

**Steve Sisolak**  
*Governor*



**Richard Whitley**  
*Director*

# State of Nevada Department of Health and Human Services

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## Overview of Prescription Drug Pricing, Rebates, and Remuneration in Nevada

Beth Slamowitz, PharmD  
DHHS Senior Advisor on Pharmacy



# Agenda

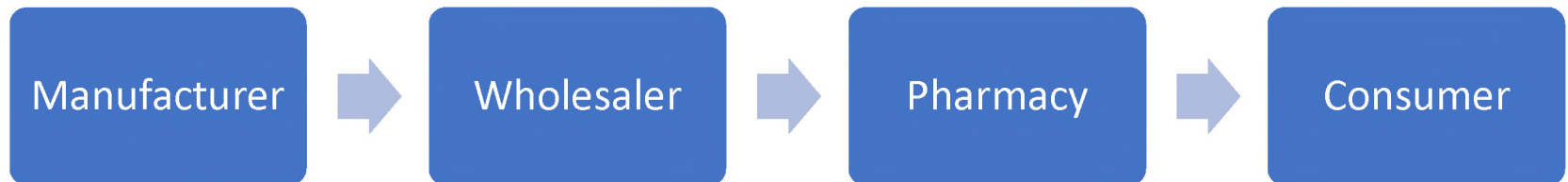
1. Prescription Drug Costs and Pricing: Definitions, terms and applicability
2. Overview of the supply chain: From Manufacturer to the Consumer
3. Rebate 101: Medicaid and Rebates
4. Medicaid vs. Commercial Drug Pricing

# Influence of Supply and Supply Chain Markup

- The abundance of pharmaceutical manufacturers makes it difficult for pharmacies to purchase drug products directly from the factory where the drug is produced.
- The supply of pharmaceuticals involves a chain of wholesalers that help distribute drugs to pharmacies before they reach the consumer.
- The business model for wholesalers relies on the ability to purchase large orders of drug products from manufacturers and sell them to pharmacies at a higher price.

# Influence of Supply and Supply Chain Markup

- Three transaction areas in the supply chain:
  - Manufacturer to wholesaler
  - Wholesaler to pharmacy
  - Pharmacy to consumer

