MassMEDIC

Reimbursement Update Conference

Trends in Coverage and Reimbursement Policies

Implications to MedTech Companies

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Boston MedTech Advisors

We support medical technology companies in their efforts to:

- Shorten time-to-market
- Accelerate market adoption
- Increase enterprise value

Aesthetic Medicine

Ambulatory monitoring

Anesthesiology

Cancer Therapies

Cardiology

Critical Care

Cryosurgery

Dermatology

Emergency Medicine

General Surgery

Health IT

Hepatology

Home care

Interventional Cardiology

In-Vitro Diagnosis

Interventional Radiology

Neurology

Orthopedic

Patient Monitoring

Pulmonary

Radiology / Imaging

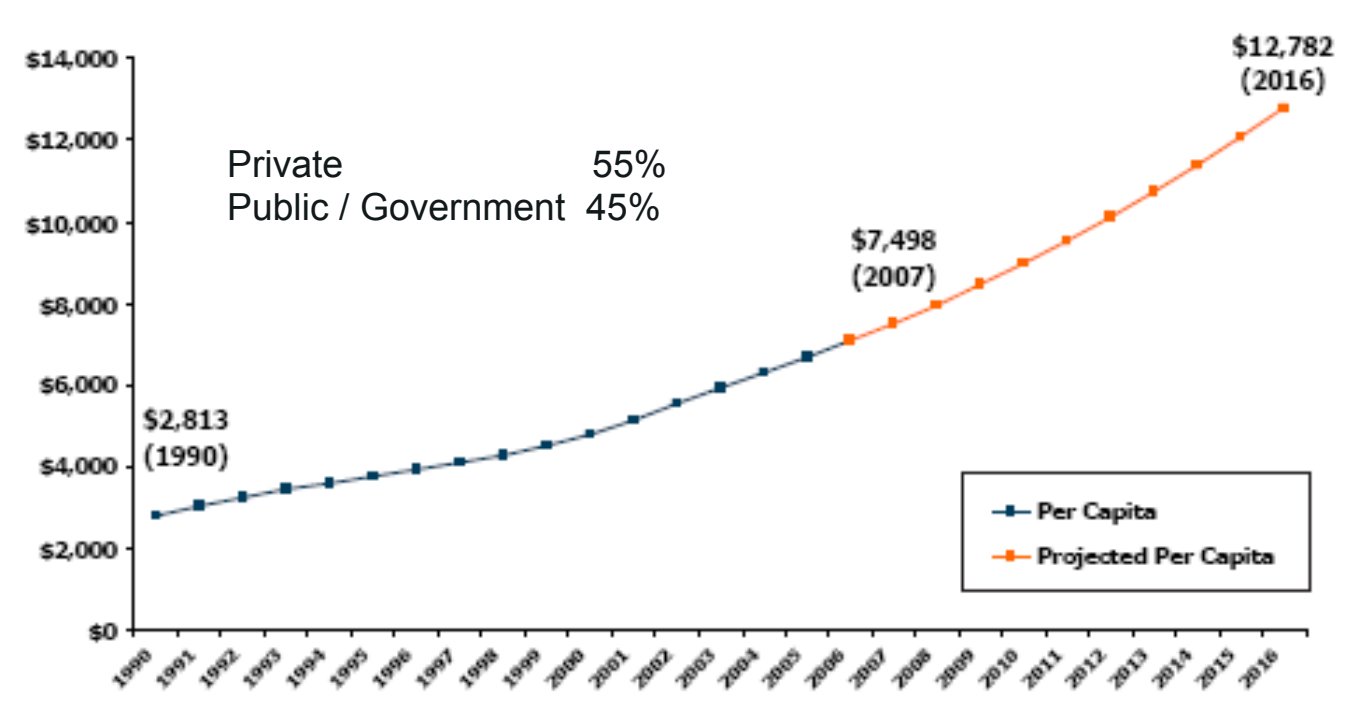
Rehabilitation Medicine

Sleep Medicine

Spine Surgery

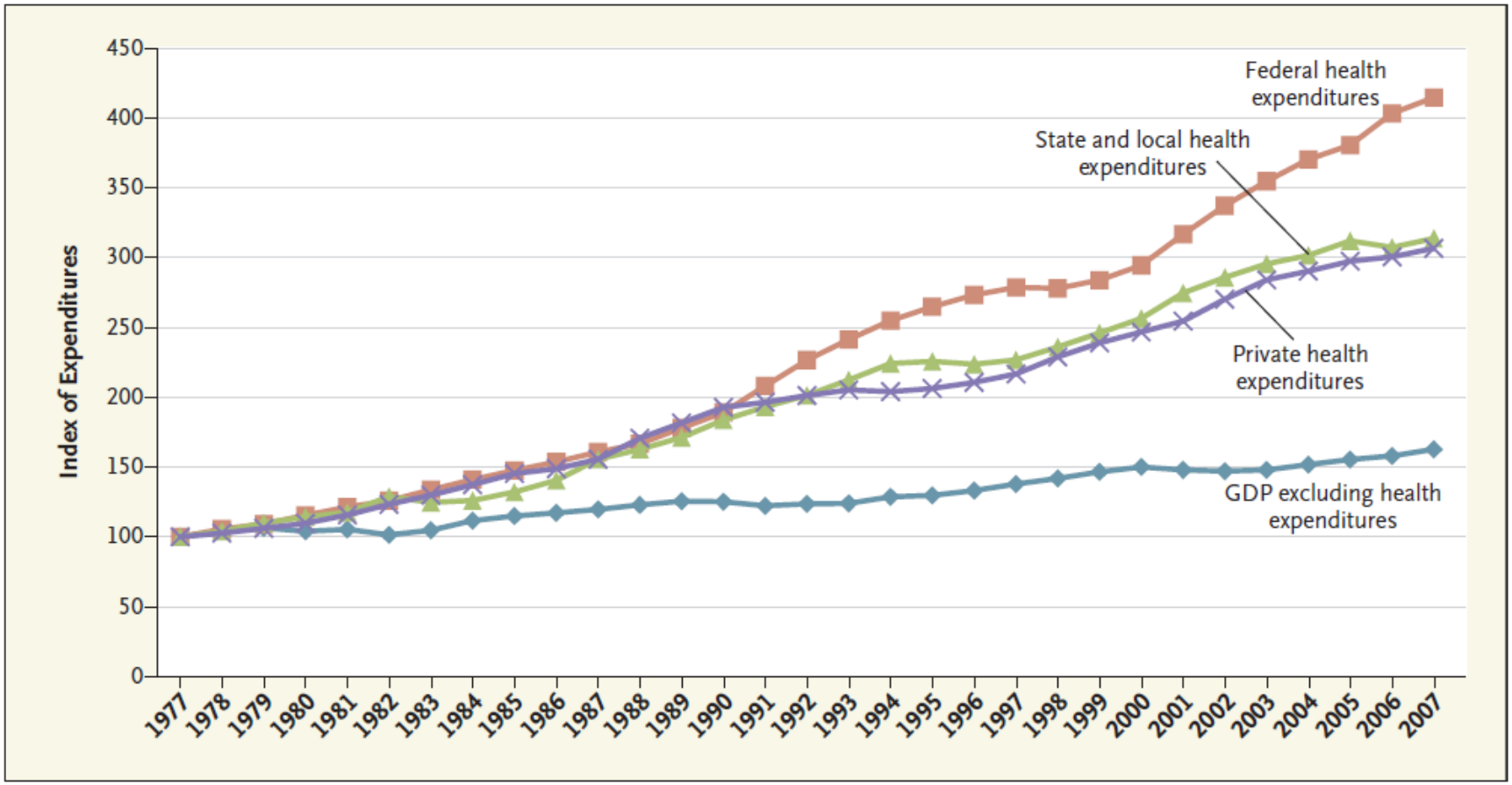
Vascular Medicine

The Problem: Healthcare Expenditures Are Mounting



	1970	2007	2016 (p)
Annual cost per capita	$356	$7,498	$12,782
Total Expenditures	75 billion	2.2 trillion	4.1 trillion
% of GDP	7.2%	16.2%	19.6%

