



The Medicare Prescription Drug, Improvement, and
Modernization Act of 2003:

Raising the Bar on Operational and Compliance Standards in the Pharmaceutical Industry

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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.
- The Act will provide \$400B of prescription drug benefits over the next 10 years (and up to \$2 trillion over the next decade).
- The Act, which affects 43% of pharmaceutical sales will have major effects on prescription drug coverage, utilization, and prices.



Pharmacy Components of the Act

- The Act establishes a prescription drug discount card program, in 2004 and 2005, that will compete with, or replace, current discount card programs.
- The Act reduces reimbursement for Medicare Part B drugs beginning in 2004.
- Allows importation of prescription drugs from Canada, subject to safety finding by the Secretary of HHS.
- Creates a new, voluntary, Part D prescription drug benefit for Medicare-eligible individuals effective 2006 (open enrollment in November 2005).



What Does this Mean for Pharmaceutical Companies?

- Pharmaceutical companies will be asked to provide rebates to support the new discount card beginning June 1, 2004.
- In 2006, Congressional estimates are that 85% of all Medicare beneficiaries will enroll in new prescription drug plans subsidized by the government (43% of pharmaceutical industry revenue is derived from Medicare beneficiaries).
- Since private drug plans (PDPs) are expected to have greater formulary management ability and will be assuming additional financial risk beyond many existing employer sponsored health plans, pharmaceutical companies could expect new contract administration and management requirements, including increasingly complex rebate structures and arrangements.



What Does this Mean for Pharmaceutical Companies?

- PwC has estimated that reimbursement for prescription drugs under Medicare Part B could be reduced by more than 10% on average
- The law has a direct impact on pharmaceutical industry compliance programs for those organizations seeking to provide outpatient drugs and biologicals to the federal government under the newly formed program payment and participation process.



Sizing the Impact on Pharmaceutical Companies

- 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 reduction in Medicare Part B reimbursement is expected to reduce sales for certain drugs.



Sizing the Impact on Pharmaceutical Companies

Studies conducted by PwC found that the Act will, on average, increase revenues, but the results will vary and be impacted by:

- *Status of Patents:* The sale of less expensive generic drugs may increase, if available, at the expense of branded products.
- *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.
- *Part B Issues:* The new legislation should reduce the competitiveness advantage of drugs with Part B coverage and help their competitors.
- *Importance of Catastrophic Coverage:* Utilization of especially expensive drugs are expected to increase dramatically under the



