Putting Numbers on the New Medicare Prescription Drug Legislation:

How the MMI Will Affect Medicare Beneficiaries and Pharmaceutical Revenues

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MMA

Medicare Prescription Drug Coverage, Improvement, and Modernization Act

MMA, DIMA, MRxCIMA, MPDIMA?

Overview of Recent Medicare Act

- On December 8, 2003, President Bush signed legislation that affects almost every aspect of Medicare (including prices for most medical services, Part B drugs, and Medicare managed care) as well as non-Medicare issues such as health savings accounts and reimportation of drugs.
- MMA will provide $400B of prescription drug benefits over the next 10 years (and up to $2 trillion over the next decade).
- The MMA, which affects 43% of pharmaceutical sales, will have major effects on prescription drug coverage, utilization, and prices.

MMA Is Not Just Drug Coverage

- Reimbursement rates for Medicare Part B drugs, the ones Medicare already covers, is reduced substantially.
- Substantial reductions in Medicare reimbursement rates for durable medical equipment (DME).
- An additional $18 billion over 10 years for rural providers.
- Increases in Medicare reimbursement rates for most hospitals and physicians.
- Health savings accounts for everyone—the major non-Medicare component of the legislation.

Impact of Medicare Rx Legislation: Topics for Discussion Today

- Present some background information on Medicare beneficiaries and prescription drug spending.
- Discuss the aspects of the legislation that affect pharmaceutical revenues.
- Provide overview of how legislation affects pharmaceutical revenues.
- Put specific numbers on the various factors and comment on overall impact on the pharmaceutical industry.
- Discuss differences in how to assess the impact of the legislation on your company.

Background on the Medicare Program

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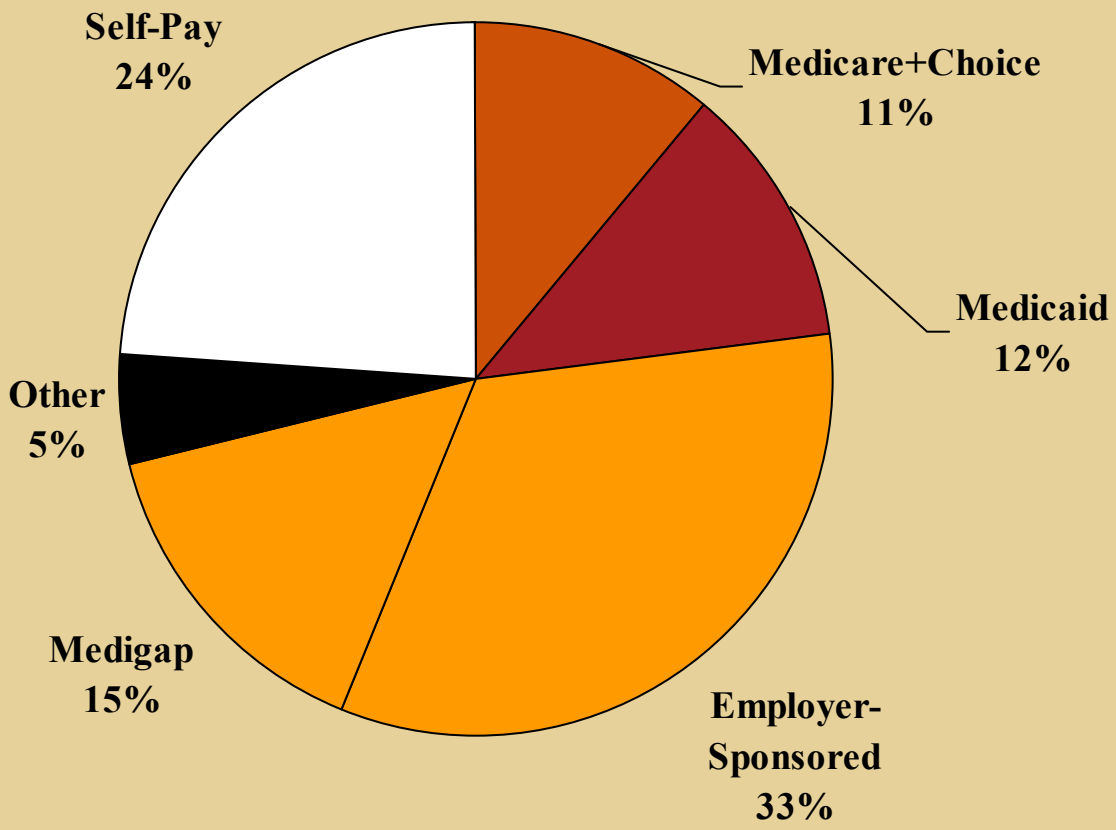
Prescription Drug Coverage of Medicare Beneficiaries, 2002

