

# **The Science and Art of Value in Pricing for Medical Technology**

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**Health Industry Forum**

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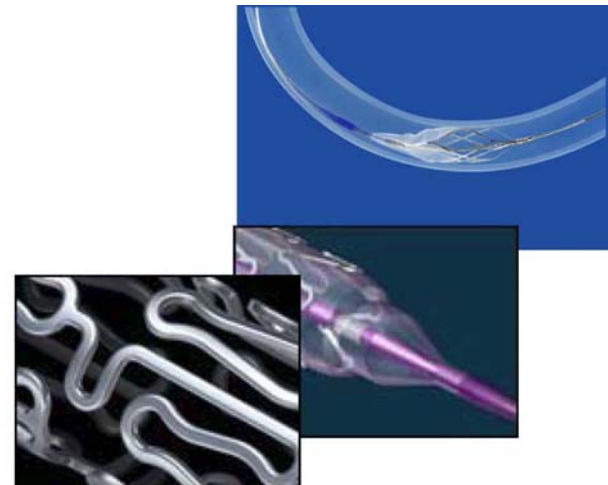
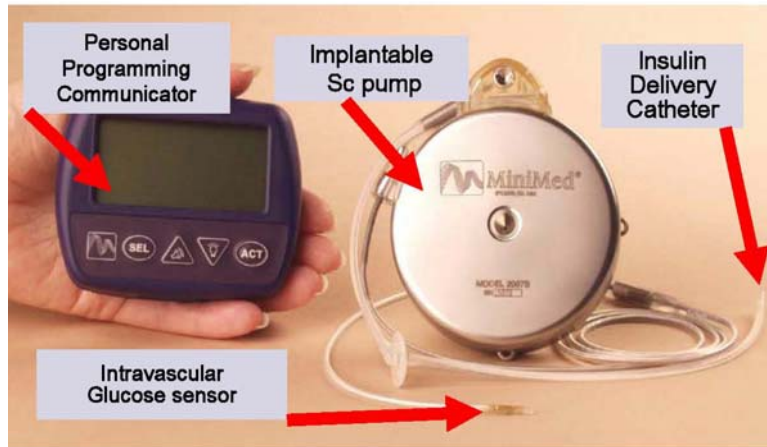
# Overview

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- Factors in Technology Pricing
  - Distinct Differences Between Pharma and Medical Technology
- Payment System Impact on Pricing Process
  - Coding, Coverage and Payment
- A Case Study
- Conclusions: Stimulating Innovation for Fair Value

# New, Innovative and Complex Technologies

- Devices are getting smarter and are providing more information
  - Intelligent Devices
  - Biotechnology Revolution
  - Personalized Medicine
  - Preemptive, Predictive, acute to home



# Unique Technology-Specific Confounders When Designing Studies to Assess Value

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- **Risk:** Range of technologies require different threshold of necessary evidence. (New non-invasive MRI tests need the same type of study as a new brain aneurysm stent?)
- **Operator Skill:** How do we capture the value of skilled physician/user techniques on patient outcomes and study design?
- **Life Cycles:** Do we expect to conduct studies on all iterative technologies with required publications when medtech's life cycles are less than 2 years?
- **Combinatorial Science:** How do we account for all the manufacturing confounders (polymers, voltages, wires and metals, drugs) on patient outcomes?

# Understanding the Structure of Financial Risk Can Help to Focus a Pricing Strategy

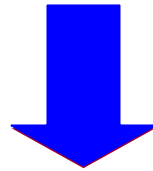
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- Financial risk flows through health plans (governments) and provider structures in different ways
- The 'holder' of financial risk typically controls decisions about purchase and use of new technology
- *The strategies and tactics associated with obtaining reimbursement and setting price depend on the integration of all reimbursement elements*

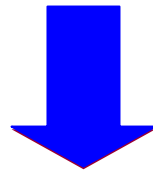
# <sup>6</sup> Challenge: Convince Providers to Purchase Technology Without a Guarantee that a Payer Will Reimburse

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Medical device company sells technology to Provider



Provider renders service (with use of technology)



Provider looks to the payer to reimburse for the service and technology

# Technology Pricing Basics

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- **External Assessment (ROI):** Value to Your Customer In Competitive Environment
  - Who Buys It (or leases it)? Hospital (GPOs), Distributor, Home Health Agency, Physician (IDNs), Direct Consumers, or Governments (VA, Global)
- **Internal Assessment (ROI):** Value and Costs of Producing
  - How to determine costs/price? Plastics, software, metals, data management, R&D, sterilization, drug licensing for combo products, electronics, plants, suppliers, regulatory rules, etc.

# Pricing Conundrums

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- Launch early at a low price, or launch later at a higher price with all the supporting evidence by financial stakeholder value
  
- Determine financial gatekeeper and perceived value before launch
  - Drugs, it's the prescriber, the patient and the payer (an insurer)—free market
  
  - Devices, it is multiple large buyers, financial gate-keepers with conflicting value systems. Budget systems are “fixed” (e.g., hospital budgets) adding to budget woes, with “benefits” realized by the INSURERS—payment gap—free riders. Payers accrue benefit while providers bare the cost.
  
