



BERKELEY CENTER
FOR HEALTH TECHNOLOGY

MedTech Innovation Amid Changing Dynamics for Physicians, Hospitals, and Consumers

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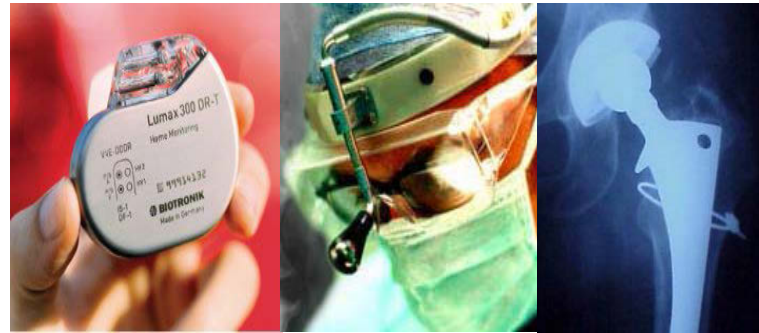


Disclosures

- The research underlying this presentation was funded by grants from:
 - California Public Employees Retirement System (CalPERS)
 - US Agency for Healthcare Quality and Research (AHRQ)
 - Robert Wood Johnson Foundation (RWJF)



Overview



- The medtech model under stress
- Payment incentives for providers
- Cost sharing incentives for patients
- Innovation in a changing environment

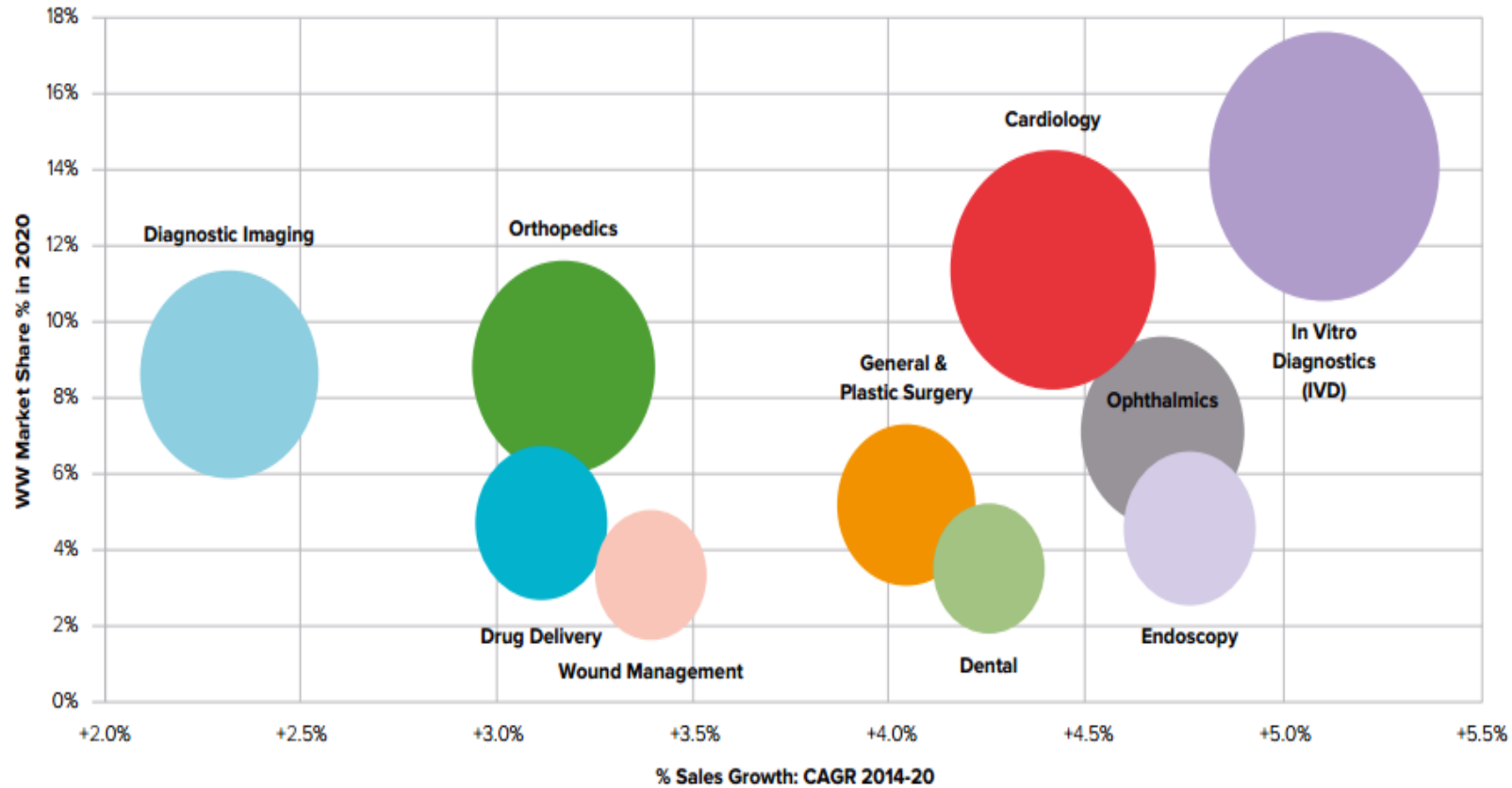
The MedTech Engineering Model is Working Very Well

- Incremental innovations emerge continually, improving performance through better designs, materials, scale, IT connectivity, ease of administration
- Breakthrough innovations emerge occasionally, offering radically new and better options to patients, supported by strong clinical evidence
- Medical devices, diagnostics, and imaging comprise important knowledge-based economic sectors, creating high-wage jobs, taxes, and exports



Analysis on Top 10 Device Areas in 2020, Market Share & Sales Growth (2014-20)

Source: EvaluateMedTech* September 2015



Note: Size of Bubble = WW Sales in 2020

Source: EvaluateMedTech® World Preview 2015. Evaluate Ltd.

