Medicare Reform: Implications for Pharmaceutical Manufacturers

G. Lawrence Atkins, PhD
Schering-Plough Corporation

January 14, 2004

Major Changes Affecting Pharmaceuticals

- Medicare-Approved Drug Discount Cards
- Medicare Prescription Drug Benefit
- Medicare Advantage (MA) and Prescription Drug Plans (PDPs).
- Transfer of “Dual-Eligibles” to Medicare Drug Benefit
- Federal Low-Income Subsidies
- Payment Changes for Existing Medicare-Covered Drugs
- Electronic Prescribing
- Canada Importation
- Hatch-Waxman Reforms

Medicare Discount Cards

- Medicare “approval” – builds on existing care programs. Manufacturer-sponsored cards not included. Together RX?
- $600 annual subsidy will expand drug spending in the short term (2004 and 2005). Estimated 4.7 million of the 7.3 million beneficiaries using the card will get a subsidy.
- Use of formularies and limit of enrollees to one card at a time are expected to increase card-sponsor leverage for manufacturer discounts. Posting of retail prices may increase competitive pressures.
- Card and subsidy will affect participation in manufacturers’ patient assistance programs.

Medicare Drug Benefit: Impact

- Implementation delayed to 2006.
- 38% of Medicare beneficiaries (seniors and disabled) currently without coverage will get coverage.
- Federal resources will be provided to entities already providing drug coverage:
  - **Medicaid** -- dual eligibles shift to Medicare plans (with clawback)
  - **Employers** -- retiree health plans receive 28% of benefit subsidy
  - **Medicare+Choice plans**
- Substantial federal assistance to low-income beneficiaries – will double the size of the population with little or no out-of-pocket costs.

Value of the Medicare Drug Benefit

Annual Drug Expenses	Medicare Pays	Beneficiary Pays	Premium (Annual)	Pct of Cov'd Expenses
$1,000	$562	$438	$420	56%
$2,500	$1,500	$1,000	$420	60%
$5,000	$1,500	$3,500	$420	30%
$10,000	$6,155	$3,845	$420	62%

Impact of Drug Benefit Muted

- Increase in drug utilization will be limited:
  - Medicare benefit will pick up only 30 to 60 percent of drug expenses.
  - Beneficiaries will have high cost sharing.
  - Much of the federal spending will subsidize existing coverage, not expand coverage.
- Major impact on utilization will come from expansion of Federal low-income assistance.
- Drugs will be sold in a more competitive environment. Use of private drug plans increase share of the market subject to private purchasing methods.
- Transfer of Medicaid “dual eligibles” to private Medicare plans will reduce the impact of state supplemental rebates and PDLs.

“Dual Eligibles”

- Will transfer 60% of state Medicaid pharmacy cost to the federal government.
- Will shift former Medicaid beneficiaries to private drug plans; with full low-income assistance.
- Will significantly reduce size of rebates. Will also reduce ability of states to negotiate supplemental rebates.
- State rebate loss and federal “clawback” will deprive states of savings from the transfer.
  - CBO estimates 10-year net savings to states of $17.2 billion.
  - States will have added administrative cost.

Low-Income Assistance

- Major expansion in assistance to low-income individuals. Doubles the number of eligible Medicare beneficiaries:
  - All 6.4 million “dual eligibles” will receive full federal subsidies (leaving only small copayments).
  - Another 5.8 million beneficiaries will be eligible for full federal subsidies.
  - 1.9 million more will be eligible for partial subsidies.

- Reduces the need for state pharmaceutical assistance programs.

- Reduces demand for manufacturer-sponsored patient assistance (“free drug”) programs.

Private Plans

- Pharma supported reliance on private competing prescription drug plans (PDPs and Medicare Advantage).
- Private approach strengthens purchaser leverage – PBMs, MCOs. Negotiated prices will be exempt from Medicaid "best price," encouraging deeper discounts.
- Question of capacity of PBMs to handle enrollment and bear drug risk.
  - Failure would lead to Fallback and HHS assumption of risk.
- Electronic prescribing standards (2008)
  - Will require that prescribers receive information on alternative low-cost drugs.

Other Issues

- Cost Containment
  - Danger of triggering near-term financing crisis and price controls.
- Medicare payment to providers for Part B and HOPPS drugs
  - Brings reimbursement closer to cost.
- Hatch-Waxman Changes
  - Eases market entry for generics.
- Canada Importation
  - Potential authority to import from Canada, pending certification by the HHS Secretary.

Positives for Drug Manufacturers

- Expanded drug benefit coverage.
- Doubling of low-income assistance.
- Private-sector management of drug benefits.
- Transfer of Medicaid seniors to private plans – reduction in rebates.
- Expansion of integrated health plan enrollment.

Negatives for Drug Manufacturers

- Substantial cost sharing for seniors with the benefit.
- Increase in purchasing clout by PBMs and private health plans.
- Potential for Fallback and government involvement.
- Shift of price pressure from seniors to government. Potential for cost containment measures and price controls.
- Potential for Canada importation.