- Produce evidence of product value to financial gatekeeper



# **Know Your Target:**

# **The U.S. Healthcare System**

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# Major CMS Payment Systems

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## ■ PROSPECTIVE PAYMENT SYSTEMS:

- Inpatient PPS
- Outpatient PPS
- Inpatient Rehab
- Long-term Care Hospital
- Inpatient Psych
- Skilled Nursing Facility
- Home Health

## ■ FEE SCHEDULES:

- Physicians
- Ambulatory Surgical Centers
- Clinical Labs
- Durable Medical Equipment, Prosthetics & Orthotics
- Ambulance
- ESRD

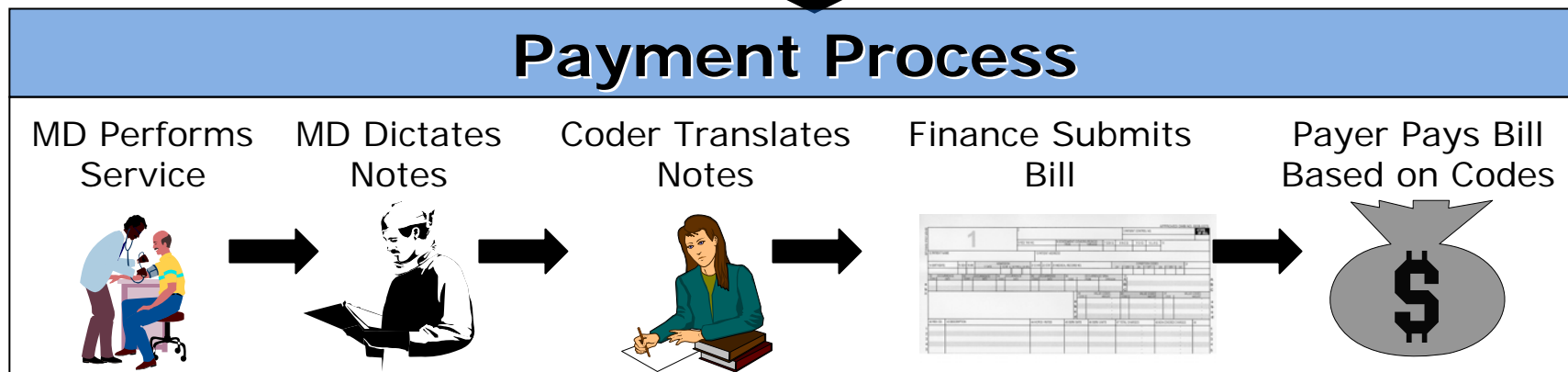
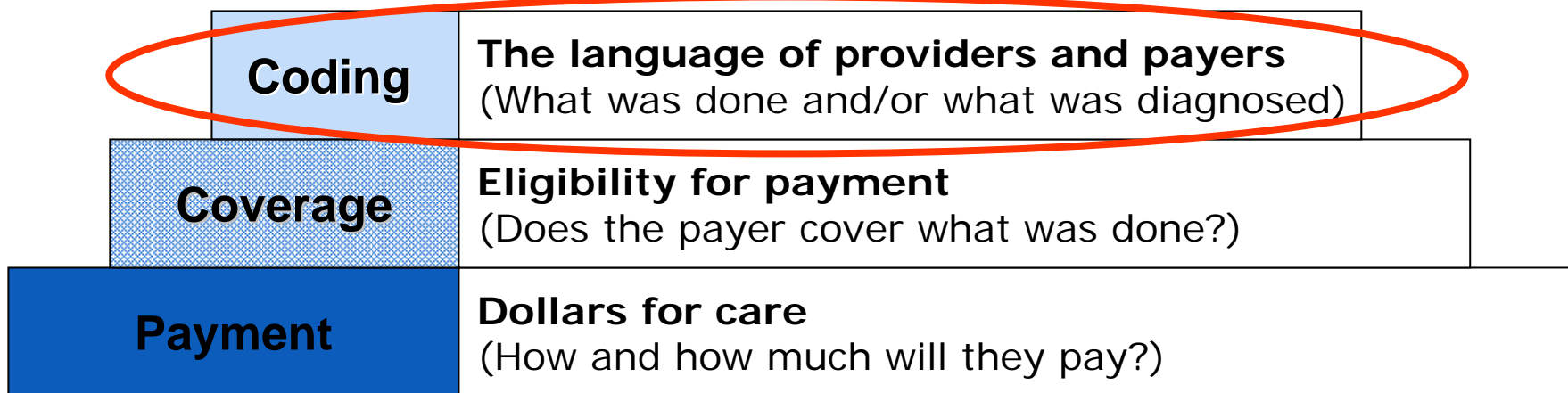


