Focus:

Techniques used by insurers and PBMs to control or influence drug use and costs

- Insurer controls over drug choice
- Prescriber controls
- Pharmacy/pharmacist controls
- Patient controls

Emerging technologies affecting drug prescribing, use, and patient behavior.

The insurer/payer dilemma. Which is better: integrated or separately managed HC plans?

Cost containment tools used by insurers

Controls on prescribing
  - Drug formularies
  - Preferred drug list
  - Prior authorization, sometimes linked to step therapy protocols
  - Patient co-payments and deductibles.
  - E-prescribing
  Conditions sometimes excluded: HIV/AIDS, hepatitis C, ESRD, cosmetic care, off-label use

Retrospective DUR: Identifies high use, high cost, high prescribing

Note the focus on drug prescribing and use
Insurer/PBM perspective... challenges

- Highly competitive market
- Industry consolidation
- Bids won on lowest fee structure

Rx cost is fastest growing segment

Brand Rx ~$130+, Generic: ~$30+

Rx cost drivers:

\[ [\# \text{Rx/pat.}] \times [\text{cost/Rx}] - [\text{patient copay}] + [\text{ingredient cost}] + [\text{qty disp.}] + [\text{disp. Fee}] \]

Targeted areas for Drug cost/quality Control

- Prospective
- Concurrent
- Retrospective

Medicaid Pharmacy Management Policies (Selected Indicators) (percentage of states reporting)

- Dispensing Limit by Quantity per Prescription
- State has PDL
- Any Prior Authorization
- Generics Required by State Law
- Co-Payment for Rx
- State Receives a Supplemental Rebate

SOURCE: KOMU state Medicaid prescription drug survey conducted by the Health Policy Institute, Georgetown University (2005).

NOTES: Based on survey responses from 37 states in 2005, 45 states in 2003, and 44 states in 2000. Not all states responded to each question.

Hard Limits vs. Soft Limits (percentage of states reporting)

- # of Refills
  - No Limit: 57%
  - Drug Denied: 5%
  - PA or Other Action: 38%

- # of RX
  - No Limit: 87%
  - Drug Denied: 11%
  - PA or Other Action: 22%

SOURCE: KOMU state Medicaid prescription drug survey conducted by the Health Policy Institute, Georgetown University (2005).

NOTES: Based on survey responses from 37 states in 2005. Hard limits result in the drug being denied when the limit is reached, whereas soft limits result in prior authorization or other type of review and additional prescriptions can be dispensed with sufficient clinical justification. 2 of 41 states with limits on the number of refills have hard limits and 4 of 12 states with limits on the number of prescriptions per month have hard limits.
Two components for optimal drug therapy

Prescribing decision → Optimal drug choice for disease state?

Disease Prevented?

Patient behavior appropriate?

Clinical outcomes → Disease Controlled?

Med Care Utilization

Policy Q: Does a near exclusive focus on optimizing drug choice deliver optimal drug-related medical care?

Controls on drug ingredient cost

- Drug eligibility
  - Restrictive drug formulary
  - Soft formulary: “Preferred” drugs
  - Preferential coverage of generics

- Methods
  - Formulary listing (booklet, handheld device)
  - Prescribing guidelines
  - Preferred drugs by therapeutic class
  - Prior authorization
  - E-prescribing (pre-clearance at the time of the drug order)

Bidding with drug manufacturers for best price

How can a health plan/PBM make formulary coverage decisions for NCE’s in a cost-effective manner?

- Should a formulary committee approve coverage of this drug under a Rx drug plan?

I am pleased to inform you that the FDA granted approval for Exforge HCT®, (Novartis), the only single-tablet available that combines the complementary actions of the angiotensin receptor blocker valsartan with the dihydropyridine calcium channel blocker amlodipine, and the diuretic hydrochlorothiazide, on April 30, 2009. Exforge HCT® is approved in the U.S. for the treatment of HTN and may be used as add-on/switch therapy for patients not adequately controlled on any two components of the triple combination.

- Up to 85% of patients have been shown to need multiple medications and many patients may need three or more to help control their blood pressure.