Most Medicare beneficiaries have prescription drug coverage, but only those with employer-sponsored and Medicaid coverage have generous plans.



Based on CBO and PwC assumptions.

Current Rx Drug Coverage for Medicare Beneficiaries

- Most Medicare beneficiaries have Rx drug coverage but only retirees with company plans (~33%) and Medicaid (~12%) have generous coverage.
- Only a minority of Medigap purchasers buy prescription drug coverage (Models H, I, J) and they pay high premiums for what they get.
- About 55% of Rx spending by Medicare beneficiaries is paid for by insurance; out-of-pocket spending averages 45%; employer plans average about 75% and Medicaid 95%.

Spending on Rx Drugs by Medicare Beneficiaries, 2006-2013

- According to CBO, annual prescription drug spending by Medicare beneficiaries is currently about $2,300 per person and will rise to $3,155 by 2006.
- Total spending by Medicare beneficiaries on prescription drugs is expected to be about $125 billion in 2006 and more than $250 billion by 2013, the last year of the budget period used by Congress this past year.
- Prescription drug spending is expected to continue to increase at an annual rate of almost 10% for the next decade.
- Total spending by Medicare care beneficiaries over the budget period is $1.5 trillion.

Distribution of Rx Drug Spending by Medicare Beneficiaries, 2006

Less than $250	17%
$251-$2,250	35%
$2,250-$5,100	28%
More than $5,100	20%

Details of the MMA

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Pharmacy Components of MMA

- The MMA establishes a prescription drug discount card program, in 2004 and 2005, that will compete with, or replace, current discount card programs.
- The MMA reduces reimbursement for Medicare Part B drugs beginning in 2004.
- The MMA creates a new, voluntary, Part D prescription drug benefit for Medicare-eligible individuals effective 2006 (open enrollment in November 2005).
- The MMA contains penalties for supplementation of plans beyond standard amount.

Medicare Prescription Drug Discount Cards in June 2004

- Beginning in June 2004, Medicare beneficiaries will be able to enroll in private prescription drug discount card programs.
- Companies issuing cards may charge enrollment fees up to $30 annually for each card.
- $600 in cash benefits will be provided to low-income enrollees who sign up for cards.
- Potential sponsors of discount cards notified CMS of their non-binding intent to bid by January 7, 2004—more than 100 did so.

Reductions in Reimbursement Rates for Medicare Part B Drugs

- Current rate, 95% AWP, will be reduced to about 85% for brand name drugs and even more for most generic drugs.
- No direct impact on manufacturers price but likelihood is that revenues will fall due to lower volume.
- Prescription drugs administered by physicians are likely to be affected the most because Medicare price will include no profit margin for dispensing physicians.
- Impact on sales is likely to be small for drugs that are sold directly to patients because 85% AWP is comparable to typical PBM prices.

Medicare Rx Coverage in 2006: General Rules

- Prescription drug coverage must be purchased from private companies.
- Participation in the Medicare drug plan is voluntary—Medicare beneficiaries assess whether to participate or not.
- Premiums for prescription drug coverage will be heavily subsidized by Medicare--only about 25%, or $35 per month will be paid by Medicare beneficiary.
- All Medicare beneficiaries, except for DoD and Civil Service retirees, will be eligible for the new Medicare plans; Medicaid shifts to PDPs, too.

