

The New Medicare Drug Benefit: “The Big Picture”

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– Revised 2.0 –

“The Big Picture”

- “*All policy has memory*”
- History – 38 Years in the Making
- Politics – Congressional and industry
- Content – Key decisions, cost, market impact
- Expectations and Unknowns
- Regulatory Timeline – *Visibility*

Orientation – Basic Facts

- Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)
- President Bush signs into law December 8, 2003
- Provides *temporary drug discount card* ('04-'05) and *Medicare drug benefit* ('06+); plus important managed care and fee-for-service changes
- Net cost to government, \$390B-\$534B (over 10)
- Post-'06, Medicare “owns” 11%-20% U.S. retail drug market, leverages 50%

History – 38 Years in the Making

- Why no drug benefit in 1965?
- Task Force on Prescription Drugs, 1967-69
- “Catastrophic” legislation, 1988-1989
- Part B covered drugs
- Clinton health care proposals (1993-94)
- *National Bipartisan Commission, March 1999*
- Kennedy, S. 841; Thomas, H.R. 4680
- Medicare Modernization Act, 2003

Politics 1 – How Did MMA Happen?

- Unnatural act for Republicans? Big government?
- Consensus wrong – Jan.-Oct. 2003 – 10%-50%
- January 2003 – Bush flipped (sorta) – 50%
- May 2003 – Kennedy flipped (not really) – 80%
- December 2002 – Lott exits
- Takeaway: Path analysis, inflection points, confirmation/reversals

Politics 2 – House and Senate Votes

- Congress votes final passage November '03
- House, 220-215, R-89%, D-8%, 3-hr vote
- Senate, 54-42-2, R-82%, D-28%
- President Bush signs December 8, 2003
- Takeaway: Partisan, little Democratic ownership. Does that matter? Yes.

Industry Politics – What Pharmacies Got

- Discount card opposed by powerful pharmacy industry in '01 – loss of retail trade, discounts
- Pharmacy network requirements
- “Any willing provider”
- No mandatory mail order – or disclosure?
- Dispensing fee
- Waiver co-insurance certain low-income beneficiaries (no marketing)

MMA Content – Bill Titles

- Title I Prescription Drug Benefit
- Title II Medicare Advantage
- Title III-VIII Fee-For-Service payments
- *Title IX CMS Administrative Reform*
- *Title X Medicaid*
- *Title XI Access to Affordable Pharmaceuticals*

Prescription Discount Card – Basics

- Temporary program – 6/1/04 – 12/31/05
- Provides “Medicare Approved” logo
- 7.4M expected; 4.7M, \$600 per year cash grant
- 106 applications to provide cards—March awards
- Attractive? Established product, no mandatory discount pass-thru; market OTC products, etc.
- Trade offs? \$0-10M NPV benefit, start-up costs, “800” call center, HHS discount disclosures, etc.
- PBMs manage 65% current senior drug benefits

Discount Card – *Visibility* Full Benefit?

- +/- Impact on manufacturers and distribution?
- CMS drug price compare website – price signals?
- Generic promotion – Pharmacy inform lowest cost generic; of 209 drug categories; half with generics
- Medicaid best price exclusion – deeper discounts?
- *Formulary design and restrictions*
- Mail order penetration?
- Savings – predicted 1.2% reduction all retail spend

Medicare Drug “Benefit Product”

- Premium (\$35) + Deductible (\$250) = \$670
- Coinsurance: 25%
- Initial benefit: \$2,250; 50-50 Bennie/Government
- Stop Loss: \$5,520, +minimal cost-sharing
- Actuarial equivalence
- Low-income subsidy: <135% poverty
- Takeaway: Good value? Average drug spend, \$1,000+; Granny needs EV calculator!

Cost Sharing under 1999 Kennedy S. 841,
“Access to Rx Medications in Medicare Act”

- Monthly premium (Past B premium increase)
- \$200 deductible
- 20% co-insurance
- Basic benefit: Up to \$1,700; then no coverage until stop loss (the original donut hole!)
- Stop-loss: Full coverage once beneficiary's out-of-pocket expenses reach \$3,000.
- Low-income subsidy: <135% poverty.

