Strategic Implications of the New Medicare Prescription Drug Legislation

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MMA Will Change the Marketplace

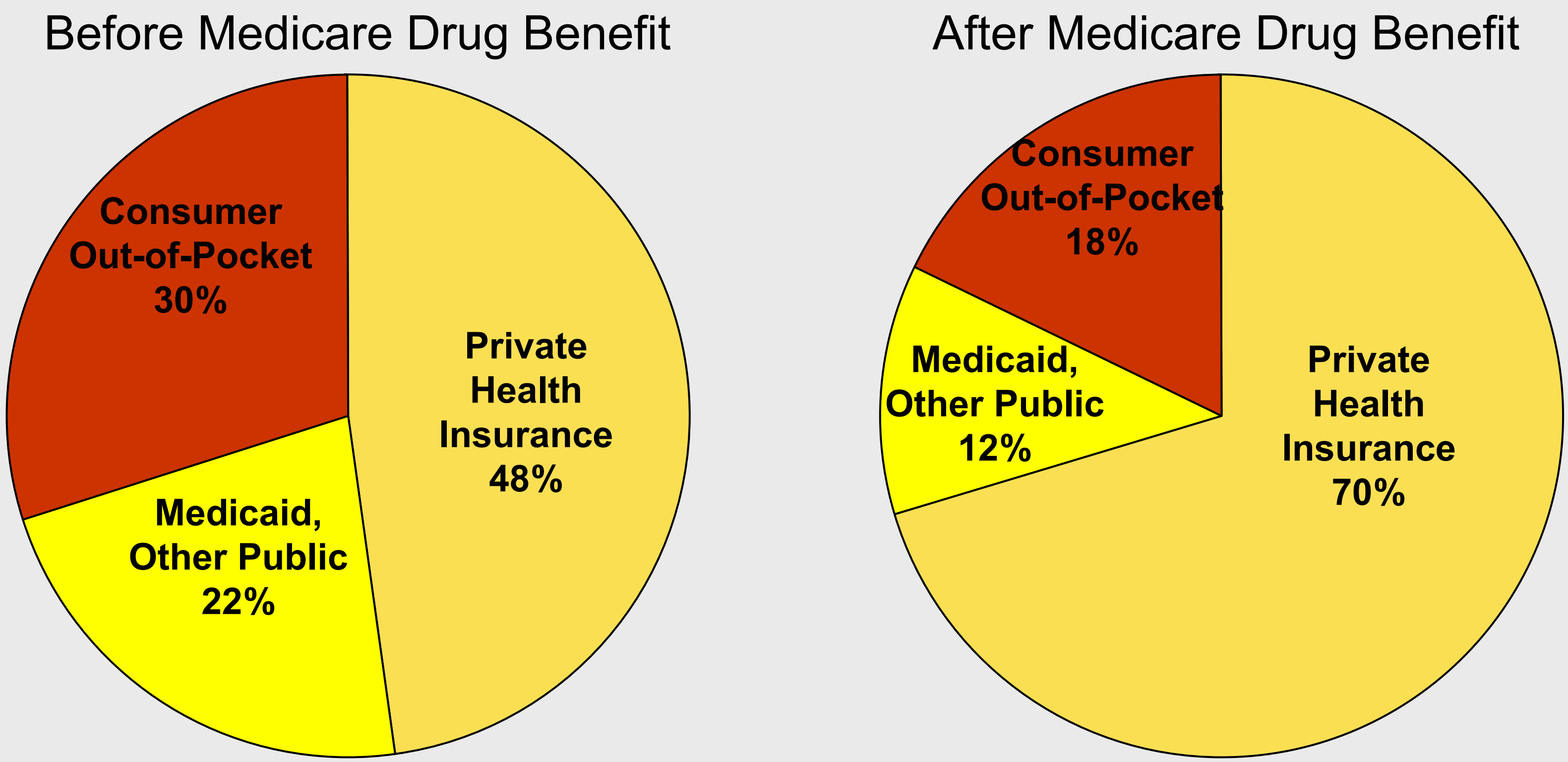
- New pricing transparency.
- Stand-alone private drug benefits.
- “Privatization” of Medicaid dual eligible drug benefit.
- Expansion of low-income subsidies.
- Comparative drug information.
- Consumer empowerment.
- “Pay-for-performance.”
- Expansion of disease management
- Parallel trade into U.S.
- Government cost pressures.

Changes Rollout over the Next Decade

- 2004 (June) Drug discount cards
- 2005 Part B – average sales price
- 2006 Medicare Drug Benefit - PDPs; MA-PDs
- 2006 Part B – ASP or competitive bidding
- 2007 Indexed drug plan limits; means-tested premiums
- 2008 Electronic prescribing standards required.
- 2010 Test of competition with traditional Medicare begins.

Privatization of Drug Market

Total Drug Spending



Sources: CMS, National Health Spending, 2002; and CBO, Issues in Designing a Prescription Drug Benefit for Medicare, Oct, 2002.