Medicare Rx Coverage: Plan Design

Beginning 2006:

- Deductible = $250
- Coinsurance = 25% of drugs costs up to $2,250
- Doughnut Hole = 100% between $2,250 to $5,100 ($3,600 OOP)
- Catastrophic Coverage = 5% coinsurance after $5,100 in spending ($3,600 OOP)
- Low-income subsidies – cost sharing and premium assistance for those up to 150% of FPL.

Medicare Rx Coverage: The All-Pervasive TROOP Rule

- The “doughnut hole” begins at $2,250 in spending and ends when beneficiary spends $3,600 in true out-of-pocket (TROOP).
- If a Medicare beneficiary purchases a plan that supplements the standard benefit package, for example by extending the 25% co-payment beyond $2,250 in spending, the Medicare catastrophic benefit begins only when Medicare beneficiary has spent $3,600 out-of-pocket.
- In this case, the catastrophic does not pick up until $13,400—the health plan or employer will have to provide coverage from $5,100 to $13,400 as well as from $2,250 to $5,100.

Medicare Rx Coverage: Provisions Related to Retiree Drug Coverage

- Employers must choose whether to drop the current plan and encourage retirees to enroll in a Medicare PDP or to keep the current plan and receive a subsidy of 28% on spending between $250 and $5,000.
- If an employer supplements a PDP, those benefits will be subject to the TROOP rules, and that employer would lose some of the subsidy value of the Medicare plan.
- Retirees whose companies drop their plans will be subject to much higher out-of-pocket expenses under the standard Medicare plan and will purchase fewer prescription drugs.

Medicare Rx Coverage: Provisions Related to Other Private Plans

- Elimination of prescription drug coverage in Medigap plans—models H, I, and J.
- Choice HMO and PPO options for those who are willing to replace traditional Medicare with private plans—new plans called Medicare Advantage in 2006 and beyond.
- Medicare Advantage plans could offer enhanced drug coverage but would be subject to TROOP rules.
- Medicare officials claim that enrollment in new managed care plans will top 30%.

Impact on Pharmaceutical Companies Revenues

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How the MMA Impacts Pharmaceutical Revenues

- Two major impacts of legislation: higher utilization offset by higher discounts.
- Utilization will increase because Medicare beneficiaries will have more and better coverage, on average—this is called induction.
- Discount, or rebates, will likely increase because competition will force the new private plans to be more aggressive, on average, than current PBMs.
- The net impact varies by type of insurance coverage and nature of the prescription drug product under consideration.

The MMA Will Reduce Revenues From Retirees in Company Plans

- Employers must choose whether to drop the current plan and encourage retirees to enroll in a Medicare PDP or to keep the current plan and receive a subsidy of 28% on spending between $250 and $5,000.
- Retirees who purchase PDPs will be subject to much higher out-of-pocket expenses under the standard Medicare plan and will purchase fewer prescription drugs.
- Retirees who move from current coverage to the standard plan under PDPs will face higher cost sharing and thus use fewer prescription drugs.

The MMA Will Increase Revenues from Medicaid Dual Eligibles

- Medicare/Medicaid dual eligibles will be required to receive their coverage through Medicare Part D—affects about half of Medicaid sales, on average.
- Medicaid rebates for dual eligible beneficiaries will be replaced by the private-sector PDP rebates; average rebates on this population will fall from around about 28% to about 15% (based on estimates from the Congressional Budget Office).
- Since Medicaid dual eligibles will continue to full coverage with only nominal cost sharing, the volume of drugs should not change.
- Thus, the net impact will be higher revenues.

Legislation Will Almost Eliminate Self-Pay Population

- The Congressional Budget Office estimates that virtually all Medicare beneficiaries will have prescription drug coverage in 2006 and beyond.
- Those who currently do not have coverage will receive coverage that pays for about 53% of drug costs (95% for low-income beneficiaries).
- Utilization for this group should increase from 20% to 35%, depending on your assumptions about to new insurance coverage.
- Net impact, after accounting for rebate, is certainly positive.

