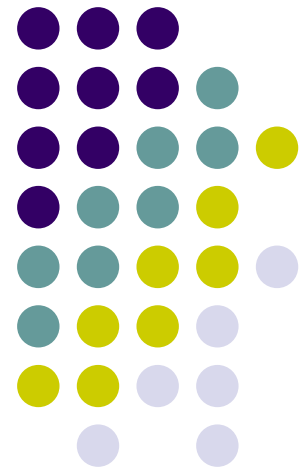
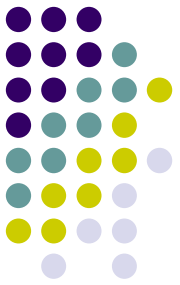

Drug Pricing and Reporting

Pharmaceutical Compliance Congress
November 15, 2004



Scott Applebaum
Shire Pharmaceuticals



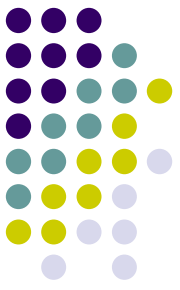
Overview

- Why Are Pricing and Price Reporting Important to Pharmaceutical Companies?
- Background on Federal Healthcare Programs
- Medicare Issues
- Medicaid Issues
- Federal Government As Direct Purchaser of Drugs
- Hot Compliance Issues in Pricing
- Summary and Steps to Reduce Your Risks

Why Is Pricing Important to Pharmaceutical Companies?



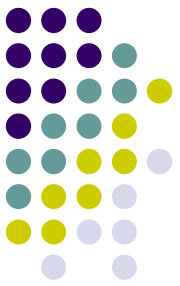
- Potential penalties under Federal and State laws for pricing-related offenses:
 - Criminal convictions and fines under criminal fraud, anti-kickback statutes.
 - Civil penalties and damages, particularly under Civil False Claims Act.
 - Exclusion from Federal healthcare programs and/or burdensome Corporate Integrity Agreements.
 - Collateral litigation by third parties.
 - Third party payors (e.g., health insurance companies).
 - Patient groups.



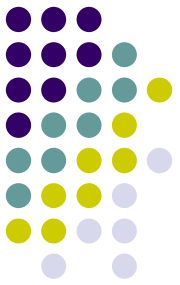
Why Is Pricing Important? (cont'd)

- Schering-Plough Corporation (2004)
 - Schering-Plough Corp., and its subsidiary, Schering Sales Corporation, plead guilty to violating the Anti-Kickback Act for \$1.8 million payment to induce an HMO to keep Claritin on formulary. Under FCA, also charged with failing to include the payments, services, and discounts to the HMO in the Claritin best price reported to Medicaid and the Public Health Services entities.
 - Agreed to pay \$52.5 million fine for its criminal liability, and settled its civil liability under the False Claims Act for over \$290 million, which will be paid to the United States, the 50-state Medicaid programs, and the Public Health Entities. Additionally, entered into a five-year CIA with HHS OIG.
- Pfizer Corporation (2003)
 - Pfizer Corp., and its subsidiaries, Warner-Lambert and Parke-Davis charged with fraudulent underpayment of Medicaid rebates. Specifically, Pfizer gave \$250,000 grant to managed care customers in exchange for favorable formulary status, which should have been included in Best Price calculation. Failure to do so caused underpayment of \$20 million in Medicaid Rebates.
 - Pfizer agreed to a \$49 million settlement payment and entered into a five-year corporate integrity agreement with HHS OIG.

Why Is Pricing Important? (cont'd)

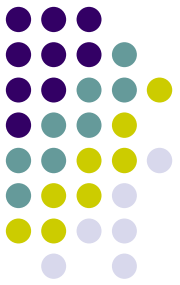


- **Abbott Laboratories (Ross Products Division) (2003)**
 - Government alleged that the company unlawfully bundled enteral pumps and disposable pump sets in a manner that disguised the “true” costs to Federal healthcare programs. Also provided “upfront” payments and “conversion bonuses,” which were alleged to be kickbacks and disguised price concessions.
 - Agreed to criminal and civil settlement, including plea to one count of obstruction; payment of \$622 million in fines, including \$400 million to settle FCA liability. Also signed five-year CIA.
- **Bayer Corp. (2003)**
 - Government alleged Bayer engaged in a lick-and-stick scheme in which it sold re-labeled products to an HOM at deeply discounted prices, and then concealed and avoided their obligation to pay millions of dollars in additional Medicaid rebates.
 - Plead guilty to one criminal count of Medicare fraud; paid more than \$250 million to settle civil FCA liability.
 - Extended and expanded existing CIA (which was for inflation of AWP in 2001).



