



PHARMACEUTICAL COMPLIANCE  
FORUM'S SEVENTEENTH  
PHARMACEUTICAL AND MEDICAL  
DEVICE REGULATORY  
COMPLIANCE CONGRESS

GOVERNMENT PAYOR SYSTEMS  
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KING & SPALDING



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# The Government Programs and The

## THE GOVERNMENT PROGRAMS AND THE POPULATIONS THEY SERVE

*Note: Please go to the Huron Booth for a reprint of the 3 Part LSC Series, Through the Wormhole, Understanding the Parallel Universe of Publically Funded Health Programs*



### 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
- Each program is administered based upon the program and the population it serves.

Medicaid

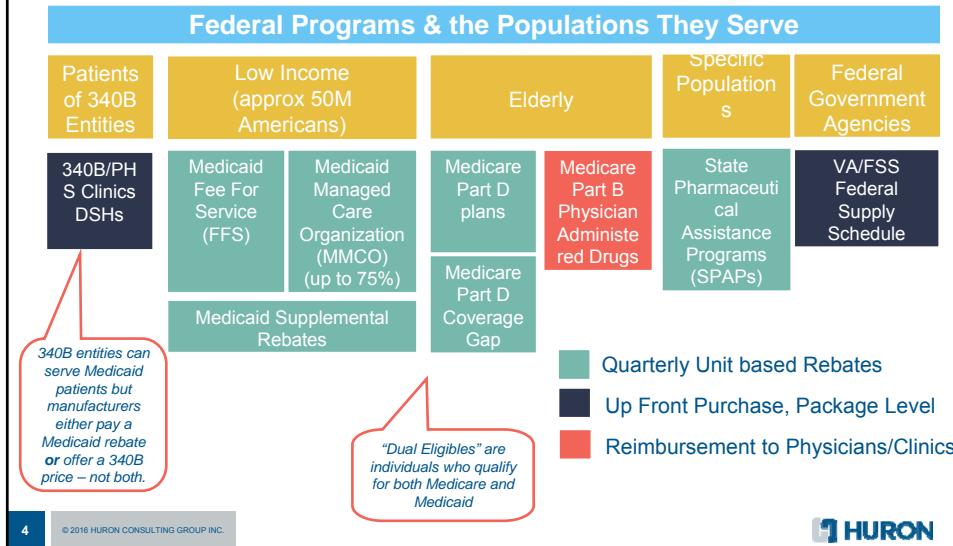
Medicare

VA/FSS

PHS/340B



# General Environment for Purchasing and Reimbursement Under Government Programs



## PROVIDERS VS. PAYERS/PURCHASERS

### Providers

(Unit Based, 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 to physicians and/or clinics 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

(Package Based, up front discount, usually indirect)

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

# GOVERNMENT PROGRAM COMPLIANCE

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

<b>As a result of increasing drug spend, federal and state governments are focusing more on manufacturer compliance</b>	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
<b>The Office of Inspector General (OIG) oversees the federal programs with the mandate to "protect the integrity of the programs"</b>	OIG/DOJ can penalize or pursue FCA remedies if data (statutory pricing calculations) reported to the government causes the government to pay more than they should for a manufacturer's 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 manufacturers must make reasonable assumptions

## Importance of GP and Commercial Compliance

**GP compliance in pharmaceutical manufacturing falls under the broader category of U.S. Commercial Compliance and is under the Office of the Inspector General's (OIG) scope and mandate.**

Government Programs and the integrity of Government Pricing are key risk areas.

- "Recommendations for Pharmaceutical Manufacturers"
  - Published guidelines for Commercial Compliance (OIG, 2003)
  - Outlines key risk areas in Commercial Aspects of Pharmaceutical sales

Agencies have their own rule making processes and various administrative agencies publish regulations and guidance that are applicable to specific Federal programs. Non-compliance with a federal program may result in: monetary fines, personal liability, and exclusion from future participation in government programs.

Manufacturers may also be subject to prosecution under:

Federal Anti-Kickback Statute

State and Federal False Claims Acts

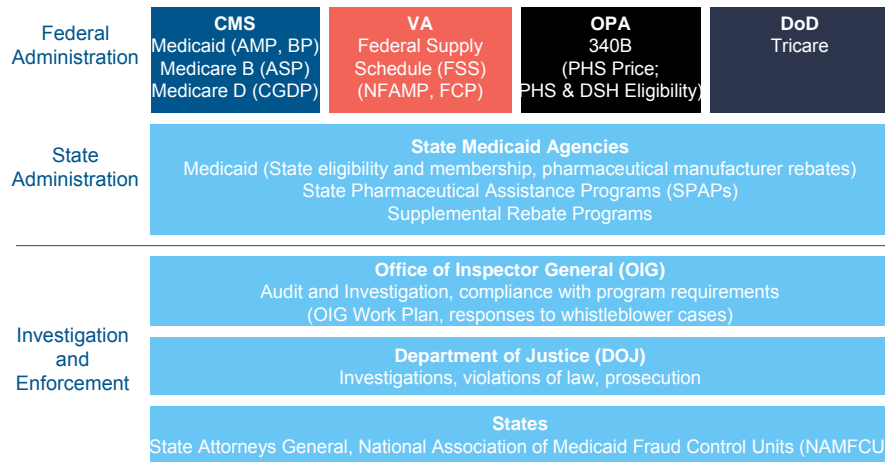
Other state and federal laws related to the MDRP

