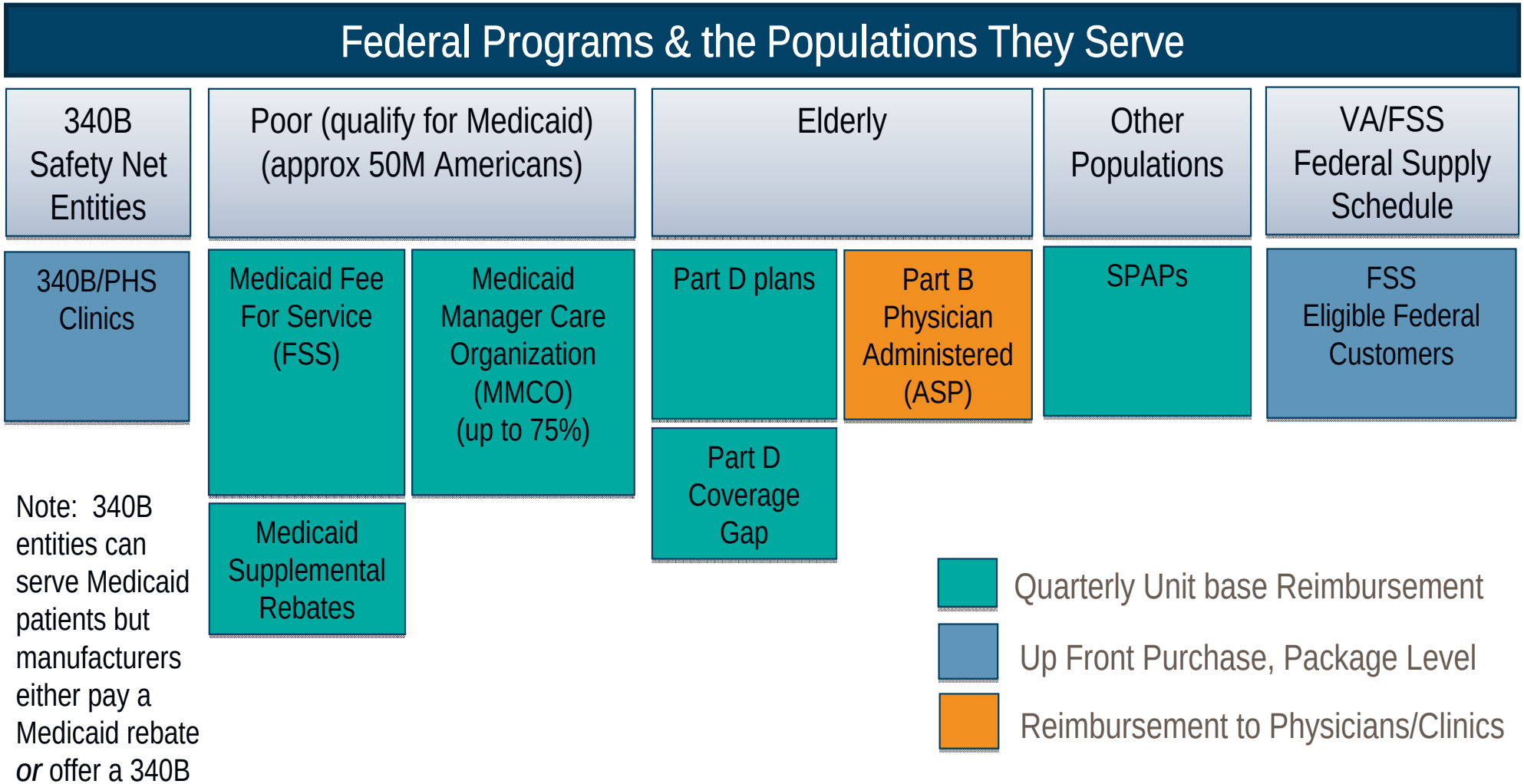
- Medicaid: Outpatient program, with states reimbursing pharmacies for units dispensed to eligible patients, a quarterly rebate paid to the state by manufacturers for Medicaid units dispensed in the quarter
- Medicare:
  - Part D – Outpatient based program, with eligible patients receiving benefits in the retail setting (co-pay, based on eligibility), with a commercially determined rebate paid to the plans for utilization
  - Medicare Part B - Reimbursement for physician administered drugs (as there is no retail prescription)
- Tricare: Outpatient benefits for military dependents and families, a manufacturer rebate paid based upon units dispensed

Payers/Purchasers

(up front discount, usually indirect)

- VA: Federal Agencies purchasing at the package level from Wholesalers (for inpatient/outpatient inventory)
- PHS/340B: Eligible entities purchasing at the package level from Wholesalers for outpatient use