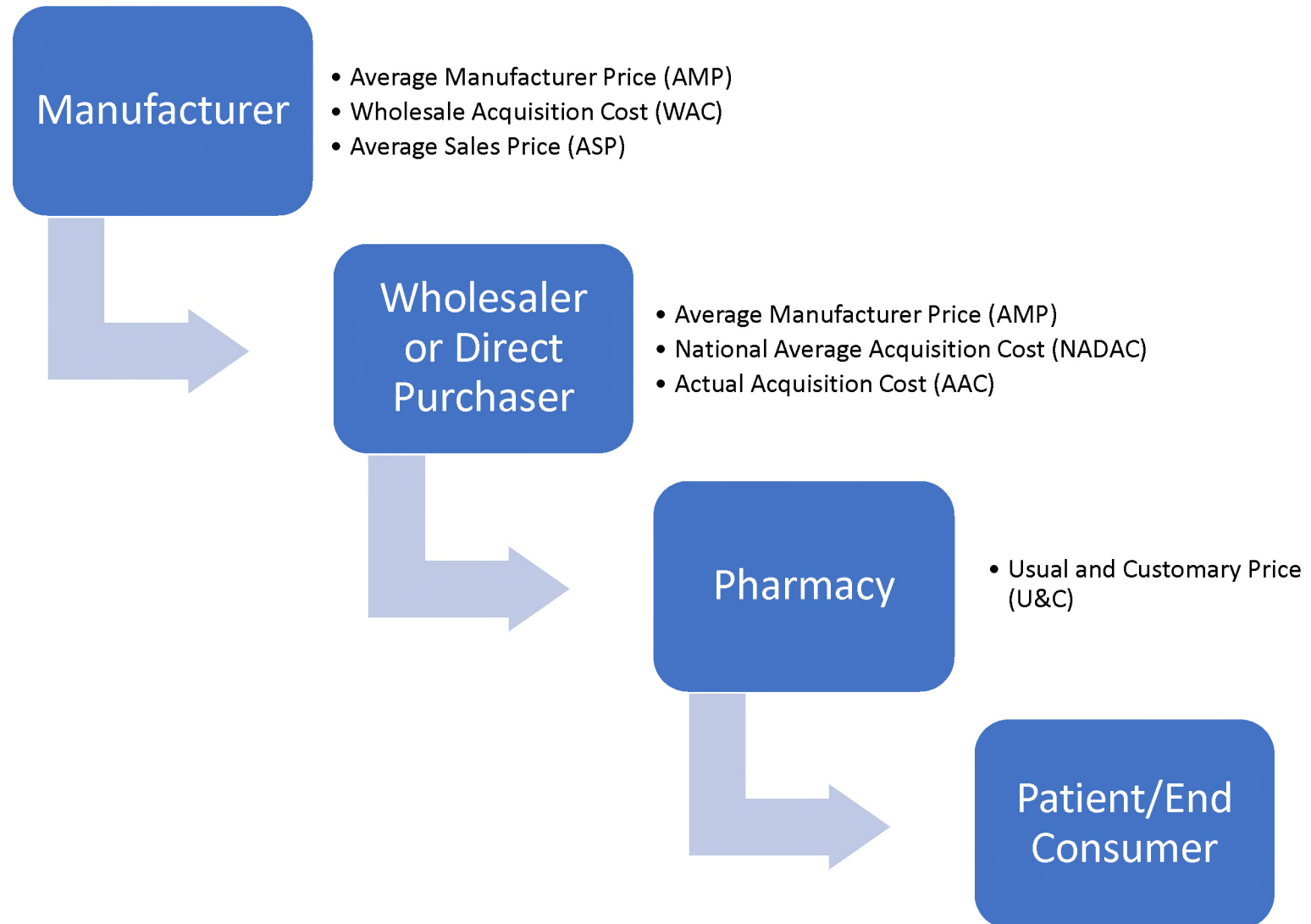




# Common Terms and Acronyms Used in Drug Pricing

Term	Definition
Federal upper limit (FUL)	A price ceiling used by CMS to control price for certain medications paid to pharmacies
Maximum allowable cost (MAC)	A price ceiling, similar to the FUL, established at the state level
Usual and Customary (U&C)	The average cash price paid at a retail pharmacy.
Average wholesale price (AWP)	An estimate of the price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by companies such as Medi-Span and First DataBank
Wholesale acquisition cost (WAC)	An estimate of the manufacturer's list price for a drug to wholesalers other direct purchasers, not including discounts or rebates. This price is defined by federal law.
Average manufacturer price (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. This price is defined by federal law.
Average sales price (ASP)	A calculation of the weighted average of manufacturer's sales price for a drug for all purchasers, net of price adjustments. This price is defined by federal law.
National Average Drug Acquisition Cost (NADAC)	Designed to create a benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs.
Actual Acquisition Cost (AAC)	An retail pharmacy acquisition costs for drugs through a review of actual pharmacy invoices.
Dispensing fee	The amount reimbursed to the pharmacy to cover the charge for professional services and overhead costs.
National Drug Code (NDC)	An 11-digit code used by Medicaid to identify a drug based on its manufacturer, strength, and package size.

# Supply Chain Transactions and Drug Pricing



# Transaction 1 – Manufacturer to Wholesaler

- The Average Manufacturer Price (AMP) was originally mandated as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), and the actual definition continues to evolve.
- The AMP is meant to calculate the cost of a drug directly from a manufacturer **after** any rebate or discount is included.
- The Wholesale Acquisition Cost (WAC), is the average price at which a manufacturer sells a drug product to wholesalers or direct purchasers, but **does not** include discounts or rebates.
- The Average Sales Price (ASP) is only available for Medicare Part B covered drugs. ASP is derived from the sales from manufacturers to all purchasers and includes practically all discounts.

# Transaction 2 – Wholesaler to the Pharmacy

- The Average Wholesale Price (AWP) is the price at which wholesalers sell drugs to pharmacies. The most common source for AWP data for drug pricing comes from the compendia produced by Medi-Span and First DataBank.
- The National Average Drug Acquisition Cost (NADAC) is the average price paid by pharmacies. It is a version of AWP created by CMS to provide more accurate pharmacy acquisition cost information for purposes of payer reimbursement.
- The Actual Acquisition Cost (AAC) is the final cost paid after all discounts have been deducted, or net cost of a drug paid by a pharmacy to its wholesaler.

# Transaction 3 – Pharmacy to Consumer

- Usual and Customary (U&C) prices reflect the costs of the drugs to the consumer at the retail level without the use of insurance. The U&C rate is often referred to as the “cash price” for patients.

# Third-Party System

# Third-Party System

- In the prescription drug market, most patients are enrolled with a third-party plan (government and/or commercial insurance company) that utilizes a Pharmacy Benefits Manager (PBM) to help manage the process.
- The patient pays the third party in the form of premiums along with a contribution from the government or the patient's employer as part of the total compensation to the PBM.
- At the point of sale when patients pick up their prescription from the pharmacy, they usually pay a smaller portion of the transaction and the PBM reimburses the pharmacy for the balance.

# Multiple Roles in the Pharma Supply Chain

Corporations are assuming multiple roles in the pharma supply chain

	 <b>CVS Health.</b>	 <b>UnitedHealthcare</b>	 <b>Cigna.</b>	 <b>Anthem.</b>	 <b>Walmart</b>	 <b>McKesson</b>	 <b>Walgreens Boots Alliance</b>	 <b>Cardinal Health</b>
 Payer	 <b>aetna</b> (Pending)	 <b>UnitedHealthcare</b>	 <b>Cigna.</b>	 <b>Anthem.</b>	 <b>Humana.</b> (Rumored)	×	×	×
 Wholesaler	×	×	×	×	×	 <b>McKesson</b>	 <b>AmersourceBergen</b> (Minority investment)	 <b>Cardinal Health</b>
 PBM	 <b>CVS caremark</b>	 <b>OPTUM</b>	 <b>EXPRESS SCRIPTS</b> (Pending)	 <b>ingenio</b> (Planned)	 <b>Humana Pharmacy Solutions.</b> (Rumored)	 <b>RelayHealth</b>	×	×
 Pharmacy	 <b>CVS pharmacy</b>	×	 <b>medco</b> (Pending)	×	 <b>Walmart</b>	×	 <b>Walgreens</b>	 <b>Cardinal Health</b>
 Specialty Pharmacy	 <b>CVS specialty</b>	 <b>brioja</b>	 <b>accredo</b> Specialty Pharmacy (Pending)	×	×	×	 <b>allianceRx</b> Walgreens + PRIME	×



