Implementing the Medicare Drug Benefit

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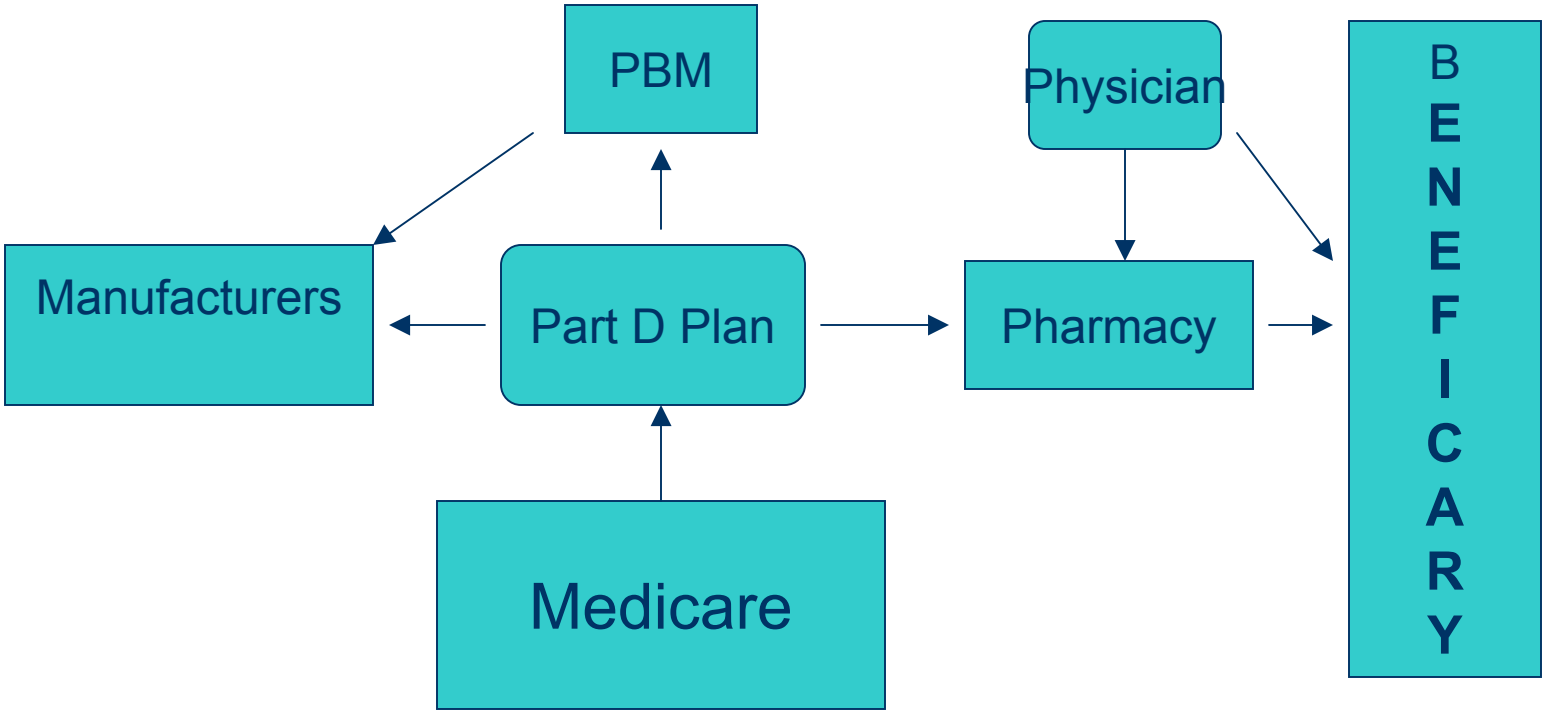
Presentation Outline

- Provide a general overview of the Medicare prescription drug benefit
- Highlight progress regarding implementation efforts
- Highlight several key Program Integrity issues

Medicare Part D



Benefit Delivery System

- Private stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage plans (MA-PD plans) will offer the benefit to Medicare beneficiaries
- At least two plans per region (only one of the plans needs to be a stand-alone PDP)
- If two plans do not exist in a region, CMS can contract with “limited risk” or “fallback” plans

