Community Retail Pharmacy

- In 2005, there were approximately 56,000 community retail pharmacies in United States
- 95% of US population is within 5 miles of a pharmacy
- About 11 percent of all prescriptions filled are Medicaid prescriptions
  - can be greater than 50%
- Operate on net 2 percent profit margins
Community Retail Pharmacy and Store Volume Over Time

What Does the DRA Do?

- **DRA =** Deficit Reduction Act of 2005
  - Signed by President February 8, 2006

- Significantly lowers the amount of money the Federal Medicaid program will pay states to reimburse pharmacists for generic drugs.
  - Starts January 2007

- Provides “AMP” data to states and on a public website

- Allows states to impose higher cost sharing on Rx drugs and make it enforceable
  - Started March 31, 2006
Components of State Medicaid Rx Reimbursement

- Drug Product Reimbursement
  - Brands: Most states use discount off AWP or mark up from WAC.
  - Generics: States use Federal Upper Limit (FUL) or "Maximum Allowable Cost" (MAC) programs.
  - DRA: Changes Federal payments to states (FULs) for generics only. (from 150% lowest published price to 250% lowest AMP)

- Dispensing Fee
  - States pay a fee to dispense each prescription; some have higher fees for generics than brands
  - Average dispensing fee is about $4.25/Rx
  - DRA: Makes no changes to dispensing fees

Medicaid Utilization and Spending for Brands and Generics

- By Prescriptions:
  - Brands: 46.4%
  - Generics: 53.6%

- By Dollars:
  - Brands: 83.1%
  - Generics: 16.9%

Generics account for over half of all Medicaid prescriptions, but only about one-sixth of Medicaid drug reimbursements.

Source: CMS Drug Utilization Data, 2004 and NACDS Economics Department.
Generic Drugs Cost Medicaid Programs Less than Brand Name Drugs

Average generic reimbursement is 1/6 the average amount for patented brand name drugs.

SOURCE: NACDS, based on Medicaid drug utilization data from CMS.

Highest/Lowest Medicaid Generic Dispensing Rates

As much as $3.5 billion per year might be saved if all Medicaid programs increased generic dispensing rates to 60.5 percent

Source: NDC Health (data for 1st quarter of 2005)
DRA Medicaid Payment Reforms

DRA Lowers Generic Payments

- States will receive less Federal matching funds to pay pharmacies for generic drug ingredient costs starting January 1, 2007.
  - FUL calculated based on 250% lowest AMP rather than 150% lowest published price
  - States cannot exceed these payments in the aggregate for about 600+ generic drugs.
  - As a result, States will likely in turn reduce the amount paid to pharmacy for the generic drug ingredient cost.

- Issues to Consider:
  - Will this affect pharmacists incentives to dispense generics?
  - Should states consider increasing dispensing fees to offset reduction in generic drug products payments?
  - Should states retain their generic MAC programs?
### Prescription Drug Marketplace Metrics

**AWP (retail only)**
- Average Wholesale Price is the average of manufacturers' suggested sales prices from wholesaler to purchasers.

**ASP (all class of trade)**
- Average Selling Price is defined as unit net revenue earned by a manufacturer per NDC across all classes of trade, net of all rebates and price concessions.

**AMP (retail only)**
- Average Manufacturer Price is defined as the average price paid to manufacturers by wholesalers for drugs sold to the retail class of trade, net of all rebates and price concessions.

**WAC**
- Wholesalers Acquisition Cost is defined as the manufacturers list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

- Hospitals
- HMOs
- Physicians
- Managed Care
- PBMs
- Mail Order

### Economic Impact of Medicaid Reform

- **CBO: DRA reduces retail pharmacy Medicaid generic payments by $6.3 billion over next 4 years (2007-2010).**
  - What does this mean for average generic payment to pharmacies?
    - **NACDS Analysis:**
      - Average generic payment in 2007 will decrease by 17% - from about $25 to $21.
      - Payments for generics with three sources of supply could be reduced by as much as 70%.
    - Approx. $4 / script
      - Payments for generics with two sources of supply could be reduced by as much as 30%.
        - Approx. $6 / script
CMS: States Encouraging Generic Use

“If states do not maintain the right incentives for generic utilization, any savings will be lost due to higher brand name utilization…CMS guidance encourages states to align incentives for generic utilization and consider paying pharmacies more in dispensing fees to support state savings from greater use of generics.”

