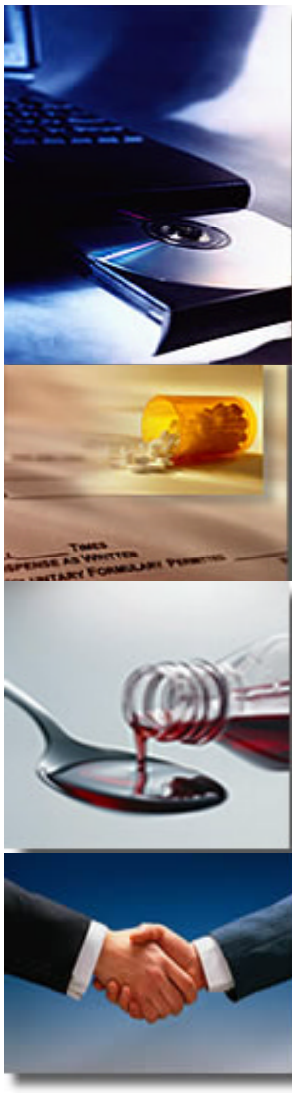

DHS Presentation

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Medicaid

Medicaid Fast Facts:

- Established in 1965 by Title XIX of the Social Security Act
- Jointly funded by the federal government and the states
- Covers a wide range of medically necessary services
- Members must fit into one or more "eligibility groups" and meet qualifications regarding income and residency

Medicare / Medicaid Dual Eligibles

- Medicaid is the "payor of last resort"- if a member has other insurance or is eligible for Medicare-they pay first, Medicaid pays what they don't.
- "Dual eligibles" are individuals who are entitled to Medicare and are eligible for some form of Medicaid benefit. (all of those over age 65 and some disabled.)
- For people who are eligible for full Medicaid coverage, the Medicaid program supplements Medicare coverage. Medicare Part D covers nearly all drug cost.
- When Part D came into effect, it reduced the Medicaid drug budget by roughly half.

Iowa Medicaid
A Few Figures

- SFY 2008 Average Monthly Eligibles: 337,282
- Average Monthly Dual Eligibles: 58,914
- Nearly 2/3 are children (< or = 21 years old)
- Nearly 2/3 of members use the drug benefit each month
- SFY 2008 drug expenditures $233M

Outpatient Prescribed Drug Program

- Prescribed Drugs are "optional" services through TXIX.
- If a state provides this service they must cover **all FDA approved prescription drugs** for which a rebate agreement has been signed.
- OBRA 90(§1927)- established the drug rebate program which requires all manufacturers to provide a rebate on each of their drugs if they want their drugs to be available to Medicaid members.
- Section 1927(d)(1)(A) permits States to subject any covered outpatient drug to a **prior authorization** (PA).

Why are Drug Rebates important?

- Up to 2001, the **mandatory** federal drug rebates returned 20% of every dollar spent on drugs to the State.
- Due to several factors including the DRA (Deficit Reduction Act), the Iowa Preferred Drug List (PDL) design, and supplemental rebates, the State now receives over 40% back of every drug dollar spent.
- The rebate agreements are confidential Federal law.

PDL and PA
Savings by SFY

SFY	Total Savings	State Savings
SFY 08	$74.5 Million (Projected)	$28.5 Million (Projected)
SFY 07	$42.3 Million	$15.9 Million
SFY 06	$42.3 Million	$15.4 Million
SFY 05	$19.7 Million	$ 7.2 Million

Note: For SFY 05 the total savings represents only six months of the program.

Pharmacy Benefit Cost Drivers

- Manufacturer price increases outpacing inflation
- Marketing induced switches to newer costly brands
- New treatments for conditions w/o prior therapy
- New add-on drugs for polytherapy of more and more conditions (2 or 3 simultaneous drugs for diabetes, hypertension, asthma, allergies, HIV)
- Poorly supported off-label drug use
- Wastage (antibiotics for viruses)

Pharmacy Benefit Cost Controllers

- Medicaid can set (reduce) reimbursement rates
- Medicaid can determine if a drug is medically necessary via prior authorization
- Medicaid can set limits on quantities, days supply, number of drugs
- Medicaid can shift utilization with PDL to preferred drugs (including lower priced generics) and away from non-preferred
- Medicaid can solicit supplemental rebates
- Medicaid can educate prescribers (DUR program)

One Pharmacy Controller Missing

- Medicaid has nominal co-pays (maximum of $3.00)
- Medicaid co-pays are not mandatory
- Many Medicaid members are exempt from co-pays
- Commercial programs can encourage generic drugs with large co-pay differences between brand and generic drugs

Drug Prior Authorization (PA)

A Prior Authorization:

- implements prescribing or practice guidelines
- requires the prescriber to obtain approval in advance
- is designed to assure that the most economical & appropriate drug therapy is used only as long as it is medically necessary
- has been used by Iowa Medicaid since October 1992

Cost Containment for Generic Drugs

- In Medicaid, generic drug cost containment revolves around two programs: the Federal Upper Limit (FUL) and State Maximum Allowable Cost (SMAC) programs.

