Medicare, Pricing, and Quality

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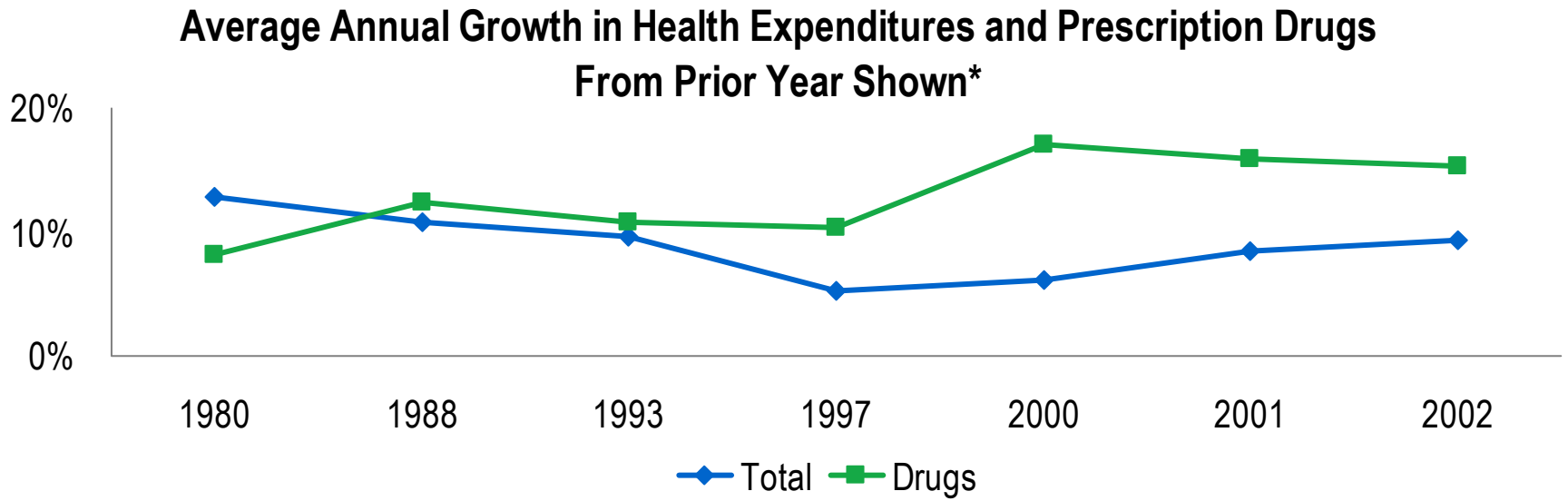
A Strategic Look at Pricing of Pharmaceuticals in Part D

- Perceptions of the industry
- MMA construct (volume and leverage)
- Formularies and medication management
- Increased price transparency
- Framing in EBM and quality
- Summary

Innovation Perceived as the Driver of Increasing Expenditures



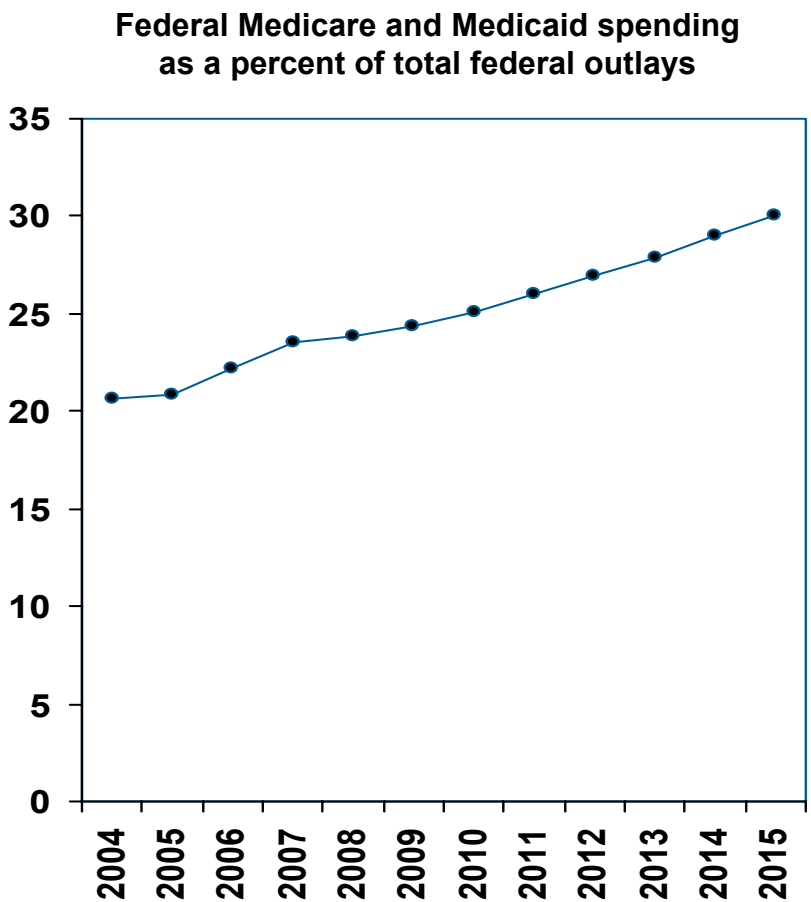
- KFF (June 2002) asked about the importance of factors in causing higher healthcare costs:
  - 71% responded “High profits made by drug companies” as very important;
  - 48% - “Use of expensive, hi-tech medical equipment”;
  - 47% - “Use of expensive new drugs”; and
  - 38% - “Patients having no incentive to look for lower priced doctors and services"