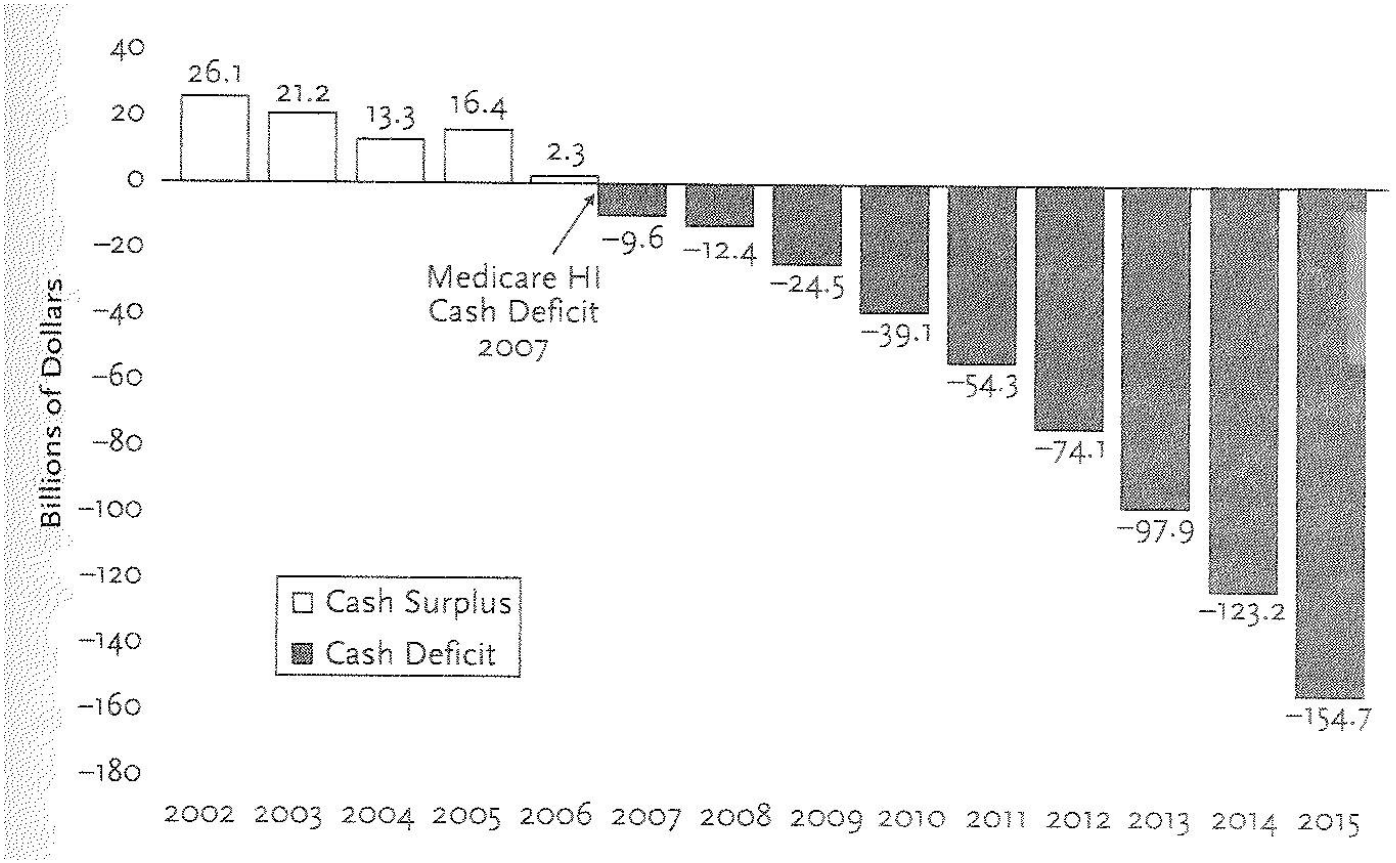
Ref: Kaiser Family Foundation, Sep 2007



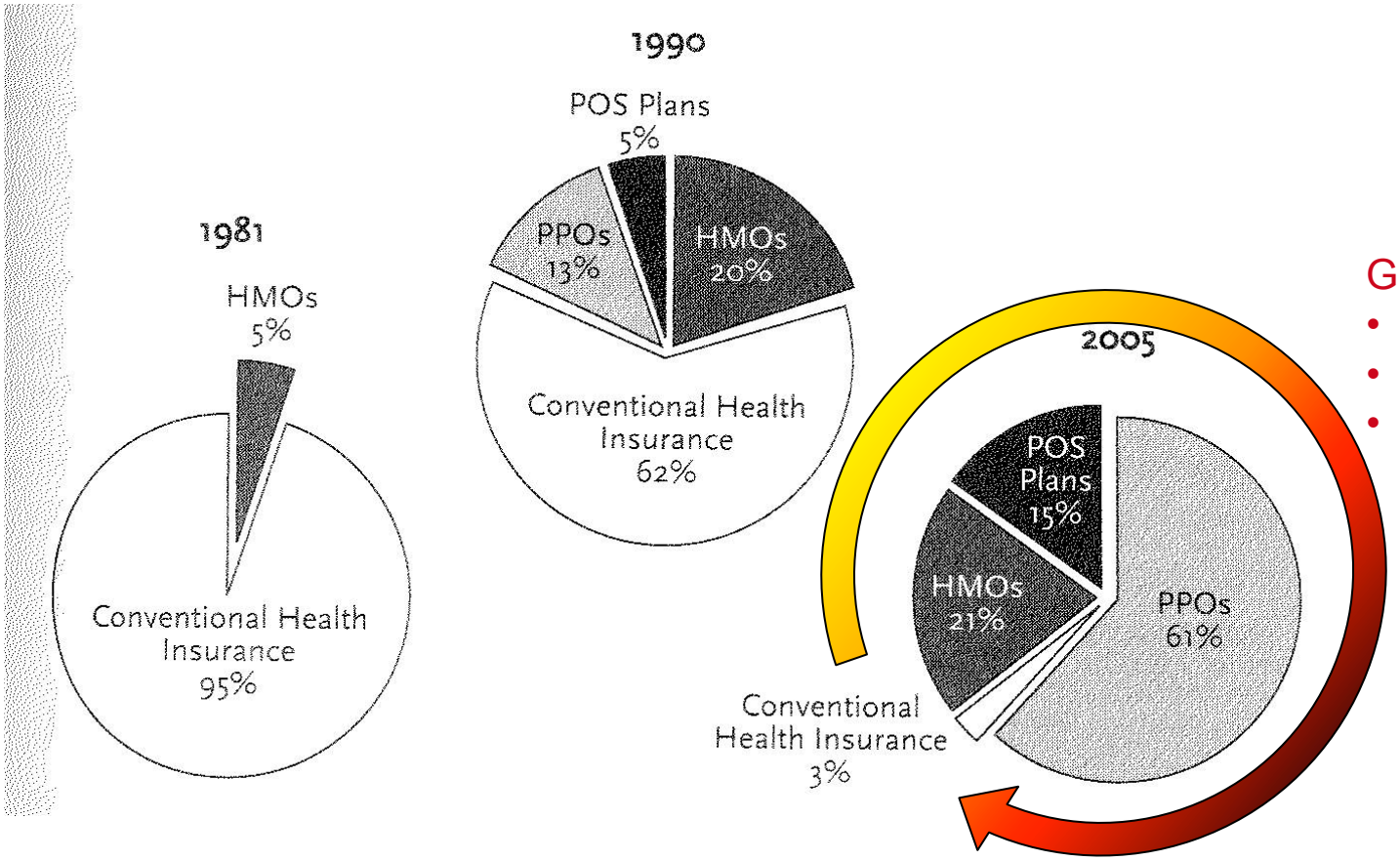
Indexes of Health Expenditures and the Gross Domestic Product (GDP) Excluding Health Expenditures, per Capita, Adjusted for Inflation, 1977–2007.

The index value at 1977 was set at 100.

Medicare: Net Cash Flow → Political Pressures



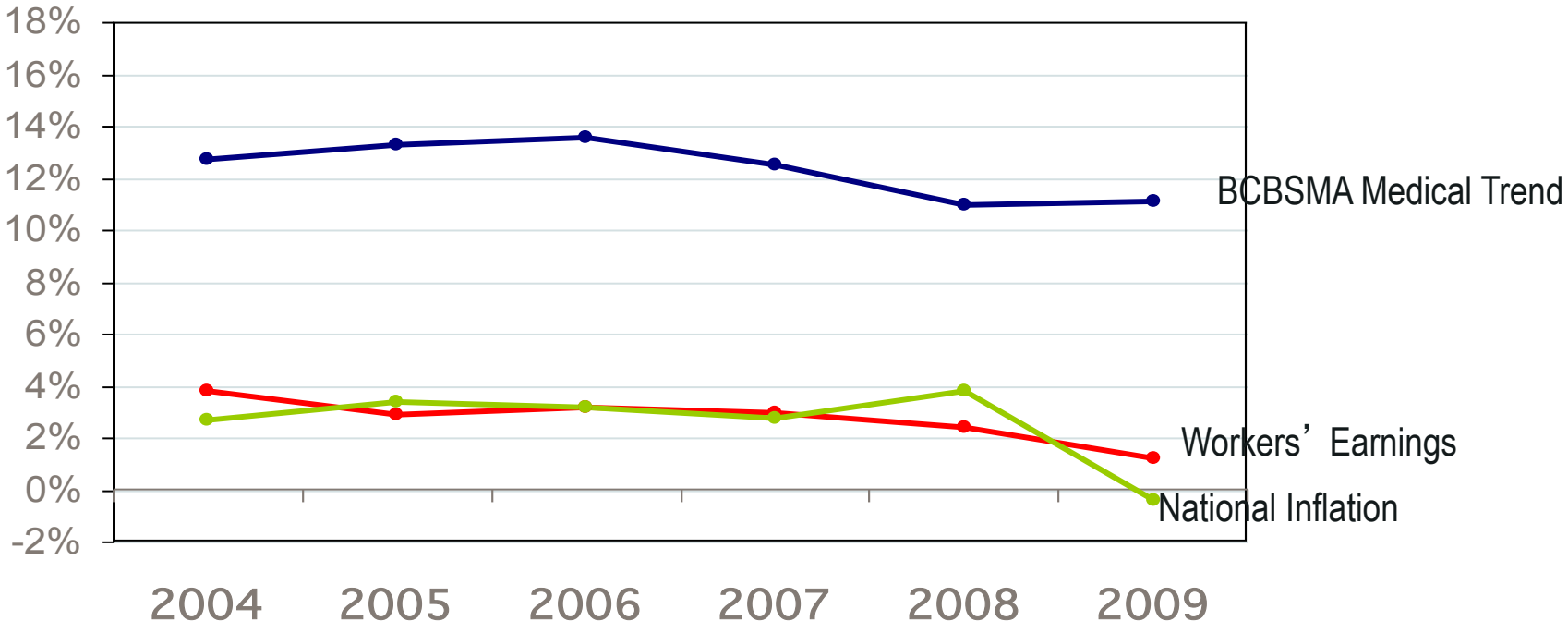
Private Market Response → Managed Care



Greater control of
- Access
- Coverage
- Payment

Medical Costs Continues to Outpace Inflation

Medical cost trend is growing four times faster than national workers' earnings and rate of inflation.



Sources: BCBSMA, Bureau of Labor Statistics

Market Pressure

The Boston Globe

Insurers may slash rates to hospitals
Some patients might have to switch MDs

By Liz Kowalczyk

Globe Staff / May 24, 2010

Insurers seeking payment changes

By Jennifer Huberdeau, North Adams Transcript

Posted: 05/26/2010 08:15:41 AM EDT

Wednesday May 26, 2010

New Bedford Standard Times

Blue Cross, Southcoast at loggerheads in contract negotiations

By Dan McDonald, dmcdonald@s-t.com
September 18, 2010

NEW BEDFORD — After seven months of talks, Southcoast Health System, the region's largest employer, and Blue Cross Blue Shield of Massachusetts, the state's largest private health insurance company, are deadlocked in negotiations over reimbursement rates for care rendered to Blue Cross policy holders at Southcoast facilities.