# Payment Divergences

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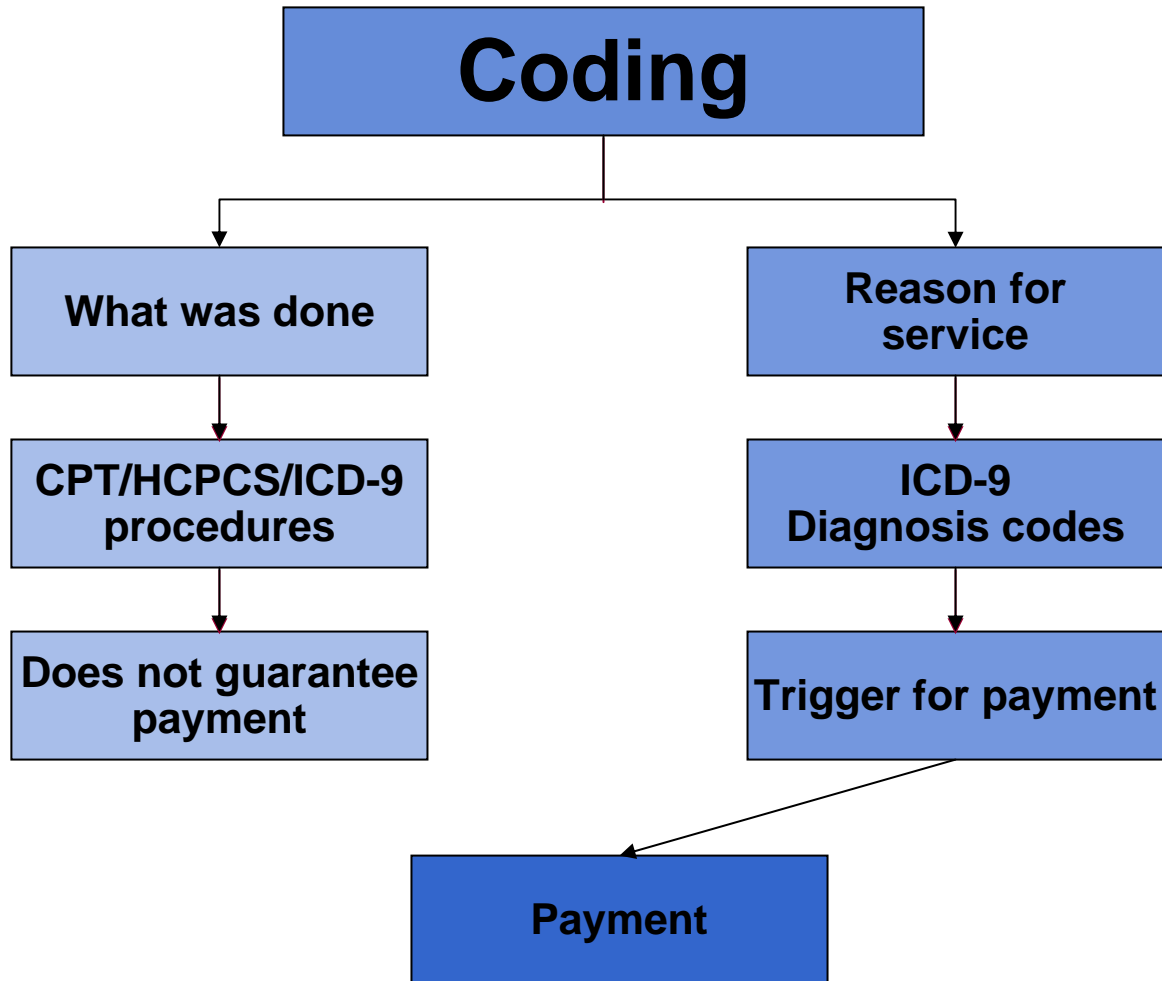
- **Each payment system has its own rules, based in statute, and uses data from the providers it pays**
  - Different payments in different sites for the same items or services
  - Can create inappropriate incentives

# Components of Reimbursement for a Device



# Where and How Does a Provider Get Paid? Follow the Code

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# Seeking a New Code Is a Strategy

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- A request for a CPT code to reflect changes in clinical practices and technologies results in short and long term strategic planning and the need to negotiate
- Key driving concept:
  - Payments for this service or existing services may be negatively impacted
- Goal:
  - To optimize RVU assignment
  - To avoid RVU devaluation

# Example of Payment Divergences

## Diagnostic Colonoscopy – CPT 45378

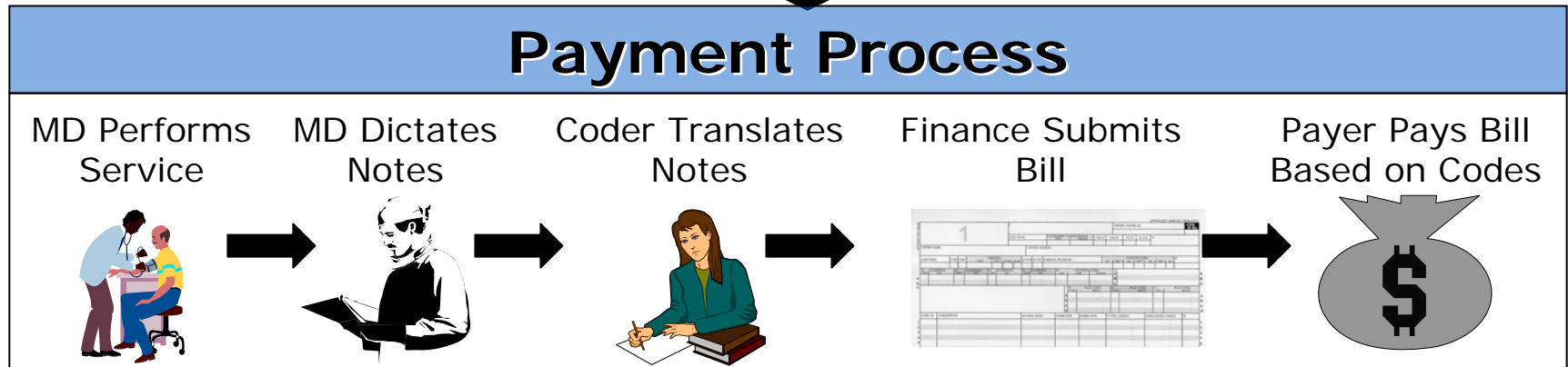
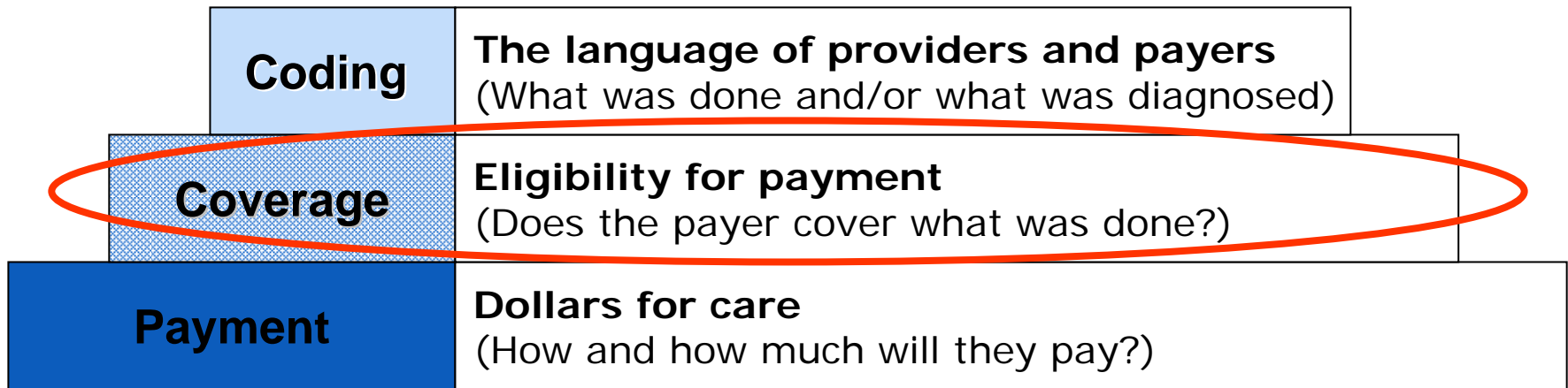
1.15 million procedures performed in 2003