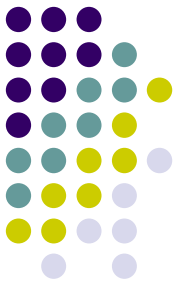
Background on Federal Health Care Programs

Reporting and Reimbursement Mechanisms



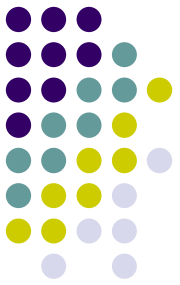
- First, manufacturers report price information to third-party services and these service use the information in establishing reported prices (such as AWP). Historically, Medicare and Medicaid based reimbursement on this published information.
- Second, manufacturers must calculate Average Sales Price and report it directly to CMS for future Medicare reimbursement purposes.
- Third, manufacturers calculate Medicaid rebate information, which is supplied directly to CMS.

Reporting and Reimbursement Mechanisms (cont'd)



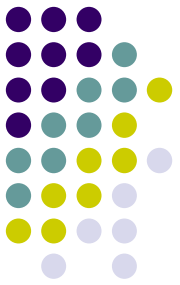
- Fourth, manufacturers submit price information directly to Government agencies that in turn purchase drugs directly from manufacturers (e.g., VA, DoD).
- Fifth, manufacturers will soon begin submitting pricing data to Medicare-approved health plans delivering the new Medicare Part D prescription drug benefit.

Medicare Coverage for Pharmaceuticals



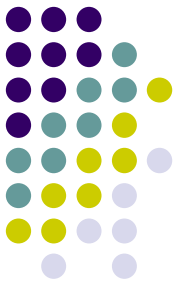
- Federal program providing healthcare to persons over 65, certain persons with disabilities, and certain other categories.
 - 85% are 65 or older; 14% disabled; 0.6% ESRD.
 - 54% women; 46% men.
- Part A (Mandatory)
 - In-patient medical services (e.g., hospitals, SNFs, hospice care).
 - Prospective payment system (PPS) based on DRGs.
- Part B (Voluntary)
 - Outpatient services (e.g., physician office visits).
 - Payments generally based on physician fee schedule.
- Part C (Voluntary)
 - Medicare managed care; expanded significantly in 1997.
 - Renamed in 2003 to MedicareAdvantage.
 - Plans permitted, but not required, to provide Rx benefits.

Medicare Coverage (cont'd)



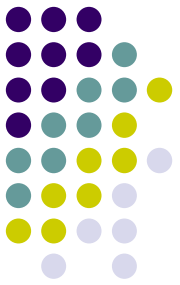
- Part D (voluntary)
 - Established in Medicare Modernization Act.
 - Establishes broad Medicare Rx benefit – essentially covering drugs for FDA-approved indications and indications listed in specified compendia.
 - Rx benefits starts in 2006.
- Summary of Medicare Rx Coverage:
 - Traditionally, Medicare did not provide coverage for most prescription drugs.
 - Exceptions (Part B drugs):
 - Drugs administered in a physician's office.
 - Drugs administered through DME, and
 - Certain other statutorily-defined categories of drugs.
 - All reimbursed under physician fee schedule.
 - Many products developed by biotech companies are covered by Part B

Medicaid Drug Coverage

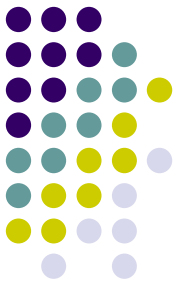


- Cooperative Federal-State program providing health coverage to low income individuals.
- While States are not required to provide Rx drug coverage, all do.
- States that decide to provide Rx drug coverage must reimburse for all “covered outpatient drugs.” Definition excludes uses that are not:
 - FDA-approved.
 - Listed in one of several compendia.
- Drugs purchased by Medicaid recipients account for roughly 10%-15% of all Rx drugs purchased in the US.

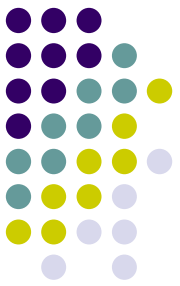
Average Wholesale Price



- AWP's reported by manufacturers are used to calculate Medicare and Medicaid reimbursement rates:
 - Medicare: For Part B drugs (through end of 2004).
 - Medicaid: Some states continue to set reimbursement based on AWP.
- AWP is not defined in any statute or regulation and is widely considered to be the “sticker” or “list” price.
- Medicare and Medicaid normally obtain AWP's from commercial price reporting services (Red Book and First DataBank).
- In the past, manufacturers provided suggested AWP's to the price reporting services. Today, many manufacturers no longer submit suggested AWP's and only submit WAC.