Dr. Mark McClellan, May 22, 2006.

Grassley: States Encouraging Generic Use

“CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid, particularly for generic drugs…”

“…states should carefully consider data regarding the cost of dispensing in determining dispensing fees at the same time they change their reimbursements for acquisition cost to be more consistent with the actual cost of acquisition.”

Senate Finance Chair Grassley, May 12, 2006
DRA: Provides Pricing Data to States

- States will receive monthly “AMP” data for patented (brand) and off patented (generic) drugs from CMS starting July 1, 2006
  - AMP currently used by drug manufacturers to calculate rebates paid to states for Medicaid drugs.

- CMS will also develop quarterly-updated “public” website so consumers can see AMPs for these drugs.
  - Delayed by CMS on May 22, 2006

- “AMP” is the average revenue received in a calendar quarter by the manufacturers for the sales of a drug to the retail class of trade.
  - CMS to release data in July 2006, but not required to issue final regulation no later than July 2007

Issues Relating to Use of AMP data

- Interest in changing the benchmark from AWP or WAC to other benchmarks because of wide-ranging belief that neither represents actual prices paid by pharmacies.
- Does current AMP or future AMP really do the trick?

Issues to Consider

- What do states need to know about AMP data?
  - GAO, February 2005: “There was considerable variation in the methods that manufacturers used to determine best price and AMP.” The GAO report went on to cite other OIG reports which “found problems with manufacturers price determination methods and reported price.”
  - Some manufacturers may include lower prices available to non-retail classes of trade (i.e. mail order, nursing home)
  - Will be reported monthly to CMS, but still may be outdated when provided to states because of lag.
  - AMP data may not reflect pharmacies purchasing costs and clearly do not include dispensing costs. (OIG: AMP is about 7 percent lower than WAC for brand name drugs.)
CMS on Use of AMP Data

“*We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement*”

- Dr. Mark McClellan, May 22\(^{nd}\), 2006

CMS on Use of AMP Data

“I am announcing today that CMS will not release the current AMP figures. They are just not the right numbers to use. We do expect to share pricing information with the states…but only for the purposes of setting up their billing systems appropriately, not for the purposes of setting reimbursements.”

- Mark McClellan, May 22\(^{nd}\), 2006
Grassley on Use of AMP Data

“While the AMP data will provide far more accurate reflection of market prices than anything currently available, I believe that purchasers – both the states in Medicaid and those in the private market – should be cautioned that this AMP data does not reflect final calculations and that significant variation could be possible between the first publication and those published under the final regulation”

May 12, 2006
**Allows for Greater Rx Cost Sharing**

- DRA allows states to impose for different Rx cost sharing for exempted and other populations.
  - *For first time,* states can use nominal cost sharing for non-preferred drugs in otherwise exempt populations.
  - *For higher income individuals,* states can use anywhere from 10% to 20% of the cost of the non-preferred drug.

- **Issues to Consider**
  - Should states use cost sharing to encourage the use of generic drugs?
  - Should cost sharing be made enforceable so that it encourages recipients to use the most cost effective medication in a class?

---

**Medicaid Timeline**

- **Key Dates:**
  - March 31, 2006: States can start using higher cost sharing for non-preferred drugs.
  - June 1, 2006: OIG recommendations due to HHS on AMP definition.
  - July 1, 2006:
    - States start to receive AMP data on brand and generic drugs.
    - Secretary starts to make AMP data available through public website – delayed by CMS
  - January 1, 2007: New generic Federal Upper Limits (FULs) take effect.
    - 250% of lowest AMP of generic for two A-rated generics
  - July 1, 2007: Secretary promulgates new regulation regarding determination of AMP, taking OIG recommendations into account.
Wrap Up: Key Questions for States

- Should states consider an increase in pharmacy dispensing fees to offset loss of generic drug reimbursement?
- Should states conduct their own cost of dispensing studies?
- Should states use AMP data now or when made final?
- Should states use Rx co-pays, what should be the co-pay amounts, at what income level, and should they be enforceable?