RUNNING A HOSPITAL

This is a blog started by a CEO of a large Boston hospital to share thoughts about hospitals, medicine, and health care issues.

Robin Hood in Reverse

Wednesday, May 12, 2010

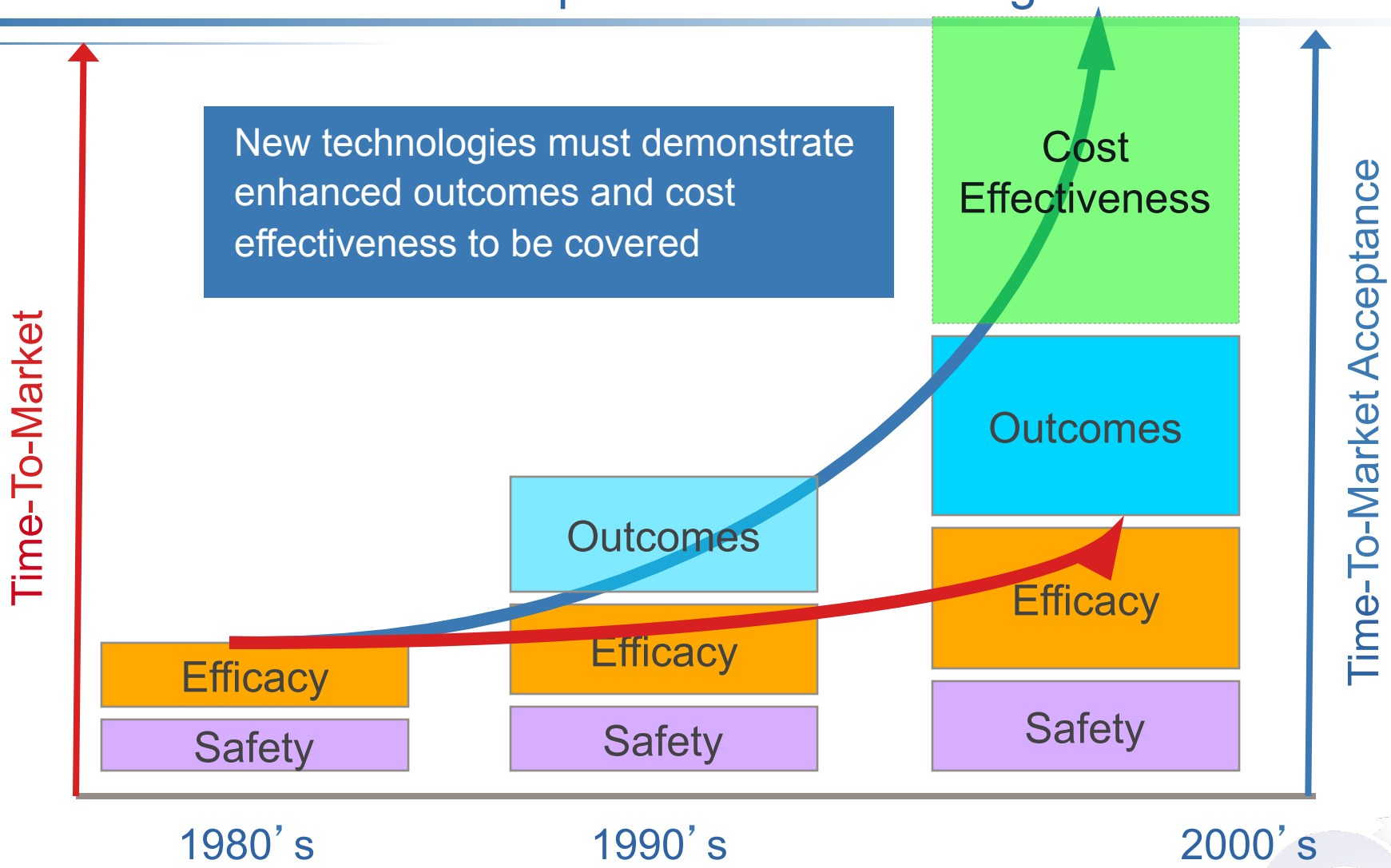
Jim Stergios and Amy Lischko from the Pioneer Institute write a well reasoned op-ed article in today's *Boston Globe* about current events in Massachusetts, where ... Insurance Commissioner has decided to ... rice controls on a portion of the ... larket. More backgr...

Pressure to Cut What Doctors Get Paid is Mounting, and There's Not Much to Stop It

By Ken Terry | June 2, 2010

Threats to doctors' incomes are multiplying — and not necessarily in a good way. While physicians are understandably focused on the latest congressional effort to head off a 21 percent cut in **Medicare** reimbursement, they should also pay attention to state regulation of insurance rates. Because if state governments decide to take a hard line on premium increases, the result will translate into lower payments to doctors and hospitals.