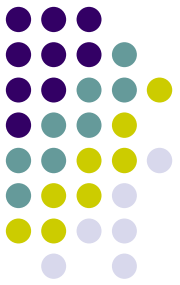
Medicare Issues



Medicare Payment – General

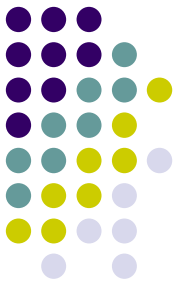
- Until 2004, Medicare usually paid for outpatient drugs at 95% of Average Wholesale Price (AWP).
- Medicare paid and still pays for some drugs using a “least costly alternative” (LCA) methodology – *i.e.*, if a drug is considered equivalent to a cheaper drug, it may be reimbursed at the payment rate for the cheaper drug. LCA policies are local policies adopted by individual Medicare carriers.
- Medicare also has “inherent reasonableness” authority to reduce payments for drugs (and other Medicare-covered items) if the otherwise-applicable payment is “grossly excessive” or “grossly deficient”.

New Payment Rules for Part B Drugs (2004)



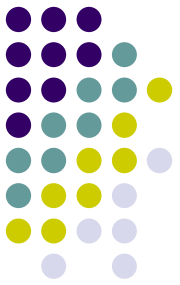
- Most drugs are reimbursed at 85% of April 1, 2003 AWP.
- Certain drugs identified by GAO/OIG as having a high AWP relative to their market prices reimbursed at a lower rate, subject to floor of 80% of April 1, 2003 AWP.
- Some drugs identified by GAO/OIG as having an AWP over 85% of market price reimbursed at rate higher than 85% of April 1, 2003 AWP.

Part B Payment Rules (2005)

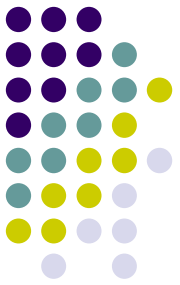


- Payment for most drugs will depend on Average Sales Price (ASP).
- ASP basically equals the average net price at which the manufacturer sells the drug in the U.S. during that quarter; sales exempt from Medicaid rebate “Best Price” calculations are also excluded from ASP calculations.
- Manufacturers must report ASPs (and other data) to CMS for calendar quarters beginning on or after January 1, 2004; first submission was due on April 30, 2004.
- Many questions about ASP calculations are not addressed by the Final Rule. Manufacturers can make reasonable assumptions about these issues but must submit a list of those assumptions to CMS.

Part B Payment Rules (2005) (cont'd)

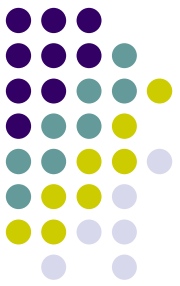


- Payment for single source drugs: Lesser of -- (1) 106% of ASP; or (2) 106% of Wholesale Acquisition Cost (WAC).
- Payment for multiple source drugs: 106% of the volume-weighted ASP for all multiple source products within the same HCPCS code.
- Payments will be lower than 106% of ASP (or 106% of the lesser of ASP or WAC) in some cases.



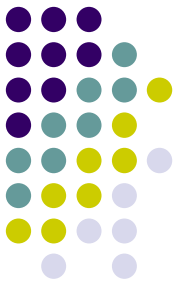
Part B Rules (2005) (cont'd)

- HHS OIG will conduct studies to determine Widely Available Market Price (WAMP).
 - WAMP is “the price that a prudent physician or supplier would pay for the drug,” taking into account “the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers.”
 - CMS will be notified if ASP exceeds WAMP or AMP by a threshold percentage (5% in 2005) and must substitute an alternative payment formula (WAMP or 103% of AMP, whichever is lower) for basic payment formula.

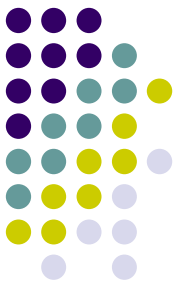


Part B Rules (2006 and Beyond)

- Phase in of “competitive acquisition program” for certain drugs.
- Physicians may make annual election to participate.
 - Participating physicians obtain drugs from a competitive acquisition contractor in their area, and contractor will bill Medicare (and collects beneficiary co-payments) for drug.
 - Physician neither pays for the drug nor obtains reimbursement for the drug.
- Reimbursement for non-participating physicians or excluded drugs is based on 2005 ASP-based methodology.
- CMS will set “a single payment amount for each competitively biddable drug ... in the area” based on the accepted bids.