- A generic drug is a drug which is exactly the same as a brand name drug and whose active ingredients, safety, dosage, quality and strength are identical to that of its brand-name counterpart.

Federal Upper Limit (FUL)

- Established in 1987, the FUL program requires the Centers for Medicare and Medicaid Services (CMS) assign upper-limit prices for certain generic drugs and requires the State to implement these reimbursement rates.

- The concept of the upper limit program is to achieve savings by taking advantage of the current market prices.

State Maximum Allowable Cost (SMAC)

- The 2001 Human Services Appropriations Bill (HF 732, Section 31) required the DHS to implement a SMAC list for prescription drugs.

- The Iowa SMAC program was implemented January 13, 2003 and the estimated costs avoided due to implementation through SFY 08 are $70 million total (state and federal) dollars.

- SMAC programs publish lists of selected generic drugs along with the maximum price at which Medicaid will reimburse. An important difference between SMAC and FUL is SMAC lists contain more drugs and assign lower prices than the FUL list. SMAC programs have greater flexibility in setting drug prices and are more reactive to marketplace changes than the FUL program.

Preferred Drug List (PDL)

- The PDL was implemented January 15, 2005
- Preferred drugs: clinically and/or economically superior choices
- Non-preferred drugs: require authorization prior to dispensing
- Goals:
  - maximize the number of people using the most cost-effective drugs
  - preserve drug benefit

Supplemental Rebates

- Under a PDL, States negotiate with manufacturers for rebates. "Supplemental Rebates" over and above the mandatory (OBRA) rebates.
- The drug rebate statute allows a State to enter directly into agreements with a manufacturer with CMS approval.
- States may require PA as a means of encouraging drug manufacturers to enter into supplemental rebate agreements for their covered drugs.
- Concomitant with the implementation of the PDL in January 2005, Iowa began the supplemental drug rebate process.

PDL Objective

- A functional PDL that will save money in the drug budget, avoid losing money in the non-drug budget and can be improved over time in successive stages
- Matched with a strong PA system that is responsive to member and provider needs
- PA's originate at the prescriber level through a fax-driven system

PDL Basics

In many PDL categories:

- Although there may be many differences in individual responsiveness to any one given product, the majority who eventually respond to any drug in the category will respond to the first drug tried

- Law of diminishing returns can be validated with utilization data

How the PDL was Constructed

- Published, peer-reviewed clinical trials
- Placebo controlled randomized trials most valuable
- Efficacy,adverse effects, tolerability
- Relative therapeutic values of choices
- Economic analyses modeling of Iowa Medicaid utilization data
- Net costs considering all rebates
- Cost/benefit ratios including PA

Three Keys for PDL Status

1. Does manufacturer have proof that their product is clinically better/safer than preferred choices for the majority of the Medicaid members-not just subpopulations?

2. Can manufacturer demonstrate that their product is as or more cost-effective than the preferred choices?

3. If the above cannot be shown, then focus on what PDL criteria should be in order to access the product via the PA process.

Generics on the PDL

- Generics usually cost 10 to 90% less than brand drugs.
- Mandatory CMS rebates can sometimes cause some brand drugs to cost much less than generics.
- A few brand drugs are even free to Medicaid (the rebate received exceeds the amount paid to the pharmacy).
- The lesson for state Medicaid programs is they must follow their final net prices after all rebates and not the pre-rebate prices of drugs paid to the pharmacy.
- We can cost-avoid millions of dollars by selectively favoring these more cost-effective brands and shunning the more expensive generics.

Maintaining a PDL

- Meet deadlines
- Reject inadequate offers
- Make tough choices (make popular drugs non-preferred if necessary)
- Tools to facilitate changes in status (i.e. grandfather existing users, provide personal letters to prescribers regarding members that are impacted by the changes, provide extended timeframes for transition)
- Seriously affect drug utilization market share
- Cope with criticism
- The State has successfully accomplished all of the above so far

Categories of Drugs

- Preferred (P)
- Preferred with conditions
- Non-preferred (N)
- Recommended (R)
- Non-Recommended (NR)

PA Criteria

- In a PDL, the objective is to designate as preferred the most cost-effective drugs that will work for the majority of the Medicaid population as initial choices.

- The PA arm or component of the PDL requires a greater level of purely clinical reasoning (the issues are different).
  - Does this individual (yes/no?) need this particular drug (yes/no?) for this condition (yes/no?) at this time (yes/no?)?