# Reimbursement Formulation and Contract Pricing

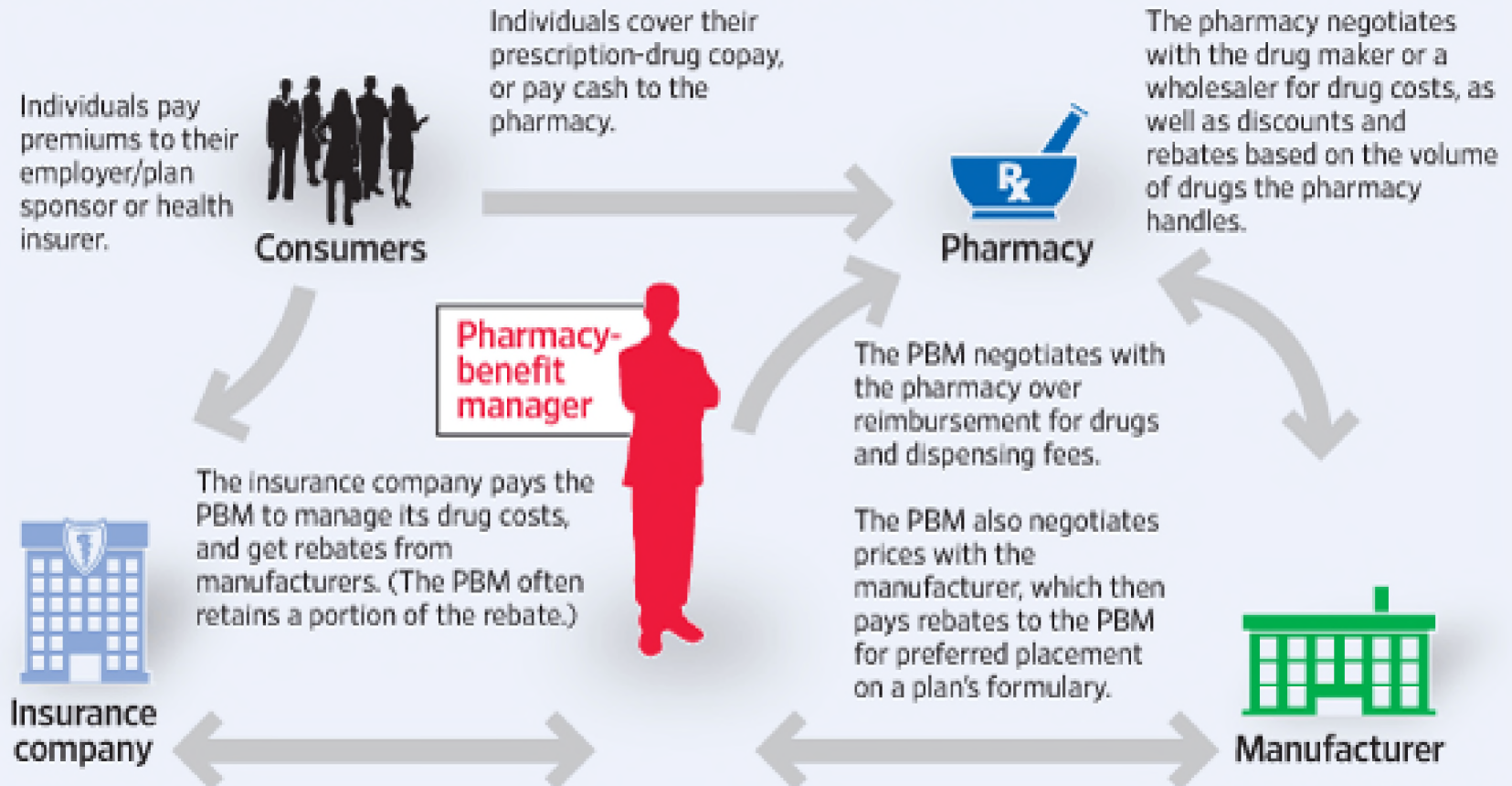
- Pharmacies pricing of medications for insured patients is determined by contracts with each PBM and the government.
- In an effort to control spending on prescription drugs in the Medicaid system, the federal government sets a price ceiling for certain drugs called the Federal Upper Limit (FUL).
- Individual states and PBMs then take this cost containment a step further by establishing a Maximum Allowable Cost (MAC) for drug products.
- If costs for a pharmacy to dispense a medication are higher than the contracted price agreements, the pharmacy will operate at a loss in order to service the patient, or the pharmacy may withdraw from participation in the network.

# Dispensing Fees

- Pharmacy revenue may also be derived from a dispensing fee added to the drug price.
- Some third-party contracts include a dispensing fee to help cover the pharmacy's professional and operational expenses.
- Dispensing fees paid to pharmacies vary.
- In reimbursement models with low dispensing fees, pharmacies are dependent on the margin they can make from the cost of the drug to the final sale to the patient.

