Pharma Audioconference: PBM Regulation, Investigation, Prosecution and Compliance

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Prescription drugs: fastest rising component of medical expenditures

- Accounted for 16.7% of total increase in health care spending in 2001 (EBRI, Jan. 2004)
- Most of cost reflects increased consumption: over half of those older than 75 filled more than 15 prescriptions annually
- Roughly half of prescriptions filled annually are for generics

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

PBMs Are Saving Payor/Clients and Consumers Money

- Findings of 2003 GAO Report on FEHBP:

  PBMs helped lower the cost of:

  (1) Brand-name drugs by 18 %

  (2) Generic drugs by 47%
- Manage about 70% of the more than 3 billion prescriptions dispensed in US annually

GAO Report (2003) says PBMs get results for consumers:

- lower out of pocket expenses,
- broader access to pharmacies, and
- nonrestrictive drug formularies with access to most therapeutic classes for enrollees

PBMs as key to implementing Medicare Rx Plan

- Medicare Prescription Drug, Improvement and Modernization Act of 2003 creates voluntary prescription drug benefit for Medicare beneficiaries as of 2006
- Act relies heavily on PBMs –which already manage pharmacy benefits for nearly 65% of country's seniors—to control drug costs.
- Many PBMs will act as PDPs, and also administer drug discount cards
- Act ensures beneficiaries protections, including requirements that (1)formularies be developed by P&T committee consisting of independent physician and pharmacist, (2) formularies include drugs within each therapeutic category, (3) changes to formularies be made only after notice to enrollees, (4) beneficiaries can appeal a decision regarding coverage for non-formulary product to external independent entity.

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 (especially drugs that have major off-label uses, such as growth hormones, or those where medical justification is needed to assure safety or cost-effectiveness)
- Consumer and physician education
- Disease management: often targeted to asthma, diabetes, depression, and other chronic diseases
- 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

"Transparency" demands are misguided:

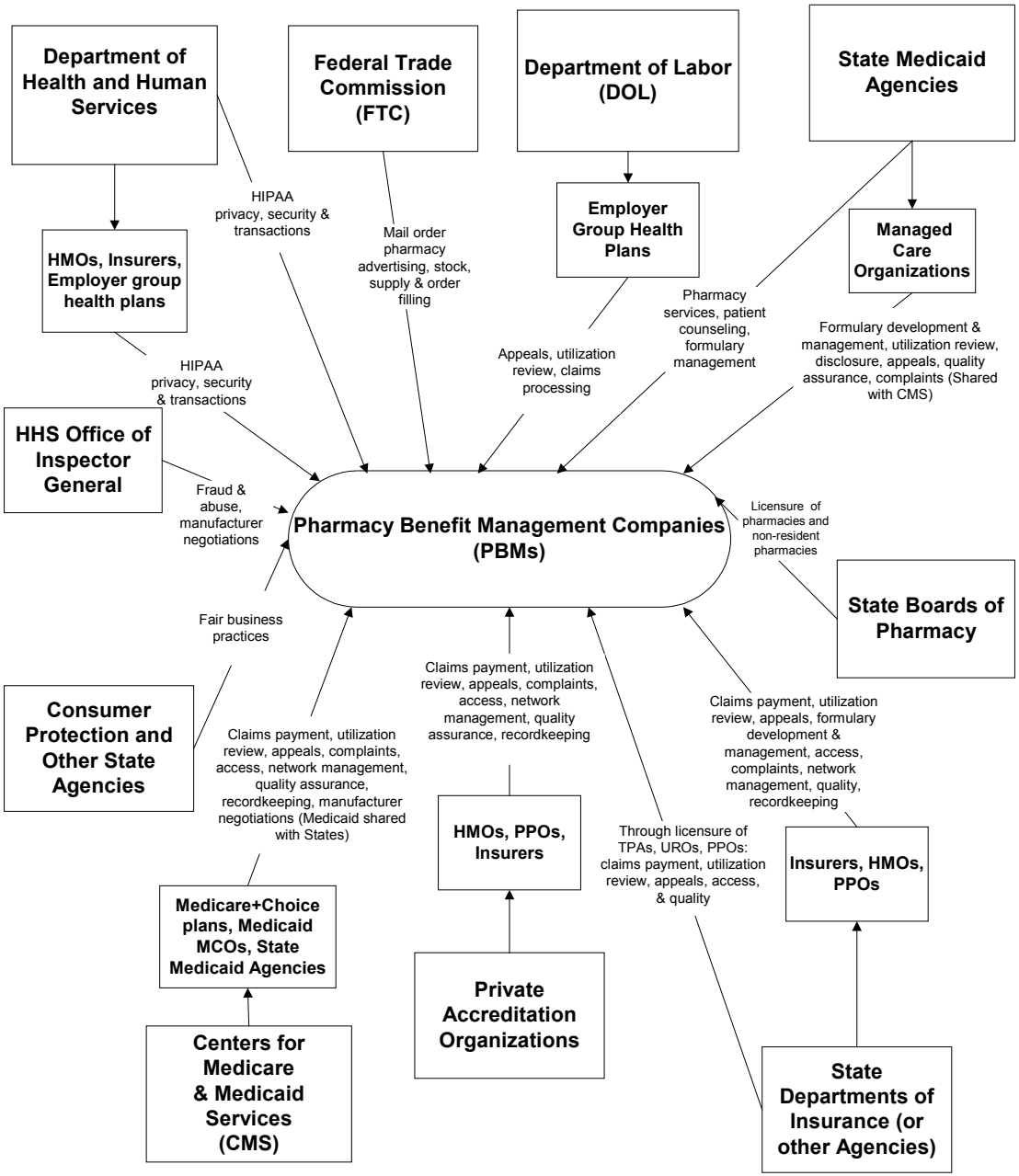
- Should mean empowering consumers with information, not interference with competitively bargained contracts between PBMs and health plans/insurers
- "Transparency" exists for clients, who usually have audit rights
- But *public disclosure* of confidential contract terms would damage competition and ultimately harm private and public sector consumers
- Market highly competitive, and "transparency" would create an artificially inflated floor for prescription drug costs
- 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.