General Environment For Purchasing and Reimbursement Under Government Programs



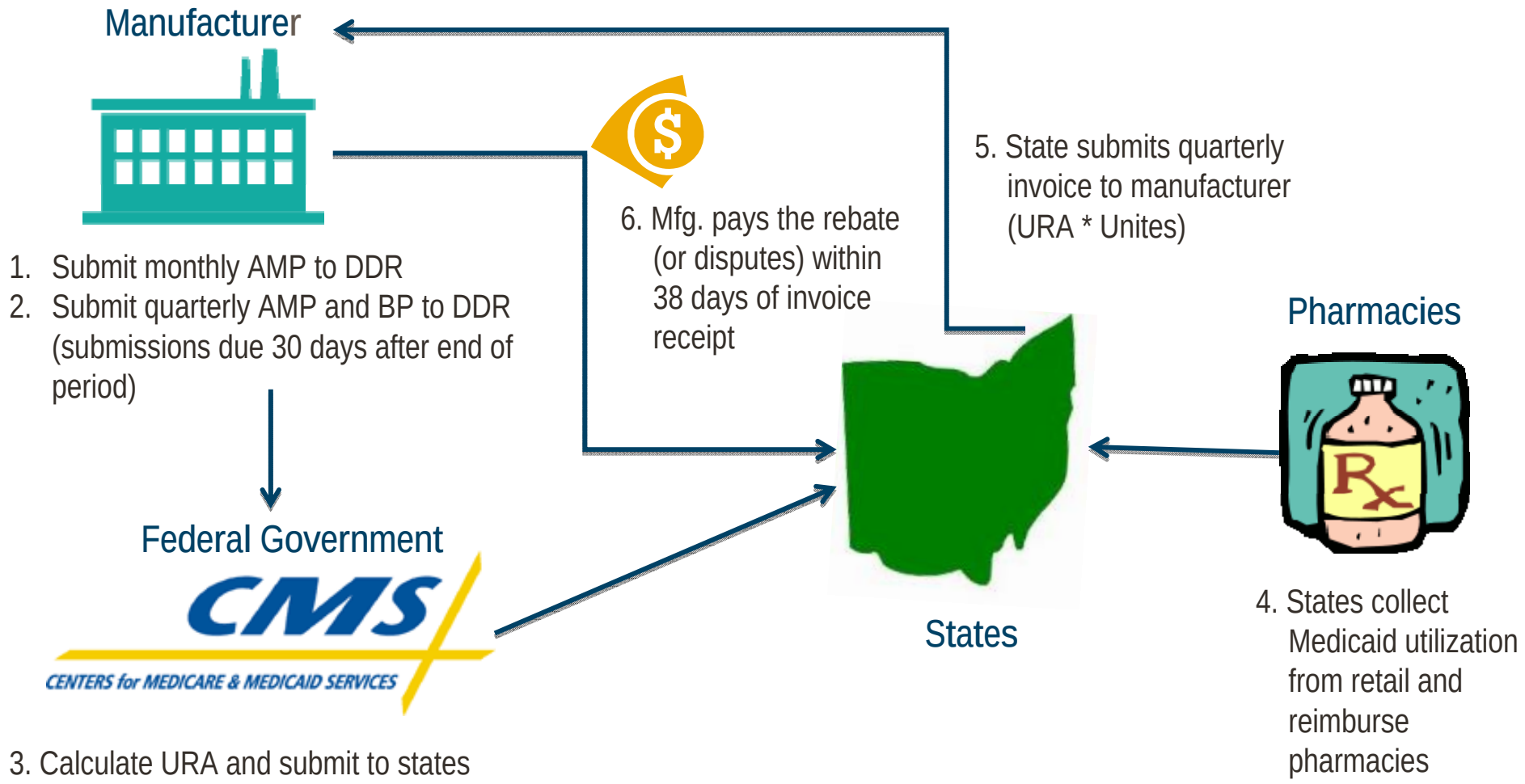
Medicaid Drug Rebate Program ("MDRP")

- The MDRP is administered by the Centers for Medicare and Medicaid Services (CMS) and is jointly funded by states and the Federal government.
- Manufactures sign the national Medicaid Drug Rebate Agreement, which along with statute and regulations, defines their responsibilities.

- Medicaid provides prescription and over-the-counter drug coverage to:
  - Low-income individuals and families
  - Individuals with disabilities
  - Individuals/families with inadequate insurance
- Over 50 million Americans are Medicaid beneficiaries