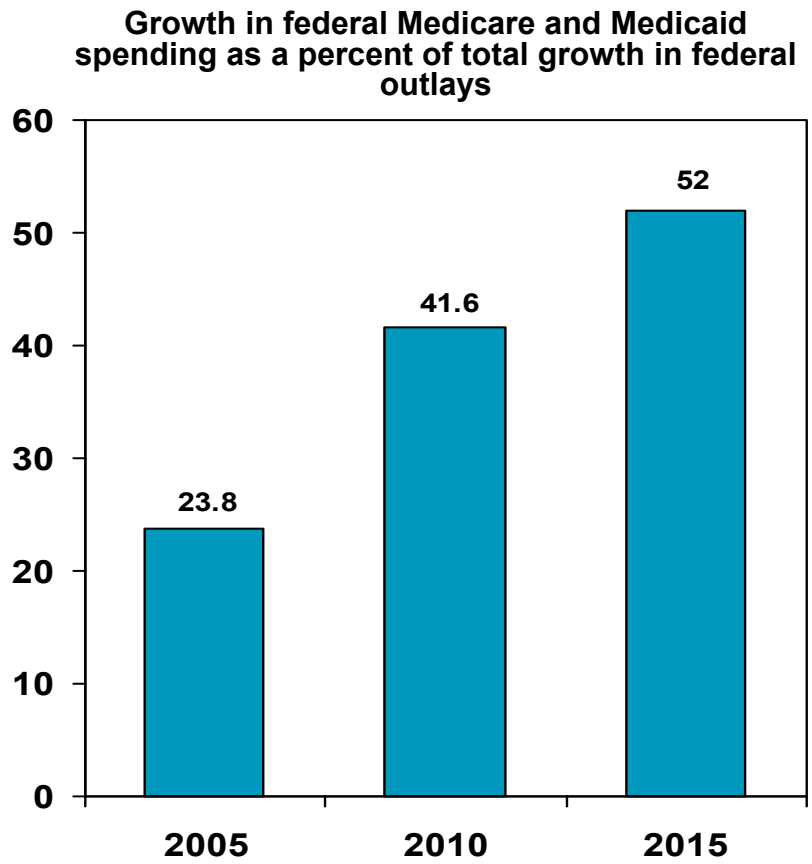
*For 1980, growth from 1970. For growth over multiple years, growth represents average across years.
Source: Levit, K., et al. (2004). “Health Spending Rebound Continues in 2002.” *Health Affairs* 23: 149.; Lohr, S. “Health care costs are a killer, but maybe that’s a plus.” NY Times. Sept 26, 2004.

Public Understanding Does not Reflect …

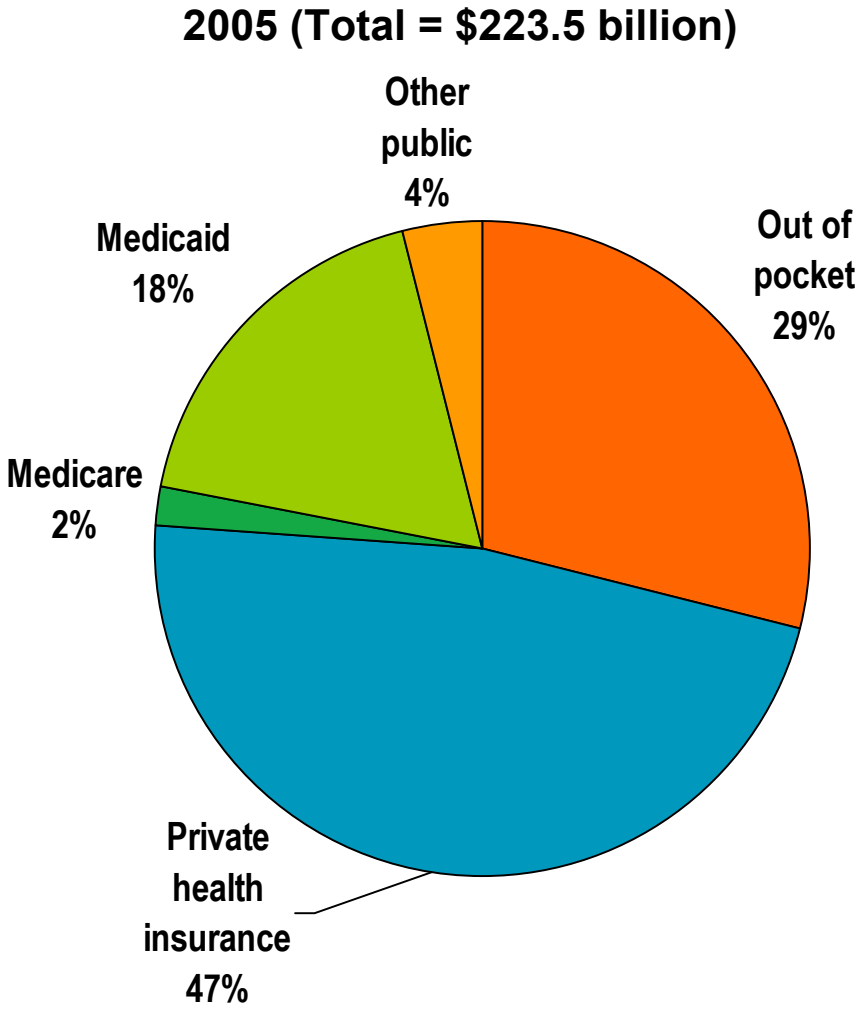
- Primary increase in Rx spending is due to volume, mix, not price
- Pharmaceuticals between 10 and 20 percent of spend
  - » Lower than in most EU countries (volume, cost of generics)
- OOP exposure has increased dramatically
  - » Grossly out of proportion to other medical costs
- Employer / PBM sets cost sharing structure
- Pharmacy markup is contained within the net cost of the drug
- Net value of medication relative to alternatives (if any)