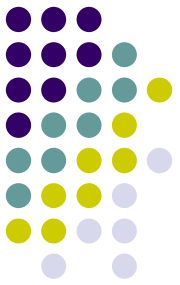


Medicaid Issues



Medicaid – General

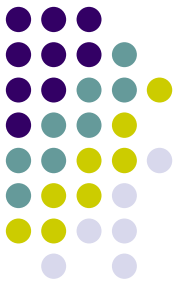
- There are two important payment issues under the Medicaid program:
 - Reporting of pricing information (*e.g.*, AWP, WAC) to price reporting services.
 - Calculation of Medicaid rebates.
- The net Medicaid payment for a drug equals the reimbursement rate minus the rebate paid to the State Medicaid program by the manufacturer.
 - Reimbursement formulas differ for each State Medicaid program (and usually also differ for different categories of drugs), but a common reimbursement rate is 90% of AWP.
 - Some State Medicaid programs have reimbursement formulas based on a specified mark-up from WAC.



Medicaid Rebates

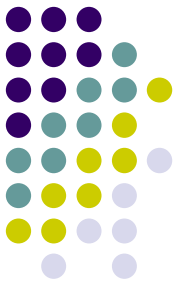
- Under the Medicaid rebate statute (42 U.S.C. § 1396r-8), the rebate formula depends on whether the drug is an “innovator” drug (*i.e.*, a brand name drug) or a generic.
- The unit rebate amount for a generic is 11% of its AMP.
- The unit rebate for a brand-name drug includes a “basic” rebate plus an “additional” rebate.
 - The basic rebate is 15.1% of AMP or AMP minus Best Price, whichever is higher.
 - The additional rebate is the difference between the inflation-adjusted “base rate” AMP and the current-period AMP.

Medicaid Rebates (cont'd)

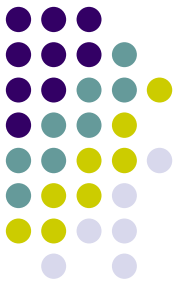


- AMP and Best Price are defined in the Medicaid rebate statute itself and the standard National Rebate Agreement executed by CMS and manufacturers.
- A series of “Medicaid rebate releases” issued by CMS also interpret Medicaid rebate requirements.
- Regulations implementing the Medicaid rebate statute do not exist.
- Best Price is generally the manufacturer’s lowest price to any domestic wholesaler, retailer, provider, HMO, or nonprofit (net of discounts, “free” goods contingent on a purchase requirement, and rebates other than Medicaid rebates).

Medicaid Rebates (cont'd)

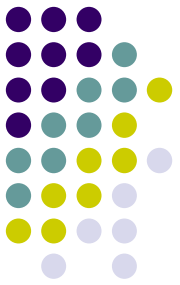


- AMP is basically the average net price paid to the manufacturer by domestic “wholesalers” (as defined in the National Rebate Agreement) “for drugs distributed to the retail pharmacy class of trade.”
- Each quarter, manufacturers calculate AMP and (for brand-name drugs) Best Price, and report these figures to CMS.
- CMS plugs the manufacturer’s reported figures into the appropriate rebate formula, generates a unit rebate amount, and reports the unit rebate to the States.
- Each State Medicaid program then bills the manufacturer for the rebates owed, using the unit rebate amount and its own data on the number of units it reimbursed that quarter.



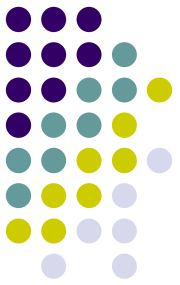
Federal Direct Purchase Programs

Federal Ceiling Prices and Other FSS Prices to Government Purchasers



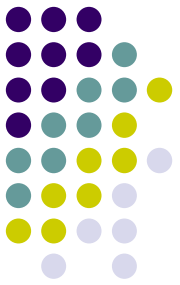
- Another route by which manufacturer-reported information affects Government payments is 38 U.S.C. § 8126 (part of the Veterans Health Care Act of 1992).
- This statute requires manufacturers to sell brand-name drugs to four agencies – VA, DoD, the Public Health Service, and the Coast Guard – at or below a Federal Ceiling Price.

Prices to Government Purchasers (cont'd)



- The Federal Ceiling Price is 76% of a drug's "non-federal AMP" (non-FAMP) minus an "additional discount"; the non-FAMP is the average price paid domestically by wholesalers (net of discounts and similar price concessions), with specified exceptions.
- Exceptions include "nominal" prices – but the VA defines this differently than CMS does for Medicaid rebate purposes.