The MedTech Regulatory Model is Working Moderately Well

- FDA adjusts requirements to device type
- Incremental innovations cleared via 510K, with minimal demands for clinical evidence
- Breakthrough innovations authorized by PMA, with extensive demands for clinical evidence, similar to drug reviews
- Some critics say PMA and 510K are too weak, allowing unsafe devices on the market, while others say FDA regulation is too slow and costly, relative to EU
 - IOM report on 510K (2011)
 - 21st Century Cures Act (2015)

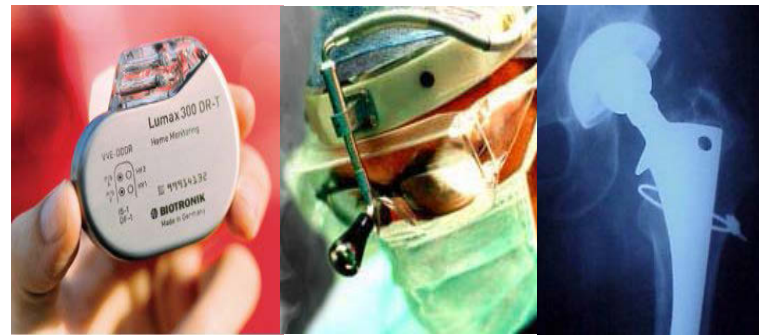


The MedTech Business Model is Broken

- Breakthrough innovations are rare, and firms rely on incremental improvements with higher prices for each annual product model
- Revenue requirements lead firms to push sales beyond the limits of the evidence
- The industry has been dependent on an unsophisticated purchasing environment:
 - Fragmentation of insurers, misaligned incentives between physicians and hospitals, and moral hazard by consumers
- Field of dreams: build it and they will buy it



Changing Payment Methods for Physicians and Hospitals



Overview of Payment Initiatives

- CMS initiatives are broad in scope, slow to be implemented, subject to lobbying, and huge in potential market impact
- Private payer initiatives are more narrow in scope, quicker to be implemented, subject to resistance from providers, and limited in impact due to insurer fragmentation
 - ACO initiatives target all specialties
 - CJR directly targets device-intensive care
 - OCM directly targets drug-intensive care
 - Anthem pathways target specialty drugs



CJR Targets Joint Replacement and, Indirectly, Imaging and Implants

- CJR builds on ACE demo, which combined hospital and MD payment (Parts A,B) for voluntarily participating hospitals, with hospitals sharing gains with physicians
- Major savings came from cheaper implants
 - FROM: (Medtech + Surgeons) v. Hospitals
 - TO: (Hospital + Surgeons) v. Medtech
- CJR is mandatory in 67 markets, combines Part A,B with incentives on readmissions
 - No sharing of savings with patients
- Could be extended to spine, PCI, other



CJR Challenges

- CJR has great strengths, compared to ACE and private payer bundled payments
 - Mandatory programs don't have to be watered down to lowest common denominator of providers
 - CMS has large market share so surgeons want and need to participate
 - Joint replacement has stable device technology, and hospitals can lower costs when aligned with MDs
- CJR model works well (from payer perspective) for procedures with incremental, not breakthrough, technologies
 - If CJR model were applied to other procedures, it would need carve-outs for breakthroughs (NTAP)



OCM Targets Oncology and, Indirectly, Drugs and Radiation

- OCM is voluntary oncology medical home program targeting 100+ large practices
- CMS pays \$160/month for patients in active chemo, above the usual FFS for visits
- CMS establishes target for total spending per patient, and measures actual spending
 - Includes oncology (visits, monitoring, infused drugs, oral drugs, radiation, surgery) but also non-oncology (lab, imaging, ED, inpatient)
- Practices share 'savings' after CMS takes cut, if they meet quality standards



OCM Challenges

- Can oncology practices really manage the full spectrum of oncology services, much less the full spectrum on non-oncology services?
- How does CMS set the spending targets?
 - How are these adjusted for patient risk?
 - How do these adapt to new drug launches?
- Most practices cannot realistically participate
 - What about small practices? Will OCM accelerate consolidation of oncology into hospital systems?
- What will be the impact on use and price of specialty drugs (pathways and prior auth)? Why does CMS not discuss this?



Anthem Pathways Initiative Targets Oncology Drug Use

- AIM pathways program is voluntary, but has been accepted by entire oncology network
- Anthem pays \$350/month for patients in active chemo, above the usual FFS for visits
- Oncologists must submit patient data (disease stage, biomarkers) and adhere to Anthem approved drug pathways
 - But practices are not responsible for non-drug oncology (radiation, surgery) or for non-oncology services to cancer patients
- Anthem does not see this as transition to bundled payment, as it does not want to put the physician at risk for cost of cancer drugs



Challenges to Anthem Pathways Initiative

- Although the largest private insurer, Anthem is only a small part of any oncologist's practice
- It will not affect practice patterns beyond drug:
 - Patient monitoring and engagement
 - Reduction in ED and hospital use
 - Radiation treatment and surgery
- Bar for participation is low and payment is high; with no risk, only limited changes?
- Hopes that, together with CMS, Aetna, United initiatives, it will influence physician behavior

