

# Implementing The Medicare Drug Benefit



Marc Benoff  
Practice Leader, Pricing and Reimbursement  
Cambridge, a unit of IMS Health

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## Overview

- A market in play
- The thin edge of the wedge
- Managed markets on steroids
- Changing physician practice economics (Part B dynamics)
- A look into the future

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## Historically, drug coverage under Medicare has been limited to one of three categories

### There are 3 major categories of covered Medicare Part B drugs:

- |  |   |   |
|--|---|---|
| <p><b>Type 1:</b> Drugs billed by physician that cannot be self-administered</p>                                       | → | e.g. Chemotherapies                                   |
| <hr/>  |   |   |
| <p><b>Type 2:</b> Drugs billed by pharmacy supplier and delivered through Durable Medical Equipment</p>                | → | e.g. Drugs administered through a nebulizer           |
| <hr/>  |   |   |
| <p><b>Type 3:</b> Drugs billed by pharmacy supplier but are patient administered and explicitly covered by statute</p> | → | e.g. Immunosuppressant agents, some oral cancer drugs |

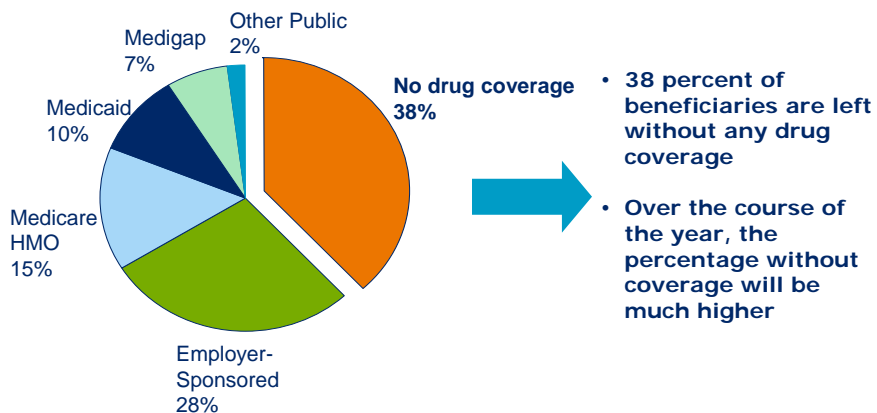
**Patients pay a 20% co-insurance for all of these drugs**

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## As a result, many beneficiaries are left without coverage of outpatient prescription drugs

Sources of Rx coverage among elderly (2003)

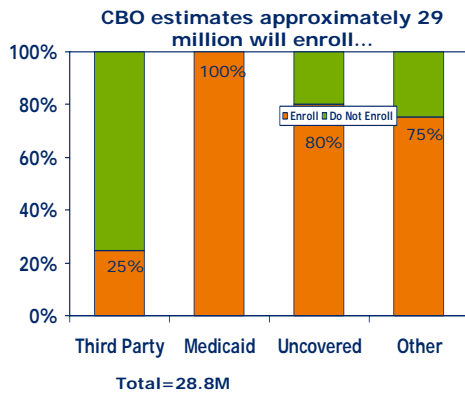


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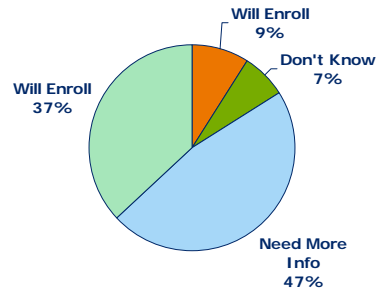
Source: Kaiser Family Foundation, 2003

**The CBO estimated approximately 29 million beneficiaries will enroll in the short term, although this is in question**



Source: CBO July 2004, Kaiser Oct. 2004, Cambridge

**...But beneficiaries suggest greater uncertainty**



Source: KFF Health Poll Report Survey, April 2005.

