



# Compliance Programs

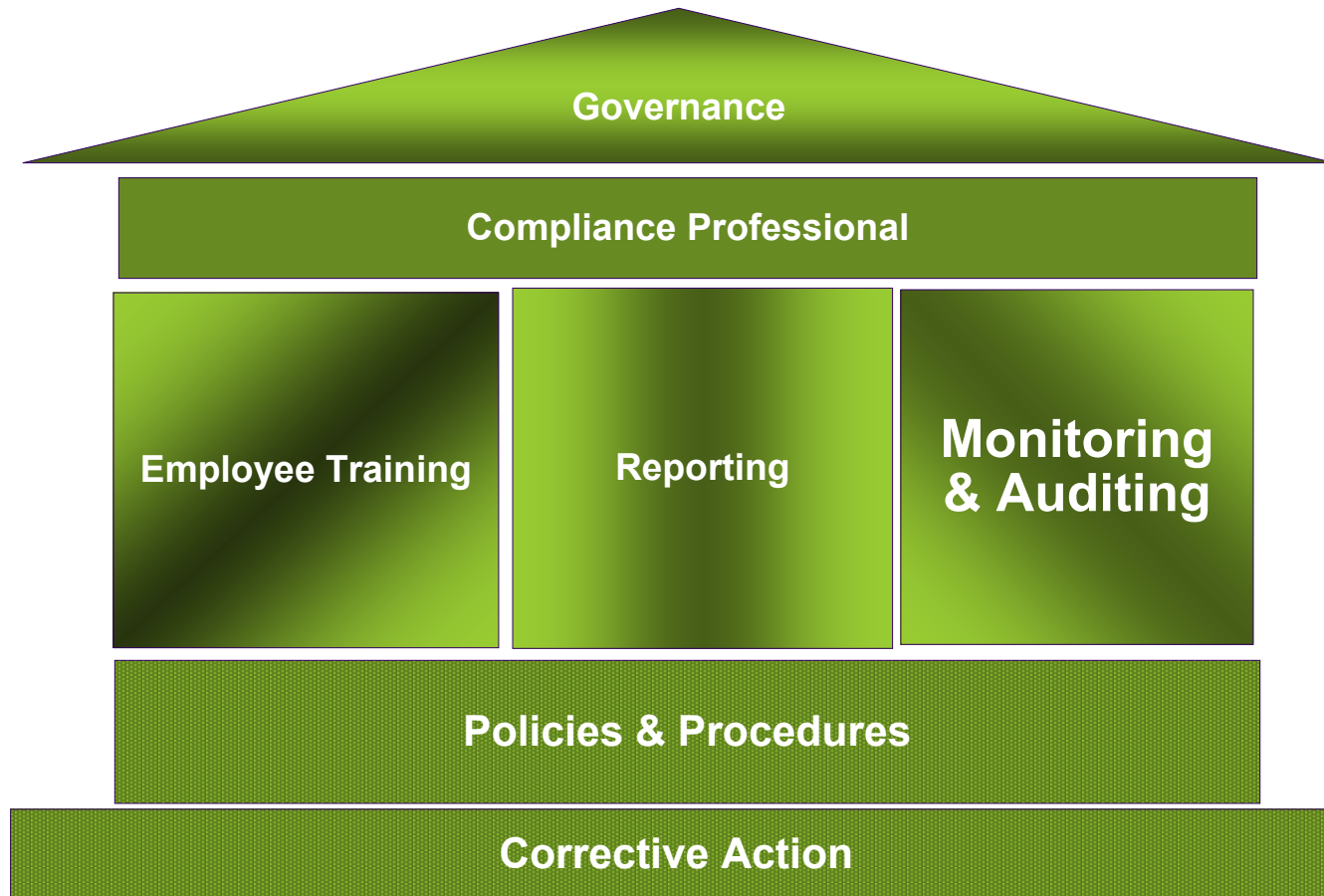
*Incorporating the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 into your Compliance Program*

