

Fraud and Abuse in Medicaid Drug Pricing & Reporting

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Limiting Factors in “Garden Variety” Kickback Cases

- **Overload** – the “Centers of Excellence” in Boston and Philadelphia are overloaded.
- **Resource Starvation** –DOJ cutbacks, OIG auditors are diverted.
- **Part D-ification** -- Hey! Let’s add a giant new program with no new enforcement money!

Why Pricing Cases Are Attractive

■ TYPE OF FRAUD

- Kickbacks
- Off-Label
- GMP
- Pricing

■ DEGREE OF EFFORT

- High Intensity – Proof “on the ground”
- High Intensity – Proof “on the ground”
- Moderate Intensity
- Prove it once – build damages model

Kickbacks as Pricing Cases

- Kickbacks effect the cost of goods sold
 - Whether intentional or not
- Kickbacks can covertly reduce price
 - Off-invoice discounts
 - Changing labeling
- Kickback thinking pervades the analysis
 - “Fair Market Value”
 - Reasonably necessary fees

Pharma's Top Ten Hits

Company	Amount	Drugs	Allegations
TAP 10/30/01	875,000,000	Lupron	AWP (marketing the spread) Best price violation
Serono 10/17/05	704,000,000	Serostim	-Off label marketing -Trips to France for 10 NRx -Adulterated diagnostics
Schering 10/29/06	435,000,000	Claritin, K-Dur, Intron,	-Best price violation -Kickbacks
Pfizer 05/13/04	430,000,000	Neurontin	- off label - Illegal payoffs to MDs
Astra Zeneca 06/20/03	355,000,000	Zoladex	AWP (marketing the spread) Best price violation
Schering 07/29/04	345,000,000	Claritin	Best price violation (\$55/dose v. \$6.29 dose)

Pharma's Top Ten Hits, cont.

Company	Amount	Drugs	Allegations
Bayer 04/17/03	250,000,000	Cipro Adalat	Concealed discounts to Kaiser by repackaging drugs
Glaxo 09/20/05	150,000,000	Zofran Kyfril	AWP – Marketing the Spread Using vial remainder for extra fills
King 11/01/05	124,000,000	Altace, Fluogen, etc	
Glaxo 04/17/04	88,000,000	Paxil Flonase	Concealed discounts by relabelling the drugs
Pfizer 10/28/02	49,000,000	Lipitor	\$250K payoff to Ochsner Health Plan created new best price
	\$3,929,000,000		

Current Trends

- **AWP**

- – The Move to Off-Invoice Discounts
- -- Biologics ... *WHICH* Class of Trade Applies?

- **BEST PRICE**

- -- Nominal price discounts as kickbacks
- -- Nominal price discounts as marketing
- -- Off – invoice discounts
 - (Schering, Bayer, Nevada Litigation, MCOs)

Enforcement Dynamics

- Markedly increased state activity
- Markedly increased state-state coordination
- Increased state – federal cooperation
 - Old model ... “We’ve done the case. Give us your numbers.”
 - *New Model ...*
 - *Closer collaboration on theories and evidence*

BEST PRICE – LEGISLATIVE INTENT

The “Medicaid program, one of the single largest purchasers of prescription drugs in the country, [should] have access to the discounts on pharmaceuticals that other smaller purchasers, such as hospitals and HMOs, routinely receive. Some of these discounts are 40 to 70 percent less” than what Medicaid paid.

The “definition of best price excludes... ‘nominal’ prices offered to charitable groups or organizations. ... Congress did not want to threaten the prices that charitable organizations and clinics such as Planned Parenthood pay for drugs, such as the pennies a pack paid for birth control pills, and therefore excluded them from the definition.”

Per Pharma advisory, the nominal price exception “was intended to allow manufacturers to continue the practice of providing drugs to charitable organizations for token payments.”

BEST PRICE – McCLELLAN LETTER

In the aftermath of Hurricane Katrina, PhRMA wrote to CMS Administrator Mark McLellan to ascertain if PhRMA's stated intention of giving free drugs to doctors, hospitals, and clinics would have to be counted for "best price reporting" purposes.

McLellan replied:

"...as you have described the program, the provision of those drugs at no charge is not contingent on any purchase requirement.

Under the plain terms of the Medicaid statute, free goods 'that are contingent on any purchase requirement' must be included in the calculation of the best price."

