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Pharmacy Management and Cost-Containment:

Pharmaceutical Fraud Investigations, Prosecutions and Compliance Strategies

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Overview

- Government Prosecutions of Medicaid Pharmaceutical Fraud
- Current Government Focus
- Compliance Strategies

Prosecution Theories Against Manufacturers

- False calculation and/or reporting of pricing data (particularly Best Price) to reduce Medicaid rebates to the states
- Manipulation and marketing of the "spread"
  - Artificial setting of AWP
  - Deep discounting to pharmacies/other customers
  - Marketing the difference (or "spread")
- Potential new theories
  - Improper provision of nominal prices (which aren't included in AMP calculations) to hospitals/others customers
  - Misreporting of pricing data for "authorized generics"
  - Improper interactions (particularly financial arrangements) with formulary sponsors
  - New state-level focus on interactions between state employees/HCPs and pharmaceutical sales/marketing

Company	Settlement Date	Alleged Misconduct	Total Recovery	Medicaid Recovery
AstraZeneca	6/20/03	Marketing the Spread False Gov't Price Reporting	$ 355m	$ 24.9m
Bayer I	1/23/01	Marketing the Spread False Gov't Price Reporting	$ 14m	$ 14m
Bayer II	4/16/03	False Gov't Price Reporting	$ 257m	$ 242.1m
Dey	6/11/03	Marketing the Spread	$ 18.5m	$ 14.8m
GlaxoSmithKline I	4/16/03	False Gov't Price Reporting	$ 88m	$ 85.1m
GlaxoSmithKline II	9/20/05	False Gov't Price Reporting	$ 150m	$124m*
King	11/1/05	False Gov't Price Reporting	$ 124m	$117m*
Pfizer I	10/28/02	False Gov't Price Reporting	$ 49m	$ 49m
Pfizer II	5/13/04	Off-label Marketing	$ 430m	$ 152m
Schering-Plough I	5/3/04	Marketing the Spread	$ 27m	$ 27m
Schering-Plough II	7/29/04	False Gov't Price Reporting	$ 345.5m	$ 282.4m
Serono	10/17/05	Inducements	$ 704m	$ 305m
TAP Pharma	10/3/01	Marketing the Spread False Gov't Price Reporting	$ 875m	$ 56.7m
Total			$3.44b	$1.49b

* Estimate based on publicly available data

Other Recent Pharmacy Fraud Cases

- April 2006 (FL): Pharmacy owner in Florida was arrested for defrauding the Florida Medicaid program out of $240,000. State Attorney General found pharmacy owner obtained reimbursements in the names of patients who were not customers of the pharmacy.

- March 2006 (NJ): Jury found pharmacy, pharmacy's former manager and pharmacy assistant submitted false prescription reimbursement claims to Medicaid and paid cash kickbacks to Medicaid beneficiaries (particularly patients with HIV/AIDS) to induce them to patronize the pharmacy.

- December 2005 (NY): Pharmacy owner sentenced to jail for stealing $257,000 from the Medicaid program. At his plea, defendant admitted he submitted hundreds of false reimbursement claims for medications which he never dispensed

Risks Extend Beyond Manufacturers

- While focus to date has been -- and will continue to be -- on manufacturers, HC entities at every stage of the pharmaceutical supply chain face some risks.

- Pharmaceutical supply chain includes:
  - Manufacturers
  - Distributors and wholesalers
  - Medicaid PBMs
  - Mail order and retail pharmacies
  - Health care providers (including physicians, hospitals, clinics, long-term care facilities, etc.)

OFFICE OF INSPECTOR GENERAL

WORK PLAN

FISCAL YEAR 2006

Compliance Strategies

- Every HC entity should have a compliance program based on "seven elements" as outlined by HHS OIG
- Even more important for entities in pharmaceutical supply chain given concerns about high drug costs
  - Plus: Current investigations (by prosecutors and Congress) are shining a light on practices beyond manufacturers
- Focus attention on areas of investigative/oversight activity by HHS OIG as outlined in FY 2006 Work Plan
- Be prepared for whistleblowers
  - Establish procedures for responding to internal complaints
  - Protect whistleblowers against retaliation

Appendix -- HHS OIG FY2006 Work Plan
Medicaid Drug Projects

Medicaid Drug Reimbursement

Average Manufacturer Price and Average Wholesale Price

We will examine the relationship between average manufacturer price (AMP) and average wholesale price (AWP). The AMP is used for Medicaid drug rebate purposes and is based on actual sales data for drug manufacturers. The AWP is a published catalogue price that most States have elected to use as a basis for Medicaid drug reimbursement. The AWP has been the subject of numerous reviews and its shortcomings as a basis for reimbursement have been widely documented. We will provide additional information to help ensure that Medicaid does not overpay for prescription drugs. We will also examine other Medicaid drug rebate trends, such as the significance of the best price in the rebate amount, to determine whether drug manufacturers are circumventing the requirements of the Medicaid drug rebate legislation.