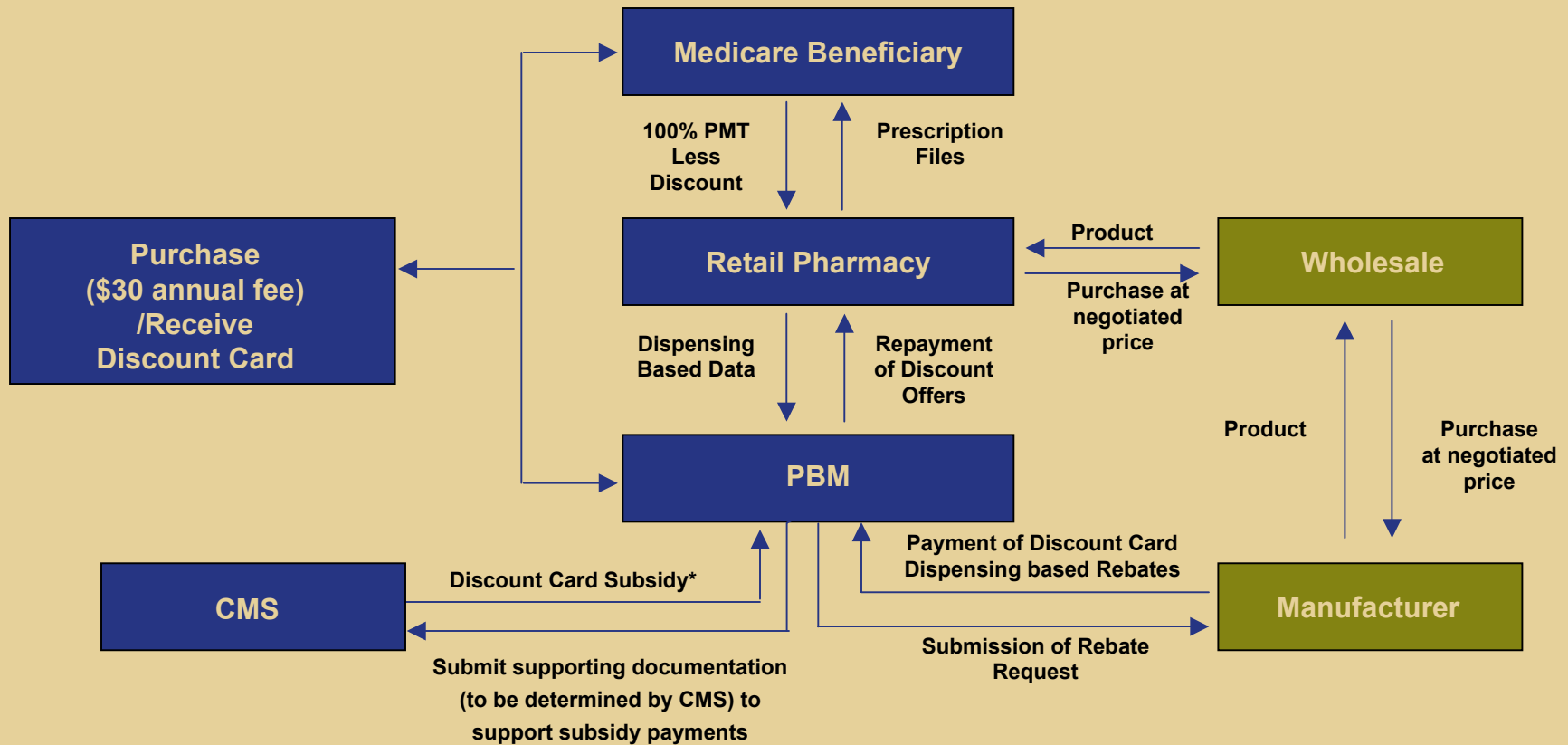
Sizing the Impact on Pharmaceutical Companies

- The quantity of free and discounted drugs that are provided through patient assistance programs and manufacturer-sponsored discount cards may be reduced significantly since almost all Medicare beneficiaries will have drug coverage in 2006. This will result in increased revenues.
- Key compliance policies and procedures, which were likely updated recently to adhere to PhRMA Code and OIG Compliance Guidance, may go through yet another round of revision. Specifically, companies must:
 - Comply with a code of conduct, specified or recognized by the Secretary
 - Comply with all applicable provisions relating to fraud and abuse, including compliance with applicable guidelines of the

Operational and Compliance Considerations for the Pharmaceutical Industry



Medicare Rx Drug Discount Card Transaction Flow





Rebate Contracting with Exclusive Card Sponsors

- 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).
- The negotiated prices for covered discount card drugs are exempt from Best Price – manufacturers will need to address this in their calculations, business policies and information systems.



