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Medicare Reform: Implications for Pharmaceutical Manufacturers

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Major Changes Affecting Pharmaceuticals

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

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 Will Expand Market

- Expanded drug coverage -- 38% of Medicare beneficiaries (seniors and disabled) currently without coverage will get coverage.
- Catastrophic benefit will limit out-of-pocket costs for expensive drug regimens.
- Substantial federal assistance to low-income beneficiaries – will double the size of the population with little or no out-of-pocket costs.
- Improved compliance from better integration and management of care.

Value of the Medicare Drug Benefit

Annual Drug Expenses	Medicare Pays	Beneficiary Pays	Premium (Annual)	Pct of Gov'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 for 2/3 of population.
 - Beneficiaries without supplemental coverage will have high cost sharing.
 - Much of the federal spending will subsidize existing coverage, not expand coverage.
- 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 increase population in private plans with managed utilization.

“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

- Reliance on private competing prescription drug plans (PDPs and Medicare Advantage)
 - reduces chances for price controls,
 - increases integration of drug and medical care.
- Private approach strengthens purchaser leverage – PBMs, MCOs. Negotiated prices will be exempt from Medicaid “best price,” encouraging deeper discounts.
- Uniform therapeutic categories and formulary guidelines (U.S. Pharmacopeia).
- Concern that private plans will cover all areas, handle enrollment, and bear drug risk.
 - Failure would lead to Fallback and HHS assumption of risk.
- Electronic prescribing standards (2008)
 - Push to e-prescribing will give prescribers 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 provider acquisition 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.