- The antihypertensive efficacy and safety of triple therapy with Exforge HCT® was evaluated in a large randomized clinical trial involving more than 2,200 patients. In the study, Exforge HCT achieved superior reductions in systolic blood pressure compared to all dual combinations of amlodipine, valsartan and hydrochlorothiazide, providing additional reductions of 18 to 29%. In addition, Exforge HCT can help patients reach their BP treatment goals, while offering convenience and potential cost savings by reducing up to three co-payments into one.

Formulary decision-making tools available to the insurer/MCO/PBM

- AMCP Format for Drug Formulary Decision-Making

- Evidenced-based reviews
  - e.g. Oregon Health Science Univ. DERP (supported by several state Medicaid programs
The Price Of Progress: Prescription Drugs In The Health Care Market  
JD Kleinke Health Affairs 2001

- "...we can draw one sad conclusion: Our current health insurance system is hopelessly out of step with the inevitable rotation of medical care delivery from services to technology.

- Federal and state laws regulating health insurance and provider risk sharing need to be revamped to encourage rather than constrain the social progress embodied in expensive, breakthrough medical technologies. “

Kleinke (cont.) A proposed re-classification of drugs

- **The fast-pays.** New drugs that lower short-term health care costs. They are a bargain vs. the cost of the services and chronic diseases that they delay, manage, or prevent. e.g., anticoagulant therapy for stroke: (lifetime costs average $100K, while anticoagulant therapy costs just $1,095 a year.

- **The slow-pays.** New drugs that decrease medical costs but only after several years. The clearest example is the new class of selective estrogen receptor modulators (SERMs), such as Evista (raloxifene). Although there are many conflicting data, they are promoted as helping to increase bone-mass density, reduce osteoporosis, and prevent costly hip fractures in the elderly—but only when taken years before any symptom onset.

- **The narrow-pays.** New drugs that decrease overall medical care costs for only a narrow clinical subpopulation and thus do not offset their aggregate medical costs. These drugs address clinical problems that are imprecise, difficult to diagnose, or highly prevalent with a broad range of symptom severity. e.g.: CHF, obesity, depression, diabetes, hyperlipidemia and vaccines that must be administered to large populations to prevent scant disease incidence and costs.

- **The diffuse-pays.** New drugs that increase medical costs but decrease non medical costs. e.g. flu vaccines, nonselecting allergy medications, SSRIs for mild depression, OCD and social phobia. Some economic value to employers via fewer missed work days.

- **The pay-me-laters.** New drugs that lower short-term health care costs but increase long-term costs. They embody the economics of smoking in reverse: e.g. Pulmozyme (dornase alfa, recombinant), for the treatment of cystic fibrosis, and Avonex (interferon beta-la), for MS, and AIDS drugs. In the absence of such breakthrough drugs, these horribly disabling diseases entail high rates of hosp. and palliative care.

- **The no-pays.** New drugs that do not save anybody money; they merely improve people's lives, e.g. Viagra, drugs to treat mild obesity, severe acne, toenail fungus, or overactive bladder.

Controls on prescriber choice of drug

**Consequence: prescriber inconvenience, resentment, “we vs them”**

Prior to prescribing (“soft controls”):
- Formulary booklets, preferred drug lists
- “academic detailing” accompanied by prescribing profiles and clinical guidelines
- Dear doctor letters from insurers or PBMs
- PDAs with drug lookup info (e.g., Epocrates), websites

At the time of prescribing: E-prescribing with screens
- Suggest preferred drug within a therapeutic class
- Notify if the drug is restricted (prior auth. required)
- Prospective DUR screening
  - Usual adult dose
  - Therapeutic duplication
  - Drug-drug interaction screening
  - Suggested monitoring criteria- e.g. flags for needed lab tests
- Restricted and specialty drugs (1-800 number, justification)

Prescriber financial controls

- Historically, few instances of controls or scrutiny on prescribing choice
- Closed panel HMOs: capitation payment systems provide prescriber incentives to use fewer or less costly treatment alternatives
- **P4P**: pay for performance. Incentives to conform to treatment guidelines, e.g. step therapy for target diseases, % generic prescribing, etc.

