PBM LESSONS LEARNED

Medicare Part D Lessons Applied

Health Care Compliance Association
12/11/07
Margaret L. Hutchinson
Assistant U.S. Attorney, Eastern District of Pennsylvania
DISCLAIMERS

- My Own Opinions
- Not Official Policy of the U.S. Department of Justice or the United States Attorney
- In Settled Cases, No Finding or Admission of Wrongdoing
Basic Pharmacy Benefit Management

- Basic Model
  - Real time prescription and claims processing
  - Accessible treatment and claims history
  - Nationwide networks of pharmacies
  - Automated Drug Utilization Review
  - Formulary
  - Mail order service for long-term drugs
Pharmacy Benefit Management Evolved

- The core business had limited profit opportunities
  - Narrow profit margin
- PBMs sought profit opportunities
  - “Partnering: with manufacturers
  - Disease/patient management
  - Information sales
  - High margin items (generics, specialty)
Advanced PCS Settlement

$137.5 million recovery

Settled claims regarding kickbacks from manufacturers and kickbacks to customers

Consent order of injunction

Corporate Integrity Agreement
VI. INJUNCTION

A. AdvancePCS Disclosures

1. Relationships with Client Plans:

   (a) In any new contract with a Client Plan or in any amendment to an existing contract in which new terms and conditions (other than pricing terms and renewal dates) are negotiated and documented, AdvancePCS will use reasonable best efforts to:

   (1) adequately and clearly describe the products and services that will be delivered or performed pursuant to the Client Plan contract;

   (2) clearly define the obligations of AdvancePCS and the Client Plan under the contract;

   (3) define in clear terms words or phrases that are used in the contract with Client Plans to describe price;
(4) adequately and clearly describe the amounts to be paid by the Client Plan for products or services under the Client Plan contract;

(5) disclose, where applicable, to Client Plans that Client Plans may pay more or less for brand and generic drugs at retail than AdvancePCS reimburses retail pharmacies for said drugs;

(6) in any client contract that refers to MAC or uses MAC as a price marker, identify drugs comprising the MAC list applicable to the Client Plan at the time the contract is signed;
(d) **Client Plan Invoicing and Audits**

1. Invoices sent to the Client Plan for retail and mail prescription claims shall clearly identify the price to be paid by the Client Plan.

2. The Client Plan shall have access, upon request, to all information reasonably necessary to audit the price paid or confirm compliance with the terms of the client contract as specified in the Client Plan contract.
Manufacturer Payments

(1) AdvancePCS shall disclose to each Client Plan with an existing contract, and to each prospective Client Plan in advance of or upon entering into a contract with such Client Plan:

i. that AdvancePCS will solicit and receive Manufacturer Payments and that AdvancePCS may pass through those payments to Client Plans or may retain those payments for itself, depending on the contract terms and whether the payments are attributable to the Client Plans; and

ii. that AdvancePCS will report, quarterly and annually, on
B. Payments to Clients

1. In any new Client Plan contract or in any amendment or renewal of an existing Client Plan contract, AdvancePCS shall not pay implementation or development fees and/or credits to a Client Plan unless such fees and/or credits to a Client Plan meet all of the following requirements:

(a) Payments are for legitimate, necessary and commercially reasonable services related to the transition, administration or implementation of the client/payer contract, related to the purchase by the client/payer of clinical or other services offered by AdvancePCS or related to purchase discounts offered by AdvancePCS to the client/payer.

(b) Services provided shall be clearly and adequately described and documented.

(c) Payments paid for services provided shall be at fair market value.
C. Relationships with Pharmaceutical Manufacturers

1. With respect to any new contract with a pharmaceutical manufacturer or in any renewal where a new base contract is negotiated with a pharmaceutical manufacturer, AdvancePCS agrees that the terms of the contract shall clearly and accurately describe and differentiate, where applicable, the following payments:

(a) Discounts;
(b) Rebates;
(c) Administrative fees paid by the manufacturer;
(d) Fees for services provided by AdvancePCS to the manufacturer;
(e) Fees received for the sale or provision of utilization data; and
(f) Any other payments paid to or received by either party.

2. AdvancePCS agrees that rebates received from any manufacturer shall be supported by the submission of claim utilization data for each product for which a rebate is claimed so that the pharmaceutical manufacturer can determine the amount paid by product.
MEDCO SETTLEMENT

- $155 million recovery
- Consent order of injunction
- Corporate Integrity Agreement
MEDCO HEALTH SOLUTIONS

- Provides prescription services for government and private beneficiaries
  - Federal employees, families, and retirees in Blue Cross and Blue Shield and other experience-rated insurance plans
  - Federal employees, families, and retirees in community-rated managed care plans
  - Medicare
  - These programs and private plans contract with Medco to manage their pharmacy benefits
WHO ARE THE CUSTOMERS OF PBMS

- Bellybuttons? (Beneficiaries)
- Employers?
- Health Care Plans?
- Who’s paying the bills?
- Who’s negotiating the contracts?
WHAT DO THE PBMS PROMISE THEIR CUSTOMERS?

