

The New Medicare Drug Benefit: What Investors Need to Know (or “Washington Eye for the Analyst Guy”)

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– Revised –

Up Next

- The “backstory” (politics + history) – “*All policy has memory*”
- Part D Content – Benefit, delivery, cost
- Pharma market impacts
- Part D Expectations and Unknowns
- Other provisions – Managed care, FFS
- Regulatory Timeline – *Visibility*
- Washington research – an edge?
- Bonus – Top Health Stories '04-'05

Orientation to Medicare Legislation – Basic Facts

- Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)
- President Bush signs into law December 8, 2003
- New Part D provides *temporary drug discount card* ('04-'05) and *Medicare drug benefit* ('06+)
- Important managed care (Part C) and FFS changes (Part A and B)
- Net cost to government, \$390B-\$534B (over 10)
- Bill length – 415 pages

Preview – Six Takeaways on New Medicare Drug Benefit

- *Pharma market* – Now a Medicare story?
- *Few new dollars* – More utilization but deeper discounts?
- *Formulary* – Food fight?
- *The question we ask* – What is a company's plan?
- *Visibility* – Backstory, discount card, regulatory pathway.
- *Contrarian views* – CROs, HIT (+), generics(-)??

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*
- 1999+ – Kennedy, S. 841; Thomas, H.R. 4680
- MMA, December 8, 2003

Politics 1 – Why Now? 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: Forecast *with* 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.

Pharma Value Chain 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 Section 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
- 104 applications (half MA) —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? For low-income, yes!
Others? 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”

- “Freestanding”, *also managed care, employers*
- 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 Payment Anomalies ('92-'03)

- Businesses built on payment anomalies “at risk”
- Home oxygen equipment (BBA 97)
- Nursing home separate payments (BBA 97)
- “AWP Drugs” (MMA '03)
- Dialysis facilities (MMA '03)
- Labs (MMA '03)
- Specialty Hospitals (MMA '03)

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
- Post-'06, Medicare “owns” 11%-20% U.S. retail drug market, leverages nearly 50%+
- Takeaway: Medicare leverage jump, <3% to 50%

Medicare Drug Benefit and Stock Market

- Market cap 650 health stocks traded on NYSE, Nasdaq, Amex, \$2.2T
- 82% market cap pharma-related
- Pharma-related stocks = 14% US stock market (by market cap)

Impact on Manufacturers and Pharma Value Chain

- *More utilization but deeper discounts?*
- *Utilization higher* because on average Medicare bennies have better coverage.
- But formularies and competitive pressures allow drug plans *get deeper discounts* than current PBMs?

Current Medicare Coverage Segments

- Self-pay (24%) – Utilization may increase 20-35%, discounts.
- Retiree employer coverage (33%) – Any migration to new Medicare benefit reduces utilization, increases discounts?
- Medicaid (12%) – higher utilization, smaller discounts over Medicaid rebates
- Medigap (15%)
- “Other” (5%)

Part D Manufacturer Revenue Impact

- PwC estimates
- Net volume increase, +5-10%
- Net increased discounts, +1-10%
- Net manufacturer revenue impact on sales to Medicare bennies, +2% (-4% to +6%)
- Net impact all retail, +1% (-2% to +3%)
- Takeaway: Few new dollars?

What About Generics?

- Federal gov't first endorses generics 1969, 1973.
- Discount card – 209 therapeutic categories, half with generic alternatives
- Discount card and Part D “favor” generics
- How will brandeds respond: Discounts, marketing (DTC, physician), clinical trials?

Recap – 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?”*
- Other pharma value chain impact – same model

Other Winners and Losers

- Plus for “catastrophic drugs”
- What about generics? Contrarian view.
- Plus for CROs – overlooked idea? Sec. 1013.
- Plus for HIT – another overlooked idea?

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

Visibility – Regulatory Timeline

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 Research – An Edge?

- Forecast timing/content legislation/regulations
- Interpret events
- Comment divergence company and Washington stories
- Propose model designs and variables
- Provide incremental company/sector information

Review— Six Takeaways

- *Pharma market* – Now a Medicare story?
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Top Health Stories – 2004-05

- Theme: Debate and consolidation
- We're waiting for Presidential campaign to supersize health issues.
- Medicare 1 – Expect mo' Democratic attacks
- Medicare 2 – Medicare discount card – April+
- Medicare 3 – No Medicare bill '04, deficit bill '05
- Medicare 4 – Chronic disease management
- Health information technology – Bush budget
- Reimportation!
- Biological generics

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