# Middlemen – The Role of Pharmacy Benefit Managers

## Middlemen | The role of pharmacy-benefit managers



Source: Avalere Health LLC

# Spread Pricing and Manufacturer Rebates

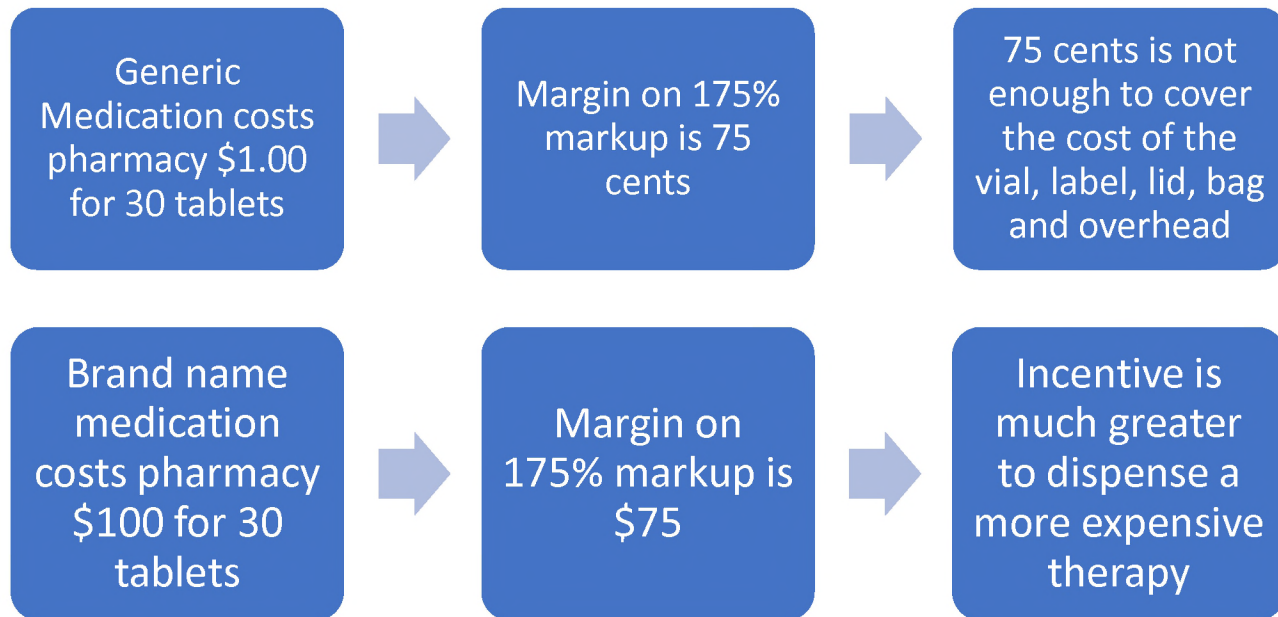
- Revenue generators for PBMs include spread pricing and manufacturer rebates.
- Spread pricing refers to the difference between what the PBM charges a patient, or patient's health insurance, and what the PBM pays the pharmacy for dispensing the medication.
- This type of markup is much more complicated than a simple flat fee per claim submitted to the PBM.
- An example would be where the PBM contracts to bill a payer using AWP, but then contracts with the pharmacy to reimburse the pharmacy using MAC pricing. The PBM would profit from the difference or spread.

# Spread Pricing and Manufacturer Rebates

- A rebate is a price concession that occurs separately from, and after, the actual purchase transaction.
- Manufacturer rebates are direct payments from pharmaceutical companies to PBMs in order to have their drug in an advantageous position on a formulary.
- Rebates are:
  - Proprietary
  - Typically dependent on volume of a drug dispensed or placement on the formulary
  - Paid periodically (i.e. quarterly or bi-annually) for all transactions that occurred during that time period

# Example of Percentages Not Equal to Dollars

- 175% Markup on a drug



# Medicaid Rebate 101

# Medicaid Drug Rebate Program (MDRP)

- Prescription drugs are an optional benefit in Medicaid programs
- More than 600 drug manufacturers participate in the MDR program
- Manufacturers must sign an agreement with the Secretary of HHS in order for their drugs to be covered by Medicaid, with the exception of certain drugs cited in the rebate statute.
- Manufacturers are required to pay statutory rebates to states on a quarterly basis as a condition of Medicaid reimbursement for their drugs dispensed to Medicaid fee-for-service (FFS) and MCO individuals, and for physician administered drugs.
- MCOs may negotiate their own rebates, but states also collect statutory rebates on MCO drugs.



# Players in the Game

- **Pharmaceutical Manufacturer** - Pharmaceutical manufacturers have the most influence over pharmaceutical prices, assessing expected demand, future competition, and projected marketing costs to establish the wholesale acquisition cost (WAC), which is the baseline price at which wholesale distributors purchase drug products. Discounts and rebates may be applied, based on market share, volume, and prompt payment.
- **Wholesale Distributors** – Wholesalers serve as the connection between manufacturers and pharmacies. They typically purchase medicines from manufacturers at a price known as the wholesale acquisition cost (WAC). Think of the WAC as the drug's sticker price. From the sticker price, the manufacturer will offer various financial incentives to the supply chain participants in order to stimulate demand. But, just as with an automobile, virtually no one pays the sticker price.
- **Pharmacies** – Retail and mail-order pharmacies contract with wholesalers to stock their pharmacies with prescription medicines. Pharmacies may negotiate with manufacturers or wholesalers for discounts and rebates based on volume sales or market share, and they may negotiate with PBMs for inclusion in their networks and for their reimbursement (drug cost plus dispensing fee).
- **Pharmacy Benefit Managers (PBMs)** - PBMs may achieve savings for their customers by negotiating discounts and through cost containment programs, including use of formularies and cost sharing.

# Players in the Game

## **Top 3 PBMs control more than two-thirds market share**

1. Express Scripts
2. CVS Health
3. OptumRx

## **Top 3 wholesalers control more than 80% market share**

1. McKesson
2. AmerisourceBergen
3. Cardinal Health

## **Top 3 pharmacies control roughly 50% market share**

1. CVS
2. Walgreens
3. Express Scripts (mail order)

# Medicaid Statutory Rebate Amounts

Brand Drugs	Brand Drugs Approved Exclusively for Pediatric Indications and Certain Clotting Factors	Generic Drugs
<ul style="list-style-type: none"><li>• Greater between: 23.1% of AMP or AMP-Best Price</li><li>• Plus Inflationary Component</li></ul>	<ul style="list-style-type: none"><li>• Greater between: 17.1% of AMP or AMP-Best Price</li><li>• Plus Inflationary Component</li></ul>	<ul style="list-style-type: none"><li>• 13% of AMP</li><li>• Plus Inflationary Component</li></ul>

- The formula for rebates varies by type of drug: brand or generic. The rebate formula is the same regardless of whether states pay for drugs on a fee-for-service basis or through payments to managed care plans.
- **CPI Penalties** – A CPI Penalty is an additional rebate paid by a manufacturer for price increases greater than inflation. This has always applied to brand name drugs, but was effective January 1, 2017 for generic drugs.

