

Tools to Improve Pharmaceutical Management and Practices:

Medication Therapy Management and Patient Safety Initiatives

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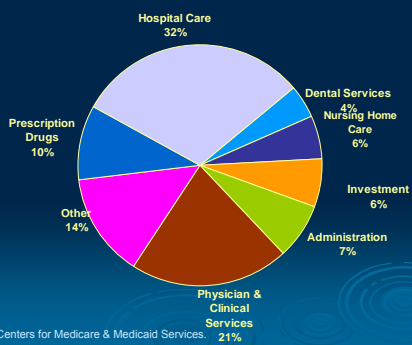
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Tools to Improve Pharmaceutical Management and Practices

- > Introduction
- > Medication therapy management
- > Adherence and Compliance
- > Patient safety initiatives

National Healthcare Costs in 2006

Total National Health Expenditures = \$2.1 trillion



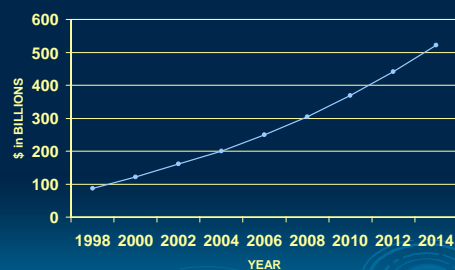
Source: Centers for Medicare & Medicaid Services

Rx Expenditures: % of Total Health Spending



Note: 2002-2012 data are projections
Source: U.S. Centers for Medicare & Medicaid Services (CMS)

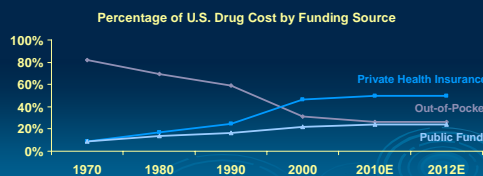
Prescription Drug Expenditure



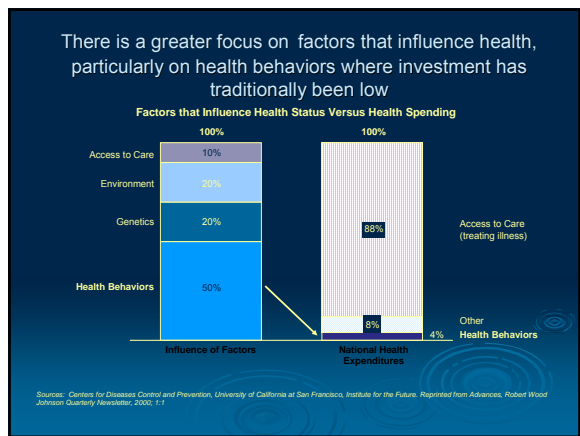
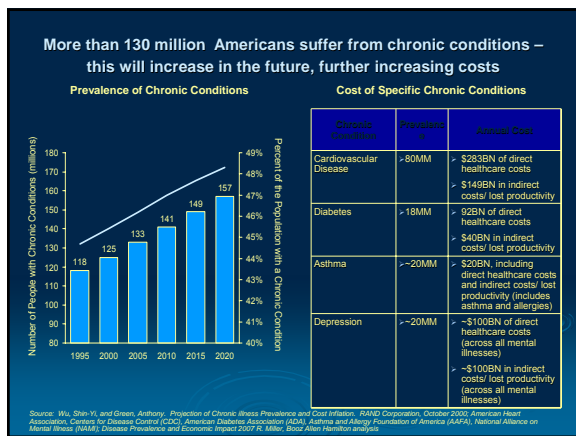
CMS National Health Expenditures Projections 2004-2014

Increased Utilization

- > Aging Population
- > Increasingly new and sophisticated technology



Note: 2002-2012 data are projections
Source: U.S. Centers for Medicare & Medicaid Services (CMS)



Drug Therapy

- > 70% of medication users today experience drug therapy problems
- > Drug therapy problems cost the U.S. health care system \$177 billion annually
- > Approximately 1.5 million preventable Adverse Events in US annually (IOM report)

Multiple Care Providers

- > About 38 million Americans ≥65 years old
 - 66% have ≥1 chronic condition
 - No chronic conditions visit 1.3 physicians
 - 1 chronic condition visit 4.5 physicians
 - 6 chronic conditions visit 9.2 physicians
 - Polypharmacy: average ≥5 medications each
 - Multiple providers coordinate care for 1 patient

Medication Related Problems

1. Drug use without indication
2. Untreated indication
3. Improper drug selection
4. Subtherapeutic dosage
5. Overdosage
6. Adverse drug reaction
7. Drug interaction
8. Failure to receive medication

> Costs Due to Drug-Related Problems

- \$76.6 billion in 1995 ¹
- \$177.4 billion in 2000 ²

1 Johnson JA, Boodman JL. Drug-related morbidity and mortality: A cost-of-illness model. Arch Intern Med. 1995;155:1949-56.
2 Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc. 2001;41:192-9.