Q1: While this aligns financial incentives, does it lead to “cookbook” medicine, and is this bad?

Q2: Some plans have incentives/policies slow the adoption/use of newly patented drugs. Is this good policy from a patient perspective?
Pharmacy level: Historic controls on dispensing

Quantity dispensed:
- 30-34 day drug supply limit for most drugs
- Maintenance drugs: 90 day limit (after 2nd refill). Mail order
- Early refill limits (N.M.T. 7 days early)

Drug choice:
- Encourage preferred drug dispensing
- Encourage generic dispensing
- Restricted drugs (time barriers in the form of prior authorization, expedited PA)

Dispensing fees:
- Terms set by 3rd parties (Medicaid/insurers/PBMs) for basic dispensing services. “Take it or leave it”

Consequence: The pharmacist is the last stop in the drug delivery process. The Rx has become a commodity. Reimbursement is at or below cost of production for many pharmacies. Pharmacists have an economic disincentive to perform any value-added services that might slow Rx production.

Cost of drug related problems (DRPs)

- The estimated cost of DRPs has more than doubled over the past 5 years to an estimated $177 B (nearly $80 B in the ambulatory setting). For every $1 spent on drugs, an estimated $1.34 is spent on treating or resolving a DRP. 1, 2
- Drug-therapy problems include underuse, under-treatment, overuse or polypharmacy, suboptimal drug or dose selection, adverse drug events, and failure to receive or adhere to medications.

1 Johnson and Bootman, Arch Int Med 1995.

Controls on pharmacies, pharmacists: contemporary incentives to improve drug choice

Concurrent. At the time of dispensing
- Incentives to identify and resolve potential drug therapy problems at the time of dispensing (e.g., Outcomes Pharm. Care)
  - e.g. therapeutic duplic., drug interactions, compliance, suboptimal drug choice.
- Incentives to provide extra services to target patients with diseases such as diabetes. (e.g, Asheville projects, VA, others)

Retrospective
- Feedback via report cards: e.g. generic use rates
- Targeted patient case profile reviews: Medication therapy management services

Quality improvement requirements under the Medicare Modernization Act Part D (Rx)

- Drug utilization management programs
- QA measurements and programs
- Medication Therapy Management (MTM) programs
- Patient satisfaction surveys
- E-Prescribing programs
- Quality improvement organization activities (QIOs)

MTM: Policy decision to selectively target patients presumably at highest risk for sub-optimal Rx therapy
Pharmacy Quality Alliance Proposed quality measures: Diabetes

<table>
<thead>
<tr>
<th>Measure Title</th>
<th>Measure Description/ Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOSING</td>
<td>% of patients receiving an oral hypoglycemic agent at higher than recommended daily doses</td>
</tr>
<tr>
<td>Denominator:</td>
<td># adults with 2+ claims for an oral hypoglycemic agent who were continuously enrolled during the 6-mo. obs’ period</td>
</tr>
<tr>
<td>Numerator:</td>
<td># patients in the denominator who are on higher than recommended doses.</td>
</tr>
<tr>
<td>Duplication of therapy</td>
<td>% of patients who were dispensed 2+ medications in the same therapeutic class.</td>
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Optimizing drug use through clinical pharmacy services.

Policy Questions:
- Should these extra services be performed in real time or retrospectively?
- What are the measures of impact? (ECHO).
- Across the board or focused on target high risk patients? What are the measures of success?
- How does one differentiate the relative contribution of RPh vs. other HC providers?

Pharmacy report card

Cost containment performance measures (historic)
- Quantity allowed per Rx, Avg. cost per Rx
- % dispensed DAW, % generic to total
- % formulary drug /total drug dispensed
- Controlled substance dispensing patterns

QA performance measures (future?)
- Preferred drug dispensing within a therapeutic class
- Patient adherence to target drugs
- Adherence to Pharmacy Quality Assurance measures
- MTM for Medicare D patients: 2010 standards for MTM reviews

Measures of impact of pharmacist services
Are pharmaceutical care (MTM) services cost-effective?