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**While total volumes are expected to increase due to MMA, the impact on any particular brand is less certain...**

**Market Level Impact**



- Based on CBO estimates, we expect the TRx impact will be 1-2% per year through 2008
- However, total dollar impact could vary depending on pricing pressures (contracting) and brand vs. generic mix

**Brand Level Impact**



- The overall impact on any given product will depend on the specific dynamics
  - Market drivers, TA dynamics, product attributes

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Source: IMS Management Consulting

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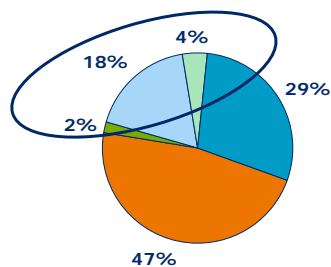
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## Part D turns the government into the largest purchaser of prescription drugs

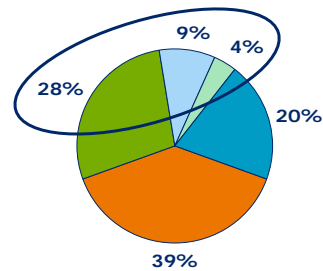
### Source of Rx Spend, 2005

Today, the government accounts for less than 25% of Rx spending



### Source of Rx Spend, 2006

In six months, the government proportion of Rx spend grows to over 40%



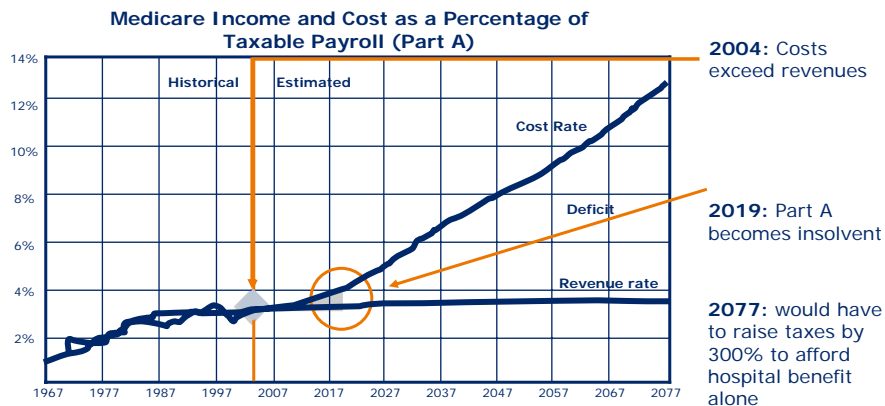
Private Insurance    Medicare    Medicaid  
Other Public    Out of Pocket

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Source: Center for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, 2005

## The costs of covering Medicare services are high and already exceed revenues



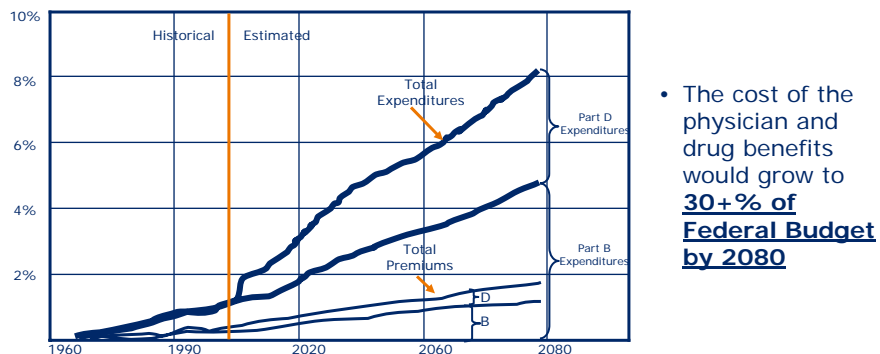
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Source: 2004 Annual Trustees Report

## With the addition of the drug benefit, even more strain will be placed on the government to reduce costs

**Physician and Rx Expenditures and Premiums as a % of GDP**

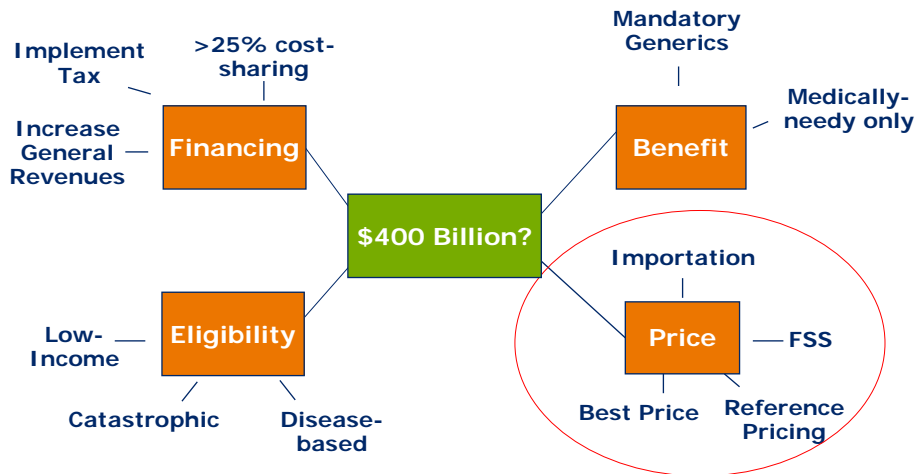


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Sources: 2004 Annual Trustees Report; Office of Budget Management