Current Congressional Interest

- Senator Charles Grassley (R-IA) and the Senate Finance Committee sent letters to manufacturers asking them to detail their use of nominal prices in an attempt to discover if the best price exception was being abused
- Last year's Deficit Reduction Act, includes language giving states additional money out of FCA settlements if they enact their own *qui tam* legislation..

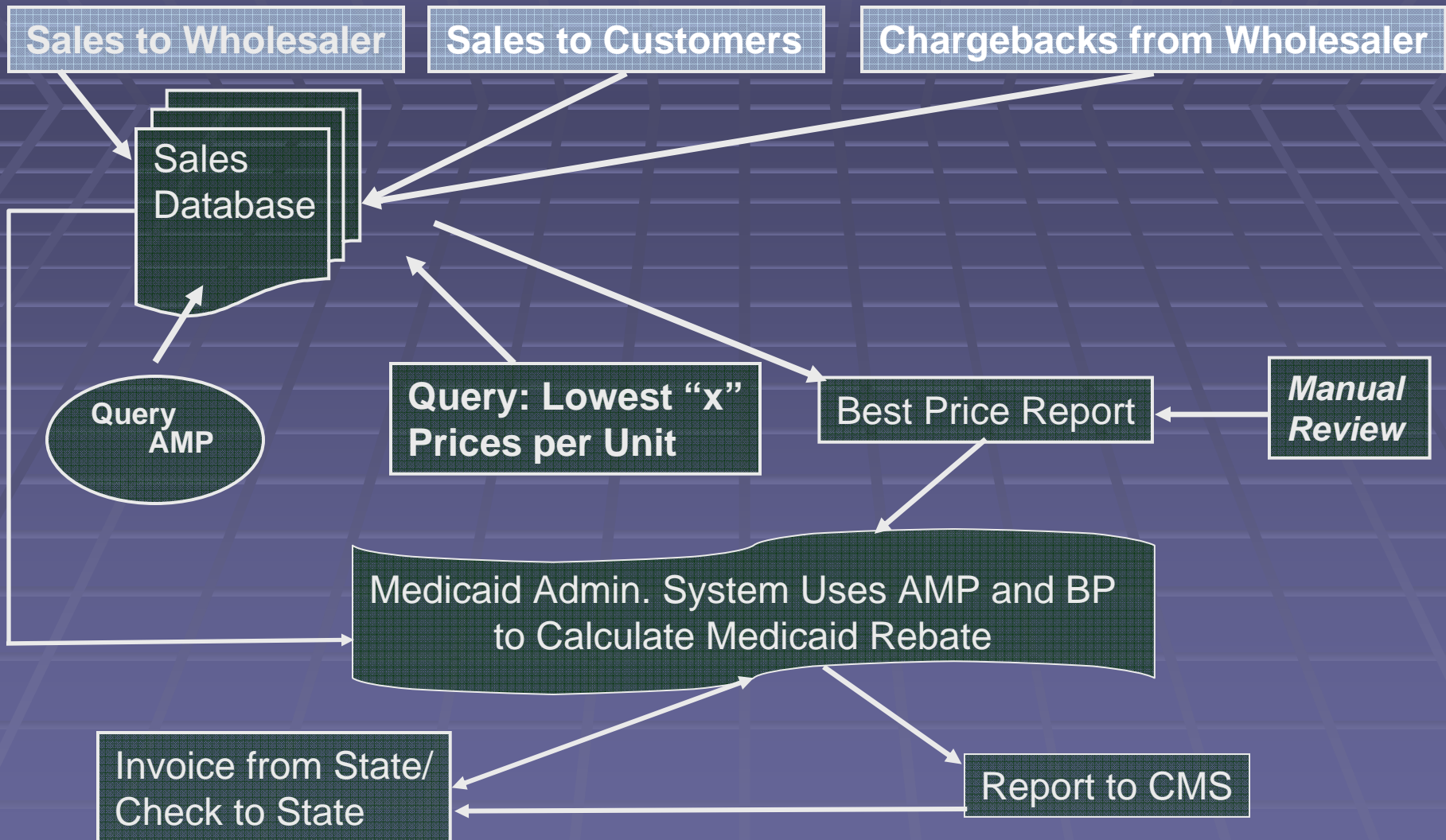
How to Tell a Kickback from a Legitimate Deal