- Cost-effective pharmacy benefit management
- State-of-the-art mail order prescriptions
- Industry-leading customer service
LEGAL FRAMEWORK

- False Claims Act, 31 U.S.C. Sections 3729-3733
- Medicare Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b)
- Stark Law, 42 U.S.C. Section 1395nn
- Theft or Bribery Concerning Programs Receiving Federal Funds (criminal) 18 U.S.C. Section 666
WHAT DID WE FIND WHEN WE LOOKED AT PBMS?

- Limited ability for plans or government to measure cost-effectiveness
  - “average” discount off average wholesale price (and selection of highest AWP)
  - No actual reporting of price of each prescription (done as “estimate” to prevent effective audit)
- Design of computer and personal interface to prevent effective audit
- Lack of incentive of experience-rated plans to audit
- Side deals for community-rated plans
- Limited authority until 2004 for subcontract audits
WHAT DID WE FIND?

2. Poor financial controls/reporting
   - Were prescriptions actually received and in usable condition? “early” refill due to loss in mail”/address changes/thefts/refrigerated goods
   - Were returned prescriptions credited to the program?
     - Mail order returns not delivered
     - Managed care prescriptions returned-refused
   - Did patients receive the number of pills ordered by their physicians?
WHAT DID WE FIND?

■ HEALTH CARE PLAN CONSULTANT/CONTRACTING ISSUES
  ■ Conflict of interest for consultants
  ■ Failure to recognize cost-drivers
  ■ Failure to understand or explain rebate process

■ HEALTH CARE PLAN AUDIT PROCESS PROBLEMS
  ■ Unsophisticated auditors
  ■ Sophisticated auditors banned
  ■ Audit limitations/non-disclosures
  ■ Relevant contracts withheld from auditors
  ■ Some provisions of contracts overlooked
WHAT DID WE FIND?

- PBM techniques to increase costs
  - Substantially higher prices for generics at mail order than at retail – if you’re a beneficiary, you can go online and compare
  - Manipulated MAC (maximum allowable charge) for generics
  - Switches to more expensive branded drugs
WHAT DID WE FIND?

- Mail Order service problems
  - Thousands of prescriptions cancelled at one pharmacy to meet turnaround requirements
  - False receive dates – tens of thousands of prescriptions
  - False error reporting to minimize error calculation
WHAT DID WE FIND?

- Drug Utilization Review problems
  - Reliance on automated system rather than pharmacist judgment
  - Purchased DUR system from First DataBank – but edits turned off
  - Limited pharmacist access to pharmacy SOPs
  - No mechanism to alert pharmacists when automated DUR stopped working
WHAT DID WE FIND?

CUSTOMER SERVICE PROBLEMS

- “It’s in the mail”
- False reports about waiting times, dropped calls
- False reports about identified problems
- False information to beneficiaries
- Holds, transfers, extra co-pays
- Ineffective contract or regulatory oversight
OTHER KEY COMPLIANCE/AUDIT ISSUES

- Process to identify claims for drugs prescribed by deceased or excluded provider and/or dead patient

- Disciplined or excluded pharmacists

- Certification and process to remove all excluded pharmacies, pharmacists, and excluded employees and board members “and take appropriate remedial actions”
OTHER KEY COMPLIANCE/AUDIT ISSUES – cont’d

- Did the patient actually receive this prescription?
- Is this the right patient?
- Process to identify overpayments and underpayments at any level of network, and report and repay overpayments
- Process for full disclosure on request of all pricing decisions, related data and pricing records. This includes contract entities.
WHAT TO LOOK FOR

READ ALL THE CONTRACTS

- They will not make it easy; PBMs are becoming more transparent as a result of litigation and some state statutes
- Check for audit rights and information retention policies
- Contract between PBM and health care plan or insurance company
- Contract between health care plan or insurance company and government or employer
WHAT TO LOOK FOR

READ ALL THE CONTRACTS

- Contracts between PBM and drug manufacturers
  - Formulary placement
  - Rebates – “Market Share” “Formulary” “Book of Business”
  - Disease Management plans
  - Data selling plans
  - Implementation allowances
WHAT TO LOOK FOR

- Look at pharmacy data as well as financial data
  - Reconcile number of prescriptions mailed and number of prescriptions billed
  - Reconcile number of prescriptions mailed/billed and number of orders received
  - Reconcile returns, credits, refunds
  - Error data – Is it maintained? Is there a mechanism for reporting? Is PBM complying with state pharmacy law regarding reporting of external errors?
WHAT TO LOOK FOR

- Look at pharmacy data as well as financial data
- Can you determine the price paid by the plan and the beneficiary for a specific prescription?
- Does the co-pay structure induce beneficiaries to select more expensive (to the plan) drugs?
- Is accurate information on price and co-pays available to beneficiaries and prescribing physicians?
WHAT TO LOOK FOR