# Supplemental Rebates

- In addition to federal statutory rebates, most states negotiate with manufacturers for supplemental rebates.
- These supplemental rebates are not subject to the best price floor.
- States often use placement on a Preferred Drug List (PDL) as leverage to negotiate supplemental rebates with manufacturers.
- Medicaid managed care plans may negotiate their own supplemental rebate agreements with manufacturers. As with supplemental rebates negotiated by states, additional rebates for managed care plans can be used to determine placement on the PDL.

# Nevada Medicaid

## OBRA (Federal)

- Fee For Service

## Managed Care Organization (MCO) - HPN, Anthem, and Silver Summit

- Supplemental
- Collected for FFS only
- Until the passage of SB378, MCOs were allowed to negotiate and keep all supplemental rebates

## Diabetic Supply

- Fee for Service

Non-rebateable drugs are not covered for the Medicaid population except for those classes excluded within Nevada Revised Statute (NRS 422.4025)

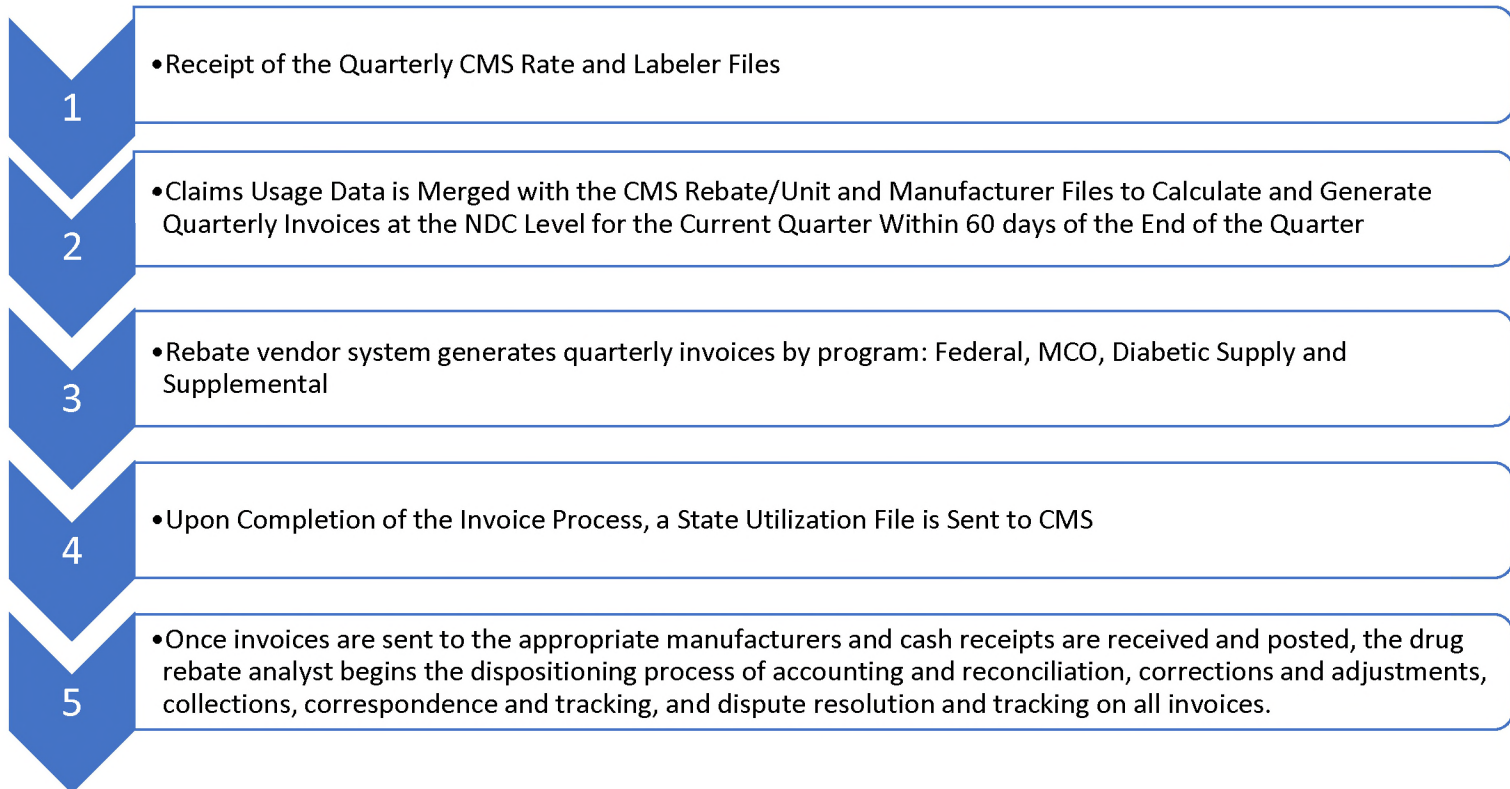
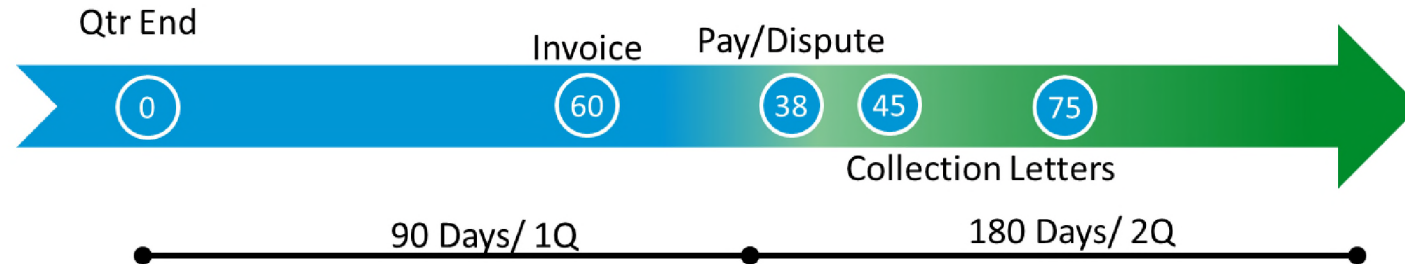
State Medicaid programs generally must cover a participating manufacturer's drugs although they may limit the use of some drugs through preferred drug lists (PDLs), prior authorization, or quantity limits.