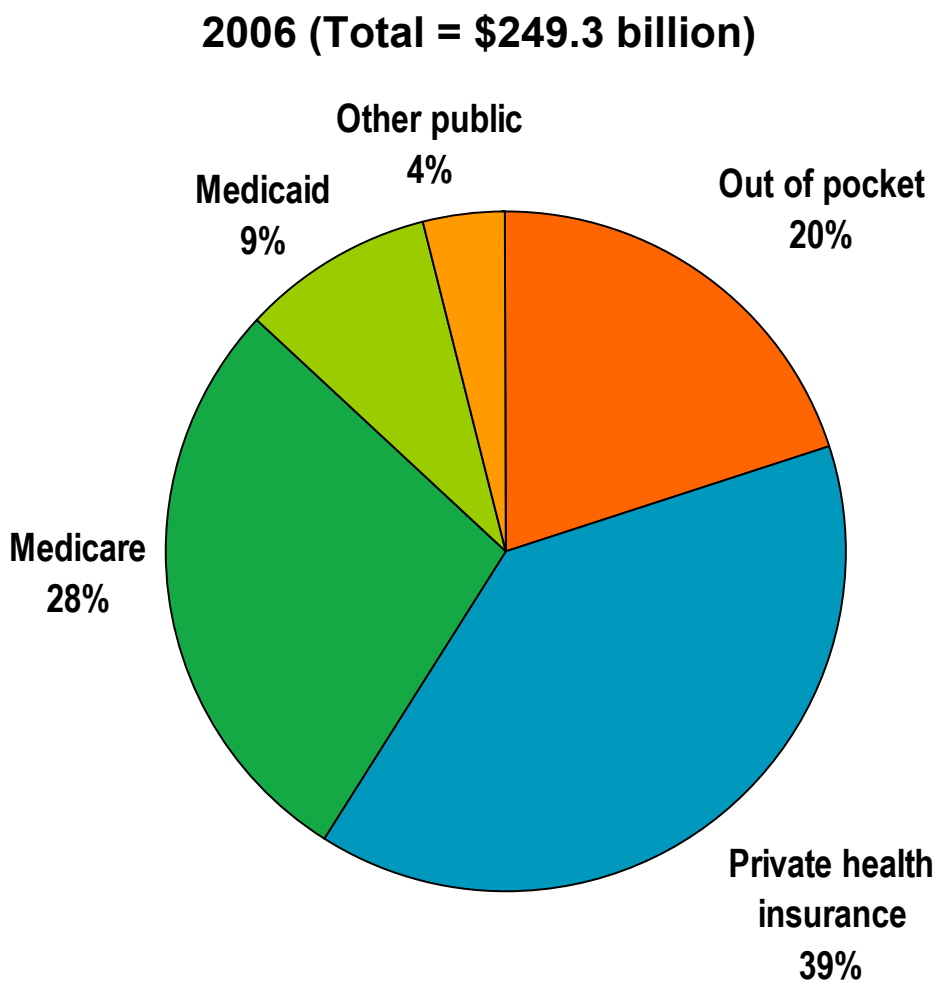
Broader Fiscal Future Will Bring Pricing Pressure





MMA: Volume, and Leverage





Source: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, *Health Affairs* Web Exclusive W5-75, 23 February 2005.

Further Medicare Observations

- Base expectation: commercial level prices
  - » More aggressive tiering of formularies (14% 5-tier)
  - » Increased interest in package pricing from plans
  - » Volume will increase with more insurance
  - » More information forthcoming over the year (currently model range)
- Cross-agency collaboration (CMS as public health agency)
  - » FDA (advisory panels, post-market surveillance)
  - » AHRQ (Quality, DERP, CERTS
  - » CDC (Chronic illness, welcome to Medicare, public health)
  - » Other government purchasing (VA, DoD, 340b)

PDP Structure Promotes Limited View of Pharmaceuticals

Question: Under Your Plan, What is Valued?