Benefit Design

- Part D Sponsors can offer the standard benefit design, an actuarially equivalent benefit, or a supplemental benefit (additional premium could be charged)
- Individuals can use their plan's negotiated discounts even if they are not eligible for a benefit (e.g., before the deductible is met)
- Formularies and tiered copayments permitted and expected

Eligibility

- An individual is eligible for Part D, provided that he or she
  - Is entitled to Part A *or* enrolled in Part B
  - Lives in the service area of a Part D plan
- An individual must have a choice of 2 plans (except in territories)
- Participation in Part D is voluntary and optional

Enrollment Period

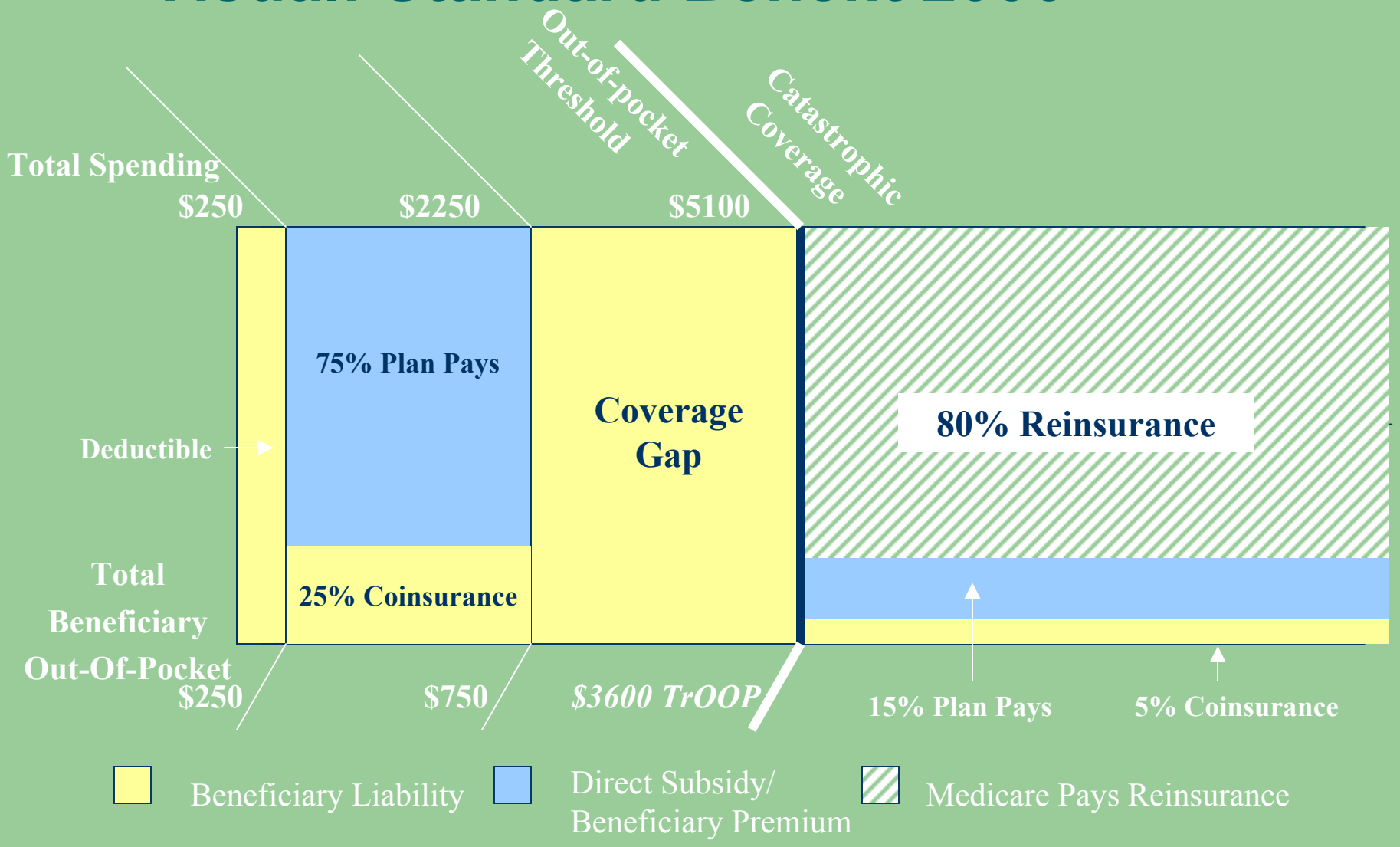
- Enrollment and election will be coordinated with the process for the MA program