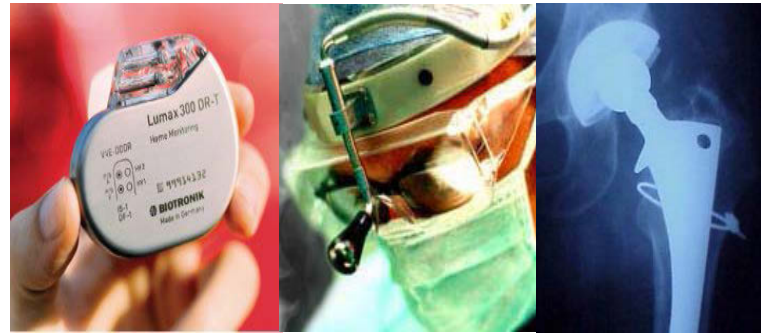




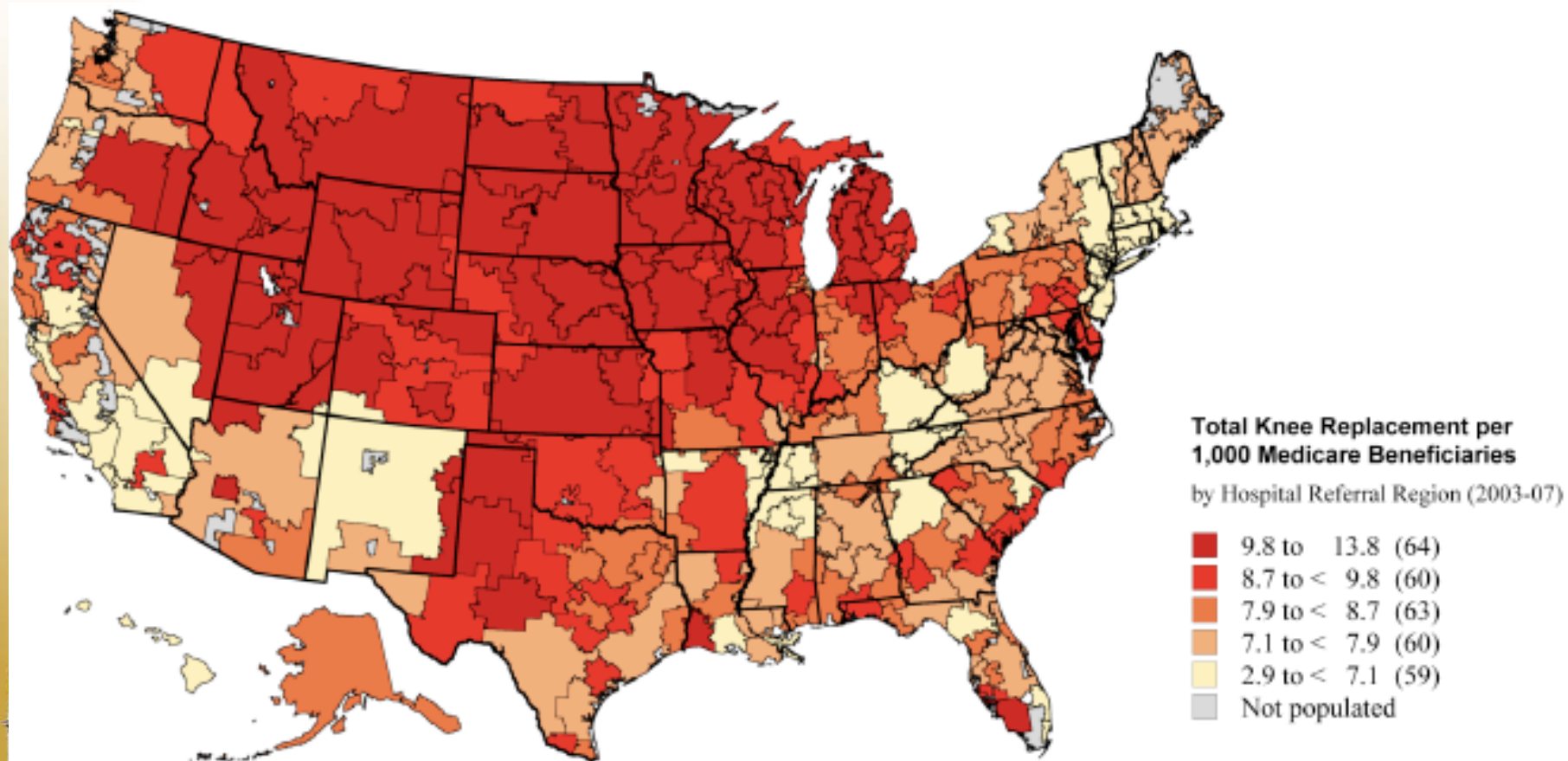
“Geez Louise—I left the price tag on.”



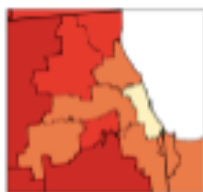
Changing Cost Sharing Designs for Consumers