Some Tentative Numerical Estimates of the Impact of the MMA on the Pharmaceutical Industry

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Impact on Medicare Part D Sales in Pharmaceutical Industry

- Based on PwC models, the impact of more coverage will increase volume of sales to Medicare beneficiaries by about 5% to 10%, depending on assumptions.
- The aggressive cost management by the new private prescription drug plans is expected to increase rebates by perhaps 1% to 10%, depending on assumptions.
- The net effect on pharmaceutical companies' Medicare revenues, outside of Part B, is likely to be in the range of minus 4% to plus 6%–best guess around plus 2%.

Impact of the Act on Sales of Drug Covered under Medicare Part B

- The previous calculations did not account for the impact of the MMA on Part B.
- The impact on some drugs, especially those administered by physicians, will be negative because incentives to prescribe and deliver Part B drugs will be reduced.
- PwC estimates that Part B sales will potentially fall by 5%.
- Since only 5% to 10% of Medicare sales are typically paid by Part B, the impact, if spread across all Medicare, would be about a reduction of less than one percent.

Other Legislative Changes Must Also Be Taken Into Account

- Revenues should be increased when the company discount cards disappear in 2006.
- Revenues should also be increased when patience assistant programs disappear in 2006. (There may be some small need for patient assistance for Medicare patients.)
- The increase from lower patient assistance and discount cards may be large enough to offset any net loss under Part B and Part D coverage.
- The impact, however, will vary by company and by product.

Differences Between Brand and Generic Drugs

- Generic drugs are sold at much higher discounts off AWP compared to branded drugs.
- Generic drugs are not usually subject to manufacturer rebates.
- The mutli-tier copay structure favors generic drugs.
- Better-insured patients may use fewer generic drugs as a percent of all scripts; this has not been shown to be a strong relationship, however.
- Pharmacies usually are rewarded for selling generic drugs by higher mark-ups.
- Generic drugs usually cost about ½ as much as brand-name drugs.

Impact of Legislation on Generic Drug Sales

- Volume should increase by 5% to 10% before considering relative sales.
- Impact on discounts should be minimal?
- Higher levels of insurance may favor branded drugs.
- More aggressive PBMs may favor generic drugs—could be worth an additional 5% to 10% in sales.
- Some companies may be favored over others.

Summary of Quantitative Estimate of Impact of MMA on Revenues

- I have argued that the overall impact of MMA on revenues pharmaceutical revenues is positive but there is room for argument and the impact certainly varies by drug and by company.
- The impact on revenues of generic companies is much more likely to positive and larger than the effect on brand-name companies.
- Companies need to assess the situation for their own companies and do so by product.

How to Assess The Impact on Your Company

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How to Assess the Impact of the Act on Your Company

- PwC has helped companies assess the impact of legislation on their companies overall and on their specific products.
- The quickest assessment, but least accurate, of the impact is to take overall estimates of impact and adjust them to reflect your company's Medicare share.
- PwC has also performed high level analyses in which company-specific data on average rebates, average sales, and other firm-wide statistics are used to provide a quick assessment of the impact of Medicare legislation on a specific company.

Assessing the Impact on Specific Rx Drug Products

- Ultimately, every company needs to know the impact of the MMA on its major products; PwC has done these assessments for a number of companies.
- PwC works with our client's product teams to estimate the characteristics of each product.
- PwC then estimates the impact on each product based on product-specific information and assumptions about third-party payers, rebates, and response to new coverage.
- Companies can use those estimates not only evaluate specific products but also to make a better overall assessment of how overall company's revenues will be affected.

Overall Impact According to the Following Factors

- *Sources of Payments:* Impact will be negative for drugs that are used primarily by retirees with employer coverage and positive for drugs used by Medicaid programs.
- *Impact on Rebates*: Drugs that have few competitors may not have to increase rebates under the new law.
- *Importance of Catastrophic Coverage:* Utilization of especially expensive drugs are expected to increase dramatically under the new law due to catastrophic coverage.
- *Part B Issues:* The new legislation should reduce the competitiveness advantage of drugs with Part B coverage and help their competitors.

Summary and Conclusions

- The MMA will affect a large part of pharmaceutical company sales.
- Pharmaceutical industry “customers” will shift significantly with many fewer Medicaid and self-pay sales and an entire new PDP marketplace.
- The net impact on revenues, after accounting for Part D, Part B, and changes in patient assistance, is positive but may be less than one percent relative to total sales.
- The impact will vary by company and by drug.