- There is little published research to date which demonstrates the P-Econ benefits of PCS.
- Evidence does exist that clinical pharmacy services have + economic benefits... It is this evidence that, at present, supports the assertion that PC has potential to increase the value of pharmaceuticals in society by minimizing drug related morbidity and mortality.
- Well-conducted research is required to determine the economic impact of PC."

Plumbridge and Wojnar-Horton  *Pharmacoeconomics, 1998.*

(2)

“There is clear evidence across different settings for the effectiveness of PCS, continuity of care post-hospital discharge, and pharmacist educational services to consumers and health professionals. There is more limited evidence of the effectiveness in managed care clinics.”

There is some evidence that these interventions can decrease drug costs....Further studies are needed to establish how long savings are maintained and how frequently interventions should take place.


Benefits to cost ratio for pharmacist clinical services.

<table>
<thead>
<tr>
<th>Clinical service</th>
<th>B/C ratio</th>
</tr>
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<tbody>
<tr>
<td>P-ther. monitoring (hospital/clinic)</td>
<td>1.7 - 9.1 : 1</td>
</tr>
<tr>
<td>Disease state mgmt (hosp/clinic)</td>
<td>5.3-17.0 : 1</td>
</tr>
<tr>
<td>Academic detailing (phys clinic)</td>
<td>2.1 : 1</td>
</tr>
<tr>
<td>Patient education (VA, clinic)</td>
<td>5.7:1</td>
</tr>
<tr>
<td>Target drug program (hosp)</td>
<td>1.6- 8.0 : 1</td>
</tr>
</tbody>
</table>

*Schumock et al, 2003*

Controls on patient drug use

- Patient Rx/month limit.
- Modified limit: e.g. n.m.t. 4 branded Rx dispensed.
- Tiered copayments
  - Tier 1: generics: lowest tier ($10/Rx)
  - Tier 2: Preferred brand ($20-$25)
  - Tier 3: non-preferred brand ($40-$50)
  - Tier 4: lifestyle choice, cosmetic drugs: *often no coverage*.
- Patient incentives to engage in healthy living behaviors.
  - e.g., financial incentives to take health risk assessments online, and to access personal health info.
Insurer/PBM perspective: Cost of single source, innovator, and generic prescriptions

<table>
<thead>
<tr>
<th>% of Rx disp</th>
<th>% of Rx total cost</th>
<th>Avg cost/ Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single source (brand)</td>
<td>28.7%</td>
<td>71.3%</td>
</tr>
<tr>
<td>Innovator (1st generic on the market after patent expiration)</td>
<td>2.9%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Generic</td>
<td>68.4%</td>
<td>24.7%</td>
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Tiered copayments...are they the best way to control health plan costs?

Consider:
- They are blunt instruments based on (relative) drug costs.
- Does shifting the cost burden to patients in this manner adversely affect patient health or use of health care services?

Pitney Bowes study: Which enrollees had the greatest increases in total medical care use and costs?

Finding: enrollees with asthma and diabetes with Rx’s refilled less than 2/3 of the time had the highest medical cost increases.

Results used to restructure their tiered Rx formulary plan

An alternative approach to structuring tiered copayments for Rx drugs (Pitney Bowes)

2001 decision: change from a fixed copayments to co-insurance rates of 10%, 30%, 50%.
- 10% for generics AND all asthma and diabetes meds
- 30% for preferred brand
- 50% for non-preferred brand name products

Result:
- Drug costs: 4% lower than national avg. (11% vs 15%).
- Diabetes: median medical costs decreased by 12%.
- Asthma: median medical costs decreased by 15%. (Rx: 10% less). Fewer rescue medicine use. Also, fewer ER visits, hospitalizations, & office visits.