- A 6 month initial enrollment period will commence on November 15, 2005, the same period established for MA plans for that year
  - The will also be enrollment periods for “special circumstances” – e.g. loss of coverage
  - Late Enrollment Penalty (1%/month): if credible coverage is ignored

Standard Benefit

- $37 estimated monthly premium
- $250 beneficiary deductible
- Medicare will pay 75% of drug costs up to $2,250. The beneficiary will pay 25%
- Beneficiary will pay 100% of drug costs between $2,250 and $5,100
- After $3,600 in out-of-pocket spending, Medicare will pay 95%
- Alternative coverage meeting actuarial tests allowed

Visual: Standard Benefit 2006



TrOOP

- TrOOP is the amount a beneficiary must spend on Part D-covered drugs to reach catastrophic coverage. It is based on the standard benefit design:

  $250 deductible
  + $500 beneficiary coinsurance during initial coverage
  + $2,850 donut hole
  = $3,600

- The above numbers are for 2006 and will increase by law in subsequent years
- Part D Premium is not part of TrOOP

Access Standards

- To ensure adequate and convenient access, standards will be no less than the TRICARE Retail Pharmacy access standards.
- PDP sponsors may not limit network to “mail order only” pharmacies.
- PDP sponsors must demonstrate adequate access to home infusion pharmacy services and pharmacies meeting LTC requirements
- PDP sponsors must ensure convenient access to I/T/U pharmacies

Employer/Union Plan Sponsor Options Under MMA

- Provide drug coverage in lieu of Medicare and receive retiree drug subsidy payments
- Provide supplemental coverage through stand-alone plan
- Purchase enhanced coverage from a PDP or MA-PD to supplement standard Medicare
- Become a PDP or MA-PD and provide customized coverage or purchase customized coverage from a PDP or MA-PD, pursuant to a CMS waiver
- Pay part/all retiree premiums
- Many factors can influence choice of option

Low-Income Subsidy Assistance

- Designed to provide low-income Medicare beneficiaries extra assistance with premium and cost sharing under the new drug benefit.
- Eligibility determination for low-income subsidies will rest with either the State Medicaid Agency or Social Security Administration.
- Low income subsidy applicants will have to meet an income and asset test.

Low-Income Subsidy Assistance

- Certain groups are automatically eligible for a full subsidy.
  - Full-Benefit Dual Eligible Individuals
  - SSI recipients
  - Medicare Savings Program Groups (QMBs, SLMBs, and QIs)

- There are special protections for full benefit dual eligibles.

Subsidy Categories

1. Full Subsidy
    - Full premium assistance up to the premium subsidy amount
    - Nominal cost sharing up to out-of-pocket threshold
    - Full benefit duals can get further reductions in cost sharing.
    - No coverage gap.

2. Other Low-Income Subsidy
    - Sliding scale premium assistance,
    - Reduced deductible
    - Reduced coinsurance
    - No coverage gap.

CMS Role in Formulary Review

- Designed to ensure there is a balance between a plan's ability to achieve lower costs and beneficiary's access to prescription medicines.

- Designed to ensure the adequacy of the benefit offered, and to ensure that plan formularies do not substantially discourage enrollment among certain groups of beneficiaries.

General MMA Formulary Principles

- General requirement: The formulary must include at least two drugs in each therapeutic category and class of covered Part D drugs.
- Represents a floor rather than an absolute standard.
- USP Model is but one option for the Plan formulary design.

CMS Formulary Review: Guiding Principles

- Rely on existing best practices,
- Protect against discrimination,
- Ensure flexibility, and
- Ensure administrative efficiency.

CMS Review: Three-Step Approach

- P&T Committee Review
  - Support MMA requirements
  - Rely on “best practices” in industry
- Formulary List Review
  - Review categories and classes
  - Review Drug List
- Review of Benefit Management Tools
  - Review utilization management tools that impact access

Payment

- Four components of payment
  - Direct subsidy
  - Reinsurance
  - Low income cost sharing
  - Risk corridors
- Direct subsidy based on bid
- Reinsurance and low income cost sharing
  - Interim prospective payment based on bid
  - Final payment based on actual costs
- Risk corridors determined based on actual costs

Data to Support Payment

Four Payment streams	Information
Direct Subsidy	Bid and claims data for risk adjustment
Low-Income cost sharing Subsidy	Difference between low-income cost sharing versus non low-income cost sharing
Reinsurance	Costs above the out-of-pocket threshold.
Risk Corridor payment	Relationship between target amount and adjusted allowable costs.