Prices to Government Purchasers (cont'd)

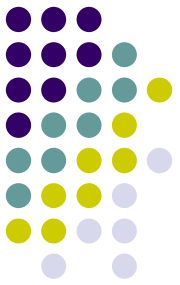


- Manufacturers must calculate the non-FAMPs for their drugs and report these figures to the VA.
- Manufacturers also must make their brand-name drugs available to all Federal agencies under Federal Supply Schedule (FSS) contracts.
- FSS contracts can contain “dual pricing” – *i.e.*, the FSS price to the VA, DoD, PHS and Coast Guard cannot exceed the Federal Ceiling Price, but FSS prices to other agencies can be higher.

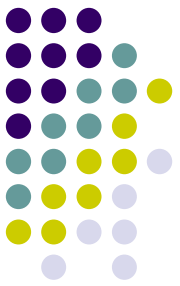
Prices to Government Purchasers (cont'd)



- The VA negotiates FSS contracts for drugs (and other medical items) pursuant to non-statutory FSS policies requiring additional pricing disclosures.
- Specifically, manufacturers must disclose certain discounts and price concessions to other customers. Manufacturers also must agree to a post-award price reduce if their pre-award disclosures were not “current, accurate, and complete” or if (after contract award) they reduce prices to an “identified customer” specified in the contract.

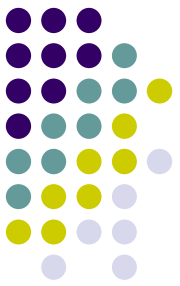


Pricing Under the New Medicare Rx Benefit



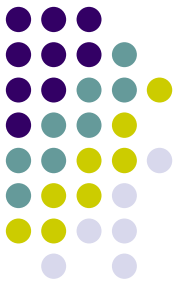
The New Medicare Rx Benefit

- The new Medicare Rx drug benefit (Part D) takes effect January 1, 2006.
- The benefit will be delivered by private-sector health plans under contract to CMS.
- The plans (either free-standing prescription drug plans [PDPs] or plans offered by Medicare Advantage PDPs) will bear financial risk; in return, they will receive substantial federal subsidies.
- The plans may employ formularies; if they do so, they must meet certain requirements specified in the MMA and implementing regulations.

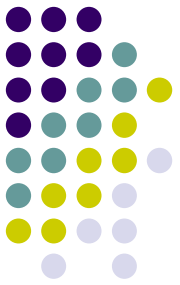


The New Medicare Rx Benefit (cont'd)

- Data supplied by manufacturers may affect the accuracy of PDP reports to the Governments, which in some cases could affect Government payments to these entities.
- Manufacturers should take steps to ensure that the rebate and discount information they provide is accurate and complete. For some manufacturers, this will require enhancements in policies, procedures, and information collection and reporting systems.
- The MMA contemplates several new rebate and discount arrangements that manufacturers will need to treat properly for purposes of:
 - Calculating Best Price, AMP, non-FAMP and (for Part B drugs) ASP.
 - Anti-Kickback Statute and relevant safe harbors.



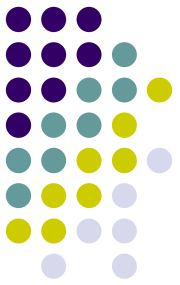
Hot Issues in Drug Pricing and Reporting



Hot Issues in Drug Pricing

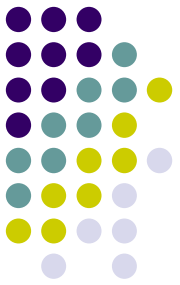
- Reporting of AWP and WAC
- Medicaid Rebates/Price Concessions
- Nominal Pricing
- 340B Prices
- Pricing Information in Sales and Marketing

Conclusion and Summary



- Pharmaceutical companies face growing number of government pricing and reporting obligations.
- For each statutory program, manufacturers face liability for “fraud” – which includes submission of false or misleading data upon which Federal reimbursement is based.
- Risk is particularly significant with respect to Medicaid rebate issues.
 - Dollars are significant.
 - HHS OIG, DOJ and whistleblowers are focused on these issues.
 - Congress likely to tackle Medicaid reform in 2005.
- Complexity of the issues requires good compliance policies, procedures and internal controls.

Conclusion: Reducing Your Company's Risks



- Written policies and procedures
- Training of key personnel
- Establish pricing committee with representation from relevant disciplines
- Review and control pricing and reimbursement materials in same manner as advertising and promotional material
- Periodically assess/audit your practices