# Drug Rebate Management

## Federal Rebates

- The Federal Rebate Amount per Unit (RAPU) is supplied by CMS on a quarterly basis for the calculation of the drug rebate amount for each NDC in the Drug Rebate program.
- Rebate amounts are calculated and paid on a quarterly basis.
- Manufacturers must report the Best Price (BP) and Average Manufacturer Price (AMP) for each covered outpatient drug to CMS within 30 days of the end of each calendar quarter.
- CMS uses the pricing information to calculate the Unit Rebate Amount (URA) for each drug. The CMS Medicaid Drug Rebate (MDR) system performs the URA calculation and provides this information to the states each quarter for purposes of invoicing.
- Rebate vendor reports rebate amounts and claims payments to the State for preparation of the CMS-64 Report to determine the State's share of rebates and Federal funding based on the Federal Medical Assistance Percentage (FMAP).

# Rebate Invoicing Process



# Drug Rebate Dispute Resolution

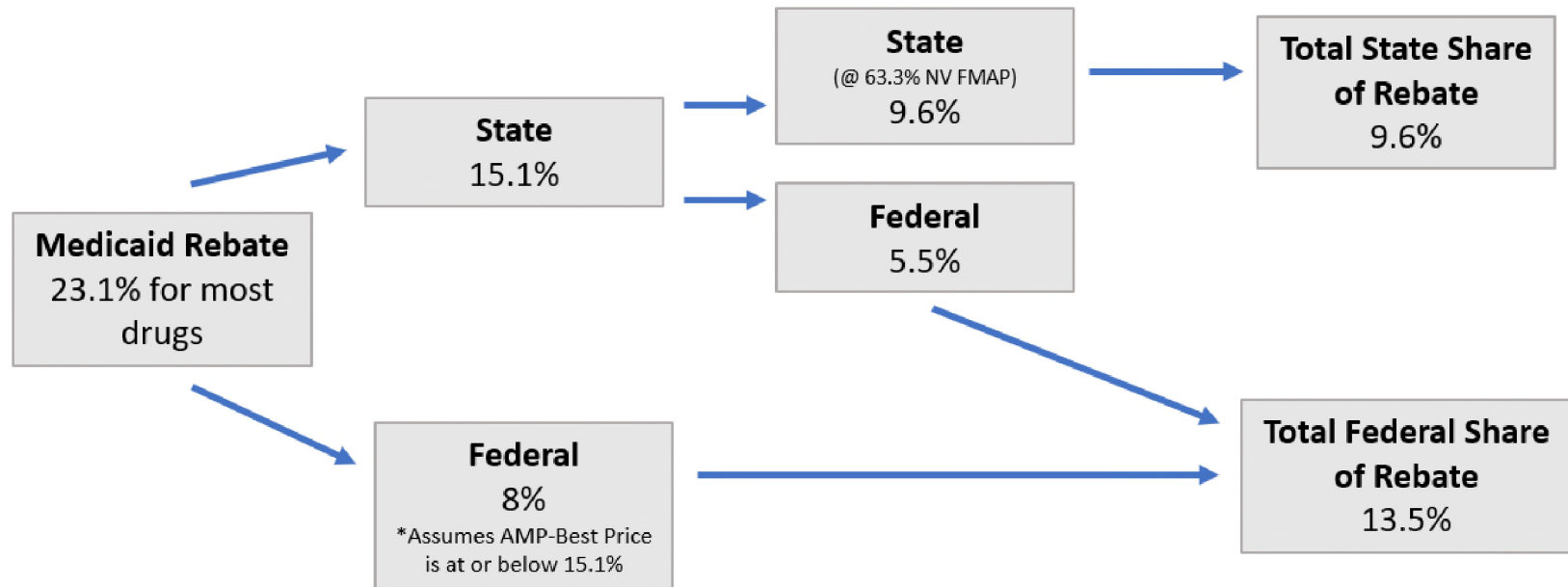
- The labeler must pay rebates on all undisputed amounts within thirty-eight days after receiving the Nevada drug rebate invoice. The labeler includes a Reconciliation of State Invoice (ROSI) document outlining NDCs paid and NDCs in dispute and not paid. In the event payment is not received, the unpaid balance becomes subject to interest based on T-bill rates. Dunning notices are sent when amounts are 45 and 75 past due. As trends in rebate dispute activities are identified, CMS and the State are notified.
- About Resolving Disputes and Payments
  - CMS Release Number 45 describes the guidelines for the dispute resolution process. In general, there are two phases to the dispute resolution process.
    - Phase 1 includes a period for the drug rebate analysts and the labelers to exchange information and seek resolution of the dispute through informal negotiations.
    - Phase 2 is considered the formal review process that includes scheduling a hearing to determine resolution.
- The most common reasons for disputes include:
  - Wrong unit of measure
  - Data entry error by pharmacy
  - Decimal errors
  - Unit and quantity appear inconsistent
  - Generic substitution
  - Incorrect NDC
  - Incorrect conversion factor