\*The Office of the Inspector General. "OIG Compliance Program Guidance for Pharmaceutical Manufacturers." *Federal Register* Vol. 68, No. 86. May 5, 2003

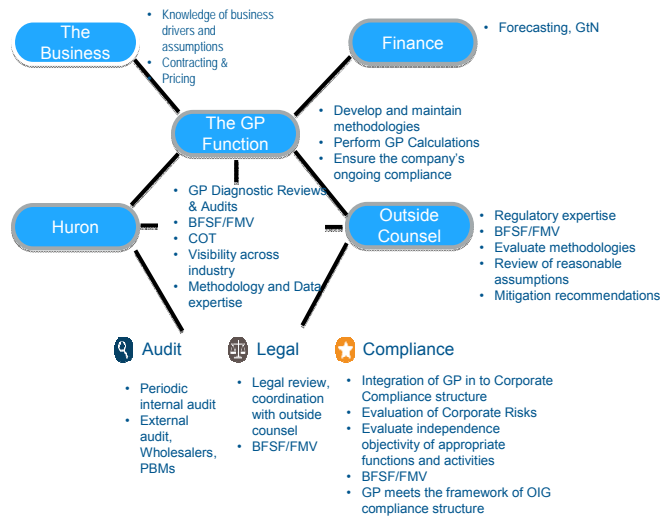
## Additional Compliance Requirements (cont'd)

- **C-suite (CEO/CFO) level certification.** Medicaid and Medicare require certification of the accuracy of AMP/BP and ASP submissions by CEO/CFO or delegated individual.
- **The Ten Year Rule.** Manufacturers must save all data and documents related to Medicaid for at least ten years.
- **\$10,000 daily penalties per NDC 11 for failure to report AMP & BP.**
  - Five days late = \$50,000 penalty per NDC
  - Thirty days late = \$300,000 penalty per NDC
- **\$100,000 CMP for false information knowingly provided to CMS.**
- **Civil and criminal charges.** May be filed against a company and senior management, especially if an intent to defraud the government or gross negligence is proven.

# Agencies and Program Oversight



# GP RELATED FUNCTIONS



# GOVERNMENT PRICING

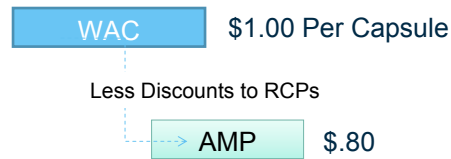
## Impact of Commercial Activity on Government Pricing

Government Pricing Calculations are functions of commercial prices & price concessions.

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

- Classes of Trade that are included and excluded from a specific type of calculation (e.g. AMP, ASP)
- 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.

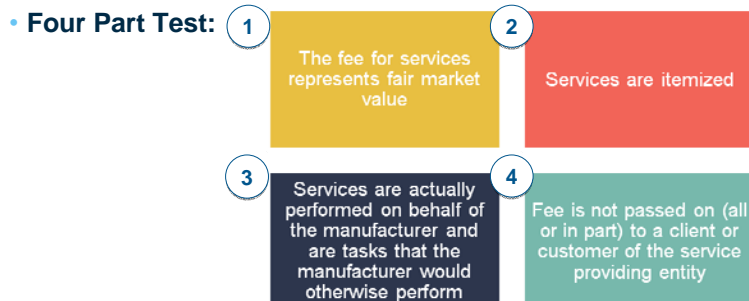
## Pricing Example – Calculating the RCP AMP



- RCP – Retail Community Pharmacy, “..an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices.” 42 C.F.R. § 447.504

## Bona Fide Service Fees

- **Bona Fide Service Fees**
  - To be excluded from CMS GP calculations, a payment must be determined to be a Bona Fide Service Fee
  - CMS requires documentation of a manufacturer’s rationale and treatment of fees