Medication Therapy Management MMA 2003

- Medicare Prescription Drug Improvement and Modernization Act of 2003
 - Signed into law December 8, 2003
 - Addition of drug benefit provided by private prescription drug plans (PDPs)
 - Expansion of patient care services by pharmacists
 - Compensation for care
 - Medicare Part D began January 1, 2006

MTM Definition

- Medication Therapy Management
 - Part of outpatient pharmacy benefit
 - Purpose
 - *To optimize therapeutic outcomes for individual patients*

Medication Therapy Management Program (MTMP)

- A program of drug therapy management that may be furnished by a pharmacist to targeted beneficiaries and that is designed to assure that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.

Purpose of MTM

- Optimize drug therapies
- Reduce risk of adverse events and drug interactions
- Increase patient adherence and compliance
- Control health care costs

MTM Requirements

- Patient-specific and individualized services directly provided to patient by pharmacist
- Face-to-face interaction is preferred
- Opportunities to identify patients eligible for MTM services
- Payment of MTM services consistent with contemporary provider payment rates
 - Based on time, clinical intensity, resources required

MTM Programs

- Minimum standards defined by CMS but actual Program is at the discretion of the PDP
- Chronic conditions will be targeted but not dictated by CMS
- All patients meeting the minimum standards set by CMS must be offered MTM services

MTM Activity Options

- Assessing patient's health status
- Formulating medication treatment plan
- Selecting, initiating, modifying, administering medication
- Monitoring and evaluating efficacy and safety of therapy
- Documenting care and communication with other primary care providers
- Verbal education and training to patient
- Providing information, support, resources to enhance adherence to medications

MTM Eligibility Criteria

- Outlined by MMA 2003
- A beneficiary must meet **ALL** 3 criteria to be eligible for a PDP's MTM Program
 1. A beneficiary must have multiple chronic diseases **AND**
 2. A beneficiary must have filled multiple covered Part D drugs **AND**
 3. A beneficiary must be likely to incur annual costs of \geq \$4,000 for all covered Part D drugs (established by Secretary of HHS)
Ex. If a patient spends \geq \$1000 in a quarter, it can be assumed they will spend at least \geq \$4000 in a year

Examples of Chronic Conditions

➤ Examples:

- Asthma
- Diabetes
- Coronary artery disease
- Dyslipidemia
- Alzheimer's disease
- Cancer
- Liver disease
- Rheumatoid arthritis
- Hypertension
- Congestive heart failure
- Chronic pain
- Osteoporosis
- Behavioral health
- Hyperlipidemia
- GI disorders
- Renal disease

Pharmacy Providers in MTM

- Retail Pharmacists
 - Chains
 - Independent
 - Mail order
- Consultant Pharmacists
 - Patient's home
 - Assisted living
- Managed Care Pharmacists
 - Managed Care Organizations
 - Pharmacy Benefit Managers

Types of Programs to Enhance MTM Initiatives

- Possible Strategies Examples:
 - Improve medication adherence and compliance
 - Address poly-pharmacy
 - Improve patient safety
 - Educational mailings to beneficiaries and providers
 - Provide consultations to providers based on prescription histories
 - MTM for outpatient and Long term care facilities
 - Case management
 - Referral to Disease state management
 - Pyramid approach for less intense management

MTM Impact on Pharmaceuticals Industries

- Drug selection process for formulary
 - Comparative data
 - Clinical effectiveness
 - Safety (Adverse events, drug interactions)
 - Utilization patterns
 - Cost effectiveness
 - Generic availability
 - Tier placement
 - Open vs. closed formularies

MTM Impact on Pharmaceuticals Industries (cont.)

- Increase demand on Outcome studies
- Utilization management (step therapy, edits)
- Compliance and adherence
- Established vs. new therapies
- Pharmacoeconomic analysis
- Off label use of medications
- Increase demand for drugs used for chronic therapies

MTM impact on Pharmaceuticals Industries (cont.)