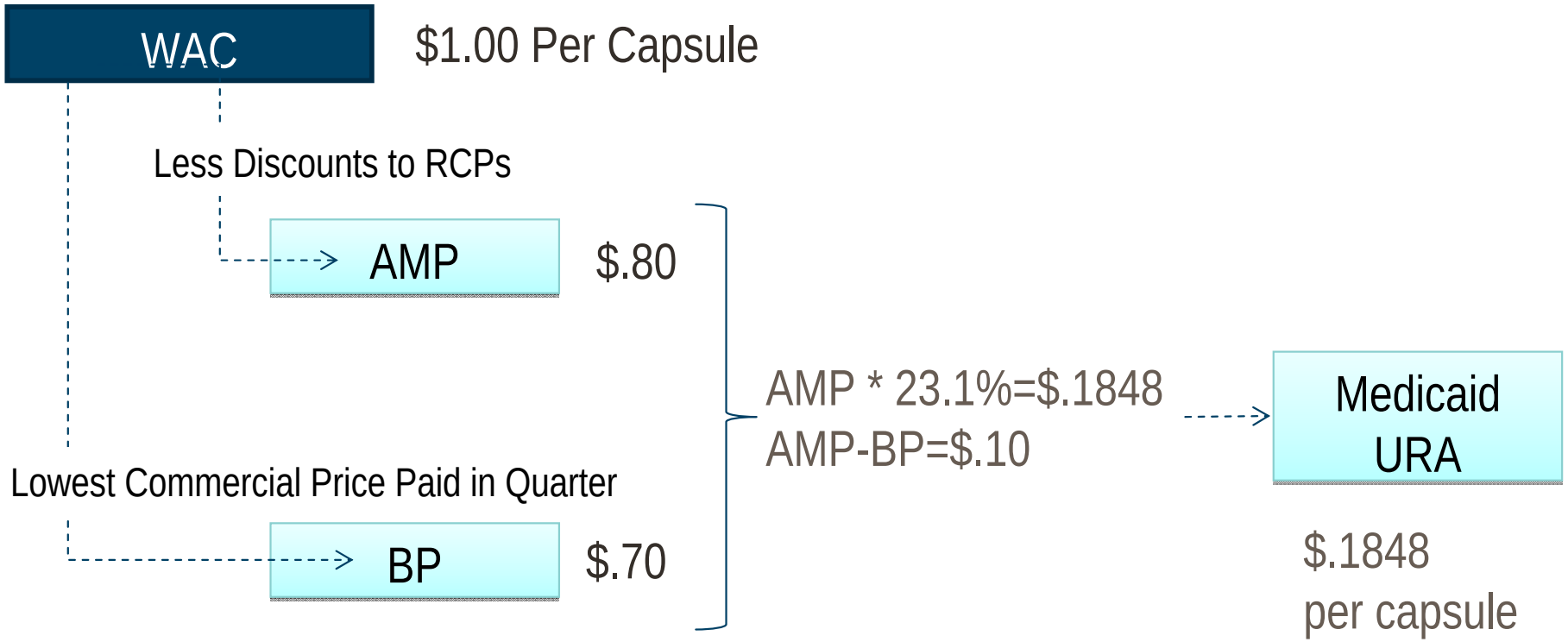
- Broad national guidelines established Federal statutes, regulations and policies. States have flexibility to design their programs and may:
  - Establish eligibility standards
  - Determine what benefits and services to cover
  - Set reimbursement rates

Medicaid Program Flow - Operations



Pricing Example – Determining the URA

Medicaid prices are calculated at the unit level



- Branded Drugs (S/I): URA = AMP * 23.1% or AMP minus BP, whichever is greater
- Generic Drugs (N): URA = AMP * 13%

Medicare

Medicare provides health insurance to certain individuals over the age of 65 and is also administered by CMS.* Medicare is split into four main parts:

- Part A – Health Insurance covers hospital stays and skilled nursing home care.
- Part B – Medical Insurance covers doctors' services, outpatient hospital care, physician administered drugs (often referred to as ASP drugs) and other medical services not covered under Part A.
- Part C – Medicare Advantage Plans offer beneficiaries the option to enroll in private health insurance plans that may cover expenses not covered under Part A and Part B. Medicare pays a capitated rate to the private insurer and the beneficiary typically pays an additional premium.
- Part D - Prescription Drug Plan intended to offset the costs of outpatient, non – physician administered prescription drugs. Medicare beneficiaries must enroll in either a stand-alone Prescription Drug Plan (PDP) or a Medicare Advantage plan with prescription coverage (MA-PD) in order to participate in Part D. Part D plans are privately designed and administered. Manufacturer rebates to PDPs/MA-PDs are commercially negotiated and are Medicaid Best Price excempt.