February 25, 2004

# Overview of a Compliance Program



# Model Corporate Compliance Program Structure

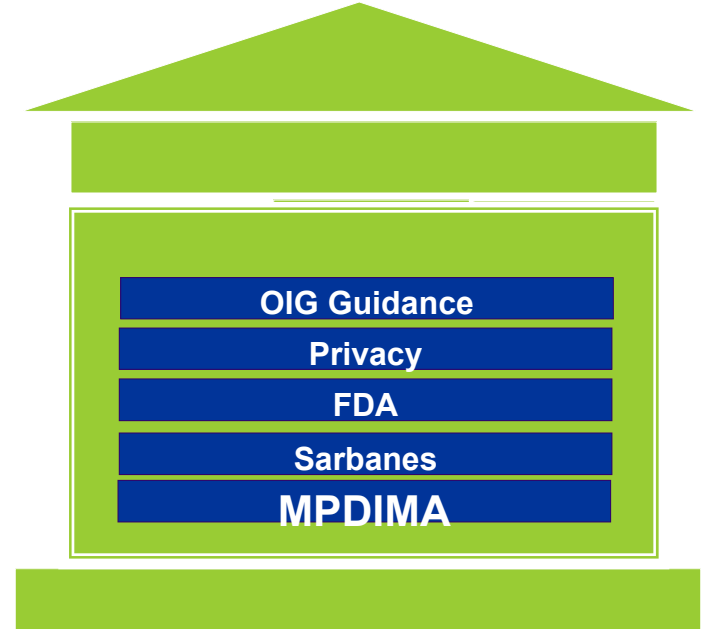


*A structure for managing regulatory risks within the enterprise includes monitoring and auditing activities.*



# Identify the Regulations

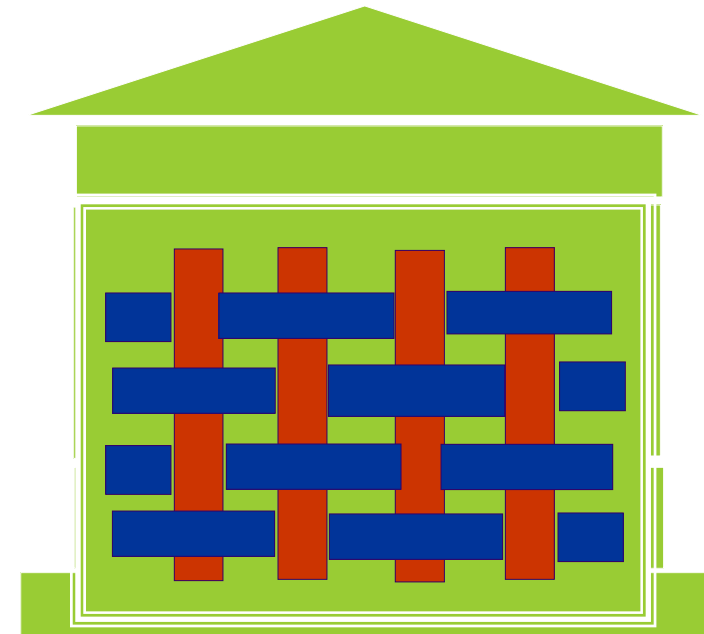
The compliance program may be based upon multiple regulations that impact the business (e.g. Privacy, OIG, FDA and MPDIMA)





# “Weave” the Regulations into the Business

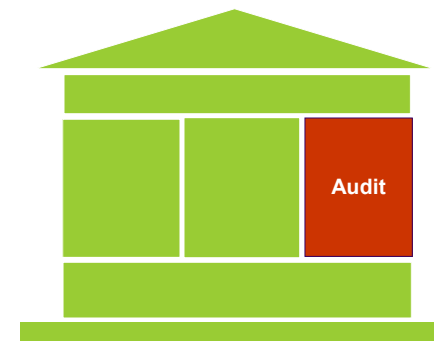
- Create the Policies and Standard Operating Procedures
- Identify the regulatory “touch points” within each business process
- Map the relationships
  - ✓ Business Process to Regulatory SOP
  - ✓ Regulatory SOP to Business Process
  - ✓ Build the requirements into the day-to-day procedures
- Train the employees
- Monitor the status of the risks
- Audit Compliance
- Correct problems
- Repeat the cycle