Medicare Drug “Business Model”

- Plan sponsors: Private contractors “licensed under State law as risk bearing entity eligible to offer health insurance or health benefits coverage”
- HHS determines “markets”; 2 plans per market
- Downside protection: risk corridors
- Keys to *government savings*: capital-at-risk and restrictive formularies

Formularies – Where the Action Is

- CBO: Saves 25% per uninsured beneficiary
- One preferred drug per therapeutic class (209)
- Additional co-pays for tiered, non-preferred drugs *do not count* as out-of-pocket for stop loss
- PBMs demand discounts – think Florida!
- For manufacturers, no Medicaid “best price”!
- Marketing to build demand for inclusion?
- Head-to-head clinical trials?

MMA Cost Federal Budget Impact

(over 10 years)

- “Advertised Cost” \$390 billion
- Gross Cost \$465+ billion
- “FFS Savings” -\$75 billion
- Drug benefit Posted \$410B
- Actual \$540+B??

Top Medicare FFS Savers = \$75B

- New beneficiary costs -\$25B
- “*AWP drug*” price cuts -\$16B
- Medicare Secondary Pay -\$9B
- Labs -\$8B
- DME Competitive Bid -\$7B
- Home Health Update -\$7B
- ASCs -\$3B

Medicare as New Pharma Market Player

- Medicare leverages 1/3 of \$1.4T US health spending – 38 years' historical lessons in other health sectors!
- Pharma Market: Medicare OPD drug spend: \$8.5B
- CBO estimates \$1.8T ('04-'13) drug spend for Medicare bennies, 42% all drug spending
- Takeaway: Medicare leverage jump, <3% to 50%
- Stock Market: Market cap 650 health stocks \$2.2T; 82%, pharma-related
- Pharma-related stocks 14% US stock market

Expectations and Unknowns

- Will anyone show up? Will know early '05.
- New political, OIG exposure.
- New utilization, but shifts more important?
- *We ask, “Does company have a plan?”*
- What about generics? Contrarian view.
- CROs – overlooked idea?
- Federal spending – downstream?

Medicare Advantage – Outlook

- *Medicare+Choice rebranded (M+C implosion, '00 6.3M to '03 4.6M)*
- *2004-05 – MA rates relinked to FFS; county-by-county story, but overall nice improvement.*
- *2006 – new regional PPOs go live, new formula.*
- *PPO Growth 10 years: CBO, 9%; CMS, 32%*
- *Government big bet, PPOs 2.3% < FFS Medicare*

Pharma-Related FFS Provisions

- Congress giveth, Congress taketh away
- 89+ provisions overall
- Other pharma: Part B drugs (“AWP drugs”), hospital outpatient transitional pass-through, sec. 641 demonstration
- Most information out, but continuing uncertainty Part B covered drugs:
respiratory therapy, dialysis

FFS – Wall St. Does Washington?

-----Original Message-----

From: [Senate staffer]

Sent: Monday, November 03, 2003

To: [Other Senate staffers}

Subject: More on US Oncology

10/31/2003 S&P MarketScope, Views and News

0:27 am EST... US ONCOLOGY (USON 9.75) UP 1.95, WACHOVIA UPS TO OUTPERFORM FROM UNDERPERFORM. YESTERDAY CO. POSTED \$0.20 3Q EPS... Analyst [...] tells salesforce Medicare reimbursement cuts may be lower than expected, co.'s internal volume growth higher than expected... Says 3Q run rate rev., EPS above expectations... Believes Conference Committee zeroing in on proposal to change reimbursement for oncology drugs from 95% of avg. wholesale price to 108% of avg. sales price, while raising practice expense reimbursement by \$500M per year... Says medical oncology visit growth could rise from below 2% in 3Q to over 5% in '04... Sees \$0.20 4Q EPS, raises \$0.69 '04 EPS est. to \$0.72./Burba

Regulatory Timeline – Drug Benefit

Effective date, January 1, 2006

- *Visibility – “If not what, when”*
- 2004-05 – Discount card
- 2005 – Proposed and final regulations, informational meetings for plan sponsors
- 2004-05 – Beneficiary education
- Enrollment, November 15, 2005 (6 months)
- 2006-2010 – Shakedown cruise

Washington Consulting – An Edge?

- *Intelligence and insight*: Forecast timing/content legislation/regulations, interpret events
- *Strategic Positioning for Business*: Can I change a law or regulation, or should I change my business model?
- *Advocacy*: Making your case before Congress and the Executive Branch