*Medicare is the single largest purchaser of drugs in the US, Wall Street Journal

Dual Eligibles

- Eligible for both Medicare and Medicaid
  - Medicare is primary payer
  - Medicaid is secondary payer and picks up partial, but invoices Manufacturer for full rebate
  - Nearly 10 million Americans
  - 14% of Medicaid enrollment, with approximately 36% of Medicaid spend
  - 20% of Medicare enrollment, with approximately 31% of Medicare dollars

Federal Supply Schedule Program

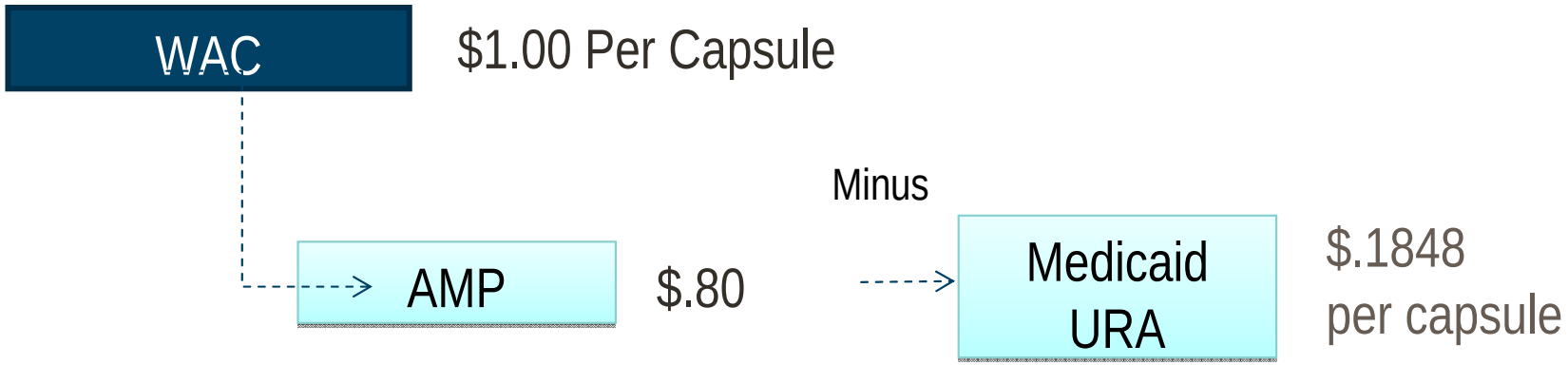
- The pharmaceutical schedule of the Federal Supply Schedule ("FSS") Program is administered by the Department of Veterans Affairs ("VA").
- The FSS is intended to provide Federal entities with a simplified means to purchase goods at negotiated prices that are based on those paid by a manufacturer's non-federal "most favored customer."
- Agencies referred to as the "Big 4," (VA, Department of Defense, Coast Guard, and PHS [including Indian Health Services]) are entitled to purchase innovator prescription drugs at a Federal Ceiling Price ("FCP") which can be lower than or equal to the FSS price, which is available to non-Big 4 Federal Purchasers. .
- Federal purchases are typically indirect purchases made through a wholesaler.
- Manufacturers *must* make their brand-name drugs (including authorized generics) available at the FSS price if they participate in the Medicaid program.
- Participation in the FSS program is optional for generic drugs.

340B Drug Discount Program

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 certain eligible entities agrees to charge a price for covered outpatient drugs that will not exceed that determined under a statutory formula (also referred to as the ceiling price).
- 340B covered entities are Disproportionate Share Hospitals, Federal Grantee Clinics, and other safety net entities.
- Manufacturers are required to communicate this price to wholesalers and distributors, but at this time government reporting of the 340B price is not required.
- The Office of Pharmacy Affairs ("OPA"), which falls under the Health Resource and Services Administration ("HRSA") an agency of the Department of Health and Human Services ("HHS"), administers the 340B Drug Pricing Program.
- Manufacturers that participate in Medicaid must participate in the 340B pricing program for both brand and generic drugs.
- To enter the program, a manufacturer signs a Pharmaceutical Pricing Agreement ("PPA") with HRSA.
- 340B purchases are typically indirect purchases made through a wholesaler.
- 340B entities may charge patients more for drugs than their discounted acquisition prices, earning a spread on each sale.

Medicaid Pricing Components then Determine the 340BPrice, for Eligible 340B entities