# Initiate a robust Audit process

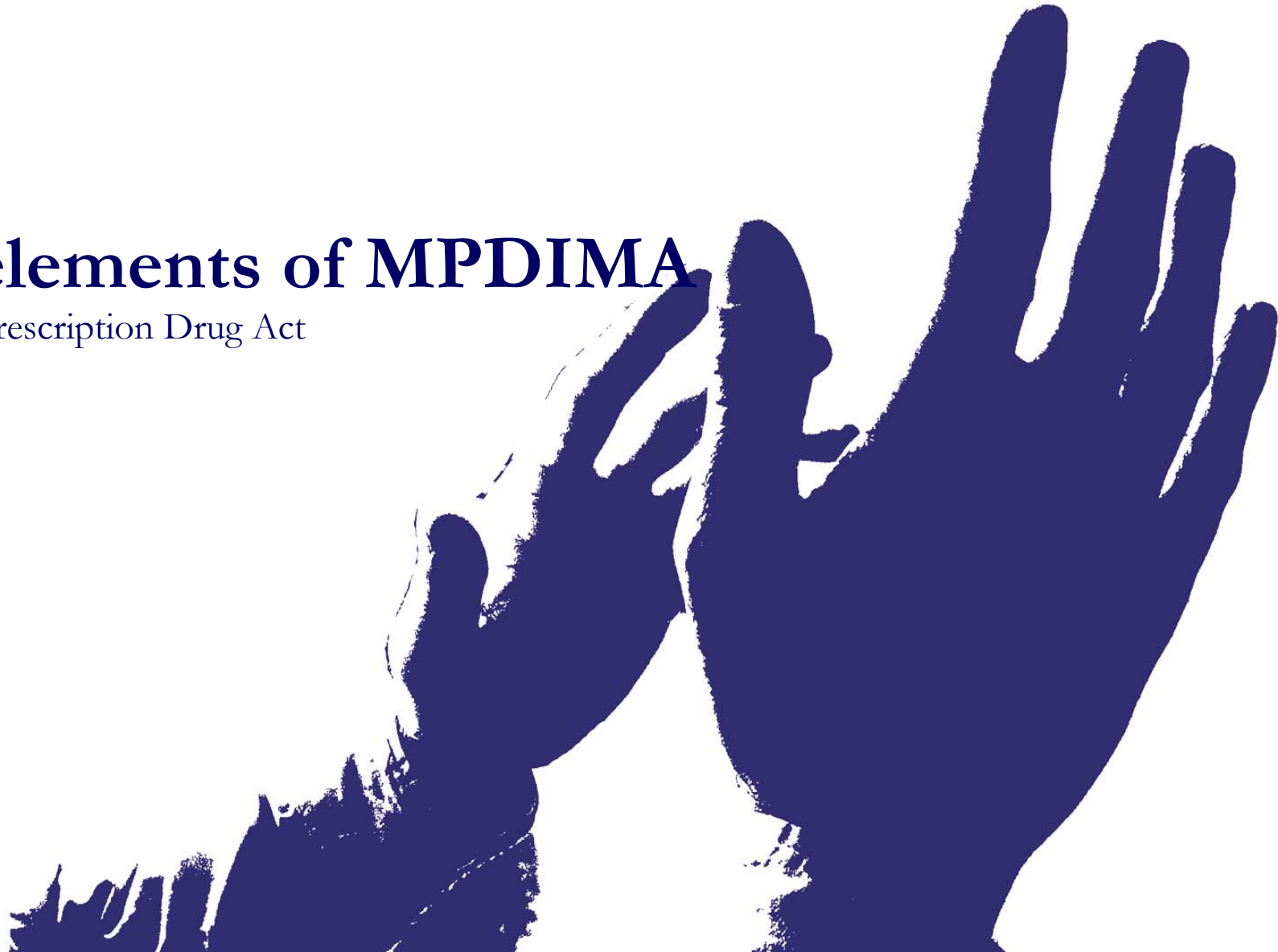


- **Define Review Scope & Assumptions**
  - Conduct interviews with Business Process Owners
  - Review Policies & Procedures
  - Review Education and Training materials
  - Document scope & assumptions
- **Develop Review Criteria**
  - Test Review Criteria
  - Enter criteria into database
- **Conduct Review**
  - Review recent audit related documentation
  - Enter findings into database
- **Document Findings and Observations**
  - Query database for exception findings
  - Summarize observations
  - Develop recommendations
- **Obtain Management Response**
  - Share findings with Business Process Owners
  - Obtain reactions to recommendations
  - Draft a Corrective Action Plan
- **Finalize Report & Corrective Action Plan**