Selecting of Data Elements

CMS goals are to ensure that we:

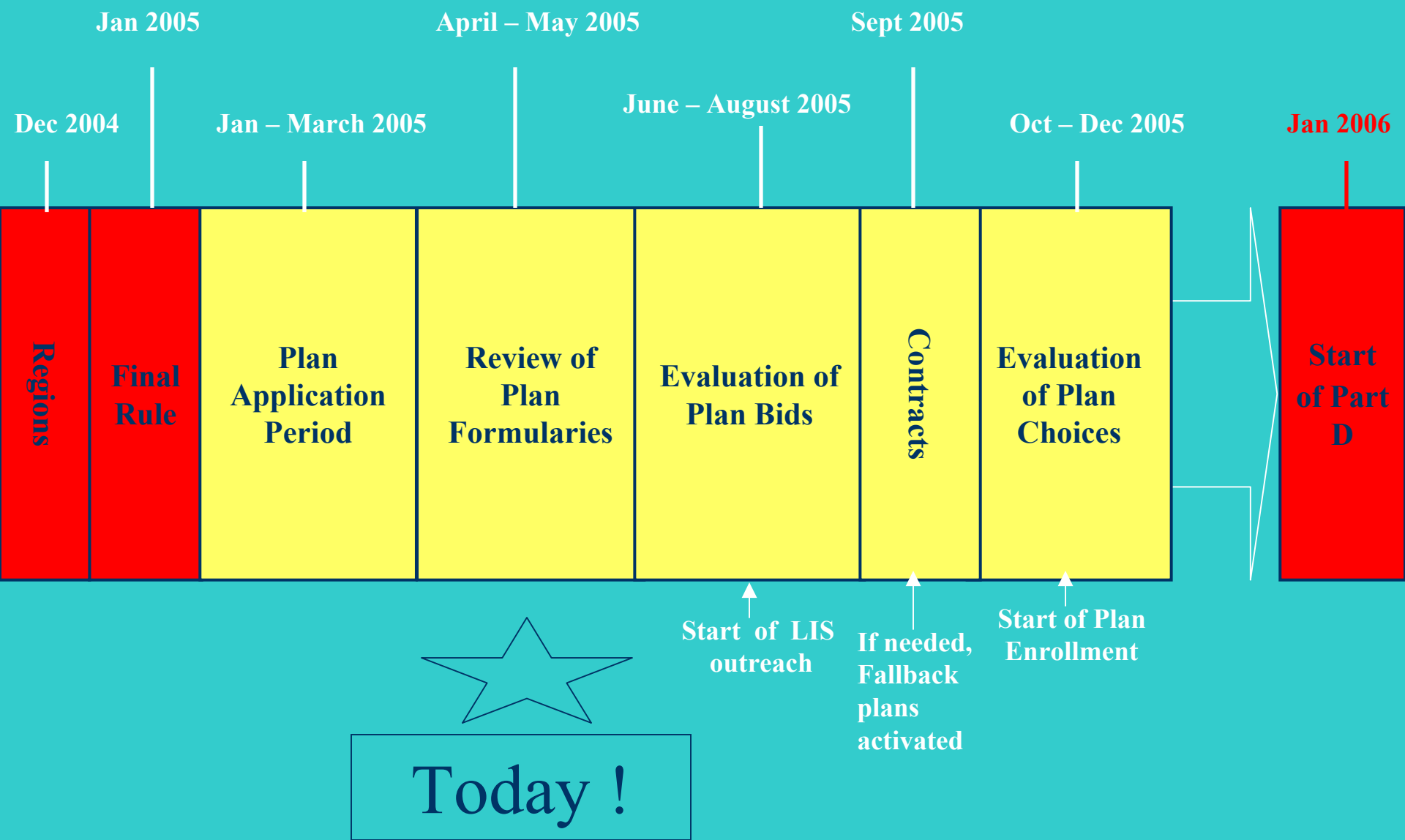
- Have the ability to pay plans timely and accurately under the 4 statutory payment streams,
- Minimize administrative burden,
- Reflect legislative authority, and
- Ensure validity and reliability of the data elements.