The Problem: Unjustified Variation in Rates of Use for Knee Replacement Surgery



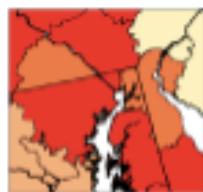
San Francisco



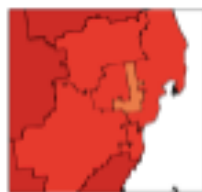
Chicago



New York

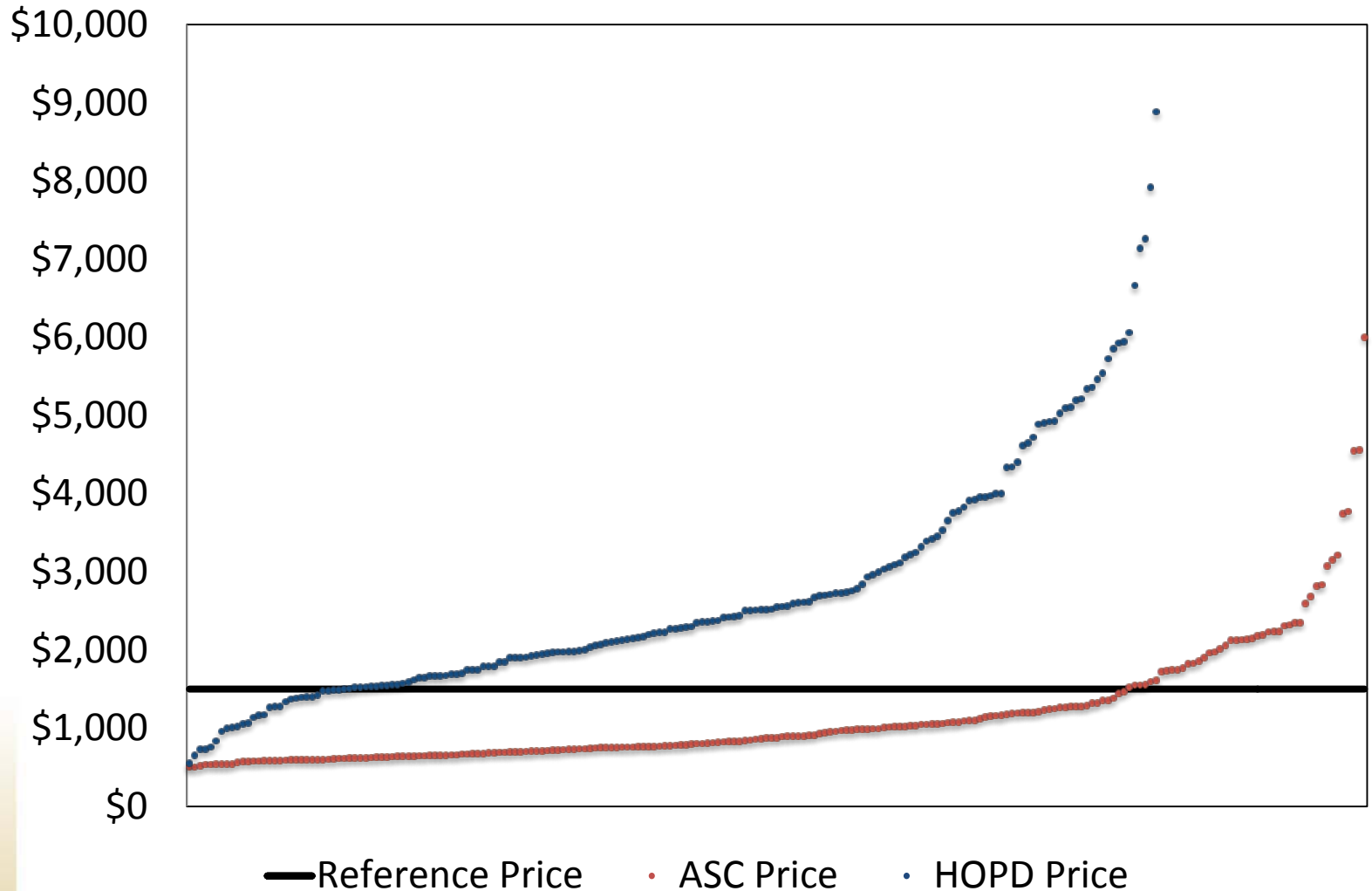


Washington-Baltimore



Detroit

The Problem: Price Variation for Similar Services in the Same Market: Colonoscopy



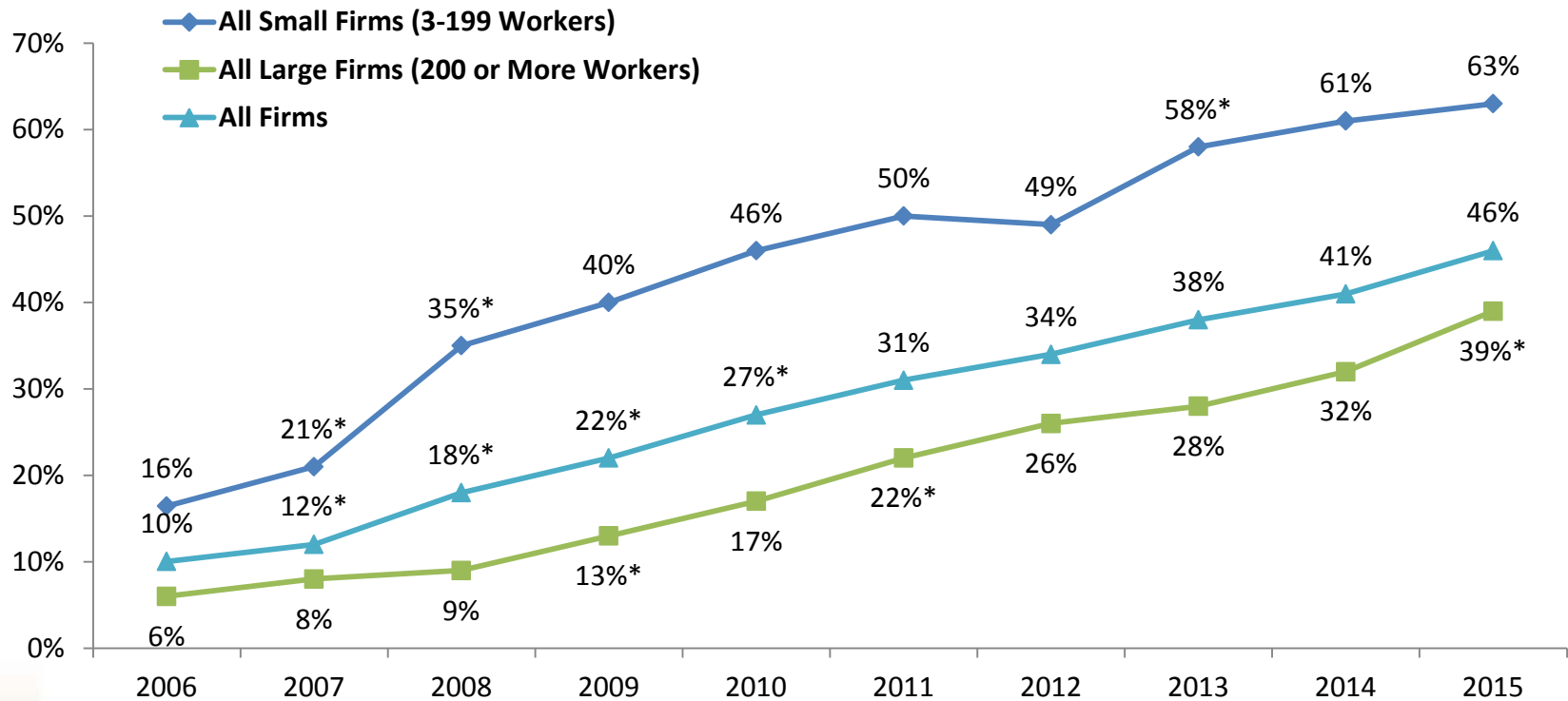
Overview of Consumer Initiatives

- CMS is politically unable to innovate in cost sharing but has strong leverage on providers and so relies on provider payment initiatives
- Private plans (and employers) are pushing consumer initiatives because they have weak leverage with providers
- Targets for private payers include inappropriate utilization, excess pricing
- Instruments include high deductibles (HDHP), narrow networks, reference pricing
- Supports for consumers facing cost sharing: price transparency, decision support