# Key elements of MPDIMA

Medicare Prescription Drug Act



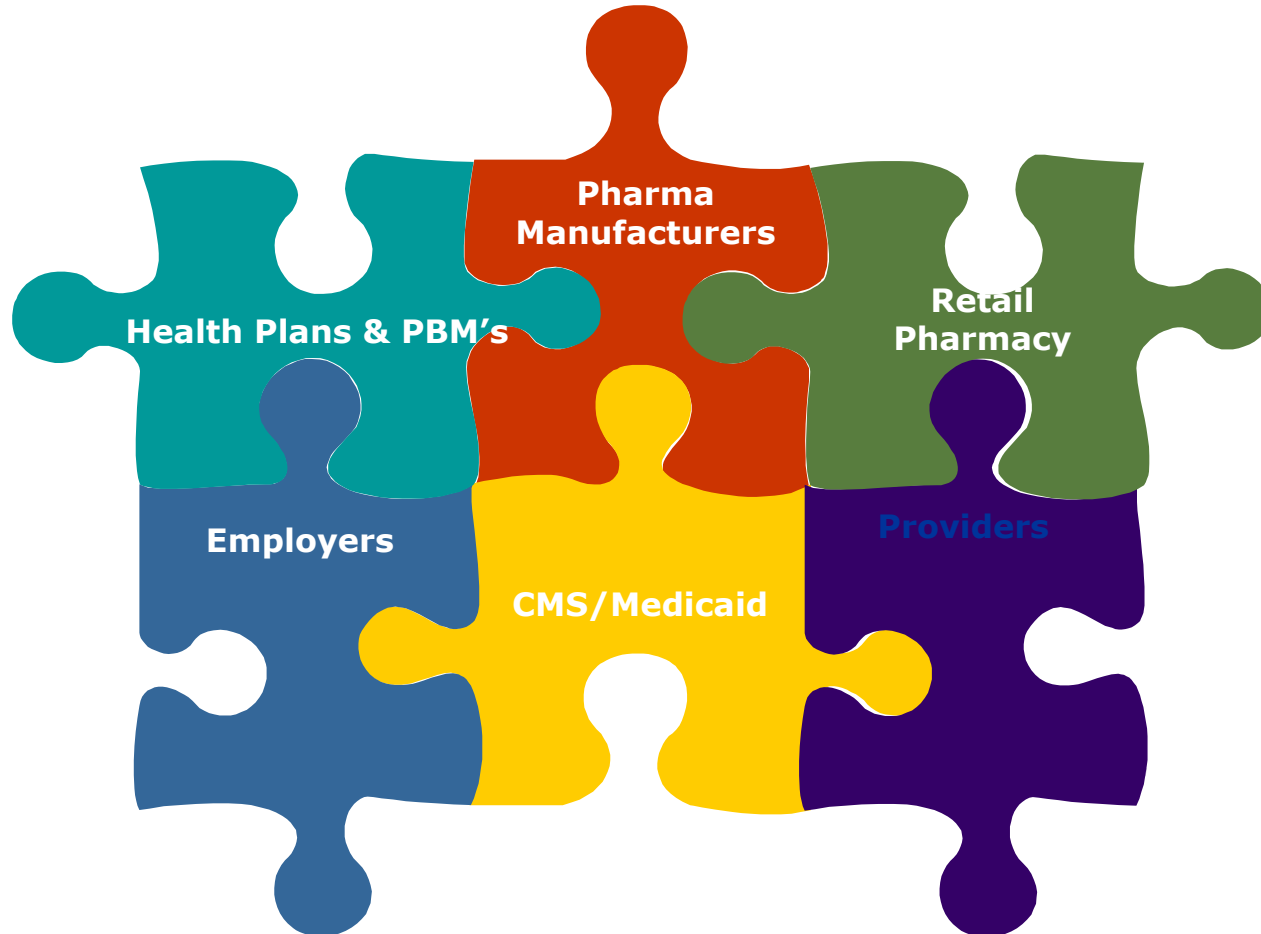


## Key Provisions of the Act

- ✓ Prescription Drug Discount Card
- ✓ Drug Benefit
- ✓ Medicare Advantage
- ✓ Provider Issues
- ✓ Medicaid
- ✓ Contractor and Regulatory Reforms
- ✓ Employers/Medigap/Health Savings Accounts
- ✓ Demonstrations, other, etc.