WSJ 5/10/04

Evolving technology in medical and pharmaceutical care delivery

**Pharmacy Level**
- Process refills by phone
- Dispensing robots
- Accept refills via internet
- Mailed refill reminders to patients
- Telephone call to patient

**Physician/ Medical clinic level**
- Mailed appt reminders from provider
- Online personal health records (Rx meds, visit hx, diagnoses, lab tests)
- Make appts and request refills online
- Followup visit info via email

**Insurer/ 3rd party Providers**
- Internet-based:
  - Drug& disease lookup, healthy living advice

**Interactive communication**
- Outreach via: telephony, email, personal phone call
Examples of patient based health promotion/disease management programs

- Web-based alone (e.g., Microsoft HealthVault, WebMD, Google, others)
- Web-based + email (e.g., WorldDoc)
- Telephonic (e.g., Varolii)
- Clinical pharmacist (e.g., UW-SOP MAP program)

How HealthVault works for pharmacies and PBMs

Pharmacies that connect with HealthVault can enable users to track their medication usage and prescription status and use their data in Web health applications that work with HealthVault. Medication data can be digitally signed to enhance trustworthiness. Pharmacy Web sites can be expanded to include health-monitoring tools and HealthVault-compatible devices that can drive customer satisfaction and loyalty.

Better customer experience

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Deliver more integrated services

For PBMs, HealthVault can make it easier for users to collect thorough medication information and share it to help their healthcare providers manage medications, prescriptions, mail-order fulfillment and other patient services.

If you’re ready to connect to HealthVault, contact the HealthVault business development team:

Aetna to offer records in Microsoft HealthVault

Associated Press October 22, 2008

- INDIANAPOLIS -- Health insurer Aetna Inc. is becoming the first health insurer to team with Microsoft Corp. to give its customers an Internet-based vault for storing medical records they can access even if they change jobs or leave their health plan.
- Starting next month, Hartford, Conn.-based Aetna will allow some customers to transfer electronic personal health records to Microsoft’s HealthVault, a platform that lets care providers look at the information, if they have patient permission.
- The vault will give the insurer’s customers “continuous access” to their claims information and anything the patient wants to add, like clinical data or past medical records, Aetna President Mark Bertolini said.
- We can avoid duplicate testing, we can avoid mistakes that occur as a result of not understanding the member’s complete condition," he said. “Because we don’t have a national health information technology network, this will stand as a first-generation of that kind of capability."
- The announcement marks the latest step in a push by several companies into the storing and sharing of medical records.
Personal Care Engine: “Pushes” Information

- Integrate Medical and Rx claims into the WorldDoc Engine and “push” personal communications to members.
- Health gap identification
- Behavior change modules
- Incentives
- Clinical reminders
- Dynamic personal health record

WorldDoc 24/7
Used by Consumers
Symptom-to-Condition Evaluations
Chronic Care Management
Electronic Health Record
2-way communication with WD engine

WorldDoc Tx
Used by Nurses:
Manage high risk population
Identify care gaps
Tracking, charting and reporting
Communication with patient

WorldDoc Rx
Pharmacy Benefit Management
Cost transparency
Consumer-centered applications
Drug value comparisons

Pharmacy section... drug search + services menu
Patient medication record - alert system

Personal health evaluation

Health risk assessments

Health risk assessment - Q: anxiety/depression
“My patient probably would have rather been anywhere else. He and his wife were in my office to discuss his erectile dysfunction for the first time.

He looked uncomfortable. For a guy who doesn’t go to the doctor much, a medical office can seem as foreign and intimidating as the dark side of the moon.

His exam was normal, but he needed to quit smoking. Would it have been easier for you to fill out a questionnaire on the Internet and skip the office visit? I asked. “You bet,” he replied.

The way I see it, he didn’t really need to come in at all. He needed a risk assessment for heart disease, a prescription for medication, counseling and help with stopping smoking. The results would have been the same online or in person.”

Q: What is the role of technology (internet, secure email) in reducing labor-intensive office visits?

Wrap-up

The drug insurance/PBM industry has historically focused on ways to control drug use and costs with little attention to the trade-off of appropriate drug use vs. use of other modalities of care.

Technology has a long history in pharmacy and Rx claims processing but the information collected has not been optimally used in DUR/QA.

E-prescribing has a great potential to place controls on prescribing in real time rather than at the pharmacy.

Until recently, little attention has focused on:

- QA controls, in the form of disease state-specific prescribing guidelines.
- influencing patient health and drug-taking behavior (e.g. adherence, self monitoring).

MTM under Medicare Part D is an important new policy in drug benefit management, as it represents a shift toward assuring optimal drug-related outcomes for target patients.

Further assessment of the impact of MTM as a policy awaits…