Employers Move towards High Deductibles

Require Patient to Pay Initial \$1000- \$5000 in Costs Incurred

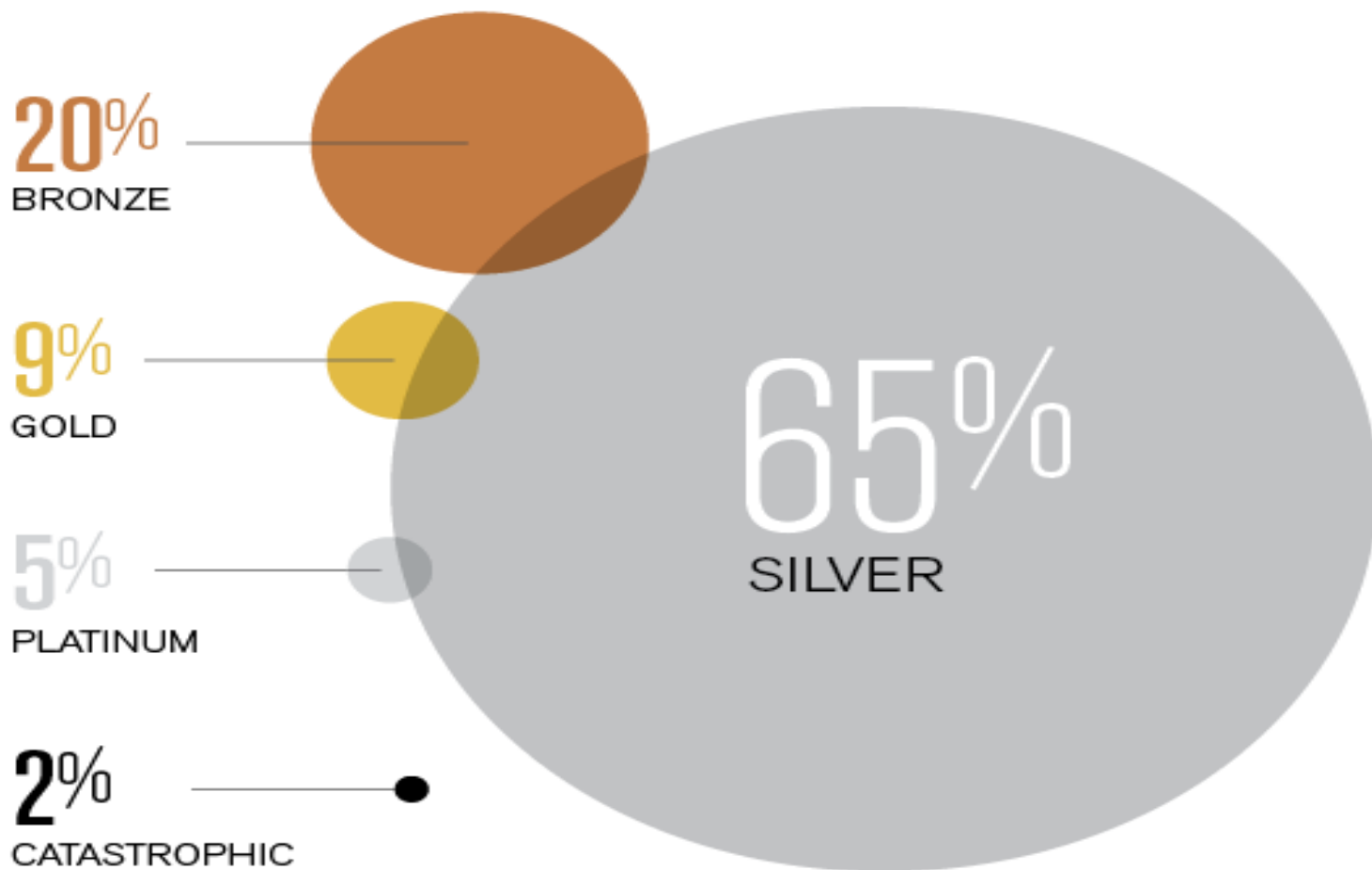


Percentage of Covered Workers Enrolled in a Plan with a Deductible of \$1,000 or More for Single Coverage

Source: Kaiser Family Foundation/HRET 2015 Employer Survey

Individual Consumers Favor High-Deductible Silver and Bronze Plans in ACA Insurance Exchanges