Over the medium term, there is significant risk for some form of government intervention



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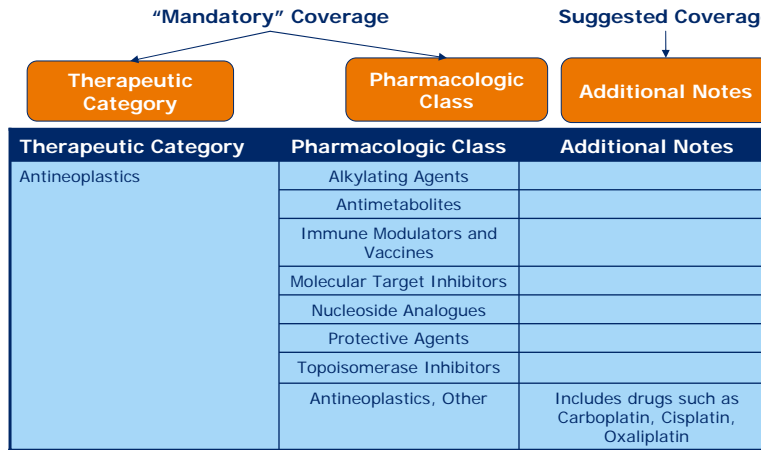
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## USP's broad therapeutic class definitions makes excluding branded products an option



**Who will determine what drugs are included?**

**How will this change the reimbursement landscape for oncology?**

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## Formulary inclusion is only half of the access battle, as CMS explicitly allows the full arsenal of management tools

- Multi-tiered formularies
  - Zero dollar co-pay are acceptable
  - 100% co-pay levels are acceptable
  - Low income co-pay limitations
- Prior authorizations
- Step therapies
- Therapeutic interchange (with physician consent)
- Mail-order
- Financial incentives to encourage use of generics

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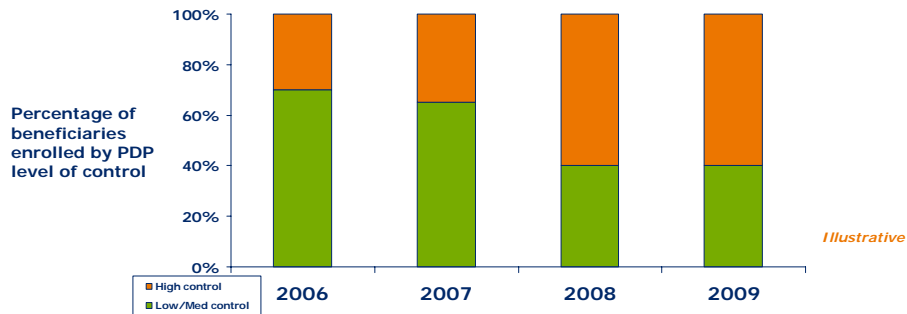
## Initially, formularies may look similar to today's commercial plans, but things may evolve

### In 2006:

- Plans compete for lives with access to commercial market
- Plans approach management similar to commercial market
- CMS endorses utilization tools and a subset of plans manage aggressively

### By 2008 and beyond:

- Profitability and sustainability correlate to level of control
- Lower control plans exit market
- Less beneficiary choice and option as high-control gains market traction



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Potential market scenario based on Cambridge analysis and market research

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## Under the FFS benefit, the MMA has altered the way IV drugs can be purchased and reimbursed

