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Five Megatrends Driving the Seismic Shift in Healthcare

Strategies for Pharma and Biotech to Succeed in a Transformed Market

Manatt Health

PharmaVoice Webinar – July 2014

Agenda

Introduction to Manatt Health

Five Megatrends Driving the Seismic Shift in Healthcare

- More with Less: From Volume to Value
- Centrality of the States
- Mega Health Systems
- Employers Recalibrate
- Healthcare Everywhere

Q & A

Our Mission is to be a practice whose multidisciplinary professionals, through excellence, deep substantive knowledge and teamwork, support clients seeking to transform America's health system by expanding coverage, increasing access and creating new ways of organizing, paying for and delivering care.

- Interdisciplinary team with over 80 professionals:
- Pharmaceutical strategy: health reform, pricing, Medicare reimbursement, regulation of research, approval, manufacturing and marketing of medicines
- Provider strategy: IDNs, academic medical centers, children's health, ACO formation
- Mergers, acquisitions, joint ventures
- Corporate structure and governance
- Medicaid program evaluation and redesign
- Payer strategy: provider-sponsored plans
- Health information exchange, health IT
- Insurance

Genesis for Manatt's Series of Megatrend Analyses Emerged from Our Wide Breadth of Experience Across the Health Industry

Associations

- AAMC
- California Children's Hospital Association
- Children's Hospital Association
- Alabama Hospital Association
- Georgia Alliance of Community Hospitals
- UHC

Government

- CMS Centers for Medicare & Medicaid Services
- NYeC New York eHealth Collaborative
- Missouri Department of Health and Senior Services (dhss)
- nc department of health and human services
- Tennessee Department of Health
- HealthConnector
- Maryland Department of Health and Mental Hygiene

Providers

- Yale-New Haven Hospital
- Ascension Health
- Dignity Health
- Loma Linda University Medical Center
- Children's Hospital & Medical Center
- Children's Healthcare of Atlanta
- Maimonides Medical Center
- Montefiore
- UCSF Medical Center
- Children's Medical Center

Health Plans

- Blue Shield of California
- Humana
- BlueCross BlueShield
- AHIP
- Coalition of New York State Public Health Plans
- aetna