Rebate Contracting with Private Drug Plans – Due Diligence

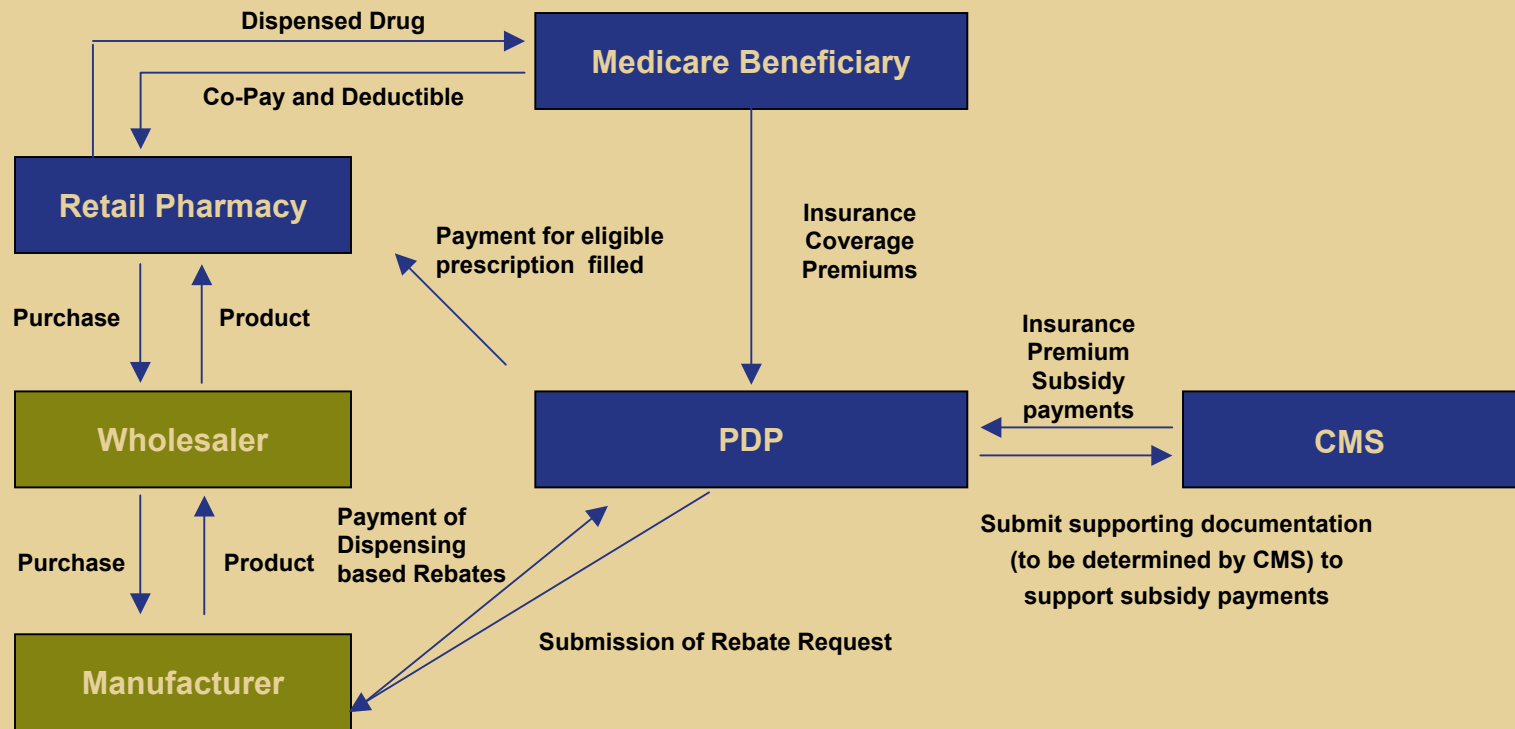
- Some important due diligence considerations:
 - ✓ If a formulary is used, does the sponsor provide at least one discounted drug in each of the 209 categories of drugs commonly used by Medicare beneficiaries
 - ✓ Is at least one generic drug being offered for a negotiated price in at least 55% of the required categories
 - ✓ What is being done to ensure transparency of pricing (remember that CMS will publish price comparisons on the Internet)
 - ✓ Are there contracts with institutional pharmacies
 - ✓ Is convenient access to pharmacies provided
 - ✓ Does the sponsor have a system to reduce medication errors and prevent adverse drug interactions
 - ✓ Sponsors are precluded from marketing non-drug products to Medicare beneficiaries
 - ✓ What are the controls to monitor drug price changes



