
CAPITOL ANALYSTS NETWORK, INC.

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February 24, 2005

WASHINGTON ON DRUGS

Revolutionary changes will soon hit the pharmaceutical industry, leaving an impact on everyone involved – health plans, retail pharmacies, pharmacy benefit managers, wholesale distributors, pharmaceutical companies, and of course, doctors, patients, and patient families. Most, but not all, will benefit from the changes; this is no surprise, given that Medicare will spend \$1.3 trillion of taxpayers' money over the next eight years to help seniors purchase pharmaceuticals.

In this paper, CAN analyzes what the Medicare Modernization Act (MMA) means for these industry sectors and their investors. First, a global summary. Next year, the Congressional Budget Office (CBO) calculates that 37 million Medicare beneficiaries will sign up for “Part D,” the new Medicare drug benefit that takes effect on January 1, 2006. These enrollees will buy \$115 billion worth of drugs in 2006, 46 percent of the national total. By 2013, CBO predicts there will be 43 million Medicare Part D beneficiaries, and their total purchases will swell to \$235 billion. As the federal government redirects this raging river of money, some “houses” will collapse and other “fields” will be irrigated.

However, the MMA did more than establish a prescription drug benefit. It contains provisions aimed at accelerating the adoption of new technologies that will make prescribing drugs and filling prescriptions more efficient, cheaper, and less prone to error. Pharmacy Benefit Managers will cut costs as this trend accelerates. In addition, medical information technology providers specializing in “e-prescribing” will grow as this market expands.

The Part D Benefit Gives Seniors Large Upside Gain for a Small Up-Front Cost

Basically, seniors will see their out-of-pocket expenses decline, in some cases by dramatic amounts, because a fourth party payor, Medicare, Part D, will now pick up much of their expenses after they pay modest premiums and a deductible. Under the Standard Design policy that private insurers must conform to if they enter the market, seniors will:

- Pay monthly premiums of \$35 and a \$250 deductible – a \$670 annual investment to a Medicare-approved private drug insurer; for seniors near or at the poverty level, the government will waive most, or all, of premiums and deductibles.
- See a return on investment of up to \$1,500 per person because their insurers will pay 75 percent of network charges on their next \$2,000 in purchases, beginning with the \$251st dollar of drug expenditure and continuing until the \$2,250th dollar of annual spending.
- Experience little further return on their investment on their next \$2,850 in purchases – those between \$2,251 and \$5,100 – because they will pay 100 percent on these network charges; this is known as Part D’s “doughnut hole” in coverage.

- Feel further financial relief if they use more than \$5,100 in drugs annually because their insurers will pay at least 95 percent of expenses for purchases above this amount.

When Seniors Pay Less, Do Their Drug Purchases Go Up?

The Kaiser Foundation projects that 39 percent of seniors enrolled in Part D will face only 25 percent co-payments because their annual drug expenditures will fall between \$251 and \$2,500. Currently-uninsured seniors will be tempted to purchase more pharmaceutical products because they will experience a price decline of at least 75 percent on the next dollar of consumption. The Foundation also announced that another 19 percent of Part D enrollees will face at most 5 percent co-payments because their drug purchases will exceed \$5,100, making incremental drug spending almost free. The Kaiser research is available at <http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=48947> .

It is difficult to imagine a good or service where the demand for it won't rise when prices decline by 75 percent or 95 percent. Pharmaceuticals aren't one of them. CBO assumes that the price elasticity of demand for pharmaceuticals is only -0.3, meaning that an uninsured senior who experiences a 75 percent price decline will buy 22 percent more drugs while a currently uninsured senior witnessing a 95 percent price decline will boost his consumption by 29 percent. Adding the two sub-groups together, Part D beneficiaries would expand their consumption by over 14 percent if all are currently uninsured. CBO believes the actual figure more likely will be 9 percent because most seniors already have some level of drug insurance. Find CBO's report at <http://www.cbo.gov/ftpdocs/56xx/doc5668/07-21-Medicare.pdf> . This 9 percent Medicare consumption boost will prove low if the price elasticity estimate proves low. The average price elasticity of demand for a good or service is -1.0. If drug consumers had a -1.0 price elasticity, then Part D consumption would leap by 30 percent, not 9 percent.