# The Act Impacts All Industry Segments



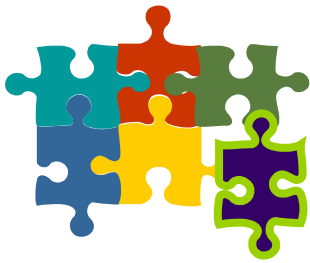


# Implications for Providers



- Will be more competitive in recruitment of clinical staff
- Improved ability to invest in new technology, information systems and physical plant
- May require specific actions to secure reimbursement for enhanced payments (e.g. wage index reclassifications, DSH payments & GME resident redistribution).

# Implications for Providers

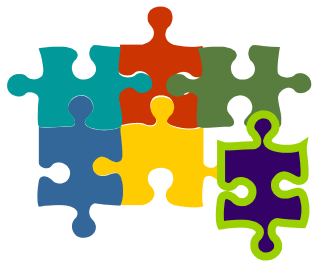


**National  
Voluntary  
Hospital  
Reporting  
Initiative**

- The benefits of participating are considerable:
  - ✓ Immediate and future increased payments from CMS
  - ✓ Reputation and stature
  - ✓ Improved managed care contracting strategy
  - ✓ A proactive, positive positioning in the face of increased consumerism.
- CMS intends to expand reporting requirements relating to quality measures and to provide financial incentives for hospitals to participate.



# Implications for Providers

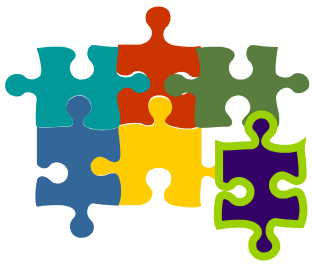


**National  
Voluntary  
Hospital  
Reporting  
Initiative**



- Short Term Strategy
  - ✓ Completely and accurately report the data
    - ❖ Perform assessments to identify gaps in the ability to capture the required data
    - ❖ Perform analyses to determine the accuracy and quality level of the documentation supporting the data elements to be reported
    - ❖ Medical records contain the necessary documentation
    - ❖ Educate and train personnel on the quality measures and required documentation
- Longer Term CIS Strategy

# Implications for Providers

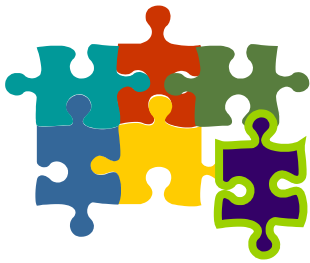


**Reduction in  
drug  
reimbursement  
for outpatient  
hospital &  
physician  
services**

- Injected treatments such as chemotherapy currently administered in doctors office may be moved to a hospital setting
- Hospitals will need to evaluate the impact of the reimbursement reduction on operations & consider alternative drug treatment options



# Implications for Providers

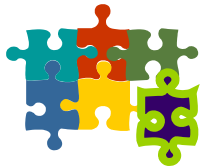


**Contracting  
with Medicare  
Advantage  
Health Plans**

- Hospitals will require enhanced information regarding their costs of providing services to Medicare enrollees
- Be prepared for Medicare Advantage plans seeking providers to participate in risk sharing arrangements



# Health Plan Implications



MMA infuses new life and funding into the Medicare private health plan marketplace, with higher payments over the next two years and a major restructuring beginning in 2006.