Current Focus	Future Focus
▪ Cost of drugs	▪ Reducing the cost of disease
▪ Reductions in drug spending	▪ Promotion of cost-effective therapies considering all healthcare interventions
▪ Utilization management of only medication use	▪ Focus on prevention and preventable hospitalizations
▪ Drug comparative effectiveness	▪ Focus on appropriate management of chronic conditions

CMS Review of Formularies: “Balancing Access and Cost”

- CMS review process included analysis of the following:
  - » Pharmacy and Therapeutics (P&T) committee structure and role
  - » Formulary drug lists
  - » Use of drug benefit management tools
- CMS announced it would use four principles to guide reviews:
  - » Reviewing existing “widely recognized best practices”
  - » Providing access to medically necessary drugs
  - » Providing flexibility for plans to design benefits that “promote real beneficiary choice while protecting [them] from discrimination”
  - » Using an administratively efficient process

Plans' P&T Committees Develop Formularies Within Medicare Guidelines

- Each Part D plan will develop its own formulary using a Pharmacy and Therapeutics (P&T) committee that meets Medicare guidelines
- Medicare P&T committees' clinical recommendations are binding on the plan
  - » Per MMA, P&T committee must determine whether drugs on the formulary have therapeutic advantages in terms of safety and efficacy
  - » P&T committee must base clinical decisions on the strength of scientific evidence and standards of practice
- P&T committee must consider peer-reviewed medical literature in making clinical decisions
  - » Includes randomized clinical trials, pharmacoeconomic studies, outcomes research data
  - » May consider data addressing total health care costs, if available, rather than pharmacy costs – but not required to use pharmacoeconomic studies

USP Model Guidelines for Part D Are "Safe Harbor" for Plans

- As required by statute, CMS contracted with USP for USP to develop list of therapeutic categories and classes that plans may use to structure formularies
- Plans allowed to submit alternative therapeutic classification systems or adapt their commercial formularies for Part D use
- CMS will check a plan's proposed classification system to determine if it is similar to USP or other commonly used classification systems (e.g., AHFS)
- Reportedly about half of Part D plans decided to use USP Model Guidelines
- USP announced on Oct. 20 that CMS had renewed its contract for 2005-2006
  - » Scheduled to release revised draft Model Guidelines on Dec. 9
  - » Final Model Guidelines for 2007 benefit year expected January 2006

Part D Plans Must Include Therapies for Certain Conditions

- Plans must provide appropriate access to drugs for these conditions, as defined in national treatment guidelines:

Asthma
Diabetes
Chronic stable angina
Atrial fibrillation
Heart failure
Thrombosis
Lipid disorders
Hypertension
Chronic obstructive pulmonary disease
Dementia
Depression
Bipolar disorder
Schizophrenia

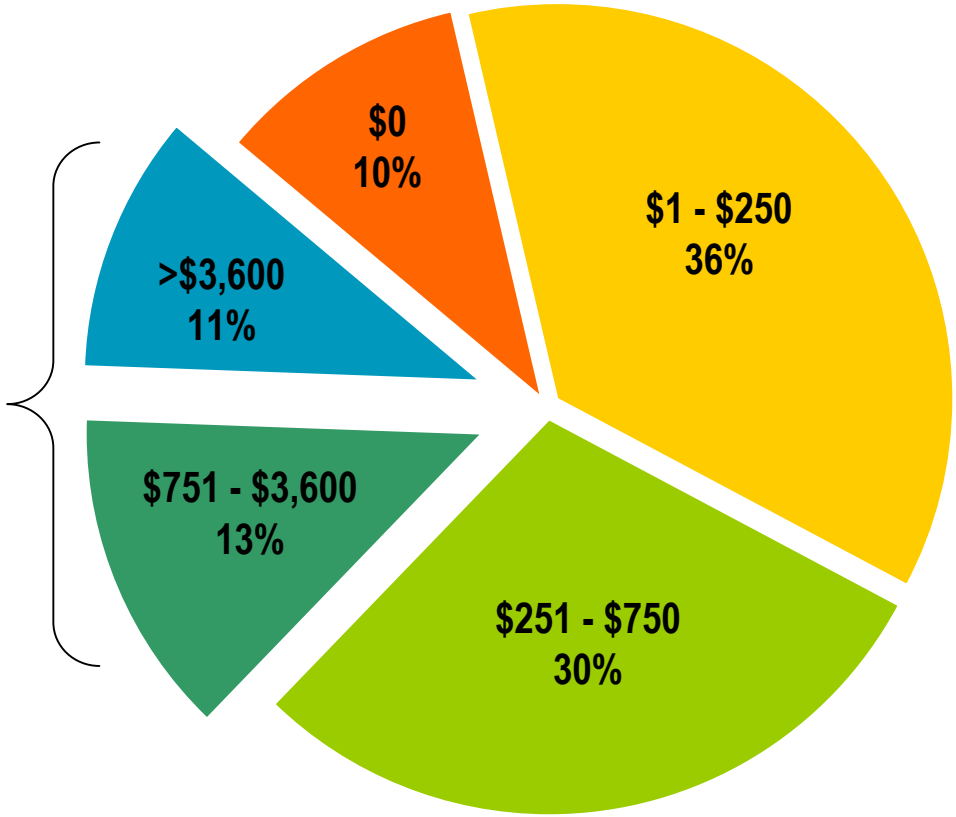
Benign prostatic hyperplasia
Osteoporosis
Migraine
Gastroesophageal reflux disease
Epilepsy
Parkinson's disease
End stage renal disease
Hepatitis
Tuberculosis
Community-acquired pneumonia
Rheumatoid arthritis
Multiple sclerosis
HIV