Who to Contact at PwC for More Information

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Appendix:

Operational Impacts to the Pharmaceutical Industry

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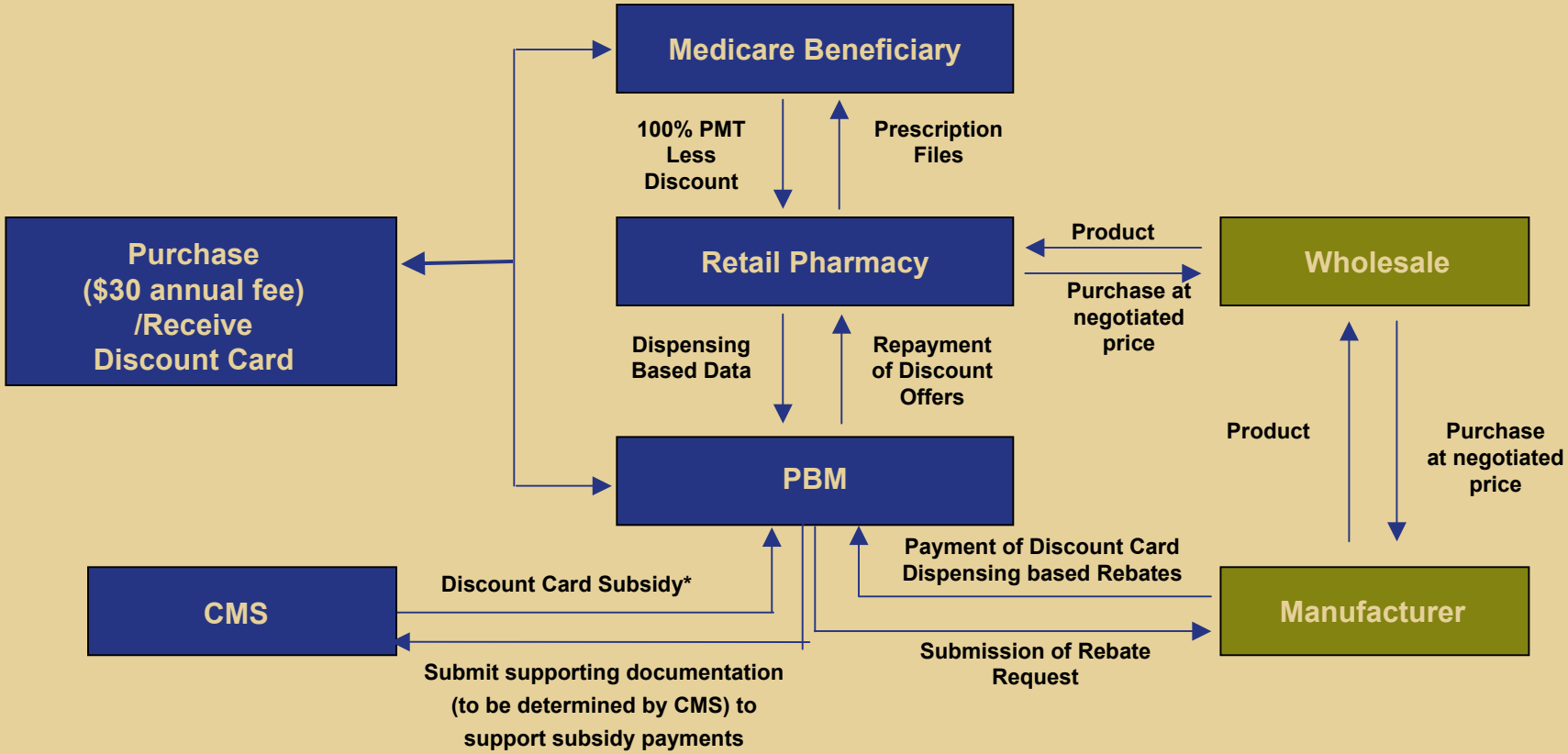
Operational Impacts – Rebate Contracting with Exclusive Card Sponsors

- Six months after the enactment of the legislation until December 31, 2005, the Secretary of HHS will endorse a prescription drug discount card for Medicare eligible beneficiaries.
- Manufacturers currently sponsoring drug discount cards for Medicare beneficiaries will need to assess the continuance of their specific drug discount card program in light the government endorsement.
- If a manufacturer decides to participate in the prescription drug discount card program (via a rebate arrangement with the Exclusive Card Sponsors (i.e., PBM) quarterly and annual administrative processes should be in place to ensure eligible utilization submitted for discount is compliant with the negotiated rebate arrangements (similar to those processes used in assessing managed care rebate submissions.)

