



McGUIREWOODS

[www.mcguirewoods.com](http://www.mcguirewoods.com)

# Preparing for the Ripple Effect: Pricing Transparency and the Medical Device Industry

Presented by:

**Leland H. Chait**

Partner

McGuireWoods LLP

Chicago, Illinois 60601

(312) 849-8100

[lchait@mcguirewoods.com](mailto:lchait@mcguirewoods.com)


# Summary

- I. Pricing Transparency in Pharmaceutical Market – Overview.
- II. Pricing Transparency and Medical Device Manufacturers.
- III. Future of Price Transparency for Medical Device Companies.

# **Pricing Transparency in Pharmaceutical Market -- Overview**

# I. Pricing Transparency in Pharmaceutical Market – 3 Drivers

- Lawsuits by States.
- State Disclosure Statutes.
- Medicare Part D Requirements.



# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States

- *Medco.*
- *Express Scripts.*




I. Pricing Transparency in  
Pharmaceutical Market –  
Lawsuits by States - *Medco*

Highlights liability risks of pharmaceutical industry, in particular pharmacy benefit managers, not disclosing revenue sources to health plans and beneficiaries.

# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States - *Medco*

- 20 states alleged Medco Health Solutions, Inc.'s drug interchange – switching – practices violated state consumer protection laws.
  - Increased manufacturer rebates to Medco.
  - Higher costs to health plans and beneficiaries.



I. Pricing Transparency in  
Pharmaceutical Market –  
Lawsuits by States - *Medco*

- Result – Consent Decree that limits Medco's switching practices:
  - Switching allowed only if proposed drug has lower net drug cost than originally prescribed drug. Net drug cost is net of rebates, discounts, credits.



# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States - *Medco*

- Result – Consent Decree that limits Medco’s switching practices:
  - No generic available.
  - Cost savings disclosed to prescriber and beneficiary.
  - Others.

# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States – *Express Scripts*

- Class Action: prescription drug plans sued PBM Express Scripts and its predecessor (National Prescription Administrators) and 25 unnamed pharmaceutical manufacturers.

# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States – *Express Scripts*

- Allegations - PBM:
  - PBM breached fiduciary duties and violated ERISA through practices that allegedly diverted health plan assets to the PBM for the PBM's benefit.



# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States – *Express Scripts*


- Allegations - Manufacturers:
  - Manufacturers knew of the PBM's practices and aided and abetted the breaches of fiduciary duties and violations of ERISA.

# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States – *Express Scripts*

- Practices Attacked:
  - Secret pricing spreads to convert a portion of the discounted retail and mail order drug price from the plan to the PBMs.
  - Negotiating rebates with manufacturers that were not passed on to the plans.

# I. Pricing Transparency in Pharmaceutical Market – Lawsuits by States – *Express Scripts*

- Practices Attacked:
  - Rebates in exchange for formulary placement or drug switching programs.
  - Selling prescription drug use information.



# I. Pricing Transparency in Pharmaceutical Market – State Disclosure Statutes

- Washington DC – Access Rx Act of 2004.
- Maine – Maine Unfair Prescription Drug Practices Act.
- Other Statutes: South Dakota, North Dakota.

# I. Pricing Transparency in Pharmaceutical Market – State Disclosure Statutes

- Legislation pending in 10 states:

Iowa, Kansas, Maryland, Missouri, New Hampshire, New York, South Carolina, Tennessee, Virginia, and Washington.



# I. Pricing Transparency in Pharmaceutical Market – State Disclosure Statutes

Washington DC– Access Rx Act of 2004

- PBM owes fiduciary duties to a “covered entity” – includes hospital, medical service organization, insurer, health coverage plan, HMO, employer, and labor union.

# I. Pricing Transparency in Pharmaceutical Market – State Disclosure Statutes

Washington DC– Access Rx Act of 2004

- PBM must pay to customers any payment it receives from drug manufacturer based on utilization of prescription drugs. Includes rebates based on volume of sales or market share.

# I. Pricing Transparency in Pharmaceutical Market – State Disclosure Statutes

Washington DC– Access Rx Act of 2004

- Other Disclosure Obligations:
  - Inform customer of quantity of drugs bought and the net cost of drugs.
  - Drug-by-drug cost information must be provided if requested.



# I. Pricing Transparency in Pharmaceutical Market – State Disclosure Statutes

Washington DC– Access Rx Act of 2004

- Other Disclosure Obligations;
  - Financial terms of any rebate or other agreement involving remuneration with a manufacturer or labeler.
  - Substitution restrictions.

# I. Pricing Transparency in Pharmaceutical Market – State Disclosure Statutes


## Maine Unfair Prescription Drug Practices Act

- Requires pass-through of all rebates and discounts to customers.
- Requires disclosure of all financial terms of PBM contracts with manufacturers.



# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D


Federal benefit whereby the federal government subsidizes the cost of certain prescription drugs provided to qualifying beneficiaries.



# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D

## Participants:

- Drug Manufacturers.
- PBMs.
- Part D Plan Sponsors.



# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D


Overarching Principal Concerning Pricing:  
Benefit of all discounts, rebates and other  
price concessions on covered Part D drugs  
provided to Part D plans to federal  
government and Medicare beneficiaries.





# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D

- CMS reinsurance payments subsidize increased costs of Part D Plans when beneficiaries reach the out-of-pocket threshold.



# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D

- CMS payments based on costs “actually paid” - net of any direct or indirect remuneration from any source. 42 C.F.R. §423.30.

# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D

April 3, 2006 CMS Call Letter of instructions for Part D Plans for the 2007 contract year.


- PBMs must give Part D Plans benefit of manufacturer rebates.
- This benefit is a price concession to the Part D Plan that must be reported to CMS.



# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D

April 3, 2006 CMS Call Letter of instructions for Part D Plans for the 2007 contract year.

- Part D Plans must contractually require PBMs to report 100% of manufacturer rebates.
- Part D Plans must contractually require that PBMs allow the Part D Plan to audit PBMs books.



# I. Pricing Transparency in Pharmaceutical Market – Medicare Part D

April 3, 2006 CMS Call Letter of  
instructions for Part D Plans for the 2007  
contract year.

- CMS and OIG have the right to audit books of PBMs and Part D Plans to ensure proper reporting.

## **II. Pricing Transparency and Medical Device Manufacturers**



## II. Pricing Transparency and Medical Device Manufacturers

- Kickback Litigation.
- Forced Pricing Disclosure: Foreign reference pricing.
- Third Party Use of Pricing Information.

## II. Pricing Transparency and Medical Device Manufacturers – Kickback Litigation

- *USA ex rel Schmidt v. Zimmer*, 386 F.3d 235 (3d Cir. 2004).
  - Whistleblower case alleging that a medical device manufacturer paid incentives to GPO participants (hospitals), and physicians and orthopedic departments to increase sales volume of cardiac products.



## II. Pricing Transparency and Medical Device Manufacturers – Kickback Litigation

- *USA ex rel Schmidt v. Zimmer*, 386 F.3d 235 (3d Cir. 2004).
  - HCFA 2552 certification of compliance with all laws was false – violated Anti-Kickback statute and the Stark law.

## II. Pricing Transparency and Medical Device Manufacturers – Kickback Litigation

- *USA ex rel Schmidt v. Zimmer*, 386 F.3d 235 (3d Cir. 2004).
  - Case in discovery.

## II. Pricing Transparency and Medical Device Manufacturers

Forced Pricing Disclosure: Foreign Reference Pricing.

- Requiring disclosure of prices of products sold all over the world, and then the sovereign pegs the price to the location with the lowest price.

## II. Pricing Transparency and Medical Device Manufacturers

Forced Pricing Disclosure: Foreign reference pricing.

- Does not take into account distortions due to government control of pricing in many markets.
- Ignores other local variations and need,
- Stifles innovation.

## II. Pricing Transparency and Medical Device Manufacturers – Third Party Use of Pricing Information and First Amendment

- *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Counsel*, 425 U.S. 748 (1976).

## II. Pricing Transparency and Medical Device Manufacturers - Third Party Use of Pricing Information and First Amendment

- *Cardiac Pacemakers, Inc. v. Aspen II Holding Co.*, 413 F.Supp.2d 1016 (D. Minn. 2006).
- *Emergency Care Research Institute v. Guidant Corp.*



## II. Pricing Transparency and Medical Device Manufacturers – Third Party Use

### *Virginia State Board of Pharmacy*

- U.S. Supreme Court held that statute prohibiting pharmacists from advertising drug discounts violates First Amendment.
- First Amendment protects purely commercial speech, specifically about discounts.

## II. Pricing Transparency and Medical Device Manufacturers – Third Party Use

*Cardiac Pacemakers, Inc.*

- Cardiac Pacemaker (Guidant) sued consultant that obtained price information from engagements and advised other clients on pricing negotiations with Guidant.



## II. Pricing Transparency and Medical Device Manufacturers – Third Party Use

*Cardiac Pacemakers, Inc.*

- Guidant required customers (GPOs, hospitals) to sign confidentiality agreements.
- pricing formula, contract terms, and each customer's contract price and terms were confidential.

## II. Pricing Transparency and Medical Device Manufacturers – Third Party Use

### *Cardiac Pacemakers, Inc.*

- Guidant granted summary judgment on claim that Aspen interfered with its contracts with its (Guidant's) customers.
- Case settled before trial. Settlement confidential.
- Aspen did not assert First Amendment.

## II. Pricing Transparency and Medical Device Manufacturers – Third Party Use

### *ECRI v. Guidant Corp.*

- Similar issues to *Cardiac Pacemakers*:  
ECRI, provider of pricing data for  
healthcare industry, sought declaratory  
judgment to prevent Guidant's efforts to  
keep ECRI from collecting Guidant  
confidential price data.

## II. Pricing Transparency and Medical Device Manufacturers — Third Party Use

*ECRI v. Guidant Corp.*

- ECRI asserts First Amendment protection to distribute truthful pricing, commercial information it received voluntarily from hospitals.
- The case is in discovery.

## **III. Future of Price Transparency for Medical Device Companies**

### III. Future of Price Transparency for Medical Device Companies

Trend throughout healthcare world, particularly pharma, is towards transparency.

- Disclosure of interests and incentives.
- Discourages fraud and abuse.
- Enhances monitoring against fraud and abuse.

### III. Future of Price Transparency for Medical Device Companies

Dynamics driving that trend in pharma  
same for medical device world:

- Both involve strong relationships with physicians.
- Sales and marketing reps.

### III. Future of Price Transparency for Medical Device Companies

Critical Differences Between Pharma and Medical Device Manufacturers:

- Physicians' choice of medical device products often limited by hospital or other surgical facility.
- Competition can be intense to become preferred provider of device to hospitals and other surgical facilities.



### III. Future of Price Transparency for Medical Device Companies

- Gainsharing efforts likely increase this competition.
- Product development: use of consultants in pre- as well as post-approval phases.