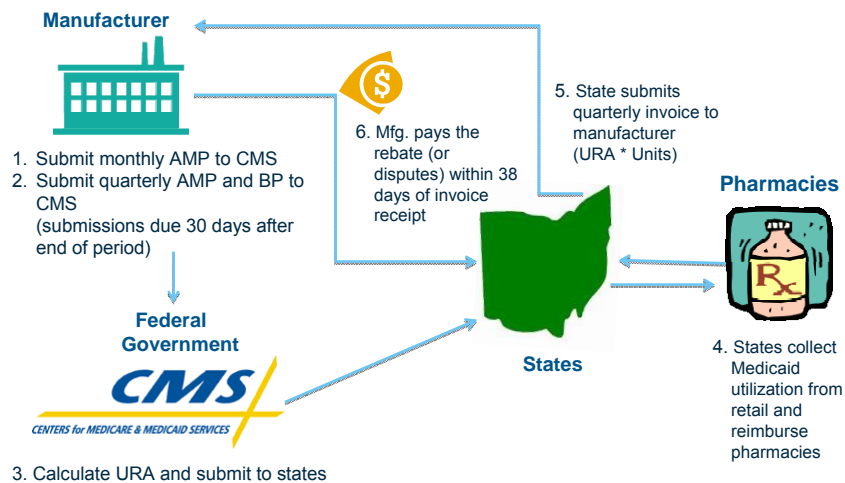


## Medicaid Drug Rebate Program (“MDRP”)

- The MDRP is administered by the Centers for Medicare and Medicaid Services (CMS) and is jointly funded by states and the Federal government.
- Manufacturers sign the national Medicaid Drug Rebate Agreement, which along with statute and regulations, defines their responsibilities.
- Voluntary program
- All or nothing participation - If a manufacturer participates in Medicaid, it must also participate in 340B and FSS.
- Manufacturers pay rebates to the states for Quarterly Medicaid Utilization
  - Manufacturers calculate and report Average Manufacturer Price (AMP) and Best Price (BP), used to calculate the Unit Rebate Amount (URA) on the Quarterly State invoice

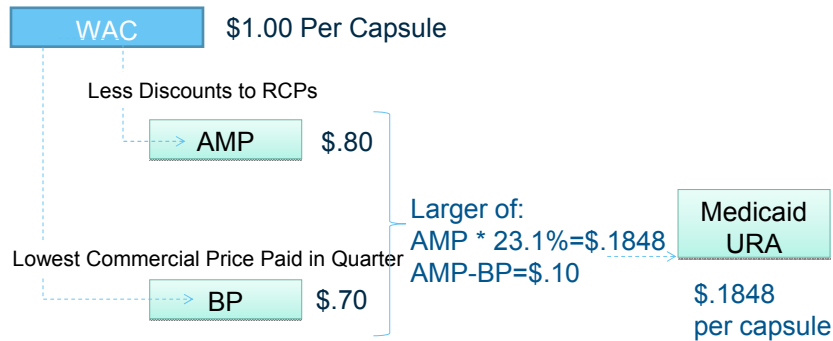


## Medicaid Program Flow - Operations



## 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%
- Separate URA formula for “line extensions”

## 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. Patient pays 20 percent coinsurance for outpatient drugs.
- **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 underwritten by Medicare dollars but are privately designed and administered with respect to drug manufactures. Manufacturer rebates to PDPs/MA-PDs are commercially negotiated and are Medicaid Best Price exempt.

\*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



## VA/Federal Supply Schedule (FSS)

### Discounted pricing for eligible Federal entities

- Purchase based program
- Products are purchased through the FSS
  - Functions like a price list
- Branded Products: Manufacturers **must** participate to participate in Medicaid
- Starts with a contract negotiation
  - "Solicitation" to set the price by product
- Quarterly and annual reporting
  - NFAMP and FCP
  - Used to determine annual price adjustments



## FSS Price Changes

- FSS Price Changes, two mechanisms
  - Annual price change – effective January 1st
    - Annual Non-FAMP and FCP (76% of Annual Non-FAMP)
    - Inflation
  - Changes to the Tracking Customer
    - A customer negotiated during the contracting process
    - A ratio is determined between the FSS price and the TC price
    - If the TC price goes down, the manufacturer has 2 weeks to change the Government Price (based on the ratio)
      - Price reductions to customers other than the TC do not trigger the obligation to lower an already-negotiated FSS price