Recent CMS Q&A on Access to Drugs in Six Specific Therapeutic Classes

- In June (after plan bids were due), CMS announced that plan formularies must cover “all or substantially all” drugs within six therapeutic classes:
  - Anti-depressants
  - Anti-psychotics
  - Anti-convulsants
  - Anti-retrovirals
  - Immunosuppressants
  - Anti-neoplastics
- Products that come to market after January 1, 2006 will be subject to the Part D plans normal P&T committee process
- CMS stated this policy is in effect to assist transition of beneficiaries’ drug regimens from 2005 to 2006; will be reevaluated for 2007

Transparency: Facing the Price of Drugs (Co-Pay, Donut)

Projected Distribution of Beneficiary Drug Spending in 2006



Estimated 6.9 million (out of 29 million) beneficiaries could experience out-of-pocket drug spending in "donut hole"

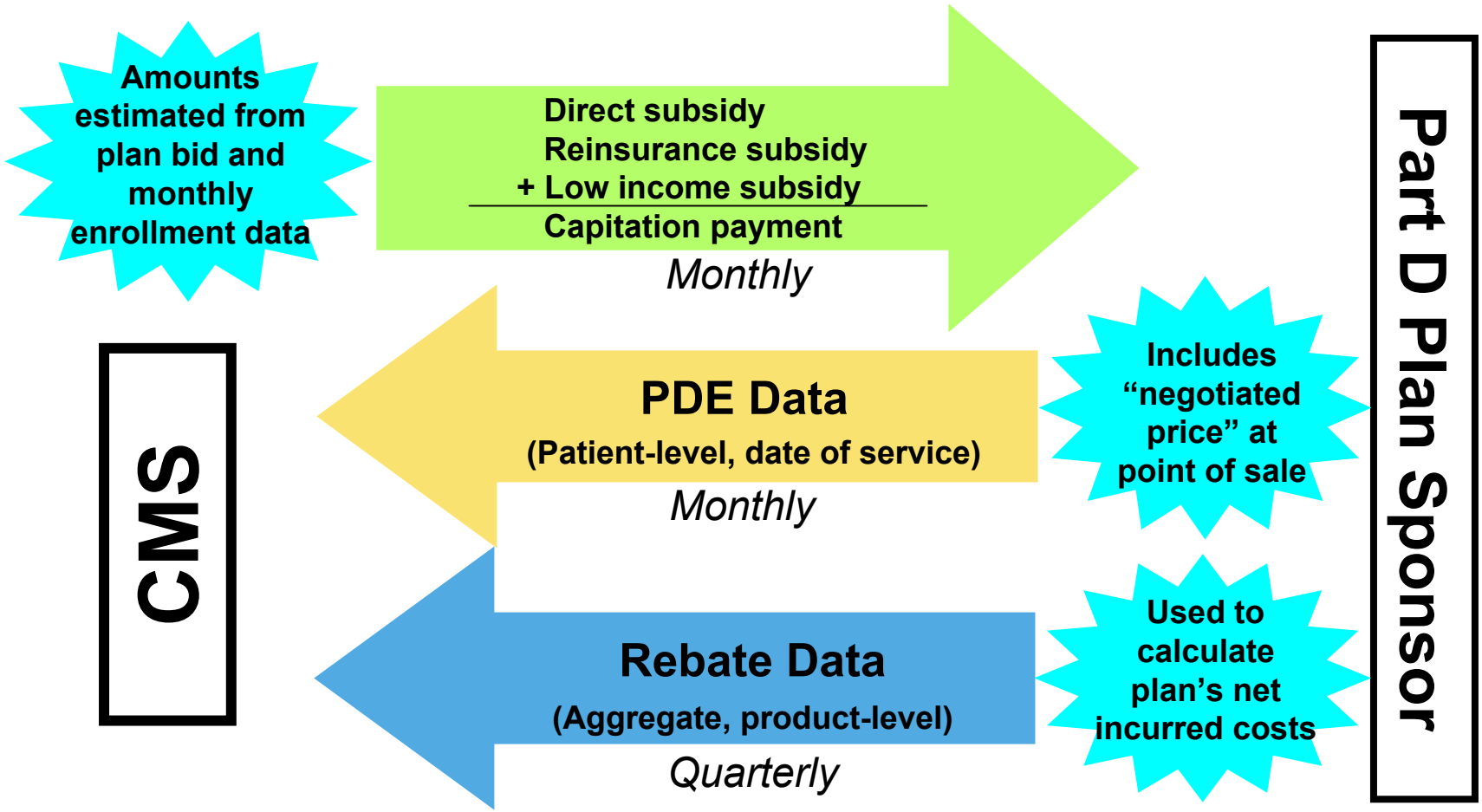
Total projected enrollment = 29 million

Source: Kaiser Family Foundation and Actuarial Research Corporation. "Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006." November 2004. Drug spending estimates exclude Part D premiums and assume no supplementation of Part D coverage.