	Payment	Site Utilization
■ <b>OPPS</b>	\$513	56%
■ <b>ASC</b>	\$446	22%
■ <b>PFS-PE</b>	\$177	6%

physician fee schedule (PFS)

practice expense (PE)

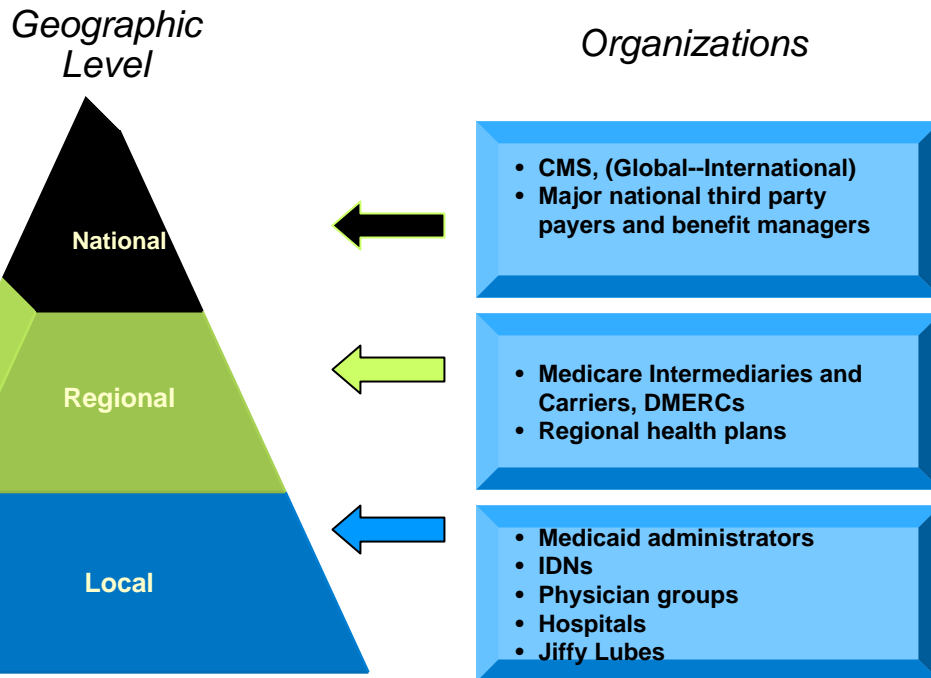
# Components of Reimbursement





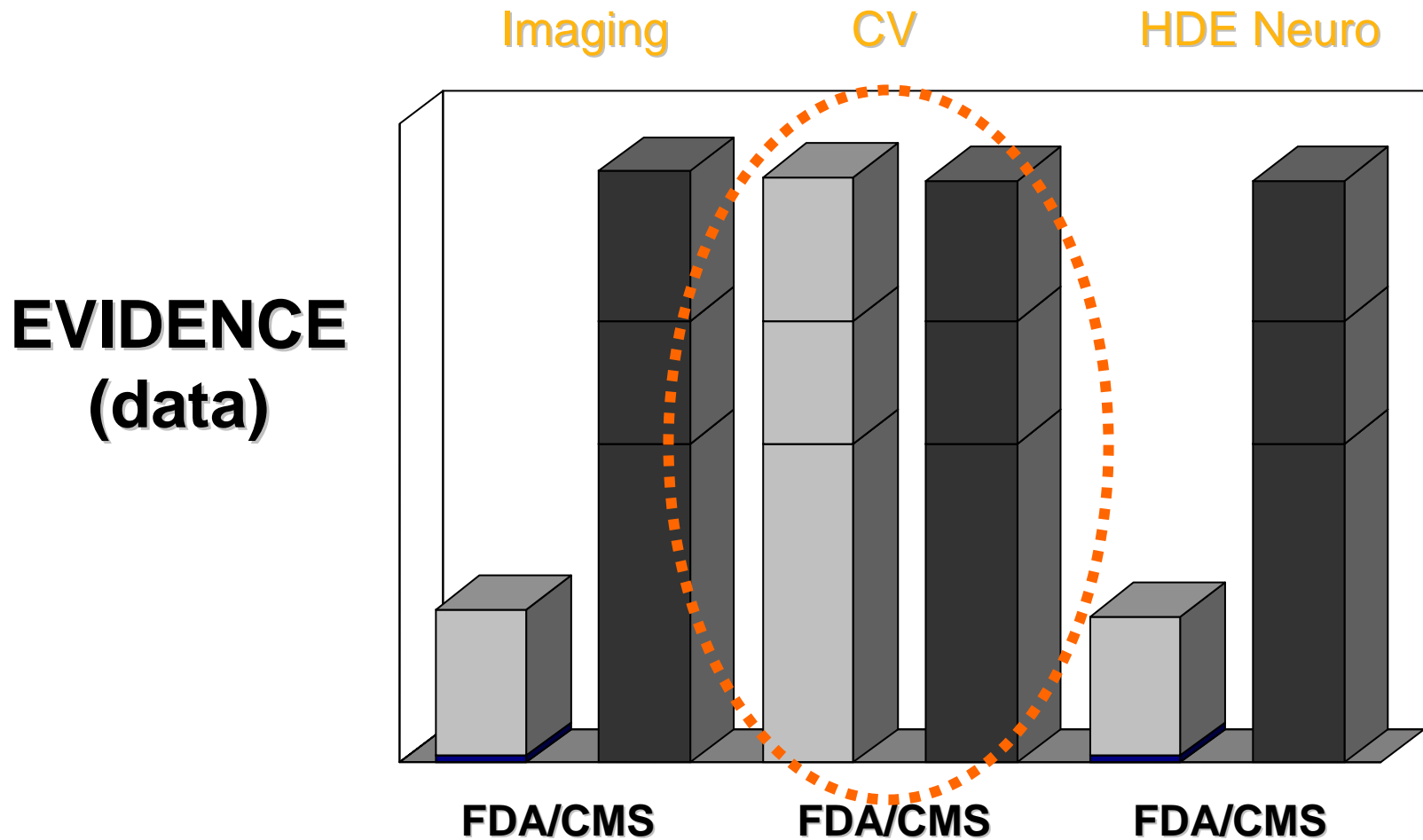
# Evidence Demands

## *Decision-Making Occurs at Multiple Levels*

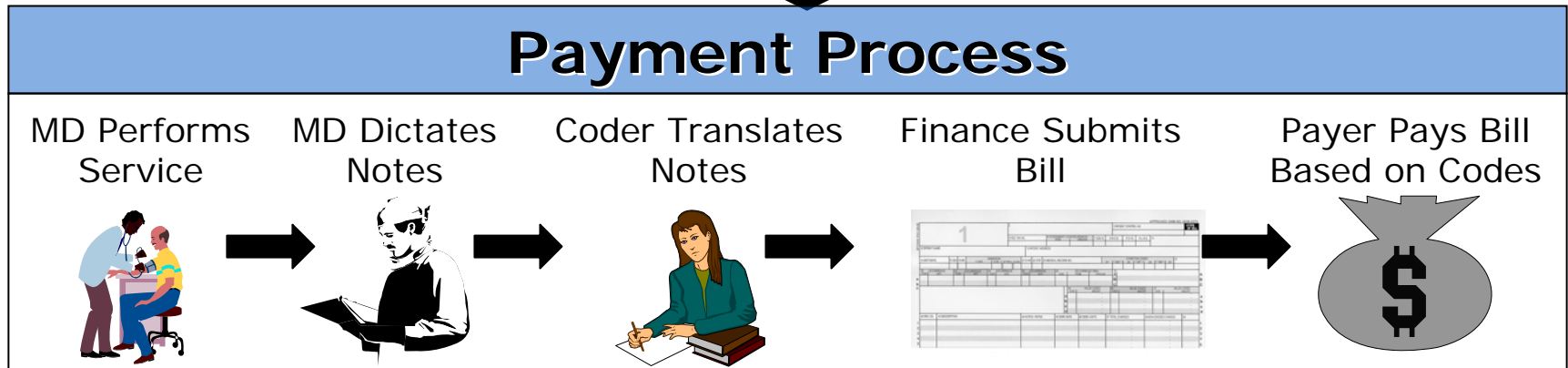