Understanding of the Medicare Prescription Drug Discount Card and Transitional Assistance Program Transaction Flow



PBM = Exclusive Card Sponsor

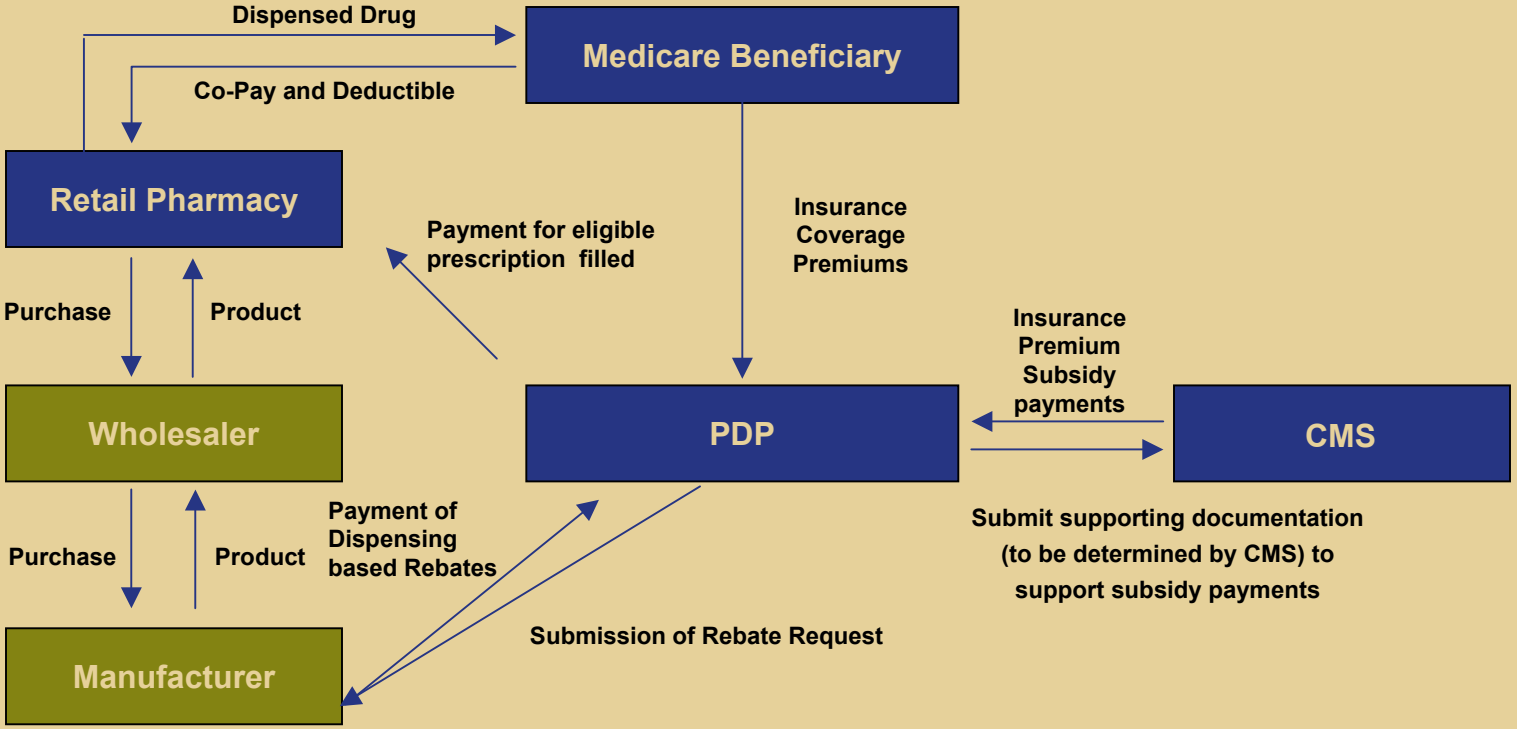
• Subsidy would be $30 annual fee and $600 annual prescription benefit for eligible low-income beneficiaries (ie transitional assistance)