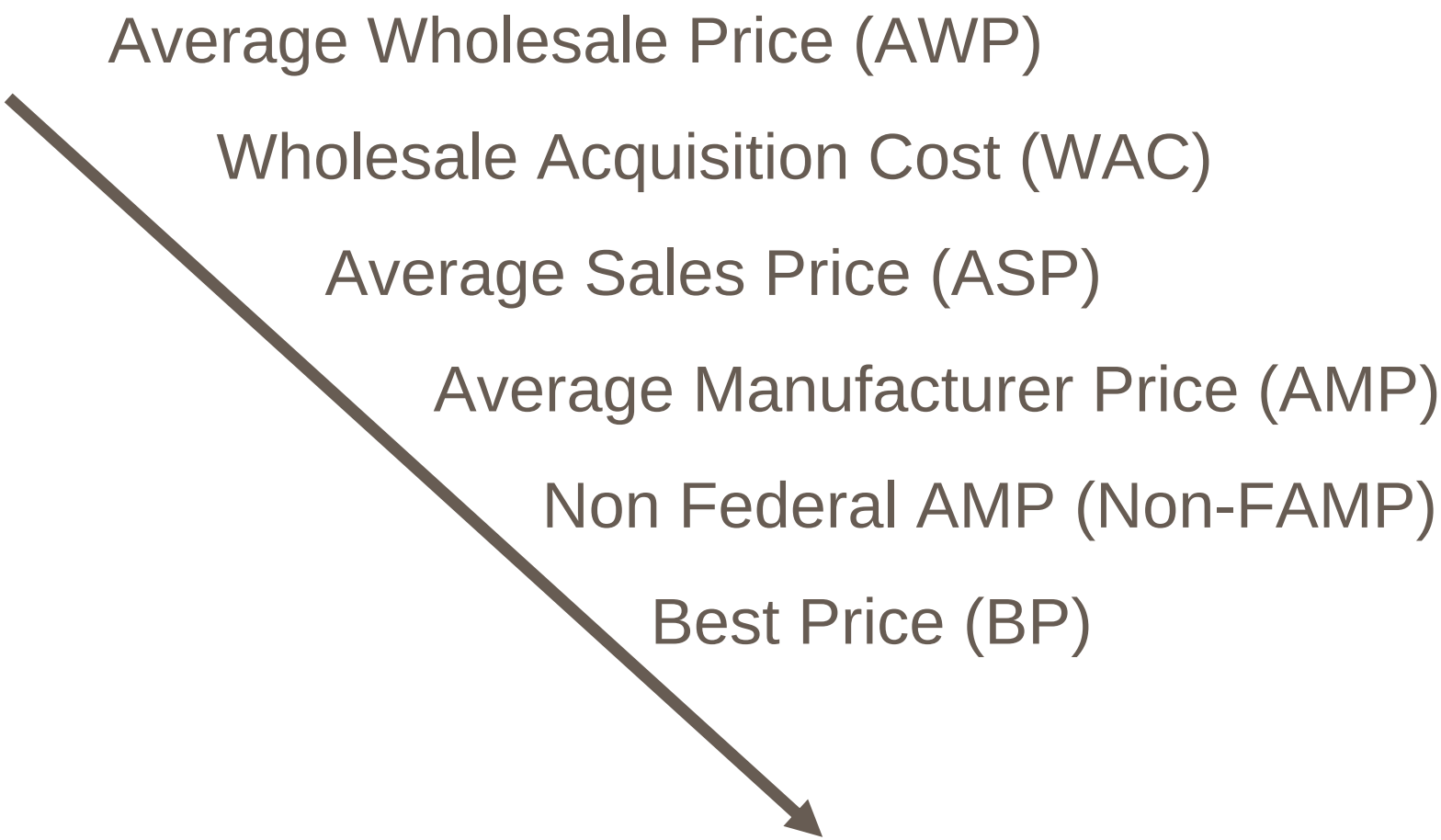
$.80
- $.1848
$.6152 per capsule
(38% Discount off of WAC)

- 340B Price = AMP minus the URA, times Units Per Package

Program	Population	Details
Medicaid (and MMCO coverage)	• State administered program providing outpatient based drug benefits to the poor (all ages) • Serves over 50 million Americans.	• Manufacturers pay quarterly rebates to the states, the rebates are based upon the URA, calculated off of the reported AMP and BP
Medicare D	• Outpatient based prescription drug benefit for the elderly • Serves 47 million, growing to 80 million by 2030	• Manufacturers participate in plans, providing rebates based upon utilization • Manufacturers also pay 50% during the coverage gap
Medicare B (ASP)	• Reimbursement to physicians for drugs administered to Medicare patients in physician's office	• Reimbursement to physicians typically equal to 106% of volume weighted ASPs within the payment code
340B Drug Discount Program	• Provides covered outpatient drugs at reduced pricing to eligible 340B covered entities	• Eligible entities purchase from wholesalers at the 340B price (Manufacturer receives a chargeback)
VA/FSS	• Mechanism for the Federal government to purchase drugs	• Eligible entities purchase from wholesalers at the FSS or FCP price (Manufacturer receives a chargeback)
TRICARE Retail Pharmacy Program (TRRx)	• A program which provides outpatient pharmacy services to TRICARE beneficiaries	• Drugs dispensed by the TRRx are subject FCP limitations • Manufacturers pay quarterly TRICARE rebates