Time-To-’Market Acceptance’ is Increasing

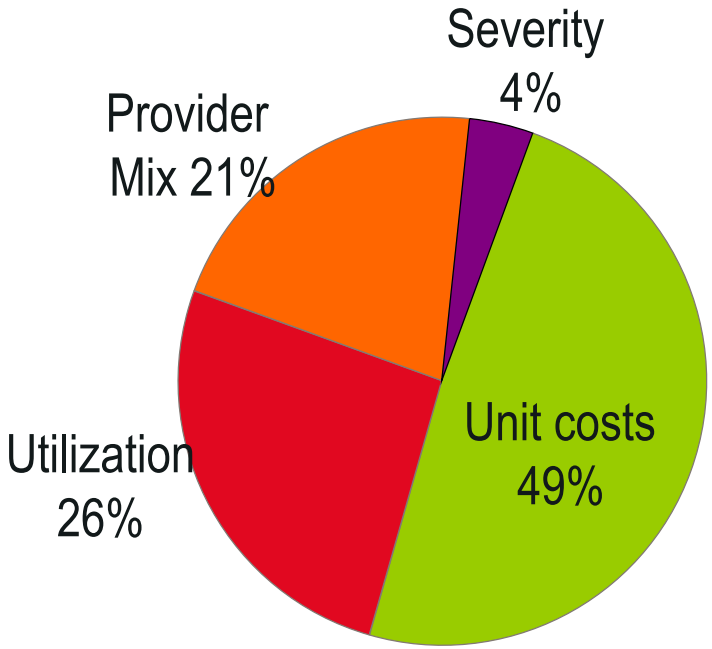


Considerable Implications to MedTech Companies

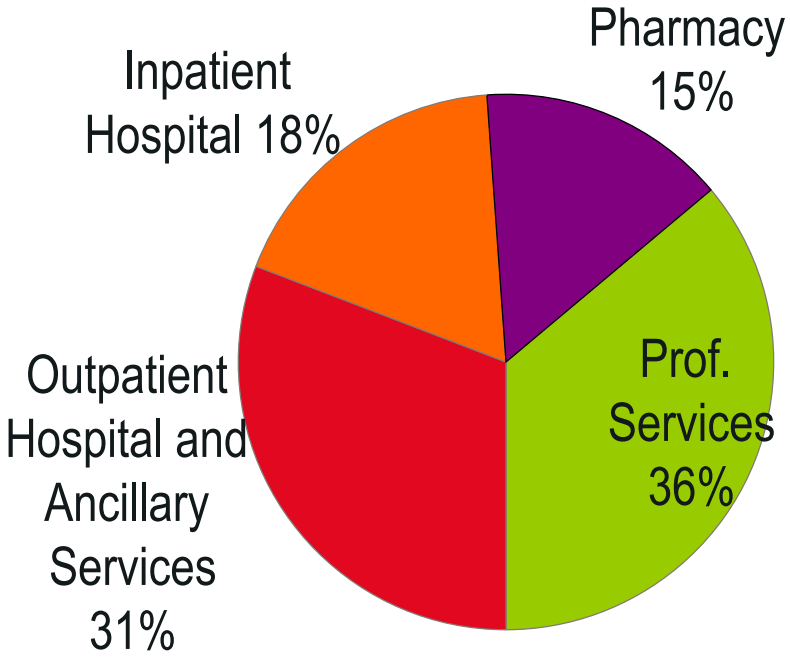
- Delayed revenue
- Need for additional funds and financing rounds
- Valuations are negatively impacted
- Business development initiatives are delayed
- Prospective distributors sit on the sidelines
- Increased risk of new competitors

Cost Drivers

By Driver



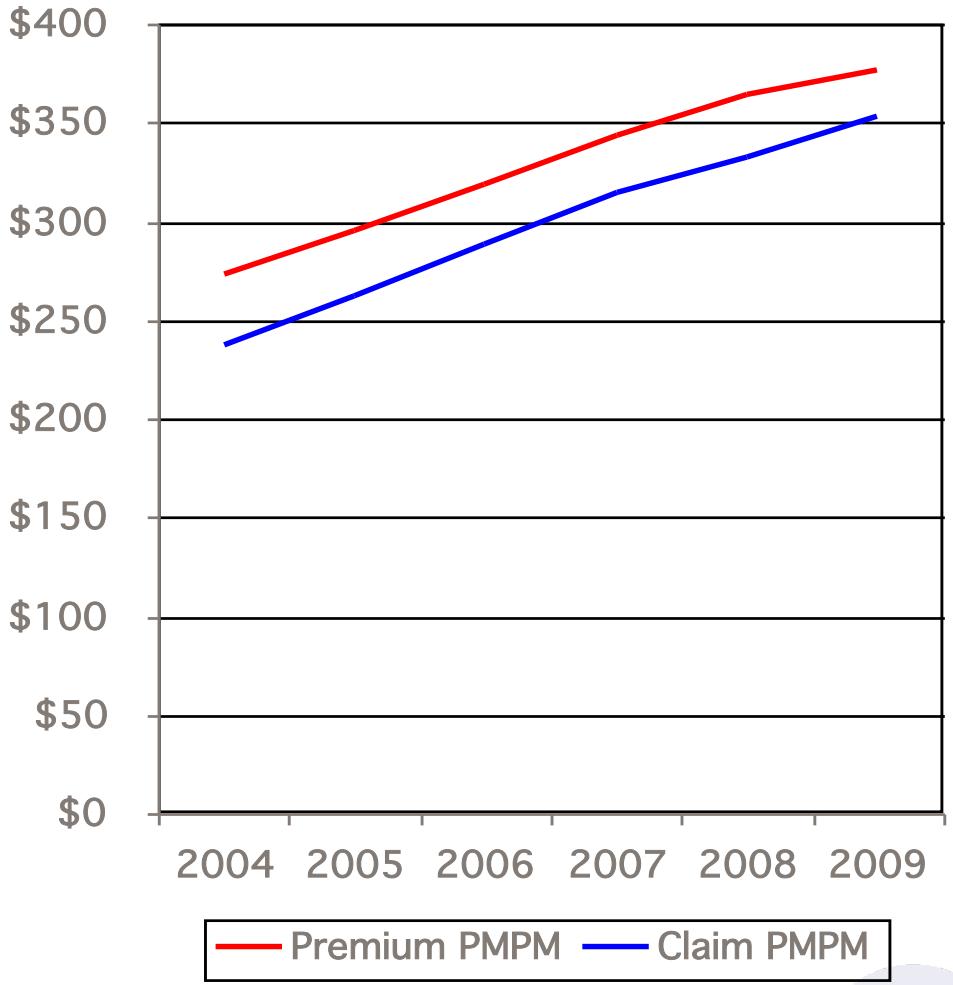
By Service Type



Source: BCBSMA Actuarial & Analytic Services.

Premium Increases Linked to Rising Medical Costs

Reported Premium and Claim PMPMs
Commercial Insured
Managed Care`



Source: BCBSMA Actuarial & Analytic Services.