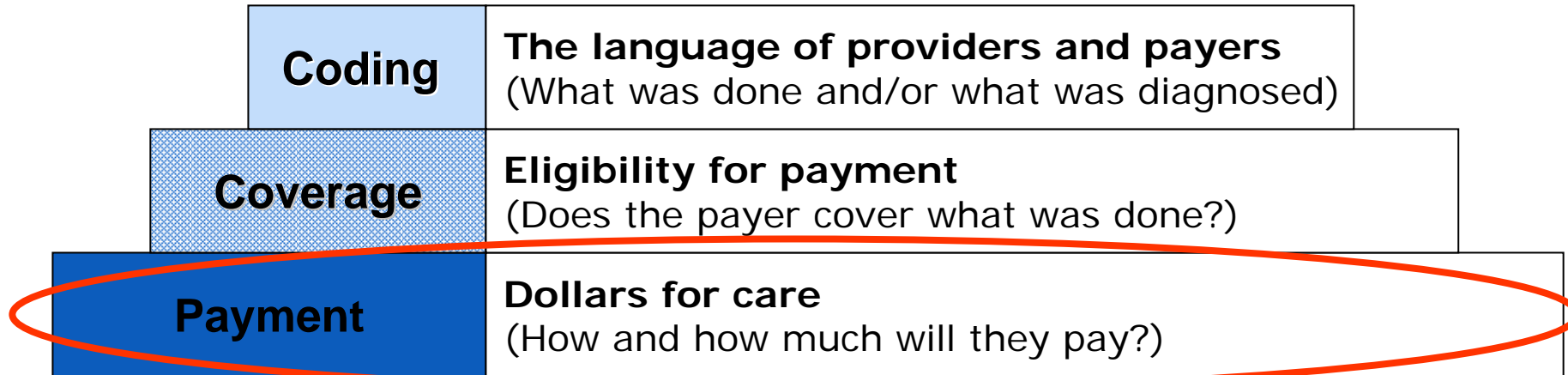


- 8,000 private payers in the US
- Contracts negotiated with “Providers”
- Providers negotiate with doctors, hospitals, suppliers, pharmacies, hospitals that own doctors, etc.
- So, where do you target to show the value of your technology? Value to whom? Primary audience?