Note – This program shall not apply to covered discount card drugs dispensed after December 31, 2005

Operational Impacts – Rebate Contracting with Private Drug Plans

- Pharmaceutical manufacturers will need to establish policies, procedures and controls to negotiate and administer rebate contracts with private drug plans specifically addressing the following:
  - ✓ What dispensing utilization is eligible for rebate
  - ✓ What types of rebates will be offered (access vs. performance based), taking into consideration the PDPs ability to manage formulary compliance and the plan designs being offered to the Medicare participants
  - ✓ Quarterly contract administrative procedures
  - ✓ Ability to perform annual contract compliance reviews with private drug plans

Medicare Prescription Drug Benefit Transaction Flow



Key Points:

- PDP will become "at risk" for the cost of the prescription drug benefit and will be developing benefit programs based on government guidelines
- PDP will negotiate with the retail pharmacy for the reimbursement of prescription drugs filled to Medicare Beneficiaries
- PDP will use the Insurance coverage premiums, subsidies from the government and rebates received from the manufacturer to cover the costs paid to the retail pharmacies for prescriptions filled to Medicare Beneficiaries

PDP = Private Drug Plan

Operational Impacts – Government Price Reporting

- The legislation will require manufacturers to submit quarterly the Average Selling Price (ASP) to the Secretary for multi-source and single source drugs reimbursed under Medicare Part B after January 1, 2005. Pharmaceutical manufacturers will need to assess their price reporting capabilities to address the following:
  - ✓ Capability of current government price reporting systems to be adapted to calculate ASP
  - ✓ Ability to capture appropriate transactions for certain ASP eligible purchasers that may differ from current Medicaid guidelines. The following transactions would be considered eligible for inclusion in the ASP calculation:
    - ❑ Transactions included when determining Best Price for Medicaid rebate purposes
    - ❑ Transactions not considered to be nominal charges
  - ✓ Process and methodology to estimate ASP eligible managed care

Operational Impacts – Importation of Prescription Drugs

- Pharmaceutical manufacturers should assess the effect of Title XI – Subtitle C – Importation of Prescription Drugs will have on the following:
  - ✓ Chargeback Models with wholesalers who may be reimbursed at a substantially higher price (WAC) then the price the wholesaler actually paid for the product (the importation price)
  - ✓ Retail customers (mail order pharmacies and long-term care facilities) receiving rebates (purchase or dispensing based contracts). Rebates may be calculated on a price (WAC) that is substantially higher then the price actually paid by the retail customer

Operational Impacts – Patient Assistance Programs (PAP)

- Currently hospitals and other providers should have administrative processes and controls in place to ensure Medicaid eligible participants are not receiving free products under a PAP, which may be subsequently billed to Medicaid for reimbursement.
- Manufacturers need to assess if their PAP hospitals and other providers have implemented new administrative processes and controls to address the Medicare legislation.
- Manufacturers should experience a significant drop in free product offered under the PAP once the legislation is fully implemented. This is due to a significant number of Medicare beneficiaries currently eligible to participate in PAP programs will be eligible for reimbursement under Medicare.

Operational Impacts – Corporate Compliance Program

- Manufacturer's compliance programs will need to be revisited:
  - ✓ Need to assess established and approved work-plans and staffing/funding requests to meet new requirements
  - ✓ Need to assess whether their current compliance program infrastructure is adequately structured, focused, and resourced
  - ✓ Identify and mitigate business risks associated with the new drug benefit
- While the PhRMA Code and OIG Compliance Program Guidance will provide some direction, it is likely that HHS will develop more stringent compliance controls associated with outpatient provisions and the drug

Who to Contact at PwC for More Information on Operational Issues

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