(OAS; W-00-04-31072; various reviews; expected issue date: FY 2006; work in progress)

Appendix (cont'd)

Medicaid Drug Rebates—Computation of Average Manufacturer Price and Best Price

We will evaluate the adequacy of drug manufacturers' methodologies for computing AMP and best price. Both the AMP and the best price reported to CMS by manufacturers are used to determine the drug rebates paid to States. Any inaccuracies in the amounts reported can significantly affect rebate amounts. Our prior reports, issued in 1992, 1995, and 1997, noted that drug manufacturers did not consistently define the retail class of trade in their computations. In addition, we will assess CMS's oversight of drug manufacturers' recalculations of AMP and best price. It is critical that CMS effectively oversee the recalculation process to ensure that State Medicaid programs are receiving the appropriate drug rebates.

(OEI; 00-00-00000; OAS; W-00-03-31042; various reviews; expected issue date: FY 2006; OEI new start, OAS work in progress)

Appendix (cont'd)

Indexing the Generic Drug Rebate

We will analyze generic drug expenditures over a period of time to determine whether pricing substantially increased compared with the consumer price index for urban consumers. For brand-name drugs under the Medicaid rebate program, the AMP is indexed to the consumer price index for urban consumers using a baseline AMP. No such comparisons and indexing are made for rebates for generic drugs, which are simply set at AMP times a fixed percentage. Our review will quantify any potential savings from indexing generic drugs.

(OAS; W-00-04-31073; various reviews; expected issue date: FY 2006; work in progress)

Drug Rebate Impact from Drugs Incorrectly Classified as Generic

We will determine whether drug manufacturers are incorrectly classifying brand-name drugs as generic drugs for rebate purposes. Drug manufacturers issue rebates to States, which remit to the Federal Government a percentage of the rebate amount based on their level of Federal financial participation. For generic drugs, the rebates represent 11 percent of the drugs' AMP; for brand-name drugs, the rebates represent the greater of 15.1 percent of AMP or the difference between AMP and best price. Both AMP and the best price reported to CMS by manufacturers are used in determining drug rebates paid to States. We will select a sample of the most utilized drugs for this review.

(OAS; W-00-05-31085; A-06-00-00000; expected issue date: FY 2006; new start)

Appendix (cont'd)

Overprescribing of OxyContin and Other Prescription Drugs

This review will analyze Medicaid paid claims data to identify beneficiaries who have received significant amounts of OxyContin and the prescribing physicians. OxyContin is a pain medication with a very high street value. In 1999, various strengths of OxyContin represented three of the top four most-reimbursed generic drugs (in terms of dollars) in the Medicaid program. Through analyses involving medical reviews, the nature of diagnoses, and physician specialties, we will evaluate the appropriateness of the prescriptions. As part of this review, we will examine prescribing patterns for other psychotropic drugs, including Hydrocodone, Xanax, Diazepam, and Soma.

(OAS; W-00-04-31075; A-06-04-00000; expected issue date: FY 2006; work in progress)

Effect of Nominal Pricing on Medicaid Drug Rebates

We will examine how drug manufacturers are complying with the nominal price provision of the Medicaid Drug Rebate law. The Medicaid Drug Rebate legislation excluded drugs sold at nominal prices from consideration in determining a manufacturer's best price. The rebate agreement between CMS and drug manufacturers defines nominal prices as any price less than 10 percent of the average manufacturer price. The concern is that manufacturers may be selling a significant volume of drugs at nominal prices to certain customers, such as hospitals, that can improve the drugs' market share. If a manufacturer can start a patient on a drug while hospitalized, the patient could be more likely to continue using that drug when discharged from the hospital. Since nominal prices are excluded from best price, there is no rebate consequence to the manufacturers from selling at the nominal price.

(OAS; W-00-06-31102; various reviews; expected issue date: FY 2006; new start)

Appendix (cont'd)

Medicaid Reimbursement of Drugs for Long Term Care Pharmacies

We will examine Medicaid reimbursement for long term care pharmacies. Previous OIG reviews of the acquisition cost for prescription drugs found that long term care pharmacies purchase drugs at significantly lower prices than traditional retail pharmacies. One State recognized this difference and now reimburses long term care pharmacies at a lower rate than other pharmacies. Therefore, the objective of this study will be to compare State reimbursement rates with the acquisition cost of drugs for long term care pharmacies. We will select several States for review. We will estimate the savings available to individual states from lowering reimbursement rates to amounts more in line with the actual cost of drugs for long term care pharmacies.