Supply Chain Confusion: Which Price?

- Prices vary along the supply chain
  - » Manufacture, Distribution, Pharmacy, Sale
  - » PBM is generally outside the supply chain
  - » See KFF / Avalere supply chain analysis
- Patients perceive end-user price
- PDPs / MA-PDs will control price perceived by beneficiaries

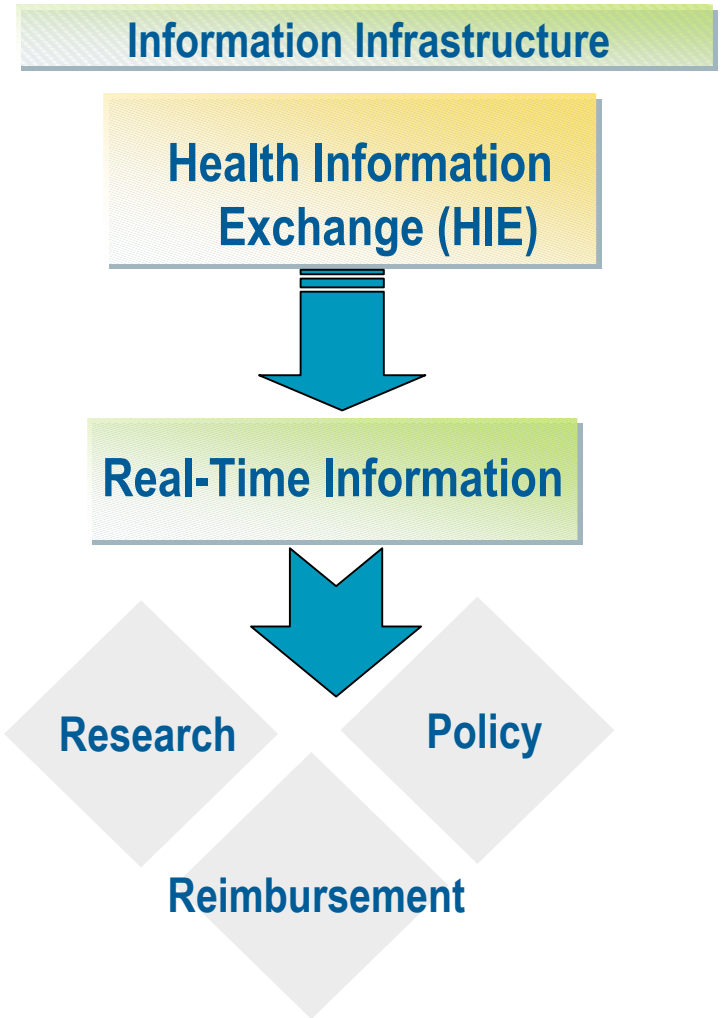
Funds and Data Flow Between CMS and Part D Plans During Benefit Year