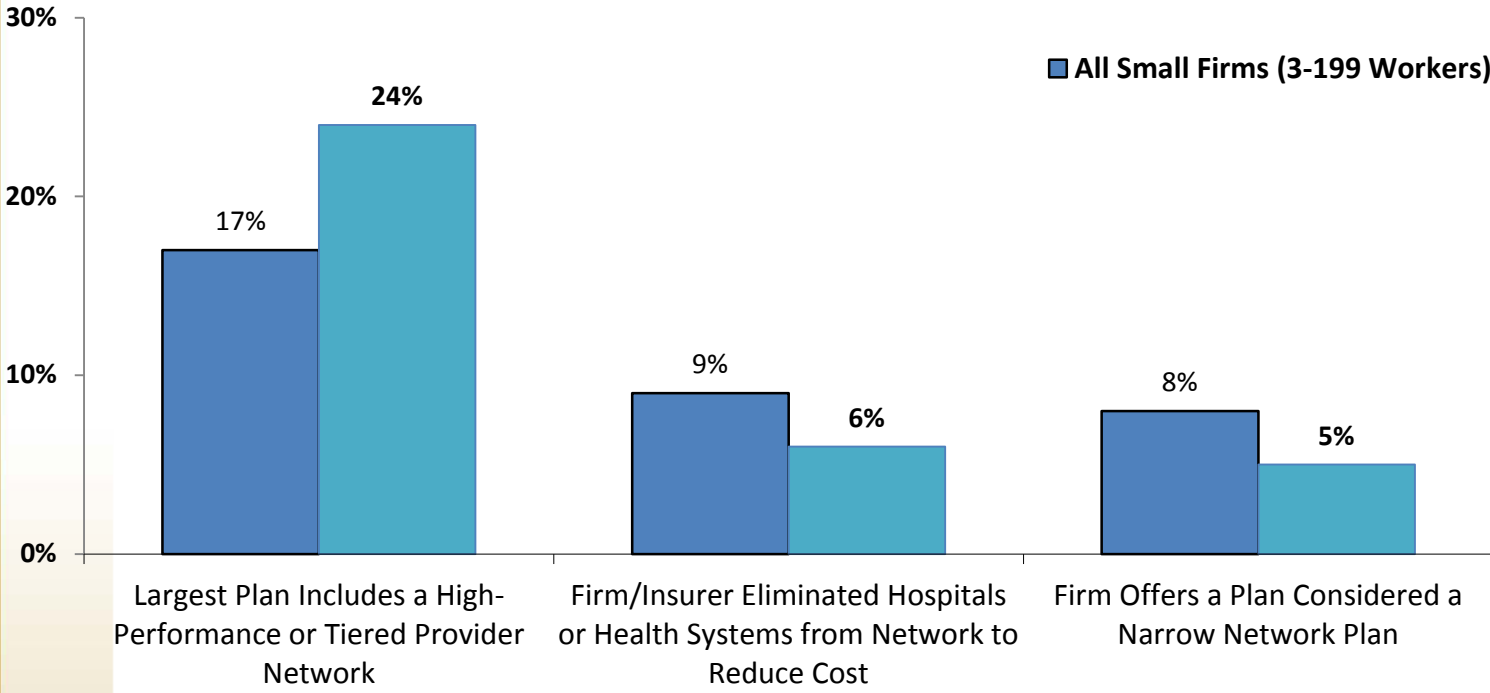
Plan selection by metal level



Note: Percentages rounded by HHS.



Narrow Hospital Networks are Spreading in Employment-Based Insurance



Source: Kaiser Family Foundation/HRET 2015 Employer Survey

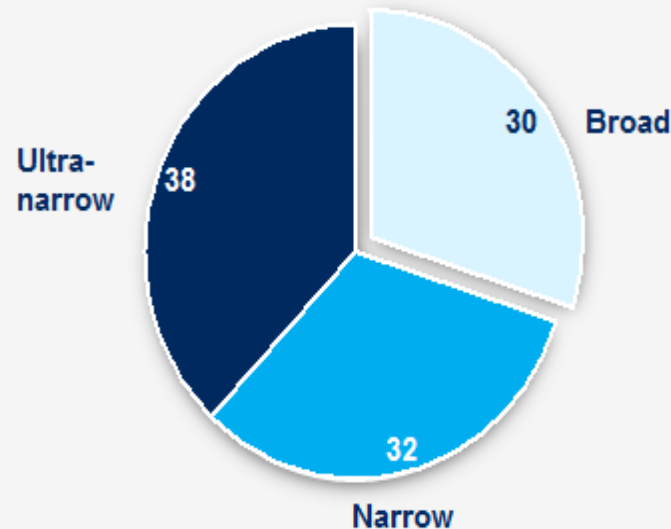
Narrow Networks are Dominant in Public Health Insurance Exchanges

EXHIBIT 1

70 percent of hospital networks on exchanges are narrow or ultra-narrow

Distribution of networks by network breadth¹

2014 individual exchange – Percent of analyzed silver networks (n = 120²)



¹ Broad networks: less than 30% of largest 20 hospitals by number of beds are not participating, Narrow networks: 30-69% of largest 20 hospitals are not participating, Ultra-narrow networks: at least 70% of largest 20 hospitals are not participating

² Networks offered in silver in Atlanta, Bridgeport, Dallas, Nashville, Houston, Salt Lake City, Miami, Tampa, Louisville, Indianapolis, St. Louis, Los Angeles, San Jose, Pittsburgh, Denver, Philadelphia, Seattle, Chicago, Washington D.C., and Portland, ME

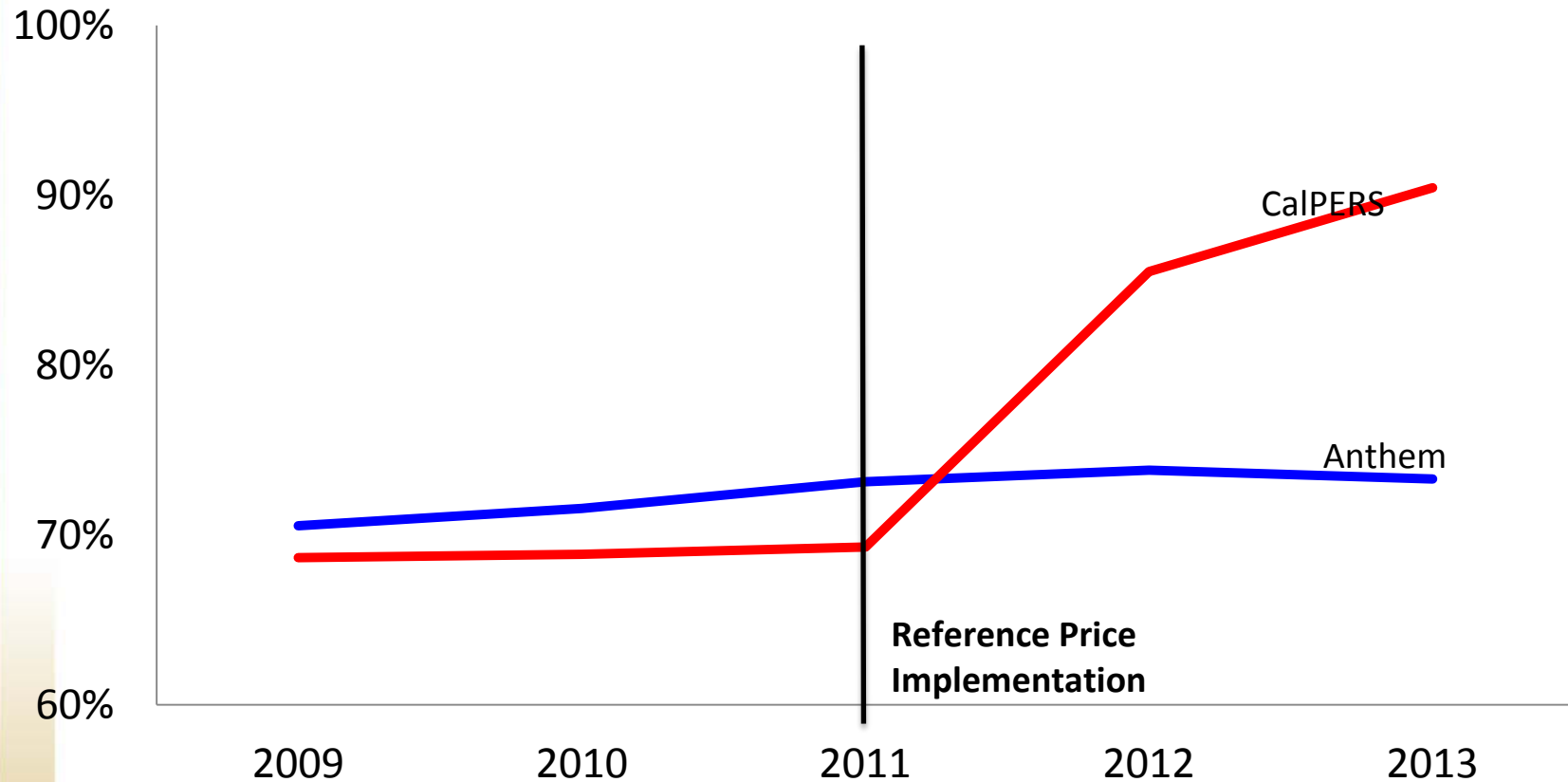
SOURCE: McKinsey Center for U.S. Health System Reform/McKinsey Advanced Healthcare Analytics analysis of publicly available rate filings and carrier information; AHA database