Mental Health Drugs

- Iowa Code gives legislative direction to the P&T Committee to determine whether or not there is a significant variation in therapeutic or side effect profile within affected therapeutic drug classes for mental illness.

- As expressly permitted under Iowa Code 249A.20A(4), Iowa Medicaid will continue to allow each sitting P&T Committee to make that determination.

- The Committee has been authorized to determine what will constitute significant differences.

Background

- Implementation of PDL/RDL: At the December 2, 2004 meeting for the implementation of the RDL, it was agreed that if a generic was available, then mental health drugs would be part of the PDL.
- Current PDL/RDL: There has been an expansion since implementation to include mental health drugs on the PDL when there are brand name drugs that have a "similar" generic available.
- Future RDL/PDL: Due to recent trends in the release of new drugs close to patent expiration, i.e. tablets that dissolve in your mouth vs. swallowed, extended release forms of immediate release drugs (one tablet daily vs. taking 2-3 times daily), and release of new versions of existing drugs, the process used by the Committee has been modified.

Annual Review & Mental Health Drugs

- The Committee is now willing to resume significant assessments on a drug by drug basis as required by the law, now that the PDL has successfully been in place nearly 4 years and everyone involved has substantially more experience and perspective.

- The Committee will evaluate antidepressants, antipsychotics and stimulants during this year's PDL annual review, concentrating on drugs (extended release, isomer, metabolite) that are derived from a preexisting parent drug.

Annual Review & Mental Health Drugs Ctd.

- Drugs determined to have significant differences in one or both of these two parameters will be designated as preferred.

- Drugs determined not to have significant differences may be designated as either preferred or non-preferred, depending on their other positive and negative attributes.

MH Drug PDL/RDL Stats

Time Period	MH Drugs On PDL
Current MH Drugs on PDL	Antidepressants 23 Antipsychotics 17 Stimulants 6
Proposed MH Drug Additions to PDL	Antidepressants 16 (P=10, N=6) Antipsychotics 12 (P=8, N=4) Stimulants 10 (P=8, N=2) *26/38 will become Preferred & 12/38 will be Nonpreferred

Summary of the PDL

- The PDL is all about creating an array of cost effective drugs that will suffice for most patients, most of the time.
- All other drugs are available via PA.
- Preferred drugs are a set of tools that can be used freely and hopefully prudently without permissions.

Is Everybody Happy?

- Everyone is going to be unhappy about some aspect of the PDL.
- We are going to make some of them unhappy some of the time.
- We are going to make some of them unhappy all of the time.
- Enable everyone to understand our reasoning process.
- Everyone will question our intelligence, motives, clinical skills and compassion.

Nothing Should Be For Free

- Manufacturers simply do not give the drugs away to Medicaid.
- Accordingly, Iowa should not give away preferred status for free (but we do).
- All drugs of participating manufacturers will always be available, although some may require PA.

SFY 08 PA Statistics

- 58,255 PAs were received in SFY 08
  - 37,271 (64%) were approved
  - 20,984 (36%) were denied
  - Average determination time was 1 hour

Iowa Medicaid Annual Drug Expenditures

- $233 Million Total Drug Expenditures for SFY 08
  - $129 Million (55%) on Physical Health Drugs
  - $105 Million (45%) on Behavioral Health Drugs

    17% for Antipsychotics 9% for Anticonvulsants

    10% for Psychostimulants 7% for Antidepressants

  - $33 Million on Generic Drugs
    - Generic utilization accounted for 14% of the total expenditures
    - Generics accounted for 64% of total drug utilization

Top 4 Behavioral Health Categories

- **Antipsychotics**: 17%
  - Age 0-21: 8%
  - Age 22-64: 9%
  - Age 65 and older: <1%
- **Psychostimulants**: 10%
  - Age 0-21: 9%
  - Age 22-64: <1%
  - Age 65 and older: <1%
- **Anticonvulsants**: 9%
  - Age 0-21: 3%
  - Age 22-64: 6%
  - Age 65 and older: <1%
- **Antidepressants**: 7%
  - Age 0-21: 2%
  - Age 22-64: 5%
  - Age 65 and older: <1%

SFY 08 PDL/PA Savings Highlights

Stimulants	$ 3.16 million
Asthma drugs	$ 2.42 million
Diabetes drugs	$ 1.14 million
Antidepressants	$ 0.97 million
Cholesterol drugs	$ 0.93 million
Proton Pump Inhibitors	$ 0.92 million
Anticonvulsants	$ 0.75 million
Hepatitis C	$ 0.48 million
Antibiotics	$ 0.31 million
Migraine drugs	$ 0.29 million