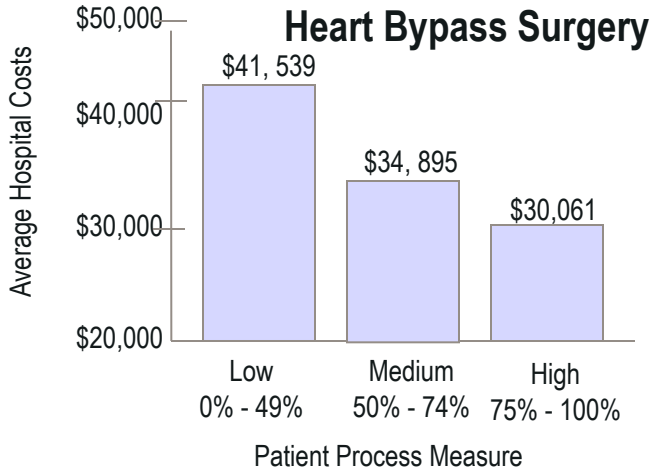
Experts Agree…

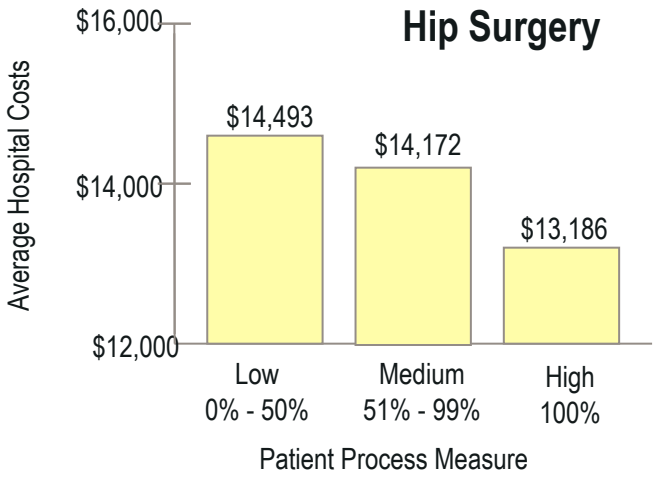
While rate review can help keep insurers focused on constraining the growth of these costs, it cannot fundamentally address the growth of health care costs…

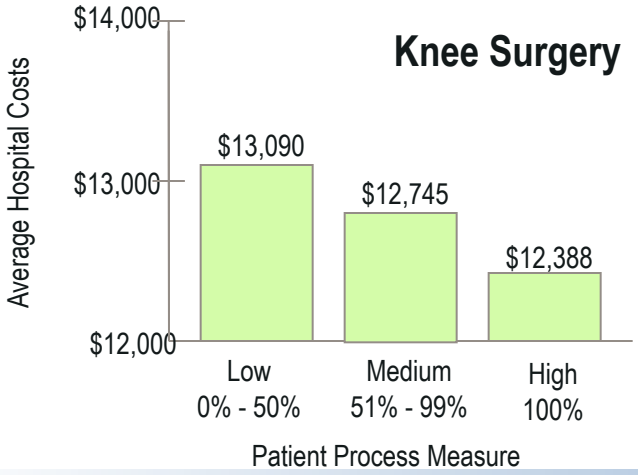
…costs must be addressed through payment reform, delivery system changes, an emphasis on prevention, and consumer engagement.

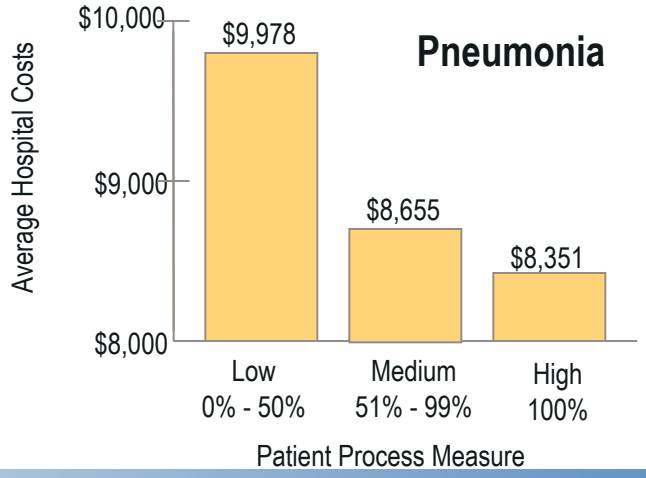
National Association of Insurance Commissioners letter to Congress February 23, 2010 `

Performance Pays: Higher Quality → Lower Hospital Costs









The Paradigm Shift

- Lowering cost requires improved quality
- Changing incentives from ‘volume’ to ‘quality’
- Paying for ‘value’ rather than for ‘service’

$$\text{Value} = \frac{\text{Quality (Health Outcomes)}}{\text{Cost}}$$

↑ Quality / ↓ Cost = ↑↑ Value

± Quality / ↓ Cost = ↑ Value

↑ Quality / ± Cost = ↑ Value

Payment Reform: Pay for Quality Not Volume

Fee-for-Service

- Incentives for increased volume
- Incentives to deliver more costly services
- Little or no incentive for achieving positive results or for care coordination
- Little or no incentive to deliver preventive services or other services with low financial margins`

Global Payment

- Emphasizes quality improvement
- Quality-based financial incentives
- Eliminates incentives to increase volume
- Eliminates incentives to provide higher-cost services over lower-cost services that are equally effective
- Emphasizes the role of primary care
- Encourages integration and coordination for care, both within acute care episodes and for patients with chronic conditions

Hospitals' Value-Based Purchasing Program (VBP)

- Shift payments from quantity-based to quality (and quantity) based system
- Requiring hospitals to report Quality Data in order to obtain 'Annual Payment Updates'
- Initiated 2004 with 10 measures; 2011 – 46 measures
- Examples:
  - Beta blockers prescribed at time of discharge (acute MI patients)
  - Percutaneous coronary intervention received within 120 minutes of hospital arrival
  - 30 days post discharge mortality (AMI, HF, pneumonia, hip fracture)
  - 30 days readmission
- Expand to hospital outpatient departments and to ASC (2014)

Quality Measures

- Acute MI
- Heart Failure
- Pneumonia
- Surgical Care
- Mortality
- Patient Experience
- Readmission Rates
- AHRQ Quality Indicators
- Cardiac Surgery
- Stroke Care
- Nursing Care
- Patient Safety

‘Partnership for Patients’ - Hospital Acquired Conditions

- Certain conditions developed while the patient is hospitalized will not justify incremental reimbursement
- 2011 – 10 conditions (more to be added)
  - Foreign object retained after surgery
  - Blood incompatibility
  - Pressure ulcers (stage III-IV)
  - Falls and trauma
  - Manifestations of poor glycemic control
  - Catheter-associated urinary tract infection
  - Vascular catheter-associated infection
  - Surgical site infection (CABG, bariatric, orthopedic)
  - Deep vein thrombosis (DVT) / air embolism (total knee, hip)
- Hospital Compare www.hospitalcompare.hhs.gov
- Expansion to rehab facilities (2012)

Bundled Payments

- Current system - surgery generates claims from hospital, surgeon, anesthesiology, radiology, pathology, post-discharge providers, etc.
- New system: a single 'bundled' payment made to the 'team' of providers involved
- Intention: align incentives and improve patient's experience during inpatient and post-discharge recovery
- Providers can determine which services will be bundled (4 models):
  - Inpatient care + 30/90 days post-discharge; single payment to all providers
  - Start at discharge up to (min) 30 days after discharge (include readmission); single payment to all providers
  - All services, incl. by physicians, during inpatient; paid to hospital (which pays the physicians)
  - Inpatient stay at the general acute care hospital; hospitals and physicians paid separately but can share gains arising from better care coordination

Accountable Care Organizations (ACO)