Price Transparency and Competition

- Comparative pharmacy prices -- Medicare drug discount cards
  - Comparative drug prices under cards -- websites/call centers.
  - Lowest-cost alternative at point of service.
  - Reporting to HHS on passthroughs
  - Continuation of price disclosure past 2006?
- Medicare reimbursement for Part B drugs
  - ASP and competitive bidding
- Reporting on rebates to HHS
  - PDPs report aggregate price concessions and passthrough
  - Manufacturers report pricing information.
- Electronic prescription price comparison information

PDPs – An Uncertain Influence

- Uncertainty of new entities
  - Will they bear risk, share risk with gov't, or administer?
  - Premiums – setting – increasing
  - Structuring benefits – tiered copays, donut hole
  - Formularies and contracting
- Dangers of the silo
  - Managing only drug cost.
  - Inability to influence physician behavior
  - Effect of a portion of enrollees fully-subsidized
- Flexibility vs access
  - Broad vs narrow formularies
  - Patients' appeal rights
- Government fallback – the price of failure
- MA-PDs – a better option
  - Integrated care -- more patient and physician management options
  - Insurable risk

“Privatizing” Medicaid Dual Eligibles

- Movement of “dual eligibles” to PDPs in 2006
  - Shift from government to private contracts
  - Better standards for formulary, better appeal rights
  - Minimal effect for Medicaid managed care enrollees
- Shrinking the Medicaid drug market
  - Est. 60% of Medicaid drug purchases leave state control
  - Medicaid rebate is reduced.
- “Clawback” leaves states on the hook for costs
  - States continue to pay 75% of drug costs for dual eligibles
  - States lose the means to control costs

An Expanded Low-Income Market

- Doubling subsidized population
  - Full subsidies ($2/$5 copay) for 1/3 of Medicare population
- Impact of full subsidies on drug utilization
  - Effect of full coverage on drug use
  - How PDPs will manage full subsidy population without financial incentives?

Comparative Drug Information

- AHRQ studies on clinical effectiveness will build the base
  - $50 million authorized but not appropriated for FY’05
  - comparative effectiveness of drugs, other interventions
  - building government capability to referee marginal value
  - precursor for cost effectiveness studies

- Industry, government and purchaser roles as arbiters of value
  - industry providing medical evidence – clinical trials, head-to-head trials.
  - government comparing evidence, validating conclusions on comparative outcomes.
  - purchasers monetize value.

- Role of comparative results in CMS and FDA decisions.
  - FDA’s role – scientific or economic?
  - CMS entering into medical decisionmaking?

Consumer Empowerment

- Drug cards and PDPs – choice or chaos?
  - Explosion of choices for seniors
  - Challenge of informing and managing selection
  - Locking in choices, limiting migration and selection risk

- Applying Medicare coverage appeals to drugs
  - Appealing coverage, copayments
  - Adjusting the process to drugs

- HSAs – a major expansion in “consumer direction”
  - A stimulant to the large employer market
  - How do HSA’s affect drug coverage?
  - Counting covered or noncovered drugs toward the deductible
  - Drugs as preventive therapy

Quality Initiatives – Selling Outcomes

- "Pay-for-performance" and other quality initiatives
  - Managing performance for the indicators
  - Driving guideline adoption and adherence

- Disease management initiatives
  - Expanding to new areas
  - Adapting to fee-for-service

- Improving prescribing quality
  - Electronic prescribing standards by 2008 or earlier.

Importation and the Market

- Illegal Internet importation creates substantial safety risk.
  - Canada Internet US sales -- $50 million (2000) to $800 million (2003)
  - Canadian Internet pharmacies -- 20 (2000) to 120 (2003).
  - Transhipment through Canada from Ecuador, Argentina, Iran, and Swaziland.

- Legal Canada importation likely with added safety features
  - Following food safety procedures – registration of traders; limited ports of entry; pedigree; testing and certification of lots.
  - Reduces margin for parallel traders.

- Canada importation impact on US revenues is limited
  - Canada is less than 10 percent of combined sales.
  - Profits go to parallel traders not consumers.
  - Potential impact on Canadian supply and prices.

- How to solve Canada and EU “free rider” problem
  - Conflict of global fixed costs and local rate setting.
  - Declining margins in US

New Pressure to Control Costs

- PDPs and cost control pressure
  - CMS imperative to make PDPs successful
  - Pressure from beneficiaries to keep premiums from increasing
  - Limited PDP techniques for controlling use – pressure on prices.

- Impact of new coverage on utilization
  - Expansion of coverage to one-fourth of beneficiaries w/o a drug benefit
  - Very low cost sharing for one-third of beneficiaries

- Fallback Plans
  - Increase in government risk and incentive to control costs.

- The “Sword of Damocles” – Congressional spending cap
  - When general revenues exceed 45% of Medicare outlays for two years.
  - President submits legislation -- new House and Senate procedures.

New Marketplace

- Expanded role of private plans – growing influence of PBMs.

- Increased information for plans and patients.
  - price (rebate) transparency
  - comparative drug information
  - increased emphasis on medical evidence and outcomes

- Growing pressure on price and performance.
  - PDP competition and premium pressures
  - pay-for-performance for providers
  - cost-effectiveness for drugs
  - consumer direction

- Increased competition
  - importation
  - increased incentives for generic substitution

Avoiding Government Intervention

- Supporting PDP success – avoiding the Fallback
- Encouraging beneficiary enrollment in integrated (MA) plans and competition with Medicare FFS
- Encouraging appropriate and effective drug use
  - integrated treatment
  - disease management initiatives
  - partnering with providers on performance and quality
- Measuring and reporting value
  - evidence-based utilization
  - total cost analysis
- Avoiding dangers for consumers of price controls

Selling Drugs in the New Environment

- Evidence-based
  - demonstrating comparative clinical efficacy -- head-to-head trials
  - building physician confidence and loyalty
- Demonstrating value
  - total programs - packaging for outcomes
  - partnering with providers
  - pricing for value
- Building trust
  - patient (consumer) focused – consumer education
  - commitment to meeting public health needs