No matter what the elasticity turns out to be, clearly drug wholesalers and pharmacy benefit managers, whose top line and bottom line growth are levered to unit sales volume will benefit. They will be triple winners – benefitting from the unit volume growth due to out-of-pocket price declines for drugs, an increase in the number of seniors, and a rise in the number of “old old” who use more drugs than the “young old.”

The Winning “Fields” and Losing “Houses” in the Path of the Money River

Drug Retailers Could Be Hurt: Depending on the drug chain store, 40 percent to 60 percent of revenues derive from pharmacy sales, and the “front end of the store” produces the balance. Profit margins in the pharmacy are highest on the uninsured, who typically pay 15 percent to 25 percent more than purchasers who are part of insurance networks. After Part D beneficiaries join insurance plans, the plans will pay pharmacies only their network rates now in effect for other people they already insure. To cut costs, many Part D insurance plans will provide incentives for seniors to drop pharmacy coverage entirely and switch to mail house deliveries instead. *It is likely that chain drug stores will be losers once they must negotiate prices with insurance companies and pharmacy benefit managers, instead of the elderly. Price*

declines of 15 to 25 percent could slice margins on pharmacy sales to seniors by twice this, much more than volume will increase.

Pharmaceutical Companies Producing Quality of Life Drugs Should Win: Mark Twain sometimes remarked that a man who had one foot in a bucket of hot coals and another in ice water was, on average, comfortable. So it is with CBO's estimate of a -0.3 price elasticity for pharmaceuticals. In reality, some pharmaceutical products are luxuries that are highly price sensitive and others are life saving that are worth almost any price and demand is insensitive to price. Thus, nationwide uninsured seniors will order the same amount of chemotherapy if the price they must pay out-of-pocket is \$20,000 or \$2.00. The quantity of life saving drugs purchased isn't sensitive to price. However, the quantity of toe nail fungus medicine ordered nationwide, for example, probably is sensitive to price. Seniors with modest means probably won't buy cosmetic treatments if it means sacrificing Christmas gifts to the grandchildren. Many will change their minds if Part D insurance plans will pick up 75 percent of the tab. Investors should anticipate that seniors will increase their purchases of "life improvement" products treating allergies, arthritic pain, depression, anxiety, insomnia, overactive bladder, and mild sexual dysfunction, for example, by much more than 9 percent, CBO's "average" projection.

Prices Paid to Pharmaceutical Companies Should Hold Steady: CBO assumes that prescription drug insurance plans selling Part D policies will lower their costs by 20 percent, compared to full retail prices, by negotiating aggressively with drug store chains. As the plans threaten to channel all their business to chains that cut prices, they will simultaneously build up their own mail order sales. Insurance plans used these techniques to drive chain store margins down sharply in the 1990s, and they did so without causing much pricing pressure to drift back toward the pharmaceutical companies. It should be the same story here.

Generics or Branded Drug Companies?: Whether there will be a shift toward generic drugs, and away from branded drugs, is ambiguous. Under the law, Part D insurance plans will have to offer at least two drugs in every therapeutic class. They also will have competitive reasons to consider making their formularies more expansive. Still, plans will have the right to use financial incentives to induce consumers to choose lower cost generics. Cutting in the other direction will be patient calculations. At full retail, the price differential between branded drugs and a generic equivalent can be substantial. However, for the 59 percent who will enjoy 75 percent or 95 percent subsidies, the savings can shrink to almost nothing. Many will opt for the brand names they recognize.

Think Twice Before Investing in Part D, Private Insurance Companies: Later this year, we will learn which insurance companies submitted the lowest bids, thereby winning the rights to offer Part D plans in the many sub-markets that Medicare is establishing. Recent history suggests that the initial bid winners likely will be disappointed by unexpected cost overruns they will have to eat. Not long ago, managed care plans entered the Medicare + Choice market, which offered seniors pharmaceutical coverage. Within two or three years, the vast majority dropped out after covering unexpectedly high pharmaceutical costs, mostly due to underestimated demand. This experience could be repeated, especially if, as CAN believes,

CBO's -0.3 price elasticity assumption proves optimistic. Federal cost estimators have made famous gaffes. When Medicare made home health care widely available in the 1980s, they assumed there would be little demand. When the government elected to cover end stage renal disease, they made a similar assumption. Usage assumptions for both proved massively wrong. Under the new law, Part D drug insurance plan sponsors will be "at risk." If insurers misjudge their future medical drug loss ratios, it will hit their bottom lines; in 2006, the federal government will not partially reinsure them until their losses exceed 2.5 percent of revenues.

