

A Short History of Pricing Related
Fraud and Abuse Issues
8th Annual Pharmaceutical
Regulatory Compliance
Congress and Best Practices
Forum
Joseph M. Metro
Washington, DC

November 11, 2007

Introduction and Overview

- Authorities for pricing regulation
- Overview of pricing settlements
- Emerging issues

Price Regulation: Discount Disclosure under the Anti-Kickback Statute

- Anti-kickback statute prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, ordering, recommending or arranging purchasing or ordering items covered under federal health care programs
- Statutory discount exception focuses on reporting of discount to facilitate potential program savings
- Discount safe harbor elements
 - Is the concession a discount?
 - Seller/offeror disclosure standards
 - Buyer reporting standards

Price Regulation: Medicaid Rebates

- Requires manufacturers of covered outpatient drugs to provide rebates to state Medicaid programs as a condition to federal matching funds for those products
- Amount of rebate
 - Single source/innovator multiple source drugs:
 - Greater of 15.1% of AMP or AMP – BP
 - CPI Rebate
 - Noninnovator drugs
 - 11% of AMP
- Quarterly price reporting by manufacturers

Price Regulation: PHS 340B Program

- Manufacturers must sell covered outpatient drugs to participating “covered entities” at discounted prices as condition to Medicaid matching funds
- Statutory discounted price equals difference between
 - AMP and
 - Medicaid unit rebate amount
- No affirmative price reporting

Price Regulation: Veterans Health Care Act Section 603

- Manufacturer must enter into master agreement as condition to Medicaid matching funds and to purchases by “Big 4” agencies
- Master Agreement obligations
 - Offer drugs for procurement on FSS
 - Charge state veterans homes prices that do not exceed FSS prices
 - Sell to Big 4 agencies at no more than federal ceiling price
- Requires reporting of “non-federal average manufacturer price” and FSS contracts require pricing disclosures in negotiation and administration

Price Regulation: Medicare ASP

- MMA modified reimbursement for Part B drugs in response to AWP concerns
 - 106% of ASP
 - WAC/WAMP/AMP alternatives
- Quarterly reporting of ASP data by manufacturers

Price Regulation: State Programs

- State price reporting statutes (NM, TX) may require reporting of pricing data different from federal data
- VT pricing disclosure law

Average Wholesale Price

- Allegations of “inflated” AWP as kickbacks, unfair trade practices, false claims

Historical Compliance Issues: The Basics

- Anti-kickback discount disclosures
- Nondisclosure of discounts leading to potentially inflated costs
- Truth-in-Negotiations/Price Adjustment Clause disclosures (FSS)
- Impact on Medicaid rebates and PHS pricing

Historical Compliance Issues: The Tensions

- Identifying price v. non-price relationships
- Reconciling pricing regulation schemes
 - “Wholesaler”
 - Nominal price
- Reconciling pricing and other regulatory schemes
 - Price reporting
 - Anti-kickback
 - Robinson-Patman
- Consideration of harm to programs

Pricing Settlements

- Effect of “Free” Goods
- HMO Relabelers
- Discounts v. Fees
- Miscellaneous
 - King
 - AdvancePCS

Pricing Settlements: Effect of “Free” Goods

- TAP
- AstraZeneca
- Schering Plough

TAP/AstraZeneca (2001/2003)

- Alleged provision of samples for billing should have been taken into account in pricing calculations
- Global settlements
 - TAP \$855M
 - AstraZeneca \$355M

Schering-Plough (2006)

- Alleged provision of “free” Claritin to HMO in connection with purchase of Claritin Redi-Tabs
- Global settlement of \$435M

Pricing Settlements: HMO Relabelers

- Bayer
- GSK
- BMS

Bayer/GSK (2003)

- Sale of repackaged products to HMO relabelers not reported in BP
- GSK \$88M
- Bayer \$257M

Bristol-Meyers Squibb (2007) (Pricing Elements)

- Alleged sale of repackaged Serzone to Kaiser not reported in BP
- Global settlement of \$515M addresses multiple issues

Pricing Settlements: Discounts v. Fees

- Schering-Plough
- Pfizer/Warner-Lambert

Schering-Plough (2004)

- \$292 million civil settlement to resolve allegations of failure to report correct BP data under Medicaid
- Failure to take into account data fees, health management services, prepaid rebates, internet development, risk sharing payments and other discounts in BP
- Civil settlement covers PHS and Medicaid
- Course of dealing

Pfizer/Warner-Lambert (2002)

- \$49 million civil settlement to resolve allegations of failure to report correct BP data
- Failure to take into account \$250k disease management grant support to managed care plan
- Course of dealing issues

Pricing Settlements: King Pharmaceuticals

- \$124 million civil settlement to resolve Medicaid rebate reporting allegations
- Alleged inadequate systems, controls, training for determining AMP and BP
- Class of trade identification
- Civil settlement covers PHS and Medicaid

AdvancePCS Settlement

- \$137.5 million civil settlement
- Covered conduct
 - “Excessive” fees represent kickbacks
 - Flat fee lump sum/flat fee percentage rebate contracts caused manufacturers to submit false BPs
 - Payments to customers for PBM renewals
- Consent decree
 - Transparency of financial relationships
 - Intervention activity regulation

Common Price Settlement Elements

- Coordination with state claims
- Provision for PHS claims

Emerging Issues

- “Participation” Issues
 - Repackagers
 - Product classifications
- Nominal prices
- GPOs
- Bundling
- New Standards
 - Impact of DRA Rule
 - Additional standards
 - Use of AMP data to establish payment
 - Implications of potential physician financial relationship reporting laws

Conclusions and Discussion