(OAS; W-00-06-31103; various reviews; expected issue date: FY 2006; new start)

Effect of Authorized Generic Drugs on Medicaid Drug Rebates

Congressional interest was recently shown in authorized generic drugs and their effect on Medicaid drug rebates. As a drug is ending its patent life, the brand name manufacturer can attempt to save market share from being lost to multiple generic producers by making a deal with a generic manufacturer to have the generic manufacturer produce the drug as an authorized generic. The authorized generic is marketed under the brand manufacturer's original drug application rather than under its own separate application. As a result, the authorized generic should be paying the higher rebates associated with brand name drugs and not the lower rebates for generic drugs. Another more complicated issue is whether the sales to the generic manufacturer should be included in the average manufacturer price and best price calculations for the brand manufacturer. We will examine authorized generic drugs and determine their effect on the Medicaid drug rebate program.

(OAS; W-00-06-31104; various reviews; expected issue date: FY 2006; new start)

Appendix (cont'd)

Medicaid Payments for HIV Drugs

There have been reports in one State about potential abuses in the Medicaid drug program related to the high-cost drugs used to treat Human Immunodeficiency Virus (HIV). These reports indicate the pharmacies have been soliciting referrals from current HIV patients through gifts and other cash incentives. These reports also appear to indicate that Medicaid is paying far too much for HIV drugs. We intend to examine the HIV drugs to determine whether abusive conditions are occurring and whether one State is paying too much for these drugs.
(OAS; W-00-06-31105; various reviews; expected issue date: FY 2006; new start)

Zero Dollar Unit Rebate Amounts

We will determine whether States are properly collecting drug rebates for drugs with $0 unit rebate amounts (URA). CMS provides the URA information quarterly to the States; however, this information may contain a $0 URA if a drug labeler (e.g., a manufacturer) did not provide timely information, or if the pricing information significantly varies from the previous quarter. The State agency is instructed to invoice the units at $0 and the manufacturer is required to calculate the URA and remit the proper amount with their quarterly payment. Our review will determine whether the rebates for these drugs were properly billed and collected.
(OAS; W-00-06-31106; various reviews; expected issue date: FY 2006; new start)

Appendix (cont'd)

Dispute Resolution in the Medicaid Prescription Drug Rebate Program

We will assess the extent to which CMS's Dispute Resolution Program has helped to resolve disputes between State Medicaid programs and drug manufacturers. For Medicaid drug rebates, CMS calculates the unit rebate amount for each drug; State Medicaid agencies use this information, along with their own utilization data, to calculate total rebates owed by drug manufacturers. CMS developed a Dispute Resolution Program to address manufacturers' disputes about State utilization data. When disputes are not properly resolved, State Medicaid programs are at risk of not receiving drug rebates. We will review the dispute process and how the program facilitates resolution between the States and the manufacturers.

(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Medicaid Generic Drug Utilization Among States

We will determine to what extent State Medicaid programs have policies to encourage generic drug use in Medicaid. In prior work, we found that the use of generic drugs is one of the primary mechanism States use to control prescription drug costs in the Medicaid program. We will also examine the potential cost savings associated with greater reliance on generic drugs.

(OEI; 05-05-00360; expected issue date: FY 2006; new start)

Appendix (cont'd)

States Compliance With Federal Upper Limit Requirements

We will evaluate if States are meeting Federal upper limit requirements for drugs covered under the Medicaid program. In 1987, CMS regulations created upper limit standards to limit the amount that Medicaid could reimburse for certain generic drugs. We will examine whether States are meeting aggregate pricing requirements for drugs subject to the Federal upper limit program.

(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Medicaid Drug Pricing in State Maximum Allowable Cost Programs

We will determine how criteria differ among States for including drugs in maximum allowable cost (MAC) programs and how MAC amounts vary among States. The study will also examine how the methodology for establishing MAC reimbursement amounts differs among States and will compare State MAC list to the Federal upper limit list.

(OEI; 00-00-00000; expected issue date: FY 2006; new start)

Fine Print

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The presentation and accompanying discussion are intended to provide a general overview of various regulatory issues and do not constitute legal advice

Biographical Summary

- John Bentivoglio is a Partner and Co-Chair of King & Spalding's FDA/Healthcare Group in Washington, DC. From 1997-2000, he served as Associate Deputy Attorney General and Special Counsel for Healthcare Fraud at the US Department of Justice. In these capacities, he advised the Attorney General and Deputy Attorney General on national enforcement initiatives, healthcare investigation and prosecution policies, interagency coordination, and related issues. From 1986-1992, Mr. Bentivoglio served as a professional staff member to Committee on the Judiciary, United States Senate, where he handled criminal law and procedure, white-collar crime issues (including healthcare and financial fraud), and international crime and terrorism legislation.
- In private practice, Mr. Bentivoglio represents a wide range of healthcare companies on a wide range of regulatory issues, including counseling companies on fraud and abuse issues under the Medicare/Medicaid Anti-Kickback Statute and related federal and state fraud/abuse laws; and pricing and reimbursement issues under federal and state healthcare programs. He also represents clients on internal investigations and compliance audits on healthcare compliance issues and in connection with investigations and enforcement actions by the US Department of Justice, HHS Office of