# Supplemental Rebates

- In addition to the Federal rebates (FFS and MCO), CMS has authorized Nevada Medicaid to collect Supplemental rebates.
- Nevada Medicaid's rebate vendor, invoices and collects the Supplemental rebates in parallel with the Federal FFS rebates.
- The main difference between the two programs is the State's ability to negotiate Supplemental rebate rates directly with the manufacturers. Nevada Medicaid's rebate vendor handles the negotiation of Supplemental rebates and the administration of Supplemental rebate agreements.
- Nevada Medicaid's current rebate vendor employs a Supplemental Rebate negotiation strategy that is based on market share movement – the theory being that the more market share that is moved to a manufacturer, the more that manufacturer is willing to pay in Supplemental Rebates.
- Manufacturers are invited to submit bids based on varying levels of exclusivity within any particular therapeutic class. The exclusivity level determines how many agents are deemed “preferred” within a particular class.
- The more exclusive the PDL position (e.g., one preferred agent versus several preferred agents), the higher the bid needed in order to achieve that status.
- This exclusivity approach demands that the net cost to Nevada Medicaid be considered when making preferred status decisions.

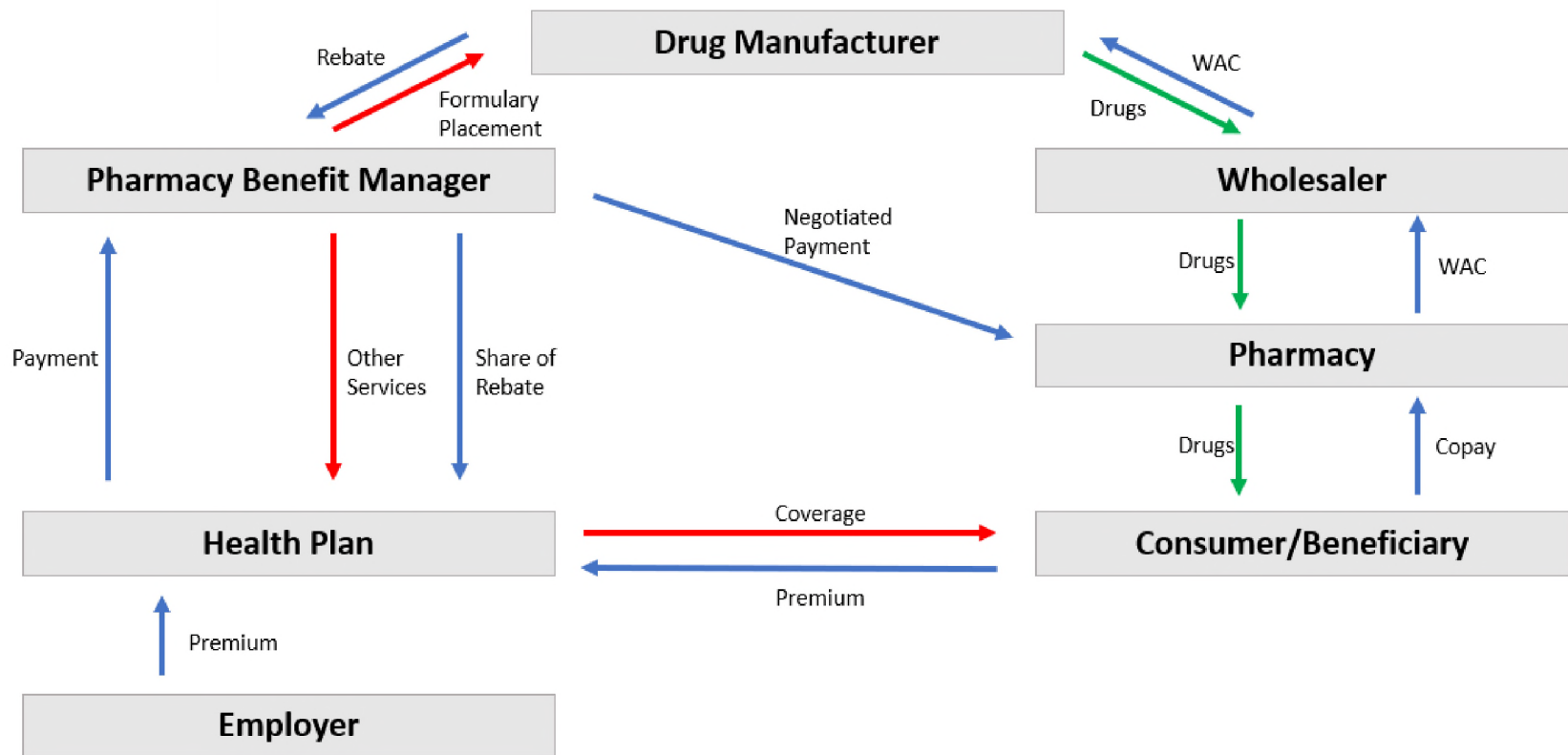
# Statutory Medicaid Rebates – State vs. Federal Share