- A local set of providers accountable for the cost and quality of care delivered to a defined population
- Min: PCPs, specialists, hospitals… other
- Goal: coordinated and efficient care
- ACO need to:
  - Provide care across the continuum of care in different care settings
  - Measure performance (sufficient volume to provide statistical validity)
- Concept: shift from fragmented and inconsistent care and volume-based payment system.
- Flexibility in type of organizations that can serve as ACO
- Bonus for achieving quality and cost targets / financial penalties to those failing to meet goals

Other Measures - Affordable Care Act, 2010 *(partial list)*

- Expanding use of electronic health records
  - Over $270MM awarded as incentive payments to providers (as of 7/2012)
- Promoting prevention
  - Free (proven) preventive services by private payers
- ESRD Quality Incentive Program
  - ~500,000 enrollees
- Independent Payment Advisory Board (IPAB)
  - Recommending policies to reduce the rate of growth in per-beneficiary costs (GDP+1%, starting 2018)
  - IPAB is prohibited from making recommendations that would ration care or increase cost to beneficiaries

DME: Competitive Bidding

- Goal: Lower payments for DME and other supplies (below payments to commercial payers)
- CMS will contract to providers offering the lowest cost
- Product line specific
- 2011: implemented in 9 markets
- Average reduction in pricing realized 30%-35%

Comparative Effectiveness Research

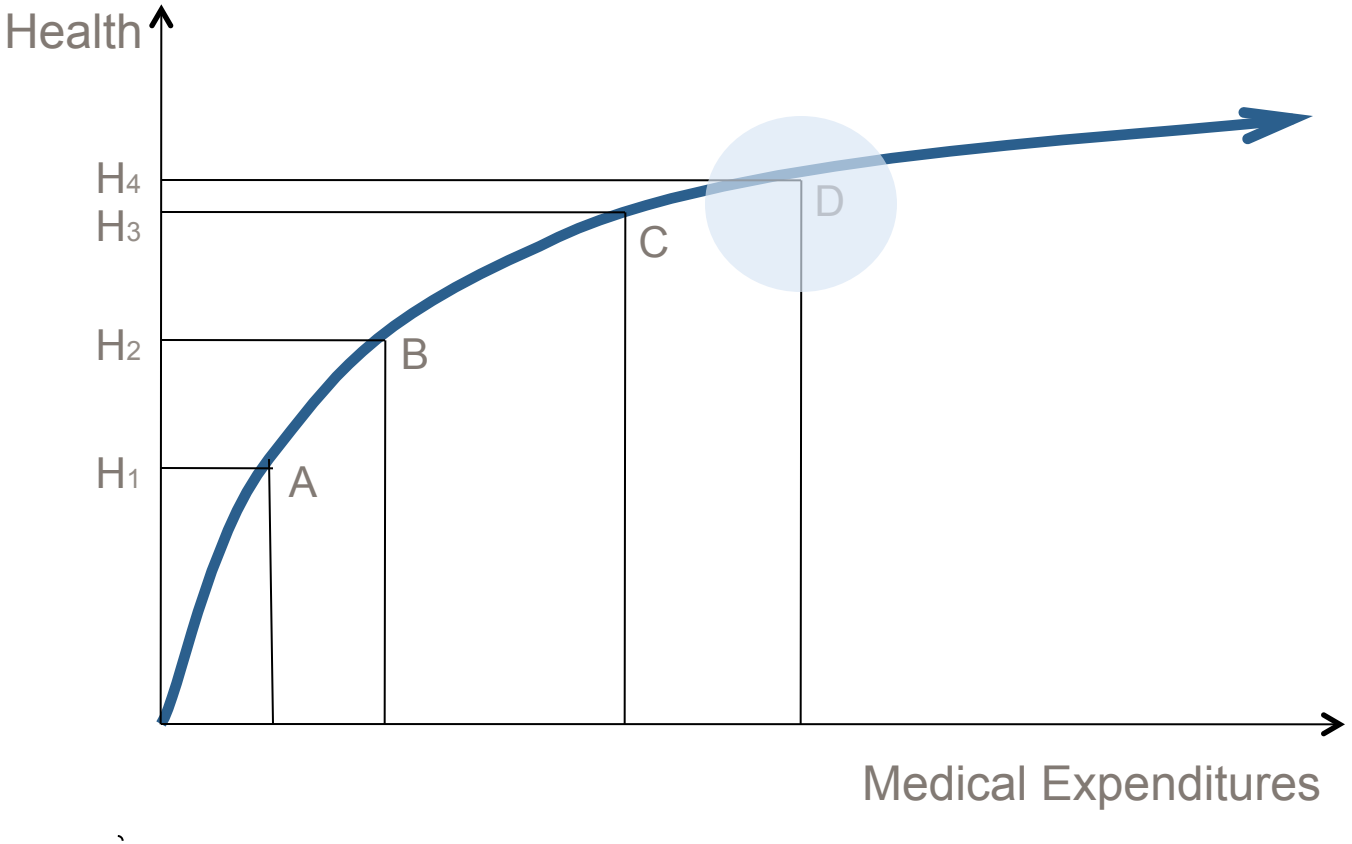
- Objective: Help clinicians and patients to make care decisions by developing evidence-based information to patients, providers and healthcare decision makers about the effectiveness of treatments relative to other options.
- Traditional clinical research: typ. examines effectiveness of one method or product at a time
- Comparative effectiveness research: compares 2+ different methods
  - Research may use clinical trials, analysis of claims records, computer modeling, review of existing literature.
  - Example: randomized trial for treatment of osteoarthritis of the knee → surgery had similar outcomes to Rx + PT
- Program accelerated in 2009
  - $1.1B funding (NIH, AHRQ, HHS, other)
  - Research areas overseen by a 15 member 'Coordinating Council'
  - Council cannot recommend clinical guidelines for payments, coverage or treatment.