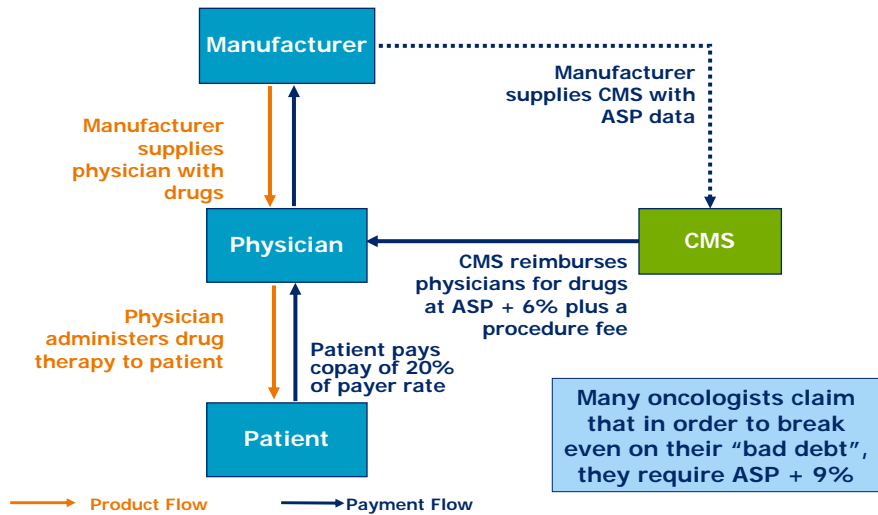


- Beginning in 2006, physicians can continue to acquire, bill, and be paid for products under
  - average sales price (ASP) methodology or
  - competitive acquisition program (CAP)
- Each year, physicians must elect a payment method per category of products and (if CAP is elected) a contractor per category of products

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## Under the ASP model, physicians remain the purchasers and hold the risk for drugs



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## However, ASP dramatically changes a physician's economic perspective

### Illustration

	2003	2005	
AWP Price	\$1000	\$1000	Moving forward, Medicare reimbursement/acquisition differentials will be decreased
Acquisition Price	\$800	\$800	
Reimbursement	\$950	\$848	
	AWP-5%	ASP+6%	
Procedure Fee	\$100	\$150	Procedure based fees for some products will be increased to compensate for lost product margins
Physician Economic Perspective	\$250	\$198	At the end of the day, this bottom-line will influence physician behavior

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## With the implementation, the market could evolve in a variety of ways

To manage growing costs under tightening budgets, plans become increasingly aggressive in using the various management tools available to them



**Managed Care on Steroids**

Beneficiaries are given economic ownership and are empowered to make treatment decisions



**The Age of the Consumer**

Despite the best efforts of the private sector, costs continue to escalate leading the government to implement some form of price/reimbursement controls



**Government Intervention**

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## Under a more extreme managed care environment, there will be intense competition for access

### Implementation

- Introduction of more limited preferred formularies
- HE increasingly used to rationalize access
- Intense competitive between competing brands for access
- Aggressive use of step therapy
- More common use of generic only formularies in TAs with strong generic options



### Pharma Strategies

- Evaluate creative contracts (risk sharing, pay for outcomes, etc.)
- Target subpopulations for which product has compelling value proposition
- Conduct head-to-head trials to demonstrate superiority
- Use access as a variable for physician targeting/messaging
- Build target market access profile early in development



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## The “age of the consumer” potentially will turn the market dynamics upside down

### Implementation

- A multitude of plan offerings available to beneficiaries
- The donut hole and coinsurance makes price a primary decision criteria for consumers
- More open formularies, with payer management replaced with choice and economic incentives



### Pharma Strategies

- Build direct relationship with consumers through more personal communication
- Target subpopulations for which product has compelling value
- Empower physicians to be product champions (not just prescribers)
- Develop workable patient assistance programs

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## Ultimately, if the budget impact becomes too extreme, government intervention could come

Government intervention could be precipitated by a variety of factors...

- Politics
- Public outcry
- Budget impact
- Failure of the private sector

... take a various forms

- Fixed reimbursement
- Price controls
- Health technology assessment
- Group purchasing

... and suggest specific strategies for manufacturers

- Intense HE/HO evaluations
- Head-to-head trials
- Target indications for sub-populations
- Partnership with patient groups for policy initiatives

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## As MMA evolves these trends likely will force the transition of the pharmaceutical industry

### The increasing aggressiveness of managed care

- The use of generics and step therapy, as well as heightened competition for preferred access...
- ....Requires clinical differentiation for specific patient populations

### Growing power of the consumer

- Allowing broad choice, but requiring patients to experience the price more directly...
- ....Necessitates building strong relationships directly with patients

### Intervention by government in pricing and reimbursement

- The government either controlling price or dictating reimbursement
- ....Suggests greater focus on HE/OR and policy to optimize price

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## Implementing the Medicare Drug Benefit

**ims** | INTELLIGENCE.  
APPLIED.

Marc Benoff  
Practice Leader, Pricing and Reimbursement

mбенoff@us.imshealth.com  
610/832-5828

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