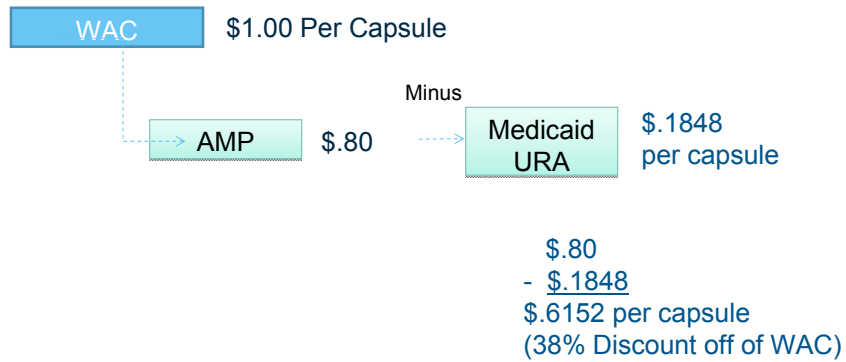
## 340B Drug Discount Program



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 “covered 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, PHS Funded Clinics, 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 Resources 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 340B Price, for Eligible 340B entities

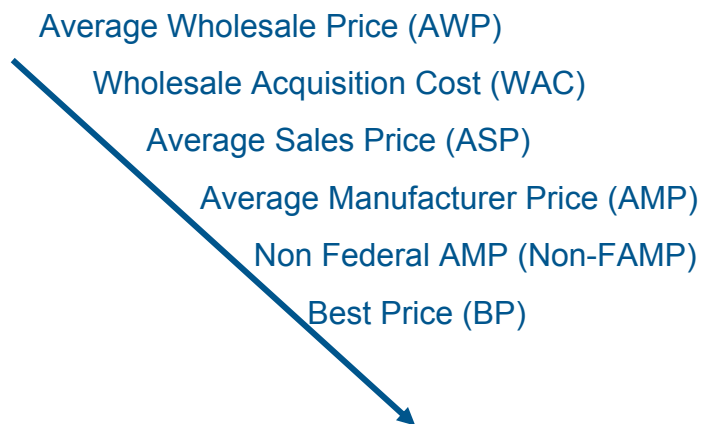


- 340B Price = AMP minus the URA, times Units Per Package
- When AMP = URA, the 340B price is 1¢ per unit.

Program	Population	Details
Medicaid (and MMCO coverage)	<ul style="list-style-type: none"> <li>• State administered program providing <u>outpatient</u> based drug benefits to the poor (all ages)</li> <li>• Serves over 50 million Americans.</li> </ul>	<ul style="list-style-type: none"> <li>• Manufacturers pay quarterly rebates to the states, the rebates are based upon the URA, calculated off of the reported AMP and BP</li> </ul>
Medicare D	<ul style="list-style-type: none"> <li>• <u>Outpatient</u> based prescription drug benefit for the elderly</li> <li>• Serves 47 million, growing to 80 million by 2030</li> </ul>	<ul style="list-style-type: none"> <li>• Manufacturers participate in plans, providing rebates based upon utilization</li> <li>• Manufacturers also pay 50% during the coverage gap</li> </ul>
Medicare B (ASP)	<ul style="list-style-type: none"> <li>• Reimbursement to physicians for drugs administered to Medicare patients in physician's office</li> </ul>	<ul style="list-style-type: none"> <li>• Reimbursement to physicians typically equal to 106% of volume weighted ASPs within the payment code</li> </ul>
340B Drug Discount Program	<ul style="list-style-type: none"> <li>• Provides covered <u>outpatient</u> drugs at reduced pricing to eligible 340B covered entities</li> </ul>	<ul style="list-style-type: none"> <li>• Eligible entities purchase from wholesalers at the 340B price (Manufacturer receives a chargeback)</li> </ul>
VA/FSS	<ul style="list-style-type: none"> <li>• Mechanism for the Federal government to purchase drugs</li> </ul>	<ul style="list-style-type: none"> <li>• Eligible entities purchase from wholesalers at the FSS or FCP price (Manufacturer receives a chargeback)</li> </ul>
TRICARE Retail Pharmacy Program (TRRx)	<ul style="list-style-type: none"> <li>• A program which provides outpatient pharmacy services to TRICARE beneficiaries</li> </ul>	<ul style="list-style-type: none"> <li>• Drugs dispensed by the TRRx are subject FCP limitations</li> <li>• Manufacturers pay quarterly TRICARE rebates</li> </ul>

# THE MANY PRICES OF A DRUG

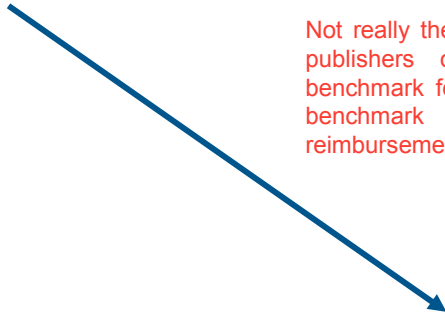
## THE MANY PRICES OF A DRUG



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### 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 and commercial contracting

## THE MANY PRICES OF A DRUG

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### 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

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### 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

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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

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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

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Very important part of the Medicaid rebate calculation for innovator products; the single lowest price commercially realized; 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)