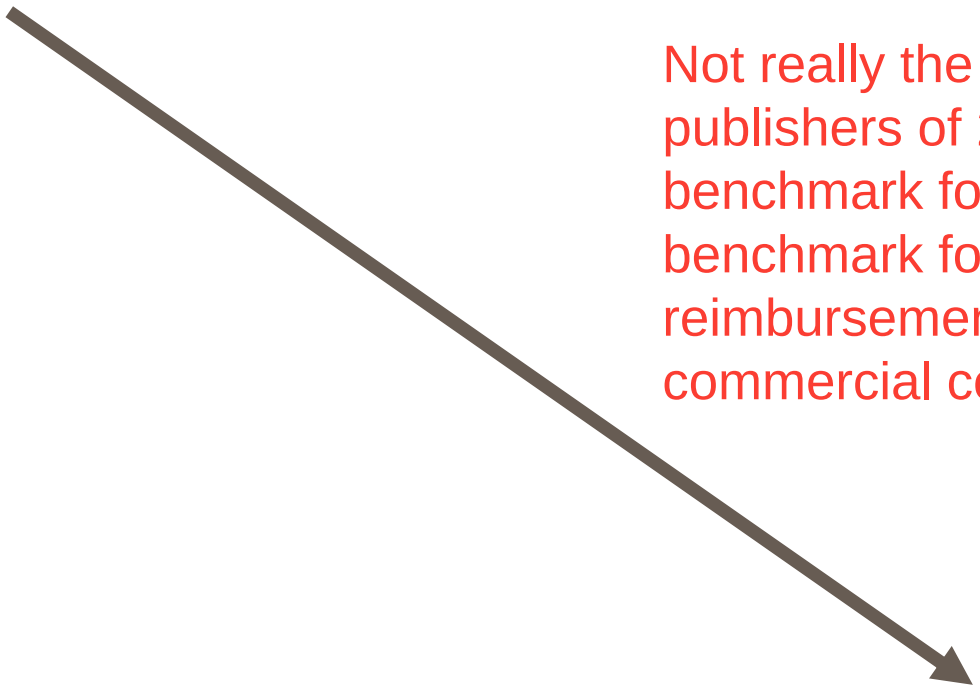
The Many Prices of a Drug

The Many Prices of a Drug



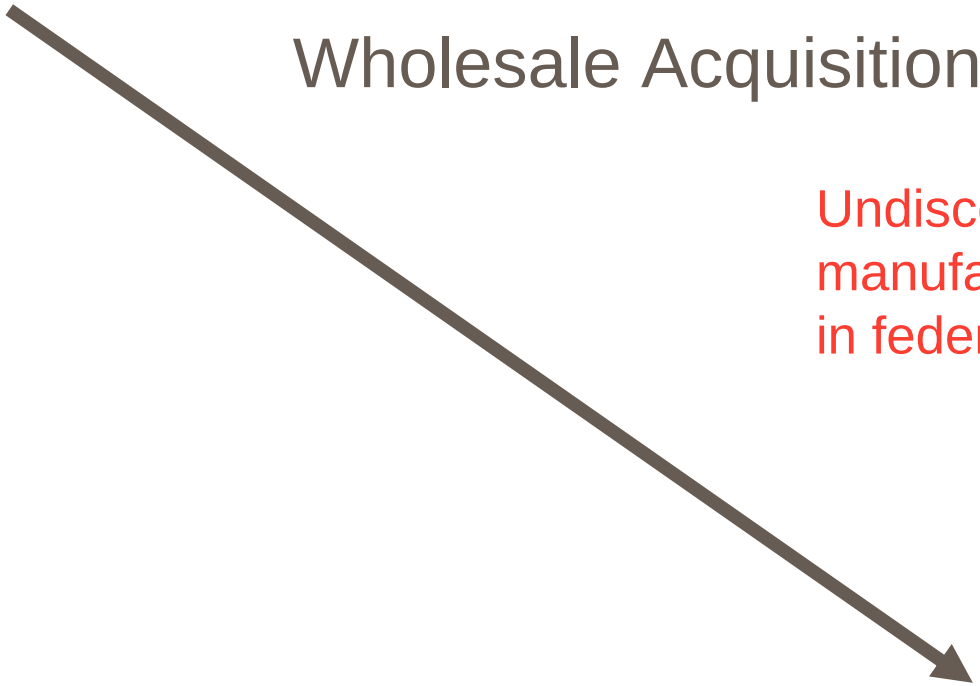
The Many Prices of a Drug

Average Wholesale Price (AWP)



Not really the average of anything; a markup by publishers of 20% over list price; former benchmark for Medicare reimbursement; current benchmark for some states' Medicaid reimbursement (single source drugs) and commercial contracting