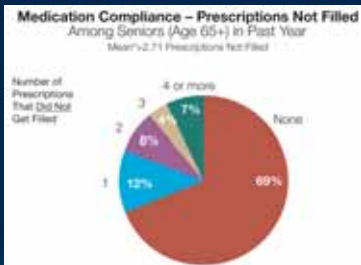
- Industry and MCO Collaborations on Outcome research
- Collaborations with Retail and Hospitals
- Collaborations in DTC and patient education
- Collaborations on adherence programs
- Joint reporting on Adverse events and side effects
- Identify treatment gaps in the elderly

Medicare Part D

- More than 39 million Medicare beneficiaries now receive comprehensive prescription drug coverage, including 1.4 million who enrolled in the Medicare Part D program since June 2006. (U.S. Department of Health and Human Services (HHS))
- Over 90 percent of all people eligible for the Medicare prescription drug benefit are receiving the prescription drug coverage they need. (CMS)
- Beneficiaries eligible for the Part D low-income subsidy (LIS) and those aging into the Medicare program can enroll in Medicare Part D without penalty in 2007.

Adherence and Compliance

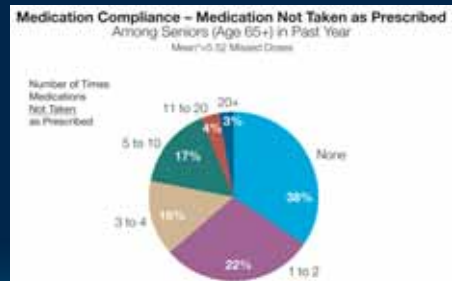
- Pharmacy and medical data used to identify non compliance
- Non-adherence is associated with significant inpatient and outpatient cost as well as poor clinical outcome
- Increase education and interventions required to improve awareness in the population



More than 3 out of 10 seniors did not fill all their prescriptions during the past year. On average, seniors did not fill nearly 3 prescriptions.

This represents a clear potential for health plans to improve these figures by reaching out to this population with adherence programs.

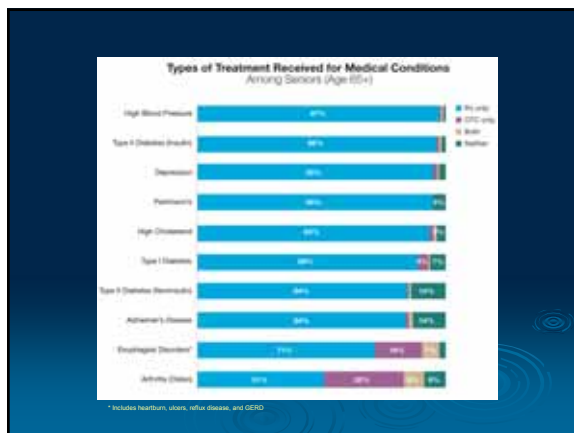
* Among those who did not fill all prescriptions



Sixty-two percent of seniors indicate that they missed a dose or took less medication than prescribed in the past year. Again, the opportunity exists to improve this performance with adherence programs through health plans and/or healthcare providers.

Q: During the past year, approximately how many times did you miss a dose, take less, or not take your medications as directed by your doctor or pharmacist?

* Among those who did not take all medication as prescribed

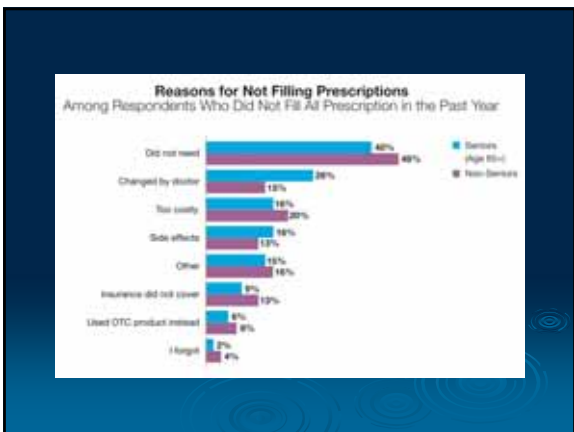


Adherence and Compliance

- Patients are identified for adherence by using Mean possession ratio (MPR)
- Gaps in therapy
- Stratification
 - MPR
 - Co-morbidities (e.g. Depression)
 - Polypharmacy
 - Early discontinuation

Adherence (cont.)