Overstated Threats: Canadian Reimportation and Price Controls

Many people do not know that Washington approved a reimportation bill in the last months of the Clinton Administration. For reimportation to be legal, the Secretary of Health and Human Resources has to certify that it is safe. Clinton's HHS Secretary, Donna Shalala, refused to make this certification. Bush's Secretary, Tommy Thompson, also declared it unsafe and refused to certify. There are two reasons why this issue matters less than the public controversy justifies. First, Congressional Republicans are not backing a strong push to make reimportation enforceable. Pharmaceutical companies know that the Canadian market represents only 2 percent of their global sales. If consumption spurts to 4 percent, they have compelling reasons to believe that Americans are reimporting at their expense. It is a simple matter to cut Canadian distribution back to its historic market share. Without expensive legal sanctions, this is what is now happening.

Second, seniors buy from Canada because it costs less than paying U.S. retail. For a majority of seniors, the price of drugs in the U.S., after Plan D subsidies of 75 to 95 percent, *will be much lower in the U.S. than in Canada!*

Both CBO and Medicare's top actuary are on record stating that changing the law to allow Medicare to make bulk purchases will not save money. They believe that Part D private insurance companies will do just as well in keeping prices down as bargaining agents as the government might. Some cynics point out that Medicaid sometimes pays more than the private sector because drug companies succeed in lobbying the purchasing agents to keep prices high. Read CBO's letters at <http://www.cbo.gov/ftpdocs/51xx/doc5145/03-03-Wyden.pdf> and <http://www.cbo.gov/showdoc.cfm?index=5145&sequence=0>.

Coming Soon: E-Prescribing

Jokes about physician handwritten skills are so common that they are part of American vernacular. The consequences are not so funny. The average doctor probably wastes two hours a day responding to questions from pharmacists or others about prescriptions he wrote. The U.S. Department of Health and Human Services calculates that there are 2 million unnecessary adverse drug interactions annually because of handwriting interpretation mistakes, or lack of knowledge about all the drugs patients are taking. The Department believes that tens of thousands of drug consumers unnecessarily die every year. America could save lives and increase its availability of general practitioners by almost 25 percent – if doctors offices were

equipped with electronic prescription equipment that communicated by email directly with the pharmacists their patients want them to use and if patients could easily show doctors their current drug usage and the contents of the formularies their health plans use. That way, cost effective, informed choices could be made virtually error free while patients were meeting with their doctors. When they got to their pharmacies, their prescriptions could be waiting for them. Refills would be a snap for all concerned.

The Bush Administration is aggressively pursuing this idea. On February 4, 2005 (see <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-1773.pdf>) it took an important step, publishing a proposed regulation to standardize e-prescribing as part of the new Medicare drug law. Once a final standard is adopted later this year, the next step will be to provide incentives to doctors and pharmacists so they invest in time-saving equipment and technology. At a later date, use will likely become mandatory for all doctors participating in Medicare. After that, expanding e-medicine to cover private patients will be a simple matter.

The movement toward e-prescribing has already begun, without government assistance. An estimated 5percent of doctors already have automated prescribing systems. Eventually, information technology will produce savings for all concerned, health plans, pharmacy benefit managers, pharmacies, doctors, and patients. The most obvious winners will be the nation's three largest PBMs: Caremark (**CMX**), Medco Health Solutions (**MHS**), and Express Scripts (**ESRX**). They will save by eliminating labor-intensive phone calls between their offices and pharmacies that instead can be automated. For aggressive small cap plays on software companies that appear active in the fight for e-prescribing market share, investors may wish to consider NDCHealth (**NDC**), Allscripts (**MDRX**), ProxyMed (**PILL**), and ZixCorp (**ZIXI**). The author personally owns shares of Allscripts.

This Flood of Taxpayer Dollars Requires Careful Navigation

The new Medicare drug benefit created by George Bush will be costly to taxpayers. Since insurance premiums and deductibles will cover only a small portion of costs, the unfunded liability of this program is an enormous \$8.5 trillion. This is more than twice the size of the liability confronting Social Security – which President Bush describes as a crisis. Every part of the drug industry will be affected by the violent Medicare river that will overflow its banks this January. Find the lands now where more water will do some good and avoid places where flooding will drown the careless.

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