The myth that PBMs are "unregulated":

- Directly regulated at state level as licensed, certified, regulated entities, such as resident or non-resident pharmacies, TPAs, PPOs, or utilization review organizations (UROs).
- Indirectly regulated through contractual compliance with state and federal requirements imposed on insurers, HMOs, employer-sponsored ERISA plans on whose behalf PBMs provide services.
- Specifics of direct federal regulation (1) Medicare and Medicaid laws re standards for timely payment, formulary decision-making; (2) Anti-kickback laws covering Medicare, Medicaid, SCHIP, TriCare; (3) DOL's regulations re notification and timeliness of benefit decisions; (4) DEA oversight of dispensing of controlled substances; (5) HIPAA regulation re protected patient information; (6) FTC regulation of mail order pharmacies' advertising.

_Source: Joffe, M.S. and Back, K., "The Regulation of Pharmacy Benefit Management Companies," 2002.

Regulation of PBM Activities



The myth of “secret rebates”:

- Rebates are price reductions that save private sector, federal and state gov’t health care programs billions of dollars a year.
- PBMs’ customers are highly sophisticated purchasers –large employers and health insurers—and the market is highly competitive.
- PBMs treat the value of pharmaceutical rebates as actual property of their clients, and/or pass them along to clients in one way or another—either directly or indirectly by providing broader discount across all products and services (depending how a plan chooses to structure its contracts)
- --Health plans may choose deeper discounts instead of rebates, leaving PBMs “at risk” to obtain manufacturer discounts
- HCFA 2001 PBM Study: “These (rebates) are obtained under contracts, and shared or passed on to clients. ..The fees the PBM receives from its clients and retains from manufacturer are a very small percentage of the total cost of a pharmacy benefit.”

The myth of PBMs "switching" prescriptions:

- PBMs do not switch prescriptions, as only a prescriber can make that decision.
- PBMs encourage prescribers to adhere to the best clinical practices.
- Formulary compliance programs also seek to keep drug benefits affordable for beneficiaries – which means choosing one drug over another as "preferred".
- Plan sponsors generally elect to include a formulary exceptions processes as part of their PBM-administered drug benefit, whereby a specific medication can be covered (and therefore reimbursed) when medically necessary.

The myth that PBMs do little to encourage generics:

- Generic drug prices are typically less than one-third that of brand name products, so encouraging generic utilization is a key way PBMs help hold down drug costs.
- PBMs advise plan sponsors on how to implement effective strategies to promote generics:
  - Designing plans with lower enrollee cost sharing for generics
  - Providing enrollee and physician education programs to promote generics
  - Monitoring pharmacy networks to improve generic substitution rates
  - Using mail service to ensure the rapid adoption of generic equivalents as they enter the market.