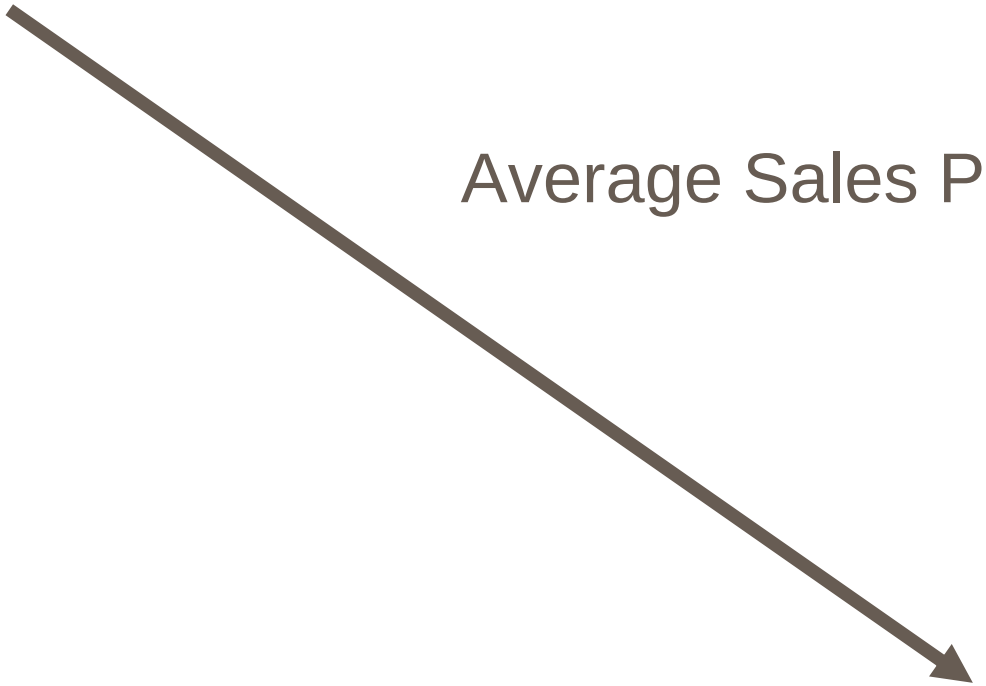
The Many Prices of a Drug



Wholesale Acquisition Cost (WAC)

Undiscounted list price set by the manufacturer; basis of AWP; defined in federal law in 2003

The Many Prices of a Drug

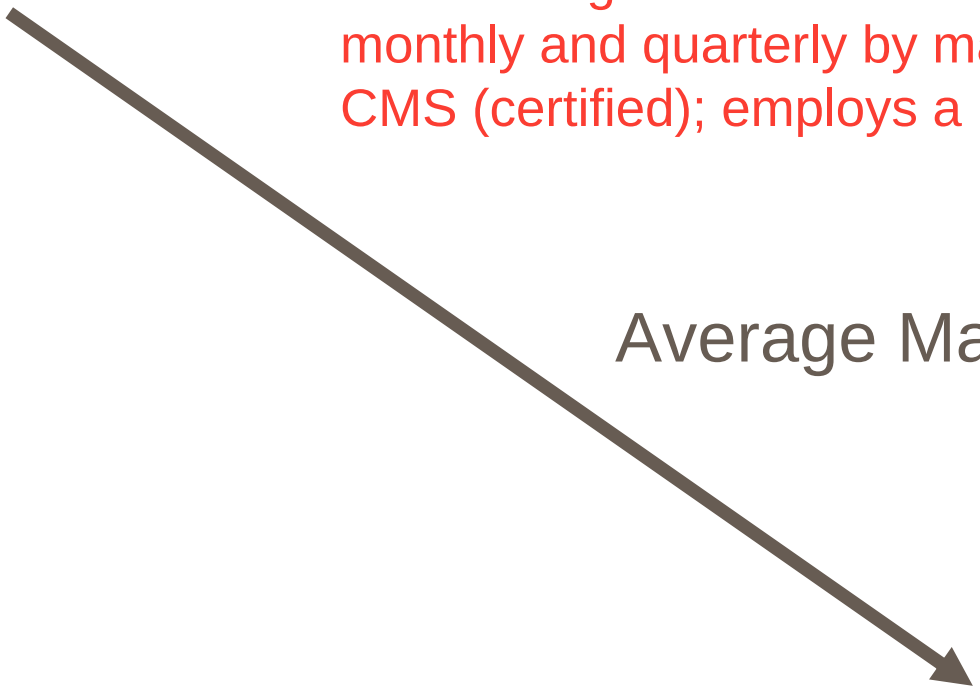


Average Sales Price (ASP)

Basis for Medicare physician administered outpatient drug reimbursement; calculated quarterly by the manufacturer and submitted to CMS (certified); employs 12-month rolling average