Rebate Contracting with Private Drug Plans – Monitoring Compliance

- The law authorizes the imposition of civil monetary penalties against any card sponsor that *“knowingly engages in conduct that violates the conditions of their endorsement agreement with CMS or that constitutes false or misleading marketing practices...”*
- CMS will develop a system to monitoring and ensure compliance:
 - ✓ Deceptive marketing and enrollment practices
 - ✓ Arbitrary variation in negotiated prices offered
 - ✓ Persistent inconsistencies in formulary or pricing information (sponsor must *“report savings from pharmacies and manufacturers obtained through rebates, discounts and other price concessions”*)
 - ✓ Persistent problems with pharmacy network services or providers
 - ✓ Denying transitional assistance to beneficiaries

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



Rebate Contracting with Private Drug Plans

- The federal government, in essence, becomes the largest customer and, as such, the regulatory scrutiny related to fraud and abuse, false claims and anti-kickback rise up to a new level of importance.
- We anticipate fraud and abuse provisions will be introduced as the legislation is rolled out.
- Pharmaceutical manufacturers will need to establish policies, procedures and controls to negotiate and administer rebate contracts with PDPs, 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 PDP's ability to *manage formulary compliance* and the plan designs being offered to the beneficiaries
 - ✓ Quarterly contract administrative procedures
 - ✓ Ability to perform annual contract compliance reviews with PDPs



Medicare Part B Drug Reimbursement Issues – Government Pricing

- The Secretary may set reimbursement of Medicare Part B multi-source and single source drugs at 106% of the Average Sales Price (ASP) beginning January 2005.
- Manufacturers are required to submit ASP quarterly (see definition on next page) beginning on or after January 1, 2004.
- The Secretary may disregard ASP if ASP exceeds available market price or the AWP of a drug.
- The law enacts civil monetary penalties that the Secretary may apply if a manufacturer misrepresents drug pricing in its reporting of ASP.
- The result – the law adds yet another set of definitions and a new manufacturer government price reporting requirement to an already complex government price reporting process.
- We do have precedent of the impact – those manufacturers required under a CIA to calculate and report ASP.



Medicare Part B Drug Reimbursement Issues – Government Pricing

ASP Calculation

Eligible Gross Sales by NDC per Quarter

- Volume Discounts
- Prompt Pay Discounts
- Cash Discounts
- Short Dated Product Discounts
- Chargebacks
- Free Goods (contingent on other sales)
- Rebates (*all rebates except Medicaid*)
- Nominal charges
- All other price concessions (*excluding Bona Fide Charity Donations*)

Eligible Total Units by NDC per Quarter

Key Points

- After 2004, the Secretary may include “other price concessions...that would result in a reduction of the cost to the purchaser.”
- There is a requirement for the manufacturer to develop and submit a methodology to account for the “lag” in the availability of certain data in the reporting quarter (e.g., rebates).
- Also excluded are:
 - Indian Health, VA, DOD and PHS
 - Sales under FSS and GSA
 - Sales under a State pharma



Government Price Reporting – Other Considerations

- Manufacturers will not have the ability to resubmit ASP data
- The items that CMS outlines for inclusion and exclusion are different than those in Best Price and CIA-mandated ASP
- Reporting false ASP data will be considered a violation of the False Claims Act.
- The OIG is required to regularly audit manufacturer submitted ASPs and compare them with market prices and Medicaid AMP prices.
- The OIG will investigate drug pricing to identify overpriced drugs and HHS will institute fines on manufacturers who misrepresent or inflate drug prices.



Government Price Reporting – Operational and Compliance Issues

- Companies 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, including those that may differ from current Medicaid guidelines. The following transactions would be considered eligible for inclusion in the ASP calculation:
 - o Transactions included for Best Price for Medicaid rebate purposes
 - o Transactions not considered to be nominal charges
 - ✓ Process and methodology to estimate ASP eligible managed care rebate and chargeback transactions using the recommended 12-month rolling average



Government Price Reporting – Operational and Compliance Issues

- Companies will need to address business policies (methodology) and operational procedures (inclusion/exclusion rules) as well as ensure effective:
 - ✓ Training and education
 - ✓ Ongoing monitoring and auditing
 - ✓ Information systems controls
- Consider performing a mock audit to test controls, application of business rules, information systems, etc.



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



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 benefit overall



PricewaterhouseCoopers: Who to Contact for More Information

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