- Barrier analysis
 - Reasons for non-adherence
 - Time frames of non-adherence
 - Partner with the patient to improve adherence
 - Number of drugs
 - Clinical outcomes or goals effected by non-adherence
 - Customized interventions based on barrier analysis



Adherence (cont.)

- Interventions:
 - Provider and Member
 - Stratification
 - Telephonic
 - Letters
 - Faxes
 - Newsletters
 - Face to face counseling
 - Combination of interventions

Adherence (cont.)

- Measure the effectiveness of interventions
- Measure the outcome of the interventions
- Establish metrics examples :
 - MPR
 - Hospitalization
 - ER visits
 - Drug utilization
 - Office visit
 - Clinical goals e.g. HbA1c, LDL etc

Pharmacy Safety Initiatives: P&T Committee

- The P&T Committee meets quarterly to review information on the safety and efficacy of each drug considered for placement on the formulary, as either preferred or non-preferred status
- Existing drugs within each therapeutic class are reviewed for updated safety and utilization patterns on an annual basis.
- The P&T committee also reviews trending data, DUE's, and FDA issued drug recalls and makes recommendations for strategies to manage any new safety issues.

Pharmacy Safety Initiatives

- Utilization analysis of in-house Pharmacy and medical data.
- Early signals
- ER, hospital admissions
- E- Prescribing and other technologies

Pharmacy Safety Initiatives: Utilization Management

- **Prior Authorization**
 - Ensures the safety of the prescription medication for the member, achievement of preferred clinical outcomes, and improves the quality of the services, e.g. blood modifiers epogen and aranesp
- **Step therapy**
 - Use of established first line agents before going to second line agents, e.g. antibiotics

Pharmacy Safety Initiatives: Utilization Management

- **Dispensing Limitations**
 - Based on FDA approved package inserts, national utilization.
 - High dose in case of Narcotics to allow evaluation of appropriate therapy
 - Quantity vs. time limit

Pharmacy Safety Initiatives: Utilization Management

- **Drug Utilization reviews**
 - Drug-drug interaction
 - Therapeutic duplications
 - Drug-disease contraindications
 - Drug-age conflicts
 - Non-compliance/refill too late/refill Too Soon
 - Beers list
 - Under-utilization
 - Over-utilization
 - Off label use
 - Disease drug interaction

Pharmacy Safety Initiatives: Drug Utilization Evaluation (DUE)

- Lyrice - assess the incidence of concomitant Lyrica and Gabapentin use. Also, assess impact on opioid utilization pre- and post-Lyrica initiation.
- Diabetes Dyslipidemia - improve the utilization of antihyperlipidemic agents among members identified with diabetes
- Asthma - improve utilization of long-acting controller medications
- Actos & Avandia - identify use of these drugs in CHF patients, a boxed warning, and intervene with the prescribing physician
- Antidepressants - identify non-adherent members and notify the physician
- Acetaminophen dose of >4gms per day
- Suboxone use of opioid before and after suboxone use

Pharmacy Safety Initiatives: Drug Utilization Evaluation (DUE)

- **Inappropriate Medication Use in the Elderly** - increase awareness and reduce prescribing of targeted drugs known to be harmful in the elderly
- **Beta Blocker & ACE/ARB use in Heart Failure** - identify members with heart failure who may benefit from the addition of a beta blocker or ACEI/ARB medication to their medication regimens
- **Polypharmacy in the elderly** - identifies members >65 years old currently filling >15 medications per month and notifies physician of the increased risk of adverse effects and duplications in therapy.
- **Osteoporosis** - identifies members using chronic glucocorticoid therapy without concurrent osteoporosis preventative medication (ie. bisphosphonate)
- **Diabetes Nephropathy** - identifies members with diabetes not receiving current ACEI or ARB therapy
- **Byetta** and off-label use for Obesity

Pharmacy Safety Initiatives: Member Utilization Management Program

- Horizon's pharmacy claims (along with supporting medical data) are analyzed quarterly to identify potential medication abuse and fraudulent claims for appropriate intervention.
- Claims are run through utilization-based clinical rules specifically designed to identify, document and correct or deter cases of potentially excessive or abusive utilization.
- The current drug list of drugs are Narcotics, Growth Hormones, CNS stimulants.
- Members may be referred to either Horizon medical case management for further monitoring or additional intervention purposes, or Horizon's fraud investigation unit for additional intervention and investigation.