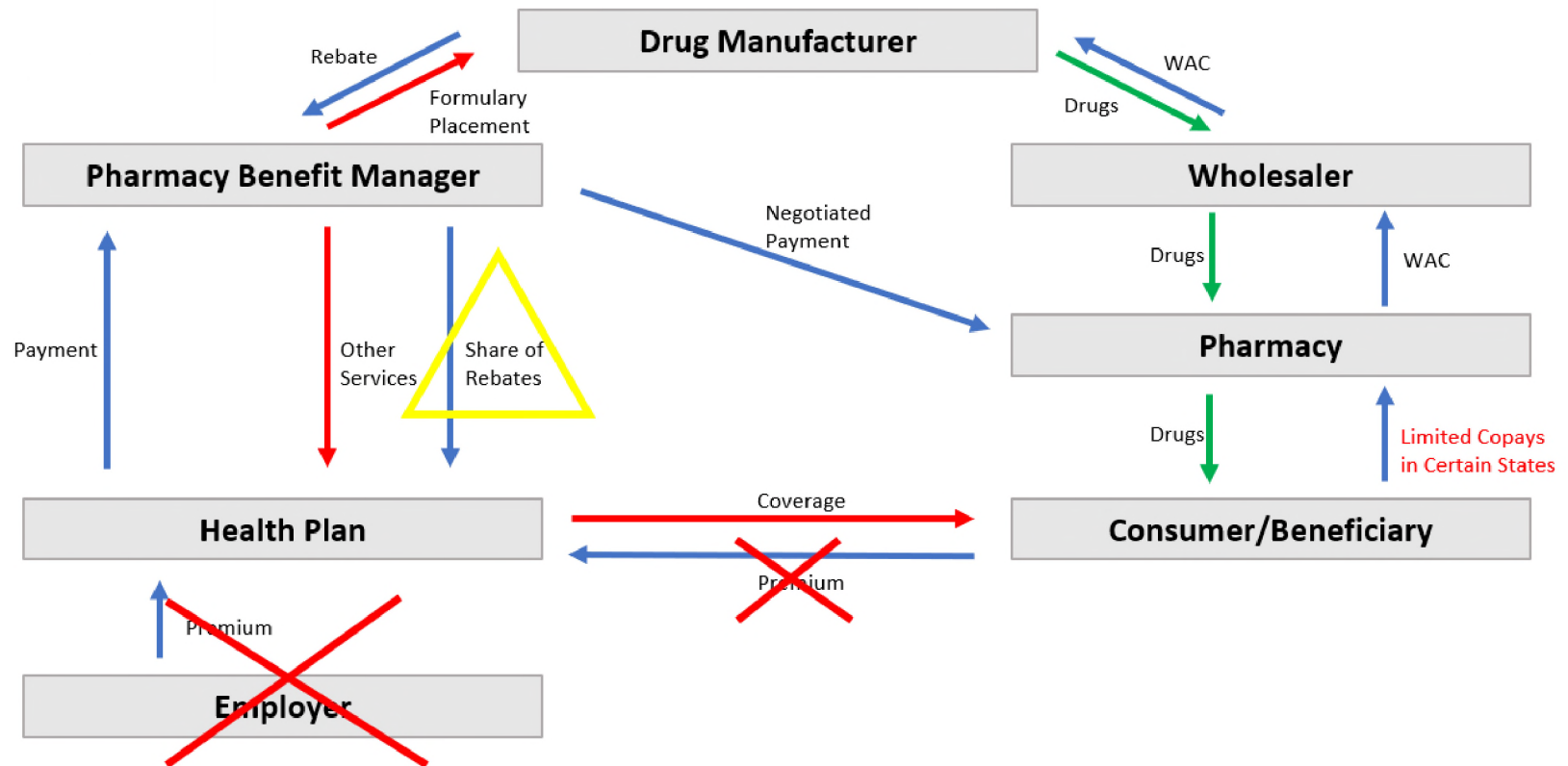
# Commercial vs. Medicaid

- Both
  - Manufacturer sells to the wholesaler at a discount to the list price.
  - Wholesaler negotiates price with the pharmacy.
  - The pharmacy dispenses to the beneficiary (consumer) and collects copay. (Nevada Medicaid has a \$0 copay for consumers)
  - The payer pays PBM to manage drug costs and the PBM passes back some (spread pricing) or all (pass through pricing) rebates and discounts to the payer.
- Medicaid
  - Nevada Fee for Service Medicaid operates under a 100% pass through contract for PBM services.
  - The PBM does not negotiate with pharmacies over reimbursement for drugs and dispensing fees.
  - Nevada Fee for Service Medicaid does not operate a network of pharmacies.
  - Nevada Fee for Service Medicaid has a set reimbursement algorithm based off of NADAC pricing and a set dispensing fee of \$10.17.
  - The PBM negotiates to receive additional supplemental rebates from the manufacturer that are passed through to the state.
- Commercial/Managed Care Medicaid
  - The PBM negotiates with the pharmacy over reimbursement for drugs and dispensing fees. Pharmacies are contracted to a network.
  - The PBM negotiates to receive additional supplemental rebates from the manufacturer that are retained by the plan or shared between the plan and the PBM.

# Drug Supply and Payment Chain – Commercial Market



# Drug Supply and Payment Chain – Medicaid Program



# Questions?

# Contact Information

Beth Slamowitz, PharmD

DHHS Senior Advisor on Pharmacy

[bslamowitz@health.nv.gov](mailto:bslamowitz@health.nv.gov)

dhhs.nv.gov

# Acronyms

- AAC - Actual Acquisition Cost
- AMP - Average Manufacturer Price
- ASP – Average Sales Price
- AWP - Average Wholesale Price
- BP - Best Price
- CMS – Centers for Medicare and Medicaid Services
- CPI – Consumer Price Index
- FFS - Fee-For-Service
- FMAP - Federal Medical Assistance Percentage
- FUL - Federal Upper Limit
- MAC - Maximum Allowable Cost
- MCO – Managed Care Organization
- MDR - Medicaid Drug Rebate
- MDRP - Medicaid Drug Rebate Program
- NADAC - National Average Drug Acquisition Cost
- NDC - National Drug Code
- OBRA - Omnibus Budget Reconciliation Act of 1990
- PBM - Pharmacy Benefits Manager
- PDL - Preferred Drug List
- RAPU - Federal Rebate Amount per Unit
- ROSI - Reconciliation of State Invoice
- U&C - Usual and Customary
- URA - Unit Rebate Amount
- WAC - Wholesale Acquisition Cost