# Higher Evidence Thresholds: Fundamental Disconnect Between Regulator and Payer



# Components of Reimbursement

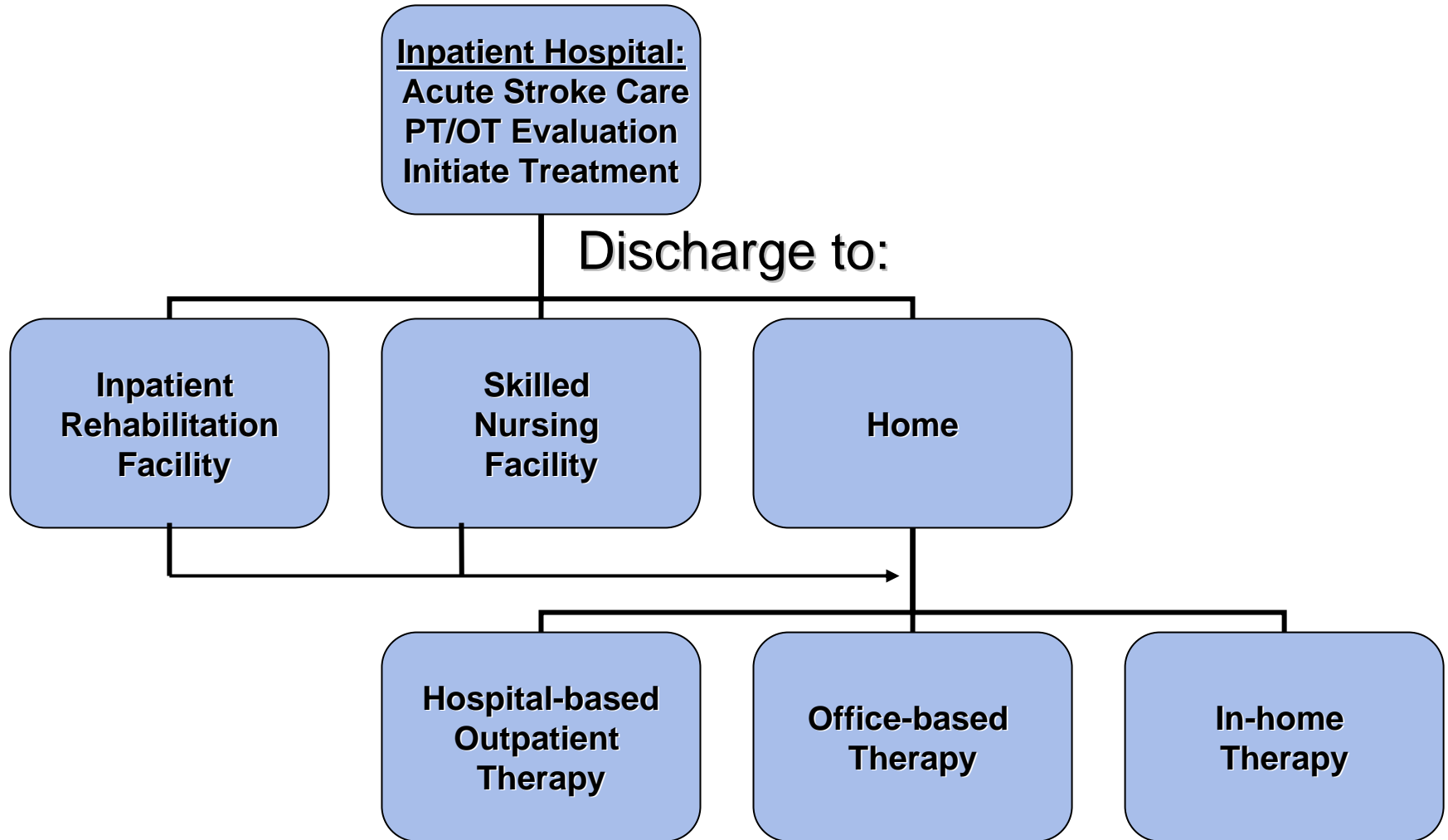


# Private/Commercial Payments

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- Negotiated rates with hospitals & physicians
- Payments: usually a percentage over Medicare's for physician services
- Utilization restrictions, pre-authorization & “case-management” arrangements for many services, particularly “post-acute” and rehab services
- Minimal, often capped, DME coverage

# Example: A Promising Technology to Moving Care From Acute to Home...



# Example: Daily home dialysis restrained by payment



**vs.**



- Major clinical benefits
  - LVH, heart failure improvement
  - Anemia
  - Rehabilitation/QOL
- 15-25% annual savings potential (\$10-17K of 70K costs)
  - Kaiser promoting home dialysis

# Daily home dialysis challenges

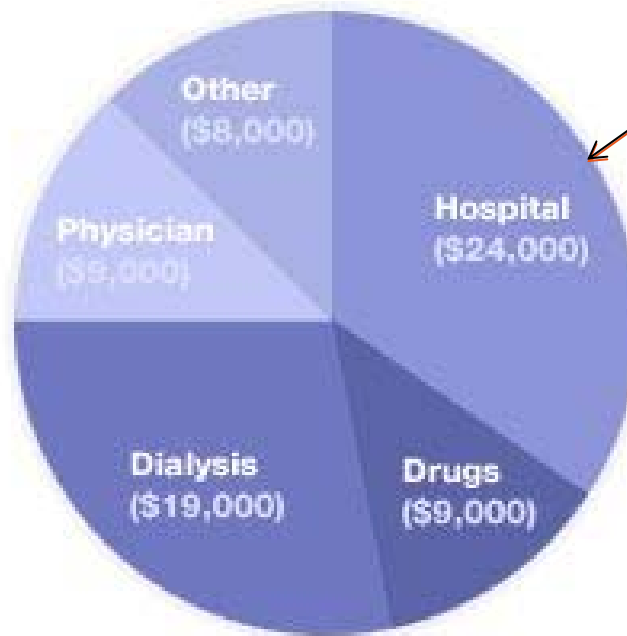
Total Annual Costs of Care  
\$65-70,000 per patient