Part D Plans Must Submit 100% Transaction Data to CMS

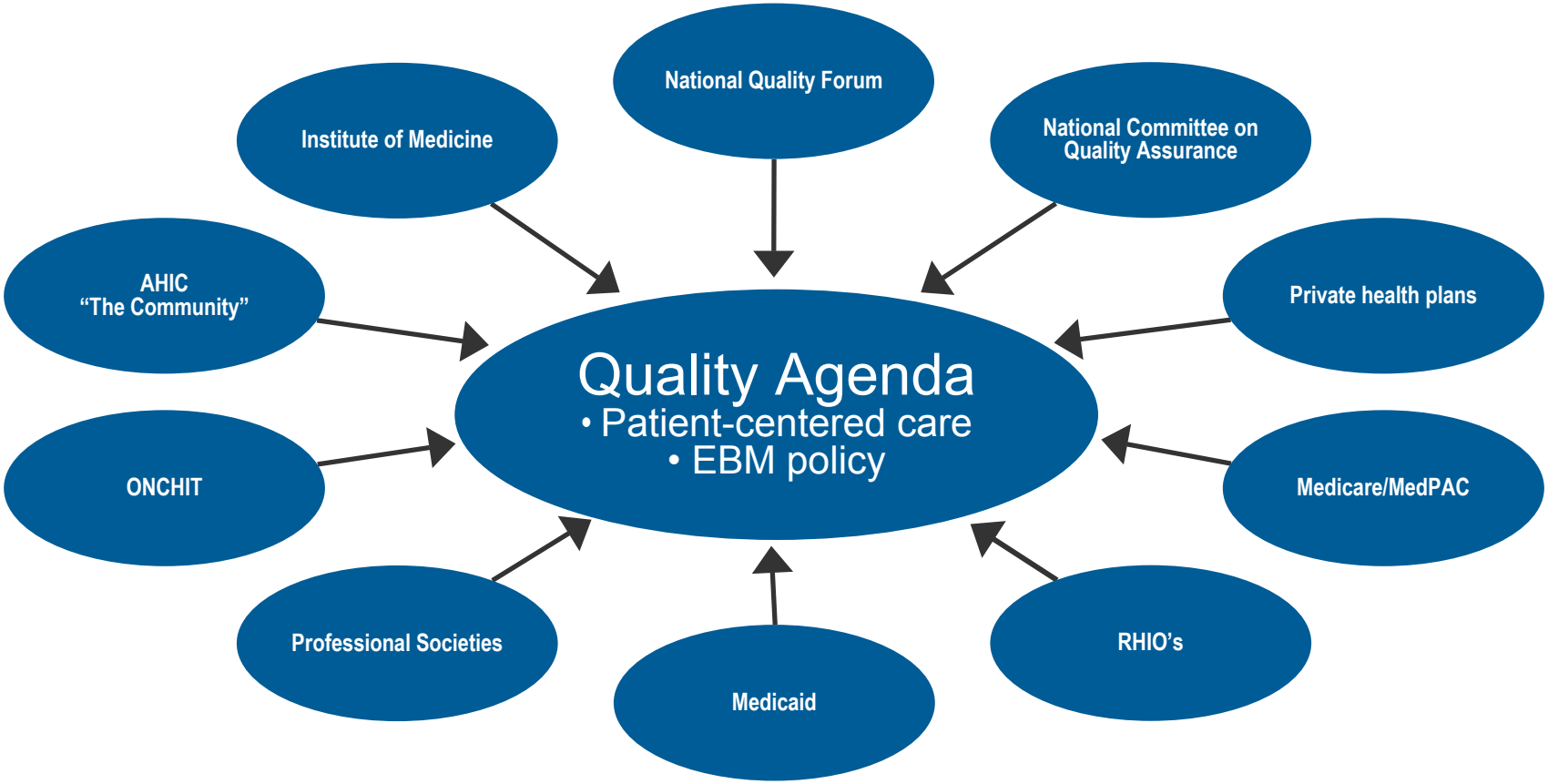
- CMS requires 100 percent transmission of “prescription drug event” data, including the following elements:
  - » Beneficiary identification
    - – Medicare beneficiary identification HIC number, date of birth, gender, name
  - » Prescription identification
    - – Prescription identification number, NDC, quantity dispensed, fill number, date of service
  - » Cost information
    - – Ingredient cost, dispensing fee, sales tax, total gross cost
  - » Payment information
    - – Beneficiary amount paid, low-income cost-sharing subsidy amount, secondary or other payer amount, supplemental insurance amount

Health Information Exchange will Increase Transparency of Information on Drug Effectiveness and Clinical Outcomes

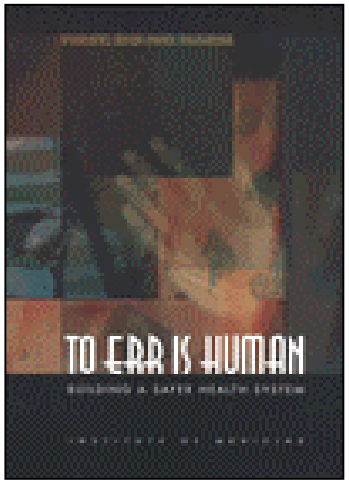


- About exchange of information—not the "technology"
- Availability of real-time information in the broader clinical context will inform policy
- Critical Questions:
  - » Data will be used to assess Rx technology, but will it be used to assess patient care?
  - » How will limitations of secondary data studies be dealt with? Will data be used responsibly?
  - » How long will it take for industry studies to anticipate the "data-rich" environment and how will they change?

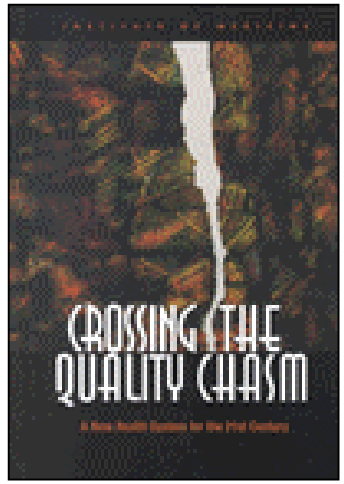
Quality is the Context for All Healthcare Pricing Discussions



Quality Agenda is Starting to Emerge



- ***To Err is Human* (IOM, 1999), *Crossing the Quality Chasm* (IOM, 2001)**
  - » Between 44,000 and 98,000 Americans die each year as a result of medical errors
  - » Medical errors is the 6th leading cause of death in the US
  - » Medical errors cost the system between $17 and $37 billion annually



A quality agenda to address the "Quality Chasm" includes:

