



**PCMA**

**The Role of Pharmacy Benefit  
Management (PBM) Enterprises  
in Transforming the Pharmaceutical  
Marketplace**

**Stephanie Kanwit, Esq.  
Special Counsel  
Pharmaceutical Care Management Association**

The Pharma, Biotech and Device Colloquium  
June 6-9, 2004



## What are PBMs?

Pharmacy benefit managers (PBMs) are companies that administer drug benefit programs for employers and health insurance plans.

Purchasers like health plans, self-insured employers, union sponsored plans, Medicaid and Medicare managed care plans, the Federal Employees Health Benefits Program (FEHBP), and other federal, state, and local government entities (e.g. CalPERS) contract with PBMs to provide affordable and accessible prescription drug benefits.

## PBMs' Value Proposition: Improved quality, safety and affordability

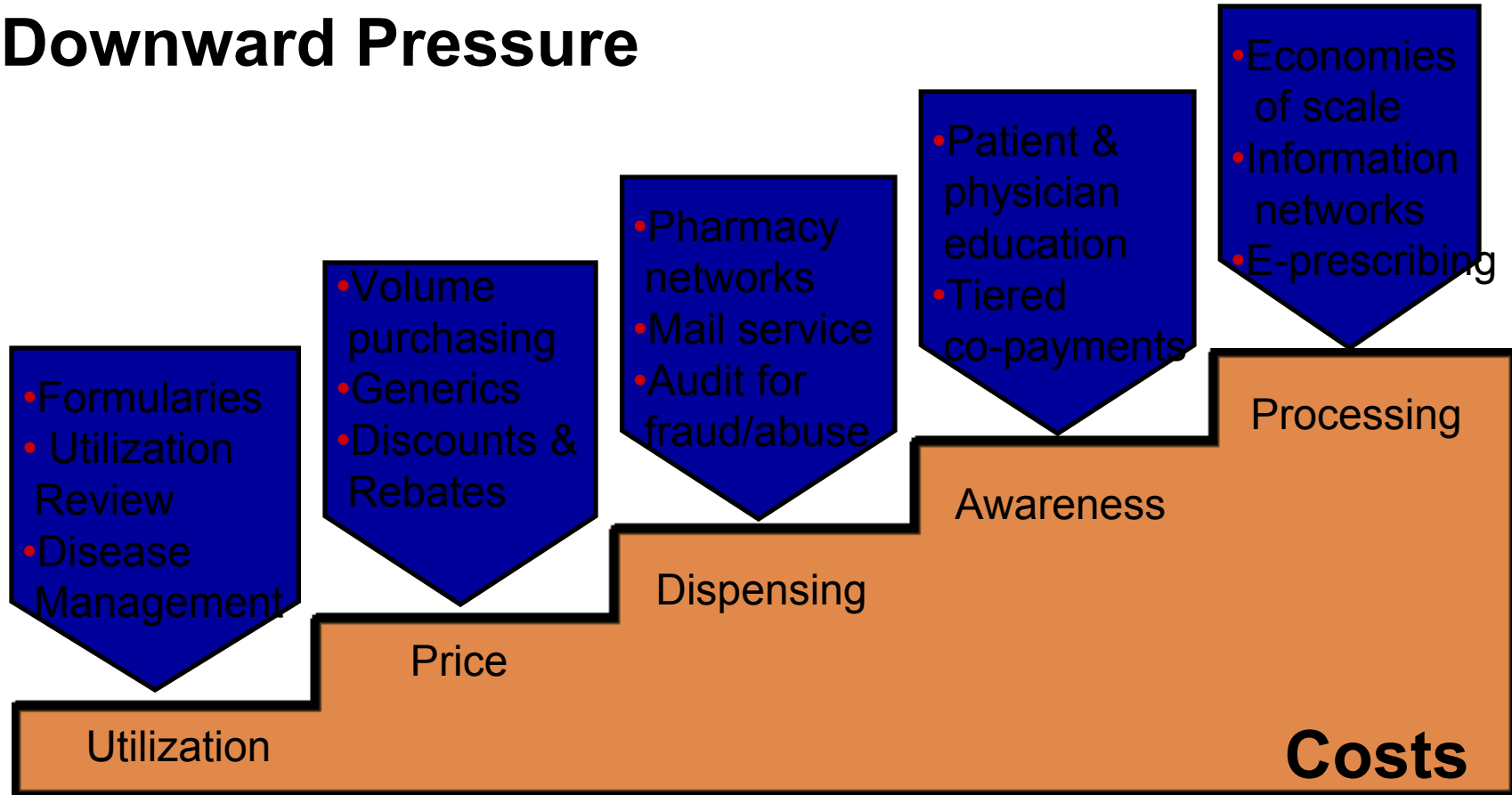
- Quality improvement programs
  - ✓ Patient screening/risk assessment
  - ✓ Patient/Physician education
  - ✓ Disease management
- Safety programs
  - ✓ Comprehensive prescription record
  - ✓ Utilization review for interactions, appropriate use, etc.
  - ✓ Pharmacist receives almost instantaneous alert
- Affordability
  - ✓ Disease management
  - ✓ Aggregate buying power
  - ✓ Encourage cost-effective benefit design
  - ✓ Negotiate lower prices