- Administrative Fees
 - Is it a “*bona fide* service fee”?
 - *Bona fide* fees were recently described in a letter from CMS
 - Itemized service
 - Actually performed
 - Commercially reasonable
 - Fair market value

Where There is Genuine Uncertainty

- Guiding Principles
 - Consistency
 - Impact on government health programs
 - Accuracy
- Disclose assumptions
- Ask for guidance
 - Written request
 - *It's the thought that counts...*

How Manufacturers Report Best Price



Calculating the Medicaid Rebate

For each NDC of a Medicaid covered drug

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

AMP * 11% for Non-Innovator products

Current AMP (Baseline AMP + CPI-U)

(Base Rebate + Additional Rebate)

Per Unit

= Unit Rebate Amount (URA)

AWP – Role of the Spread

Since manufacturer sell below AWP, the difference between AWP and the acquisition cost, the “spread”, establishes the retailer’s profit margin.

If manufacturer can manipulate AWP, it can make its product more attractive to retailers without having to reduce the product’s cost.

Post-Bayer – In May of 2000 FDB entered into an agreement with DOJ to base its AWP reports on surveys of wholesalers. CMS and state Medicaid agencies trusted these reports.

AWP – Role of the Spread in Unique Markets

- **Biologicals and Generics**
 - **Equivalence** – nearly any of the products may be used
- **Role of the Spread** -- Pharmacies that can choose among competing products will choose those offering the greatest profit margin. Manufacturers are pressured to maintain or increase the spread.
 - AWP manipulation
 - Volume Discounts

AWP is Based on WAC

So....What Is WAC?

Manufacturer's list price to wholesalers or direct purchasers in the U.S....

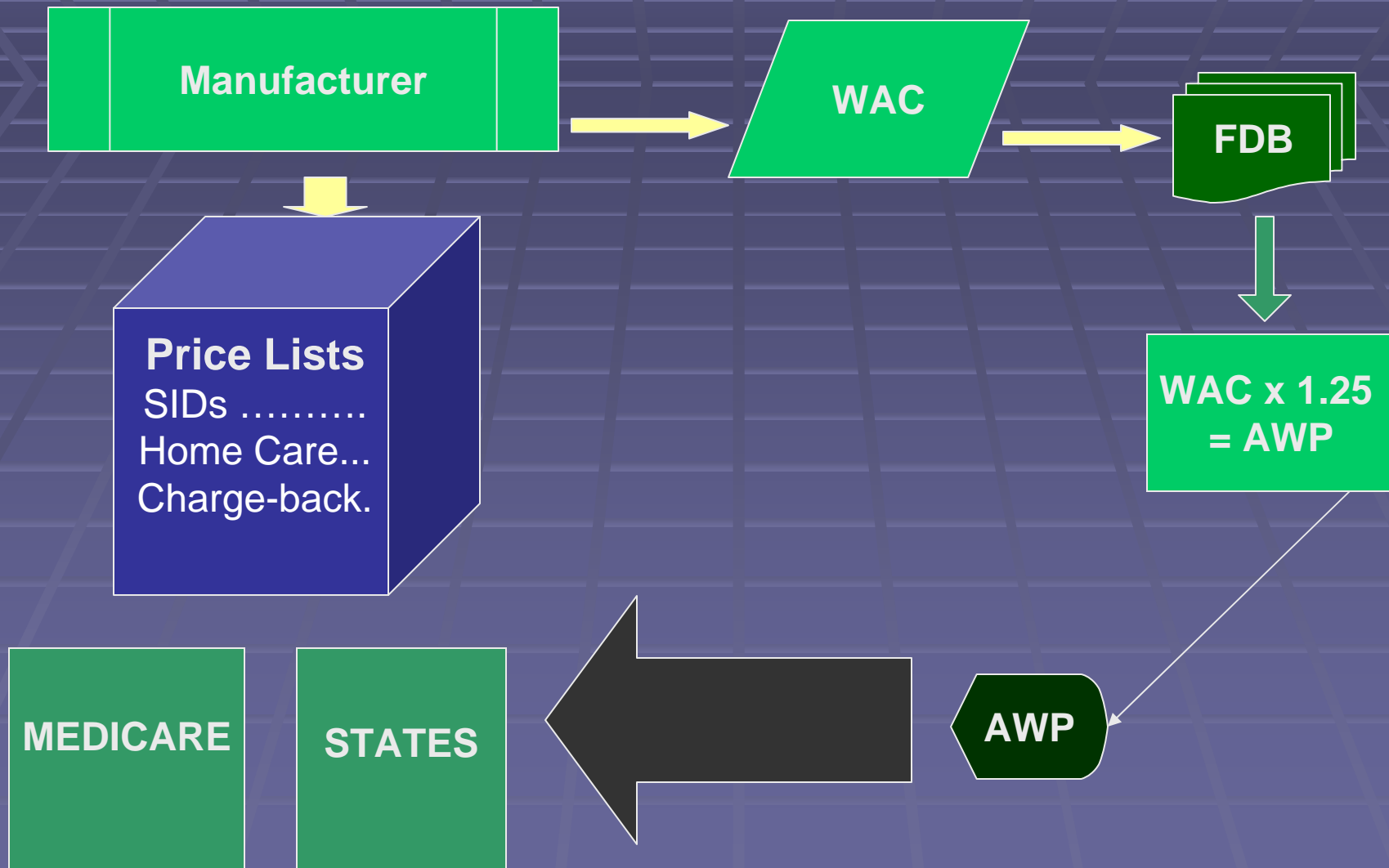
not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. **42 U.S.C. §1395w-3a**