Data as of 11.15.2013

McKinsey & Company

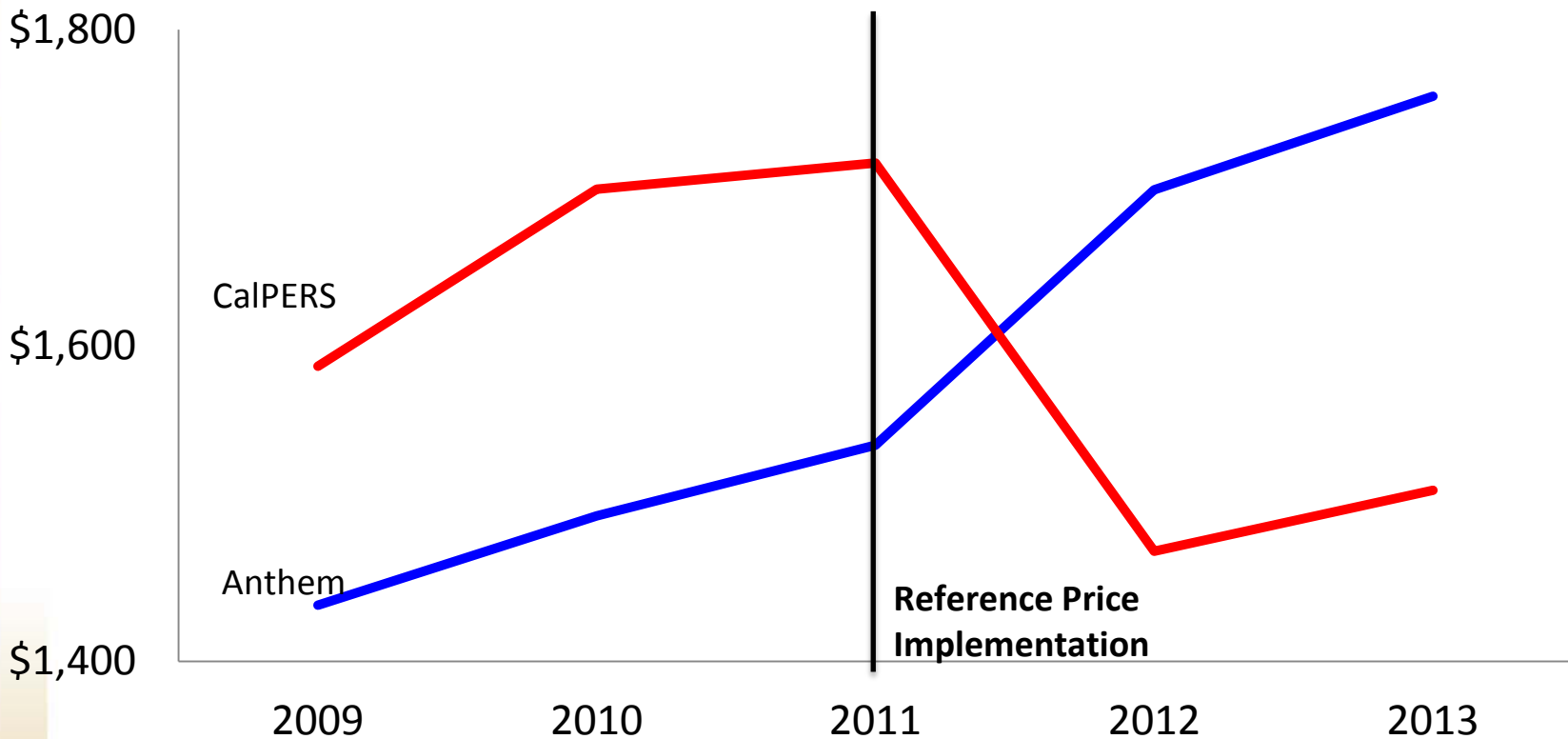
Reference Pricing: Consumers Switch to Lower-Priced Facilities When Spending Their Own Money

Percentage of Patients Selecting Ambulatory Surgery Centers (ASC) over Hospital Outpatient Departments (HOPD) for Colonoscopy Before and After Implementation of Reference-Based Benefits