## Basic PBM Statistics

- Roughly 95% of all patients with drug coverage receive benefits through a PBM
- PBMs manage about 70 percent of the more than 3 billion prescriptions dispensed in the United States each year
- PBMs manage pharmacy benefits for nearly 200 million Americans, including 65% of the country's seniors

# PBMs Take Steps Toward Savings

## Downward Pressure



## GAO Confirms PBM Savings

- Mail Order Service:
  - 27% savings on brands
  - 53% savings on generics
- Retail pharmacy:
  - 18% savings on brands
  - 47% savings on generics



Source: GAO, "Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees and Pharmacies," January 2003

## Recent Estimates of Savings for Consumers Using PBM-Sponsored Medicare Discount Cards



### CMS (April 2004):

- 17% brands
- 34% generics

### PCMA (April 2004):

- 17% brands
- 35% generics

### Harvard (April 2004):

- 14% brands
- 41% generics

## PBM Role in Assuring Safety and Quality of Prescription Drugs

- Drug utilization review (DUR): to assure appropriate utilization of prescriptions; can be done at point of sale and retrospectively
- Clinical prior authorization: to assure appropriateness and suitability of the prescribed medication (e.g. drugs that have major off-label uses, such as growth hormones)
- Consumer and physician education
- Disease management: often targeted to chronic diseases like asthma, diabetes, and depression
- Compliance and persistency programs: letters and Internet reminders to patients to take the full course of medication, or refill medication, etc.
- Clinical management initiatives: increasing computer technology and use of the Internet

## Government Oversight of PBMs

- Congress: Medicare Modernization Act
- CMS: regulations on Medicare Act
- OIG: Compliance Guides/Rx safe harbors
- DoJ: Investigations/consent orders re anti-kickback laws in Medicare/Medicaid/SCHIP/TriCare, etc.
- DOL: regulations re timeliness of benefit decisions
- FTC: regulation of mail order pharmacies' ads
- States: “fiduciary”/disclosure legislation, state AG oversight, consumer protection statutes

## “Fiduciary” or “Disclosure” Requirements As Misguided Solutions to Rising Costs

- Consumers/legislators often frustrated at rising healthcare costs
  - Spending climbed to \$1.6 trillion in 2002, or \$5,440/per person
- Prescription drug costs are fastest rising component of medical expenditures: 16.7% of total increase in spending in 2001 [EBRI, Jan.'04]
- Simplistic solutions like transforming PBMs into fiduciaries or mandating disclosure of competitively sensitive information don't work: Multiple reasons why costs are rising:
  - Some good: new technologies, greater use of pharmaceuticals to prolong lives
  - Some bad: higher litigation expenses, rising hospital costs
- Consumers really need reliable data about cost and quality of prescription medicines---not legislation and litigation that increases costs

## What Should “Disclosure” or “Transparency” Mean?

- Should mean empowering PBM clients and consumers with information, not interference with competitively bargained contracts between PBMs and clients
- “Transparency” exists for clients, who have audit rights by contract
- But public disclosure of confidential contract terms would damage competition, creating an artificially inflated floor for drug costs, and ultimately harm private and public sector consumers
- Congress rejected “Cantwell Amendment” in Medicare Rx bill (requiring detailed reporting to HHS and Justice Department) after GAO reported that it would cost taxpayers \$40 billion over ten years

## PBM Market: Highly Competitive

- Over 70 PBMs in U.S.:
  - Some affiliated with health plans (Wellpoint, Anthem, Cigna, Aetna)
  - Some stand-alone (Medco, Caremark, Express Scripts)
  - Some affiliated with drug-store chains (Eckerd Health Services), PharmaCare (CVS), Walgreens Health Initiatives
  - Some smaller, regional PBMs

## Competitive Concerns Misplaced

- Not highly concentrated market: FTC says “vigorous” competition \*
- No geographic limitations: Nature of PBM business means it can perform services for client, wherever the client (and ultimate consumer) is located
- Employers/clients choose type of PBM and how to structure benefits to achieve cost objectives
- No high barriers to entry:
  - Not capital intensive businesses, once past initial systems; see Lehman Bros., “PBM Roadmap,” March 11, 2003
  - Continual market entry: e.g., entry of PBMs affiliated with drug chains

\* Statement of FTC, File #0310239 (Feb 11, 2004)

## Key Issues Facing PBMs and Their Partners

- E-prescribing
- Expansion of entitlement programs – Medicare Modernization Act
- “Transparency”/Disclosure
  1. Government imposed
    - Medicare/State regulation
    - Spillover effect
  2. Market driven
- Government investigations/litigation
- Importation
- Specialty pharmacy (Biotechnology)

## Challenges Ahead in Medicare Discount Card and Part D Benefits

- Ensuring a competitive market in Medicare: e.g., rejecting call for a Veterans' Administration-style model where Secretary of HHS negotiates prices for all
- Maintaining flexibility in formulary design: PBMs need clinically-based formularies to ensure beneficiaries have access to safe, effective and proven Rx drugs; Medicare discount card program requires that beneficiaries have access to drugs in 209 therapeutic classes