Claims Data for Payment

- 100% claims or events collection
- CMS will collect a limited subset of data elements per event
- *Proposed* Summary record with 30 data elements

Data source	Number of fields
*NCPDP billing transaction	10
*NCPDP billing response transaction	7
CMS	13
Total	*30*

Implementation Timeline



Training and Assistance for Plan Sponsors

- Bidders' data sets
- Weekly calls through June
- Bidding conference
  - April 4-5 in DC
- Submitting claims data for Part D
  - July 18-20th in Baltimore July 26-28 in Las Vegas
  - August 1-3 in Chicago August 9-11 in New Orleans
- Payment and enrollment conference
  - August 29th – September 2nd in Baltimore

Application Review

- Applications due on March 23rd
- March/April
  - Applicant notified of missing information and/or deficiencies
  - If sent letter of intent to deny, than Applicant has 10 days to submit information or correct deficiencies
- April/May --Additional information reviewed
- Late May --Application Approved or Disapproved

Additional Guidance To Be Released

- Fiscal Solvency Standards
- COB Guidance
- Prescription Drug Event Data
- Reporting Requirements

Formulary Review Timeline

- Formulary Submission 03/28 – 04/18
- Review of Formularies 04/19 – 05/18
- Negotiations with Plans 05/02 – 05/18
- Resubmission of Formularies 05/09 – 05/31

Formulary Review

- Formulary submitted by close of day on April 18th is expected to be the actual formulary for Plan use
- Minor changes may be allowed once in October – this might be change of 'like' agent in a therapeutic class, otherwise Plan will be held up pending new, complete formulary review
- Changes will be allowed once per month with specific time and notification requirements beginning in March 2006

Rebates

- All rebates, discounts, and considerations of value (including “value-added” programs) provided to Plan Sponsor must be disclosed to CMS as part of the Bid
- Plan Sponsor must submit estimated total value of all rebates, discounts, and considerations with Bid
- Actual rebate amounts will be reported to CMS – 1Q06 will be due end of 3Q06 and so forth

Rebates

- Program is expected to deliver best possible, low-cost pharmacy benefit
- Rebates are not limited by Medicaid ‘best price’ implications
- Separate Medicare contract is encouraged
- Recommend separate contract for each subordinate under larger contract (i.e. PBM contracting for MA-PD)

Bid Review and Approval

- Review bids -- due June 6
- OACT/Use of outside contractors
  - Determine reasonableness of assumptions/methods
  - Compare to appropriate benchmarks
  - Statistical analysis of bids submitted
    - Compare to national, regional, organizational bids
- Negotiate
- Bid Approval
- Audit

Review of Plan Marketing Materials

- Different levels of review required according to type of material, availability of model language, whether or not model language is modified, and plan's previous standard of performance

- Materials may be submitted beginning June 7

Contracts

- Draft contract will be out on web in June with at least a two week comment period
- CMS expects to complete contracting process by early September

Compliance Plan Requirements

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well-publicized disciplinary guidelines.

Compliance Plan Requirements

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract, including:

- ✓ Timely and reasonable inquiry into evidence of misconduct;
- ✓ Appropriate corrective actions including but not limited to, repayment of overpayments and disciplinary actions against responsible individuals in response to potential violations referenced.

(7) Procedures to voluntarily self-report potential fraud or misconduct to the appropriate government agency.

Compliance Plans

The MMA requires Part D Plans to have a program to control fraud, waste and abuse.

A fraud and abuse plan may be a separate plan within an overall compliance plan or may be fully integrated into the overall compliance plan. If the latter is adopted, fraud and abuse must be to be addressed specifically in each required element of the overall compliance plan.

Compliance Plans

Compliance plans should:

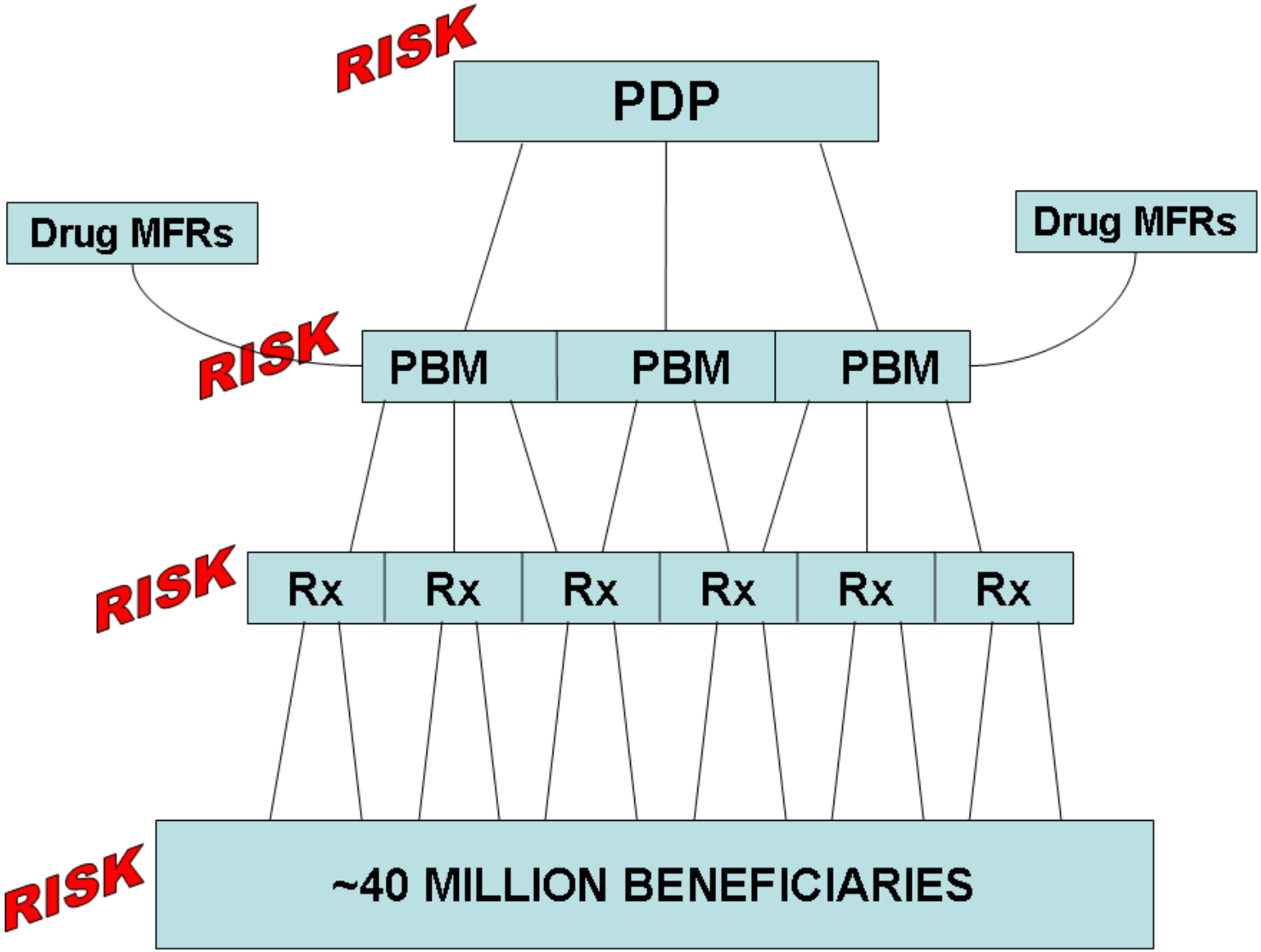
✓ Address and discourage participation in identified fraud schemes;

✓ Not be too generalized, it should address issues unique to the industry;

✓ Consider industry best practices in developing their compliance;

✓Strongly encourage the disclosure of misconduct to management and/or the appropriate government authority.

Program Integrity Identified Risk Areas



Program Integrity Issues

- CMS will use thorough analysis of data to monitor all areas of Part D program:
  - Formularies and Benefit Design
  - Pharmacy Networks
  - Over/Under-utilization
  - Potential Fraud, Abuse, Waste
  - Quality, Safety, Adherence, Complaints
- CMS has created a multi-layer approach to oversight, accountability, and program integrity
- Licensure, Solvency, Regulatory compliance and other market intelligence issues are incorporated

Closing Thoughts

- CMS has made great strides to implement the drug benefit.
- We encourage flexibility and are willing to work with the industry as we move forward.
- CMS has established a thorough oversight program to monitor all aspects of program compliance in partnership with OIG, DOJ, and others

Questions???