Pharmacy Safety Initiatives: Clinical Consultants

- Conduct educational, in-person visits to network physicians to guide clinically appropriate drug therapies
- Influence prescribing behaviors and provide physicians with current, objective drug information
- Discuss drug safety issues with the physicians including new drug warnings, drug interactions, and patient adherence to chronic medications, duplicate therapy

Pharmacy Safety Initiatives

- Evaluation of new online disease management program and its effect on medication adherence.
- Asthma DM program
 - Pharmacy identifies members over-utilizing quick acting inhalers and lacking long-term controller medications for intervention by case managers.
 - Clinical consultant pharmacists visit the physicians of the members identified to reinforce the current treatment guidelines and recommend a change in the member's medication therapy.
- Identification of members with poor medication adherence (MPR<80%) through pharmacy claims and intervention using member and physician targeting (currently done for the CHF and Hypertension programs)

e-Prescribing

- **Adherence Improvement Messaging (AIM) Program** - using e-prescribing tools to deliver point of care messaging to physicians and IVR outreach to members. Research findings: 35 – 60% of prescriptions for cardiac and pulmonary drugs are not being filled (paper submitted to *Health Affairs*, collaboration with Merck & Co, Inc)
- **E-Lab Pilot**: program to support increased use of e-lab by our network physicians.

e-Prescribing (cont.)

- **E-Prescribing** - over 1,400 New Jersey physicians installed with e-prescribing technology and over 2.5 million prescriptions written
 - Creates legible prescriptions which have been checked for formulary compliance
 - Can print Rx in office or send directly to patients' pharmacy
 - Provides drug-drug interaction alerts
 - Provides drug-allergy interaction alerts
 - Provides duplicate therapy alerts
 - Allows prescribing of medications and dosing which are currently available
 - Provides reporting capability to quickly identify patients who have been prescribed a recalled drug
 - Provides drug safety alerts for elderly patients based on Beers criteria
 - Can prompt for enrollment into disease mgmt programs
 - Can remind physicians to prescribe aspirin for patients greater than 50 years old
 - Reduces administrative burden on physician office and pharmacy staff
 - Prompts for lower cost and/or generic alternatives, therefore decreasing costs for members which can indirectly increase compliance

Research Collaboration for Patient Safety

- **Collaborations with major academic research groups to facilitate clinical research:**
 - Use of Thiazolidinediones (TZD's) in members with Cardiovascular disease.
 - Assessing risk of fracture in members using Beta Blocker, Selective Serotonin Reuptake Inhibitors (SSRIs), Proton Pump Inhibitors (PPIs), antiepileptics, and non benzodiazepine sedative medications
 - Identify the prevalence of use of drugs with black box warnings in the elderly population
 - Evaluation of improved prescription labels on medication adherence and adverse events
 - Prescription Drug Utilization Among Obese Children and Adolescents
 - Translating Research Into Action for Diabetes (TRIAD)- a national multi-center study that was created to determine how managed care systems influence the processes and outcomes of diabetes care
 - Evaluation to compare pharmacy utilization, medical utilization, total healthcare and pharmacy expenditures and member cost sharing for Medicare beneficiaries with selected chronic disease states who were enrolled in the Medicare Choice benefit in 2005 and then switched to a Medicare Advantage Part D plan in 2006

Safety Initiatives (cont.)

- ICERx -our members' prescription medication information is available thru an online resource called ICERx in the event of a disaster. This online resource provides licensed prescribers and pharmacists caring for disaster victims secure access to a patients' medication history.
- RxHub MEDS (Medication and Eligibility Delivery Solution) - provide hospitals with funding to connect to RxHub allowing physicians treating patients in an inpatient setting access to outpatient prescription drug history electronically. Helps hospitals meet JCAHO's new medication reconciliation requirements

Future

- More partnership between patients and a health care provider.
- Using Technologies in prescribing and Monitoring medication
- Labeling requirements and advertising limits for new medications
- Clarified authority and additional enforcement tools for the agency
- Clarification of FDA's role in gathering and communicating additional information on marketed products' risks and benefits

Future

- Mandatory registration of clinical trial results to facilitate public access to drug safety information
- An increased role for FDA's drug safety staff
- A large boost in funding and staffing for the agency