Different Classes of Trade

Biologic Distribution Channels

- **SPECIAL INFUSION DRUG WHOLESALERS (SIDs)**
- **SPECIALTY PHARMACIES** (Home Care)
- **TRADITIONAL WHOLESALERS**
(Chargeback Wholesalers – Bergen Brunswig, McKesson, et.) **1%** of the trade

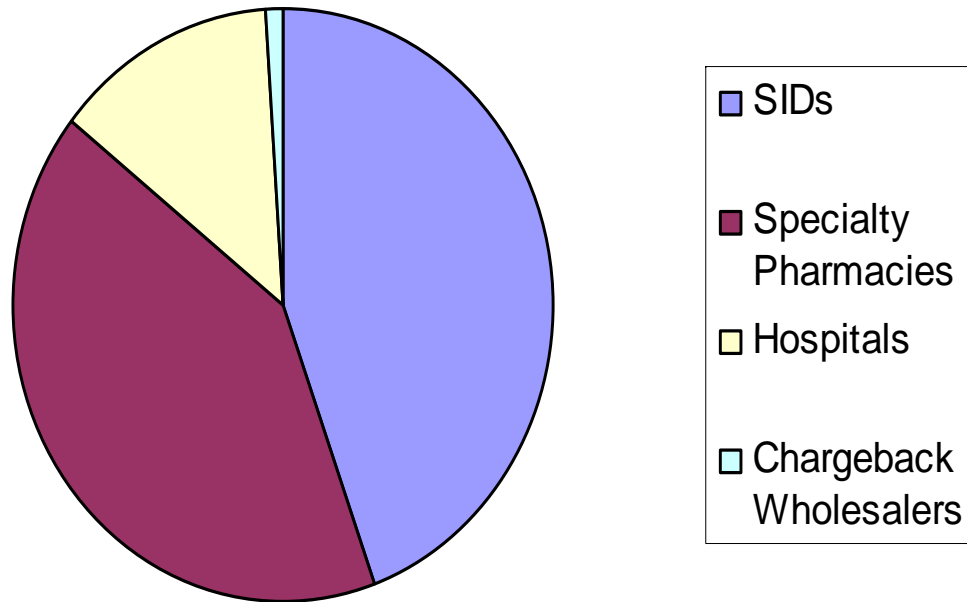
The Role of First DataBank



Class of Trade Fraud

Which Class of Trade's Prices Are Reported?

Drug Volume by Class of Trade



A manufacturer can raise prices to The nonchargeback wholesalers as much as it likes. The one percent "slice" of market share will never affect business.

State-level Enforcement

■ Texas

- Sued 12 drug manufacturers for ignoring a three-year-old state law that requires the companies to report the average manufacturer price (AMPs) of Medicaid-covered drugs
- Sued (and collected over \$55 million) from manufacturers for AWP violations [Dey, Warrick]
- **Mandatory** 10-year exclusion from Medicaid

■ Michigan

- Omnicare Prosecution