Price-Conscious Consumer Choices Reduce Spending by Employers and Insurers


Average Price (Allowed Charge) for Colonoscopy Before and After Implementation of Reference-Based Benefits



Price Transparency


Company and Product	Information Offered	Platform
	<ul style="list-style-type: none"> • Price transparency – flagship firm • Plan benefit information for consumers • Employer analytics 	<ul style="list-style-type: none"> • Varied: web tools, delivered insights, mobile tools for employees
	<ul style="list-style-type: none"> • Price comparison information from Healthcare Bluebook • Healthcare services information • Adding new services in future 	<ul style="list-style-type: none"> • Mobile integrated data platform, including an app
	<ul style="list-style-type: none"> • Online health care shopping tool for consumers with high-deductible plans 	<ul style="list-style-type: none"> • Integrated in with members' claims, transparency tools, and in-network providers
	<ul style="list-style-type: none"> • Cost information for over 70 common health conditions and services based on claims data from four major insurers 	<ul style="list-style-type: none"> • Consumer-facing website • Has received Medicare data as a “qualified entity”
	<ul style="list-style-type: none"> • Comparison of licensed providers, including doctors and dentists • Discounts and deals • Online appointment system 	<ul style="list-style-type: none"> • Consumer-facing website • Providers can sign up to create a profile

Active Information Outreach

Company and Product	AIM Specialty Health Specialty Care Shopper Program 
History	<ul style="list-style-type: none"> • Began as American Imaging Management, a radiology benefit management company • Acquired by WellPoint in 2007 • Current services expand beyond radiology
Approach	<ul style="list-style-type: none"> • Through the Specialty Care Shopper Program, an AIM specialist proactively contacts a health plan member once a service (e.g. an MRI or CT) has been approved if there is a high-quality, lower-cost site-of-care option available within their local community • If the member decides to accept the recommendation, AIM assists the member in scheduling the appointment
Rationale	<ul style="list-style-type: none"> • The cost of a given procedure can vary widely across providers and care delivery settings within the same geographic area • Giving patients information may help them select lower-cost options
Results	<ul style="list-style-type: none"> • Since its implementation in one market in 2011, AIM has redirected more than 4,900 cases, at an average cost savings of \$950 per case • A study published in Health Affairs found that for patients needing MRIs, the AIM program resulted in a \$220 cost reduction (18.7%) per test and a decrease in use of hospital-based facilities from 53 percent in 2010 to 45 percent in 2012

Sources: <http://www.aimspecialtyhealth.com/solutions/management-solutions/member-management>;
 Sze-jung Wu, Gosia Sylwestrzak, Christiane Shah and Andrea DeVries, "Price Transparency For MRIs Increased Use Of Less Costly Providers And Triggered Provider Competition," *Health Affairs*, 33, no.8 (2014):1391-1398

Decision Support

Company	Optum (UnitedHealth Group) 	
Product	Emergency Room Decision Support	Treatment Decision Support
Goal	<ul style="list-style-type: none"> Engage health plan members after each emergency room visit to address factors that drive inappropriate ER use 	<ul style="list-style-type: none"> Connect members with the right treatment, right provider, right medication, and right lifestyle
Approach	<ul style="list-style-type: none"> Identifies and engages individuals after each emergency room visit – up to five times during the course of a year Leverages both “live” nurses and automated voice call technology to engage consumers Refers to case and disease management programs and behavioral health services Connects individuals with primary care providers (including appointment scheduling) 	<ul style="list-style-type: none"> Connects members with specially trained nurse “coaches” who address a consumer’s immediate symptom in addition to issues that impact their quality of life and care <ul style="list-style-type: none"> Right treatment — guidance on when and where to seek care Right provider — scheduling appointments with high-quality network providers Right medication — coaching on lower cost options, drug interactions and appropriate use Right lifestyle — referring to wellness and behavioral health services
Results	<ul style="list-style-type: none"> Individuals who were engaged by ER Decision Support had a decrease in avoidable ER visits, while individuals who did not participate had an increase in avoidable visits (2007-2008) 	<ul style="list-style-type: none"> 2-to-1 average return on investment 70 percent of callers with ER pre-intent avoid the visit after a Optum NurseLine call 8.8 hours reduced absenteeism per employee/per event

Sources: <https://www.optum.com/health-plans/clinical-management/member-support/clinical-care-management/navigate-care-options/emergency-room-decision-support.html>; <https://www.optum.com/health-plans/clinical-management/member-support/clinical-care-management/navigate-care-options/treatment-decision-support.html>



“The gentleman at the other register would like to cover your co-pay.”



Innovation in a Changing Environment



Adapting to Change

The medtech market (insurers, hospitals, physicians, patients) is moving from an emphasis on performance improvement, with little concern for cost, to an emphasis on cost reduction, with only a secondary concern for performance improvement.



Raising the Bar for Breakthrough Products

- Breakthrough products will always gain coverage and generous pricing, but must demonstrate their value with better evidence
 - FDA may accelerate approval, but this just shifts burden of assessment to insurers, hospitals
 - Real world, comparative, clinical and cost data are the industry's friend (HTA, CEA)
- Industry must work with insurers to ensure that value-based payments and consumer cost sharing do not block adoption
 - NTAP, exemption from deductibles



Raising the Bar on Incremental Products

- The medtech business model of incremental innovations sold at higher prices each year is coming to an end. This change favors:
 - No-frills product designs
 - Low manufacturing costs (global sourcing)
 - Low distribution costs
 - Products used in low-cost ASC, office, and home settings
 - Greater role for patient self-care
 - IT integration for continuous monitoring



The Future

- The tests and treatments of the future will help patients lead longer and better lives, but also will cost less to develop, less to manufacture, and less to use than the products of today
- They will generate savings inside (e.g., low-cost settings, shorter LOS) and outside the health care system (e.g., improved productivity, reduced disability)
- The savings must accrue to those paying (insurers, hospitals, patients) not just to those not paying (society at large)
- This is value, as interpreted by the purchaser





PURCHASING MEDICAL INNOVATION



THE RIGHT TECHNOLOGY, FOR THE
RIGHT PATIENT, AT THE RIGHT PRICE

JAMES C. ROBINSON