Portion of Medicare savings occur in drugs, which are profit generators for providers

# Daily home dialysis challenges

Total Annual Costs of Care  
\$65-70,000 per patient



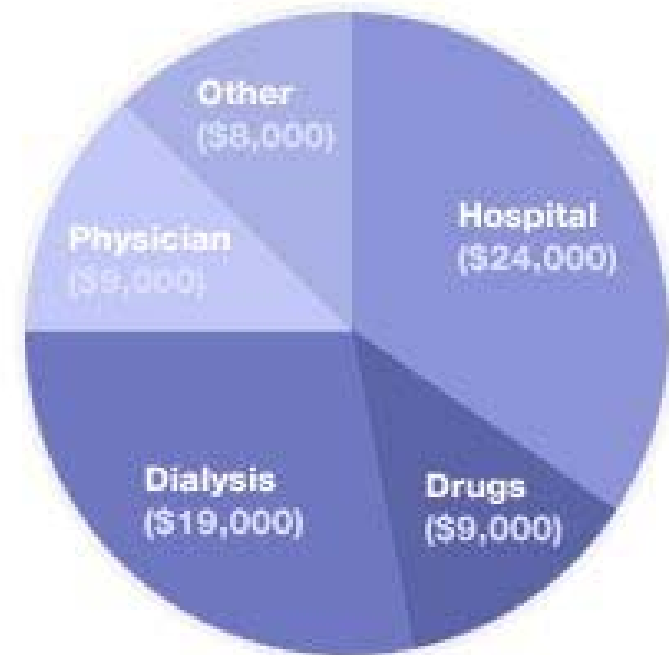
Largest savings in hospital costs, which are part of a different budget (Part A vs. Part B) and are not realized by the dialysis provider



# Daily home dialysis

- In-center dialysis continues to dominate, despite data
- Product pricing/market potential not sufficient to attract broad investment given payment system
- Patient access is skewed to those with commercial insurance, and Medicare beneficiaries are denied

Total Annual Costs of Care  
\$65-70,000 per patient



# A True Story: Finding the Right Path

## Physician-Delivered Model Works Best

	Existing Category	Physician Delivered	Home Health Delivered	Weight	Control
▪ Pharmacy Risk					
▪ Speed to Discrete Coding and Payment					
▪ Market Potential					
▪ Prescriber Motivation/Feedback					
▪ Justification of Medical Necessity					
▪ Speed to Commercialization					
▪ Number of Economic Stakeholders					

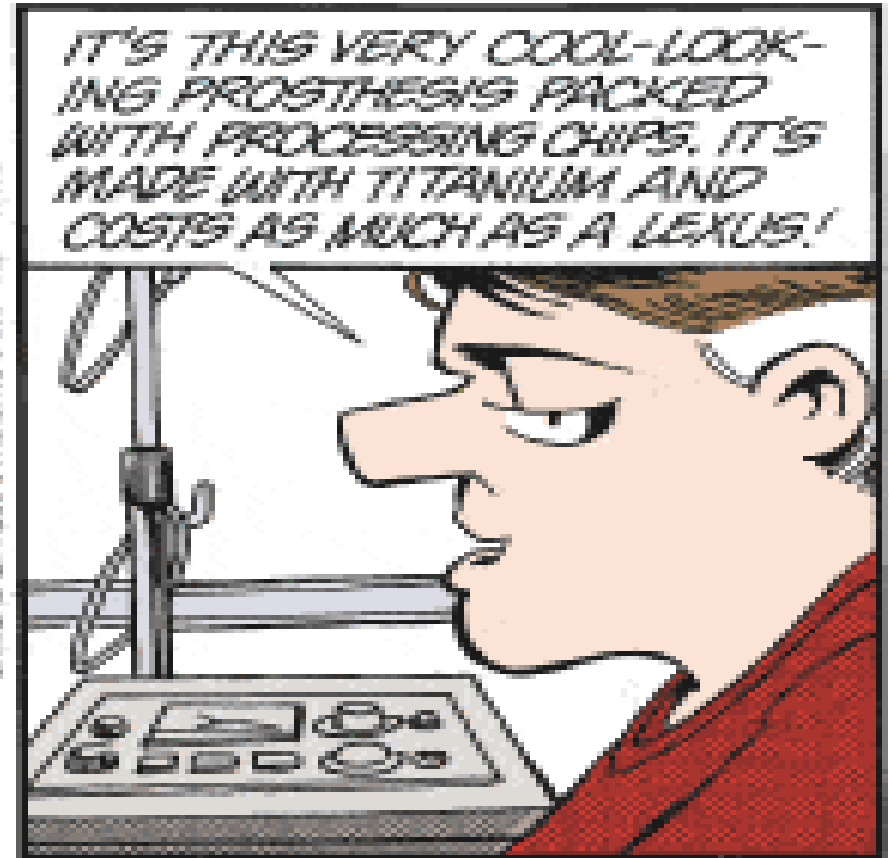
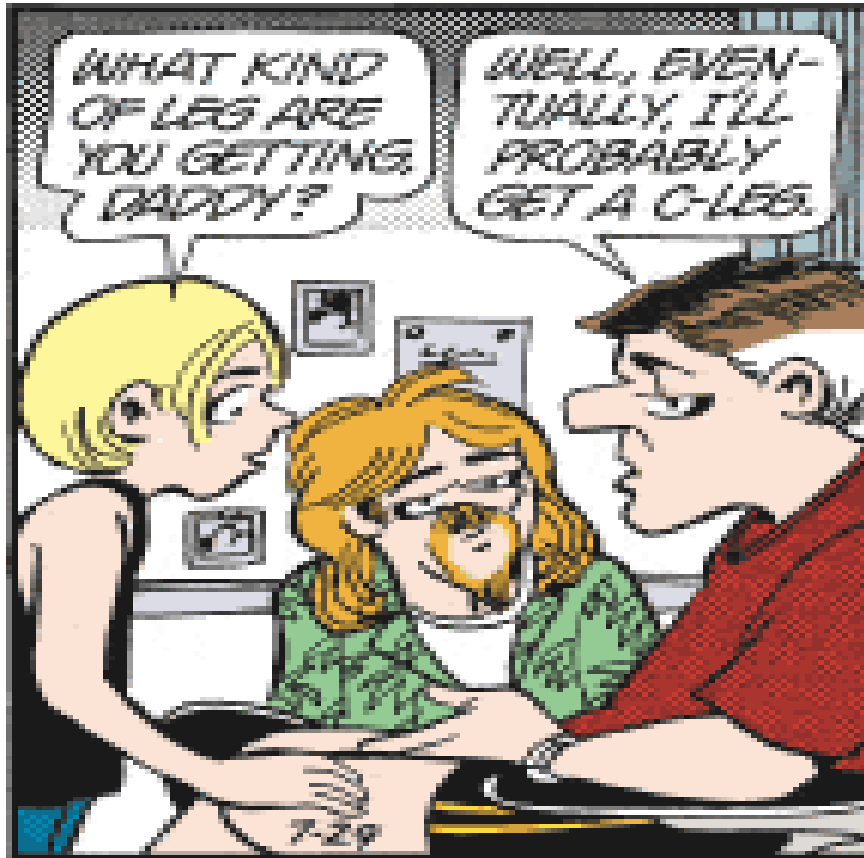
Good   Better   Best