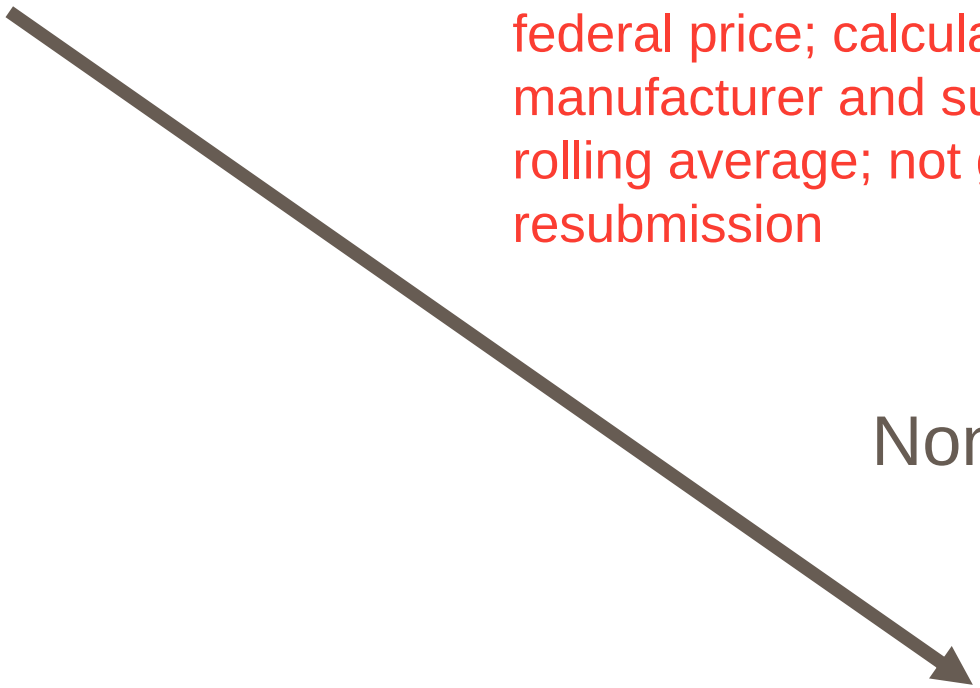
The Many Prices of a Drug

Basis for the Medicaid rebate and the 340B price; two methodologies for calculation (standard and 5i); calculated monthly and quarterly by manufacturer and submitted to CMS (certified); employs a 12-month rolling average



Average Manufacturer Price (AMP)

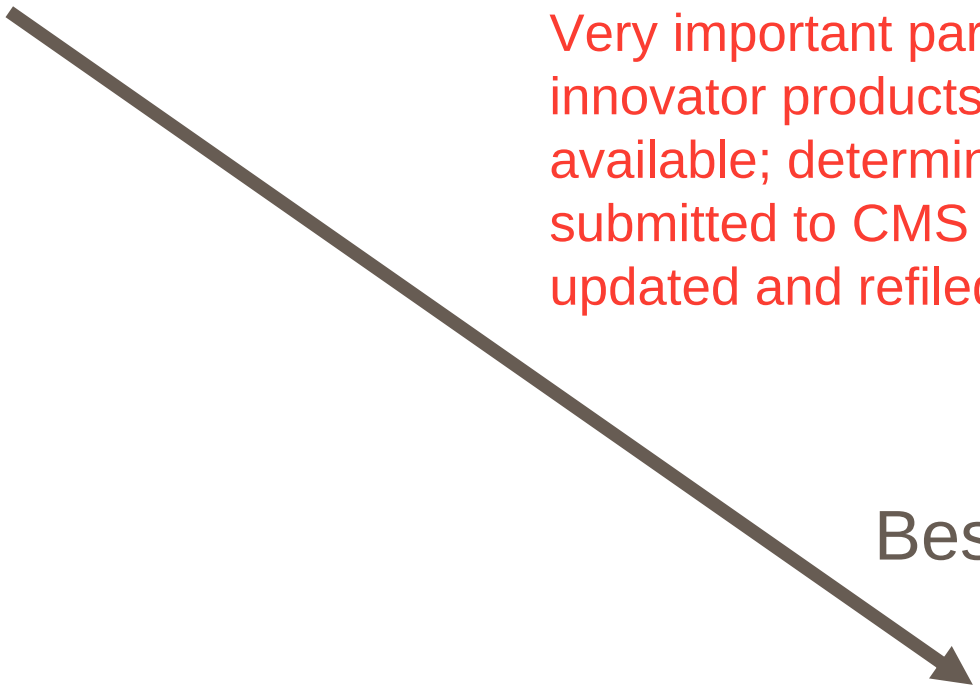
The Many Prices of a Drug



Potentially the basis of the FSS price; average non-federal price; calculated quarterly and annually by the manufacturer and submitted to the VA (not certified); no rolling average; not generally subject to updating or resubmission

Non Federal AMP (Non-FAMP)

The Many Prices of a Drug



Very important part of the Medicaid rebate calculation for innovator products; the single best price commercially available; determined quarterly by the manufacturer and submitted to CMS (certified); not an average; must be updated and refiled over time

Best Price (BP)

The Many Prices of a Drug

- What makes the prices different from one another?
  - How they are used
    - Set price (Non-FAMP)
    - Set rebate (AMP and BP)
    - Set reimbursement (ASP)
  - How they are calculated
    - Classification & Filtering
    - Mechanisms for addressing temporal disconnect
      - Refiling (BP)
      - Rolling average methodology (AMP and ASP)
  - How they can be restated
    - As needed within 3 years (AMP and BP)
    - No mechanism for restatement (ASP and Non-FAMP)

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Strategies and Risk Mitigation.
It's in our DNA.