## Program Provisions:

- ✓ Improved payment rates for 2004 and 2005
- ✓ CMS national "Marketing Blitz"

## Major Changes for 2006:

- ✓ Regional PPO focus
- ✓ Standard drug benefit
- ✓ Competitive bidding
- ✓ Risk corridors
- ✓ Incentive programs
- ✓ New demonstrations



## Industry Reaction:

- ✓ Overall, quite positive and optimistic
- ✓ Medicare strategy reformulation
- ✓ Product positioning and brand development/repair
- ✓ Provider network strategy
- ✓ Medical management and chronic care initiatives



# Implications for Pharmaceutical Manufacturers

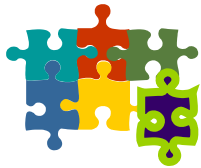


While MMA did not result in price controls for pharmaceutical manufacturers, it will provide both challenges and opportunities in the following areas:

- **Utilization**
  - ✓ Will increase as a result of expanded coverage & reduction in net selling price
- **Supply Chain Adjustments**
  - ✓ Utilization may occur at different delivery points
- **Contracting Approaches**
  - ✓ Formulary coverage is key
- **Technology and Compliance**
  - ✓ Quarterly reporting of ASP & rebates
  - ✓ Inclusion of price reporting under False Claims Act
  - ✓ Will require investment in new technology and processes



# Employers: Retiree Health Plan Relief



## Option 1

Receive a federal government rebate of 28% of “qualified costs” of drug plans actuarially equivalent to Part D

## Option 2

Redesign the employer drug plan to “wrap around” Part D benefits

## Option 3

Dropping drug coverage entirely in favor of letting Part D cover the retirees

**Actuarially**

Which option improves cash flow and liabilities?

**Legally**

Do contracts bar changes?

**Accounting/Balance sheet**

How will the change affect financial statement disclosures?



# CMS Medicaid Implications



State Medicaid Programs and CMS are facing major challenges from the MMA and its impact on Dual eligibles.

## Program Provisions:

Major Changes for Medicaid:

- ✓ January 1, 2006 dual eligibles to receive prescription drug benefits through Medicare
- ✓ Additional responsibilities and cost for administering Medicare's low income-subsidy program

Major changes for CMS:

- ✓ State Medicaid waiver programs
- ✓ Data transfer between States and Intermediaries
- ✓ Chronic Care Management Programs requirement



## Implications:

- ✓ Loss of best pricing and negotiating strength
- ✓ \$88.5 billion in "clawback" payments
- ✓ \$10.2 billion in low-income subsidy administrative costs
- ✓ Significant Operational and technical challenges
- ✓ Staff, technology and funding challenges



# Medicare Prescription Drug Act – Implications for Compliance Programs

- Identify applicable provisions of the act, the operational implications and whether they present compliance risks, opportunities or both
- Define the compliance parameters
  - What is going to be measured
  - How is it going to be measured
  - How is “success” defined
- Develop the Auditing and Monitoring procedures to address provisions of the act



# Parking Lot



# Medicare Prescription Drug Act – Implications for Compliance Programs

- MSP Provisions: Auditing and monitoring cash reconciliation procedures to avoid duplicate payments and confirm repayment to Medicare, when appropriate.
- Charge capture, coding and billing processes for certain outpatient drugs, biologicals and related services in:
  - ✓ Acute Care Hospital Setting
  - ✓ Free-standing oncology centers
  - ✓ Physician practices, and
  - ✓ Critical access and Rural Hospitals.
- Purchasing and pricing processes for certain drugs.
- Understanding hospital quality data reporting requirements to receive full DRG payment increase
- Cost accounting changes for critical access hospitals



## **Employers**

- Confirm health plans to determine if “high deductible”, making individual employees eligible for HSAs
- Monitor accounting guidance regarding certain post-retirement benefit plans



# Pharmaceutical Manufacturers and Life Sciences Organizations

- Major impact on compliance programs and practices to comply with provisions related to fraud and abuse
- PhRMA code and OIG Compliance Program guidance may evolve
- Increased risk of government scrutiny into pricing practices due to complexities of ASP calculations - False Claims Act implications
- Auditing and monitoring new and generic drug application process



## **Payers and PBMs**

- Proper entry/re-entry into Medicare Advantage
- Appropriate plan benefit design, and
- Appropriate PDP Sponsor bid submission and benefit design
- Prescription drug importation requirements