# Pricing Technology means navigating U.S. Reimbursement System

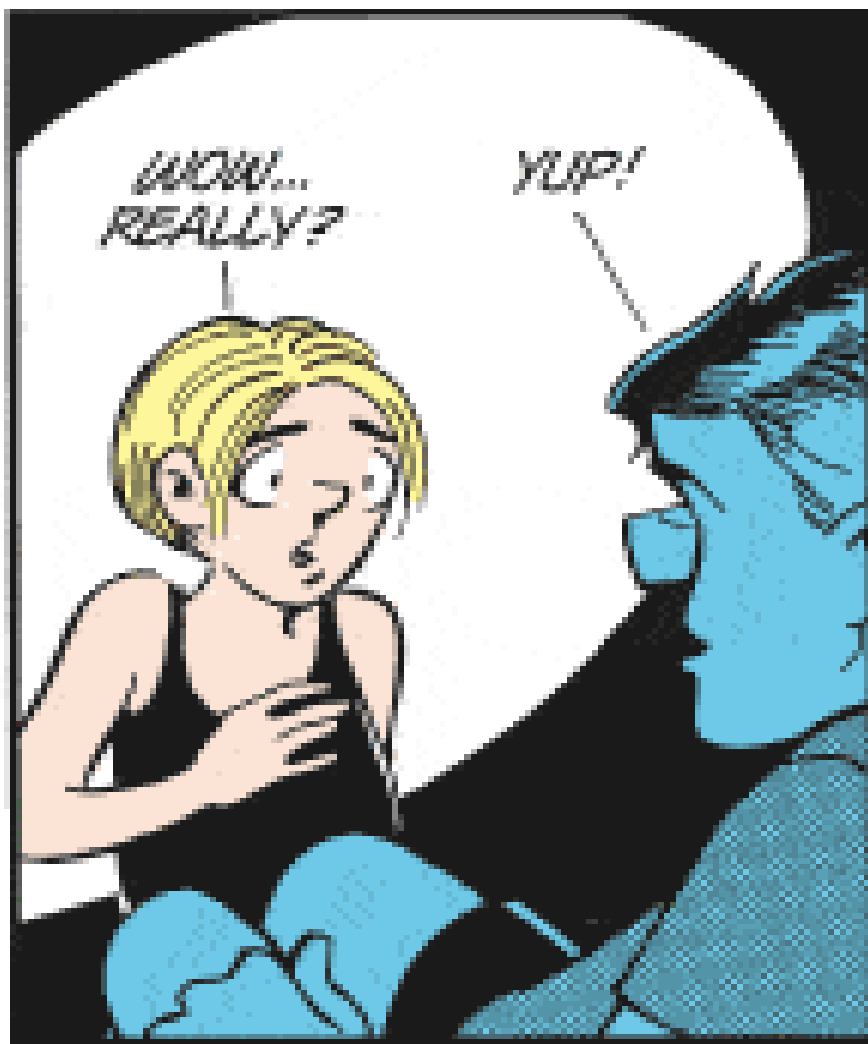
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- Pre-launch Environmental Analysis
  - Investigate the coverage, coding and payment issues
  - Develop precise strategies for addressing these issues, e.g. applying for new codes, developing alliances
  - Develop materials and data that are both credible and compelling for distribution and presentation to providers and payers
- Post-launch: Customer and Reimbursement Support
- Build the Value Story
  - Develop data to demonstrate the financial impact of the technology under realistic assumptions of coverage, coding and payment by Financial Gatekeeper

# Doonesbury - 7/29/04



# Doonesbury - 7/29/04



# Conclusions

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- Medtech pricing is subject to site of service, payer considerations
- System reform is needed to appropriately align incentives
- Works in Kaiser-like systems where physician payment is not linked to utilization; providers and payers are aligned
- Imposing new evidence requirements prematurely without alignment in payment systems may have irreversible consequences in the growth and adoption of new technology