CER: Effect on Drug and Device Pricing

- Devices pricing based on ability to remove costs from the system
  - Stents versus CABG
  - Less invasive procedures, e.g. laparoscopy
  - Diagnostics screening, e.g. hospital acquired infections
- Drug prices will be based on performance and outcome
  - Cholesterol drugs – shift from surrogate endpoints, e.g. LDL, to clinical outcomes, e.g., heart attacks, mortality
  - Diabetes drugs - cardiovascular outcomes
  - Oncology drugs - show overall survival benefits

Open questions:

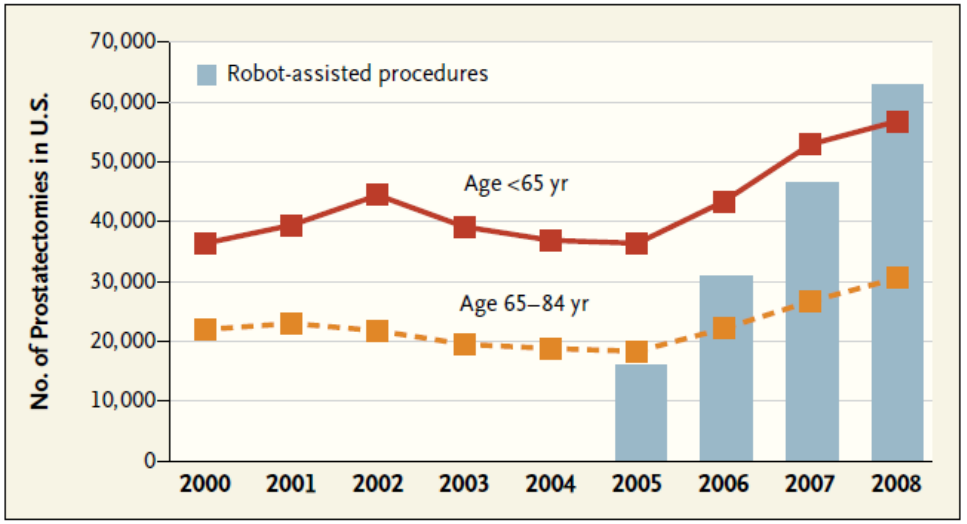
- What kind of treatments will be compared?
- Should c/e research include measures of cost?
- Will results used to make coverage decisions?
- Will c/e research save money?



Ref.: Health Policy Issues, PJ Feldstein, 2007

The Case of Robot-Assisted Surgery

- Rapid adoption in last 4 years
- Costs
  - Additional total cost of $3,200 (13% increase)
  - Increase in numbers of procedures performed
- Quality
  - Short term benefits
  - Similar long term outcomes (for prostate cancer)



Prostatectomies in the United States, 2000–2008.

N Engl J Med 2010; 363: 701-704

FDA and Payers are Looking for Different Benefits

FDA

Does the product do what it claims?

- Safety and efficacy
- Data generated in controlled setting
- Academic focused review / KOL
- Scientific method
- Substantial equivalence or comparison to placebo
- Intermediate or short-term outcome
- No cost considerations

Payers

Does the product / procedure improves outcomes?

- …Everything listed on the left, plus
- Reasonable and necessary
- Use in “real world” / general, non-academic and routine conditions
- Professional societies input is important
- No standard methodology for determining coverage
- Long term health outcomes
- Cost is often key consideration

CMS/FDA Parallel Review of Medical products

- Ad hoc parallel reviews by FDA and CMS led to a select number of simultaneous market approval (PMA) and CMS coverage
  - Human recombinant erythropoietin (EPO), 1989
  - Drug eluting stents, 2003
- Jun 2010: MOU FDA-CMS, information sharing
- Oct 2010: Proposed parallel review of medical products; requesting comments
- … no timelines for implementation
- Mixed review by industry; concerns
  - Limited to NCD, not always preferred option for manufacturers
  - Not addressing time required to obtain new codes
  - Review by CMS requires additional clinical data; early generation of such data may increase risk by company still pending FDA approval
- FDA may use Medicare data to support post marketing surveys

National or Local Coverage Decisions?

NCD

- Risk assessment: “all or nothing” decision
- Positive decision leads to consistent coverage nationwide
- Risk of non-coverage decision or restricted access to treatment
- Private payers often follow national decisions

LCD

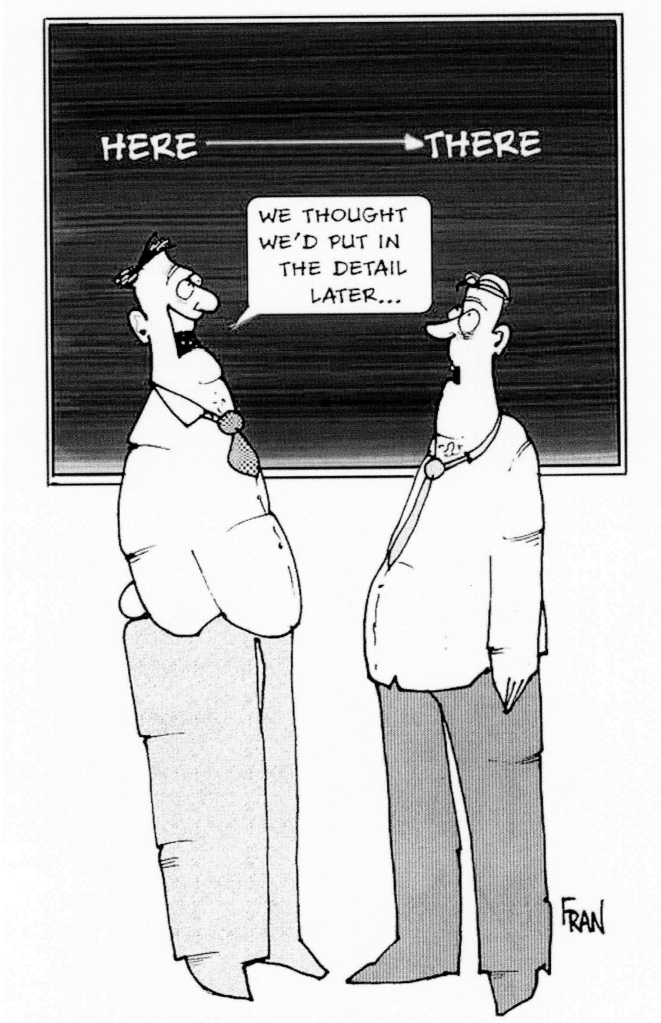
- No risk of “all or nothing” decision
- More flexibility in the process
- Standards of coverage vary
- Inconsistent LCD can lead to initiation of NCD

Some Interim Observations for Medical Device Companies

- Must understand the 'value' proposition early on.
  - 'Value' - defined by customers and payers, not own marketing department
  - Identify the degree of differentiation needed to obtain reimbursement, clinical acceptance?
  - For payers – impact on major cost drivers
- Product should be designed to meet the expected value, not vise-versa
- Clinical trials should demonstrate the value; Budget for clinical trials ↑
  - Superiority in comparison to Standard-of-Care
  - Surrogate outcomes are becoming inconsequential
- Must understand the 'cost-per-episode', not only cost of procedure
- Need to identify early on the specific patients benefiting from the new product / best responders (likely not everybody)
- Need to continue and assess efficacy post-approval
  - Require special systems

"New therapies and medical technologies have to be significantly cost-effective in the near term, and they need to come with serious appropriate use pathways and monitoring. Value-based purchasing is on the way"

Thomas Hawkins, MD
MA BCBS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WE THOUGHT WE'D PUT IN THE DETAIL LATER...
FRAN

Thank You

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