- Look at pharmacy data as well as financial data
  - Is there a mechanism in place to refund co-pays for drugs that are not received by beneficiaries or are returned by beneficiaries?
  - Is there a mechanism in place to refund plan payments when beneficiaries return or do not receive drugs?
  - Is there a mechanism in place to determine whether Drug Utilization Review has been performed on a given prescription?
WHAT TO LOOK FOR

- Look at pharmacy data as well as financial data
  - Is there a mechanism in place to determine whether patients actually received their drugs?
- Patient complaint records
  - System of retention of complaints
  - Records of customer service responses
  - Pattern of complaints – for example: shorting, switching
  - Complaints alleging injury
WHAT TO LOOK FOR

- Electronic Data
  - Does software catch:
    - Double billing
    - Failure to refund both plan and beneficiary
    - Pricing mistakes
    - Failure to perform DUR
    - Deletion or disappearance of mailed prescriptions
    - Secondary payor mistakes
WHAT TO LOOK FOR

- Failure to certify
- Lack of effective compliance plan
- Compliance program in legal department
- Incentives to cheat
  - Rewarding employees for meeting unrealistic productivity goals
  - Punishing employees for spending too much time on prescriptions, record keeping, compliance
  - Quotas/goals
MANUFACTURER DOLLARS to PBM

- Rebates
- Access rebates
- Market share rebates
- Administrative fees
- Money for incentive and intervention programs
- Data fees
- Disease/patient management programs
PLAN DOLLARS to PBM

- Dispensing fees
- Per claim administrative fees
- Money for incentive and intervention programs
- Disease/patient management programs
PBM DOLLARS to PLAN

- Lower costs
- Percentage of rebates (which ones?)

Diagram:

- PBM product
- $Plan Dollars to PBM$
- $Manufacturer Dollars to PBM$
MEDICARE PART D: SOMETHING TO LOOK FORWARD TO

- Medicare Advantage Prescription Plans for Medicare Managed Care patients (20%)
- Prescription Drug Plans for traditional Medicare beneficiaries (80%)
MEDICARE PART D

- Major Players
  - Aetna, Independence Blue Cross, AARP, United, Humana, Highmark
  - Medco, Caremark
  - Drug manufacturers
WHERE ARE THE STANDARDS?

- CMS PRESCRIPTION DRUG BENEFIT MANUAL-CHAPTER 9-PART D PROGRAM TO CONTROL FRAUD, WASTE, AND ABUSE issued 4/25/06

- CMS FRAUD MANUAL-

- 71 pages of Implementing 42 CFR 423.504(b)(4)(vi)(H)

REQUIRED BY LAW-
COMPREHENSIVE PLAN TO
DETECT, PREVENT AND
CONTROL PART D FRAUD

- Medicare Advantage Compliance Plan
  required by MA regs
- Medicare Part D required 1/1/07 by Part D regs
QUESTIONS FOR PART D
PLANS AND PBMS

- DO YOU HAVE A DEDICATED AUDIT UNIT?
  ANNUAL AUDIT PLAN? VULNERABILITY ASSESSMENT?

- DO YOU DO FIELD AUDITS? WHAT HAPPENS TO THE PROCEEDS?

- DO YOU HAVE A CLAIM SAMPLING PROCESS?

- DO YOU OBTAIN REFUNDS OF ALL CLAIMS IMPROPERLY PAID?
MORE PART D PLANS AND PBM QUESTIONS

- HOW MANY PHARMACIES/PHARMACISTS WERE NOT ADMITTED/EXCLUDED FROM YOUR NETWORK LAST YEAR? WHY?
- DO YOU CAPTURE ATTEMPTS (NEAR MISSES)?
- WHAT DO YOU DO WITH BILLING FOR RETURNED GOODS?
- DO YOU TAKE MONEY FROM DRUG COMPANIES? WHAT FOR?
- DO YOU HAVE A FRAUD CONTROL SYSTEM FOR BENEFICIARIES?
WEBSITES YOUR AUDITORS SHOULD KNOW ABOUT

- NABP (National Association of Boards of Pharmacy) - www.nabp.net
- FDA counterfeit drug initiative – www.fda.gov/oc/initiatives
- CMS - www.cms.hhs.gov/pdps
- OIG exclusions list - http://oig.hhs.gov/fraud/exclusions/listofexcluded.html
WEBSITES YOUR AUDITORS SHOULD KNOW ABOUT cont’d

- YOUR STATE BOARD OF PHARMACY website
  - Statute
  - Regulations
  - License Suspensions/revocations/discipline/
  - Inspections (both pharmacist and pharmacies)
  - Newsletters
DISCLAIMER

- My own opinions and impressions – not DOJ or U.S. Attorney policy

- Thank You