- Focus on the promotion of evidence-based medicine and the development of clinical guidelines
- Investments in health information exchange
- Measuring and paying for quality
- Promotion of prevention, early treatment, personal responsibility, and the creation of a person-focused healthcare system

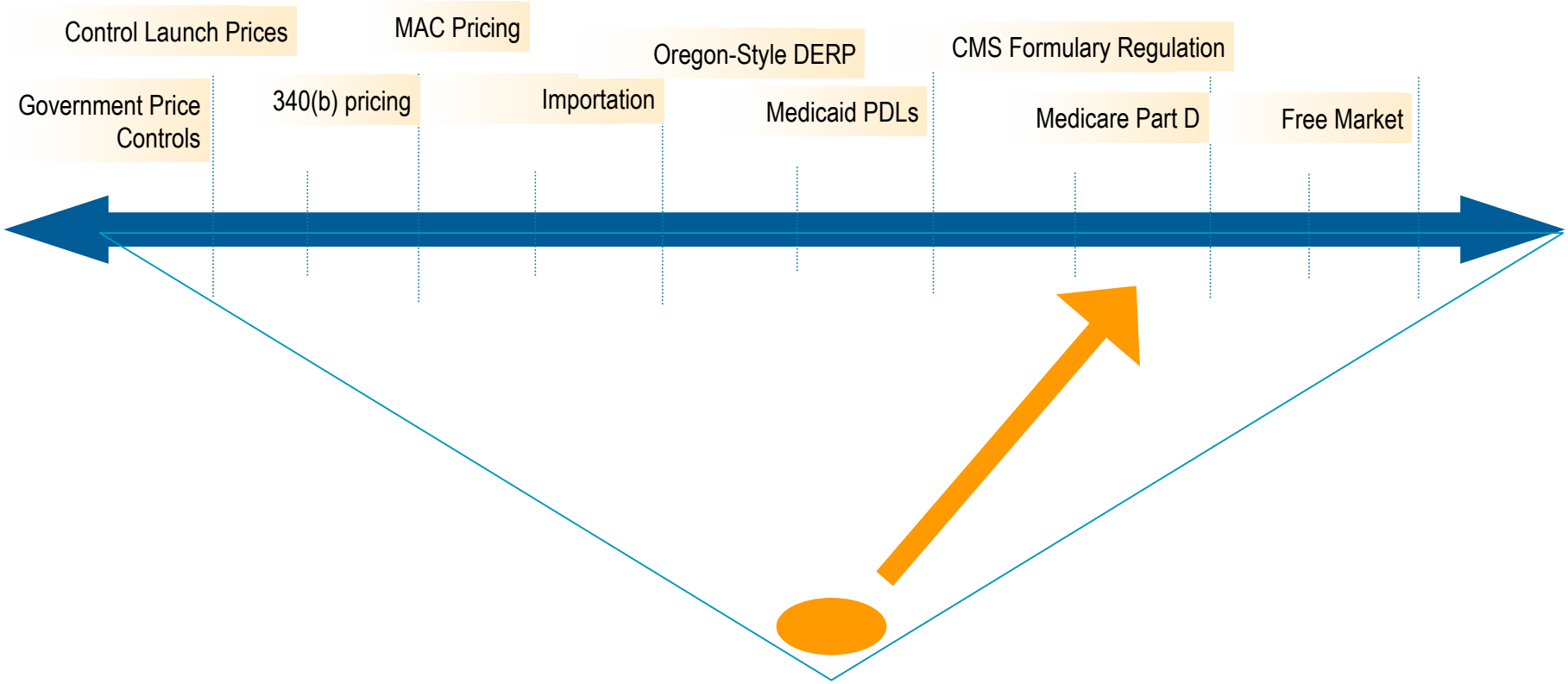
Current “Quality” Agenda in Rx Driven by Cost Concerns

Existing Medication Measures	Ideal Medications Measures Should Also Include
Over-utilization	Under-utilization
Generic Prescribing	Prescribing adherence to clinical guidelines and published evidence
Use of contraindicated drugs in the elderly	Compliance with medication regimens
Average cost of prescriptions, per member, per month	Average out-of-pocket spending on prescriptions PMPM

International Analogies are Present in Policy Debate

- Internationally payers have played a dominant role in EBM by:
  - » Defining evolving standards of EBM
  - » Seeking to redefine industries' research agenda
  - » Focus on comparative and cost-effectiveness research

Future Options for Medicare Rx Cost Control Span Range



- *Is Current Construct Sustainable and Comfortable?*
- *Scoring Implications of Moving to Other Options?*
- *Results of Data Analysis of Medicare Experience*

Summary: A Strategic Look at Pricing

- Industry perceptions challenge pricing environment
  - » Cost sharing is a major issue, especially under MMA
  - » Price transparency will increase with uncertain effects
- MMA generally promotes commercial construct
  - » PDPs contain perverse incentives that may be managed
  - » Medicare Advantage is more of a known quantity
  - » Formularies appear to be more aggressive
  - » Medicare will guide construct through regulation / guidance
- EBM and quality are a critical construct for pricing in the future
  - » Information flow (HIE) will drive expectations