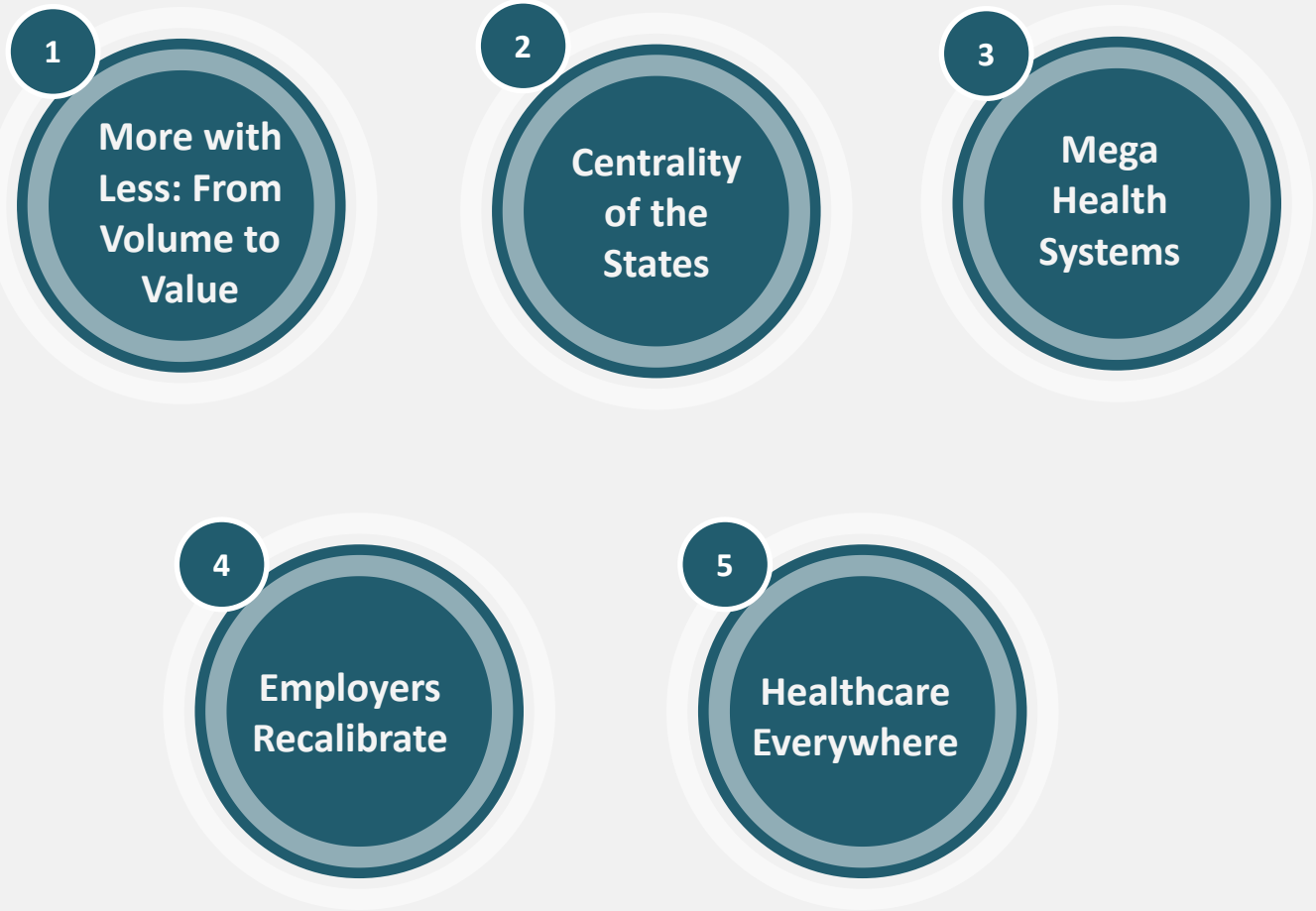
Foundations

- United Hospital Fund
- The Commonwealth Fund
- Robert Wood Johnson Foundation
- The Atlantic Philanthropies
- NYS Health Foundation
- California HealthCare Foundation

Plus . . . 8 of the top 10 pharmaceutical companies.*

* Due to confidentiality, client names cannot be disclosed.

Today's Focus



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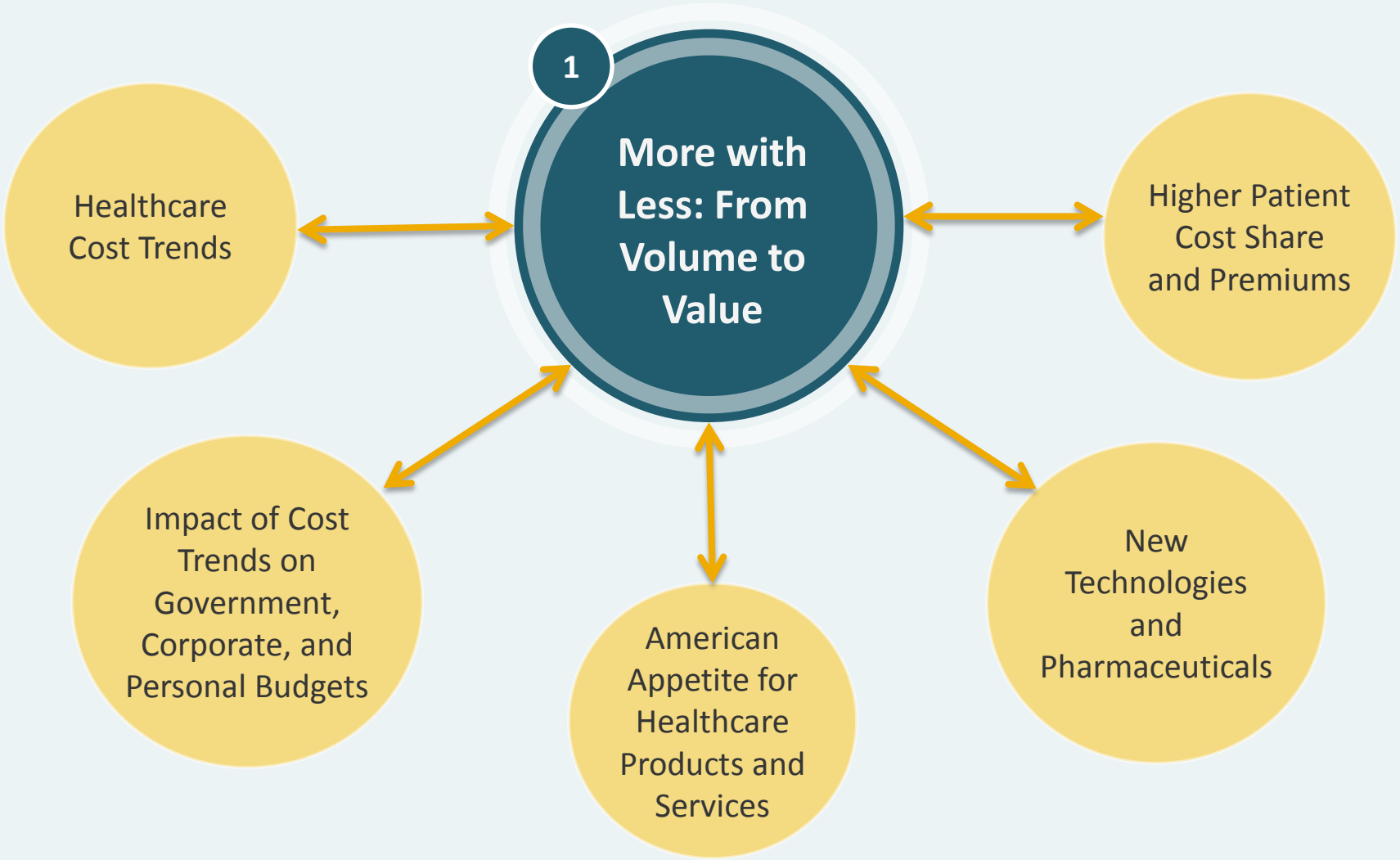
Something Has Got To Give



Pharma's Challenge: Defining Value to Integrate Stakeholder Decision-Making While Succeeding in Two Paradigms

Align Value Framework Around Triple Aim

1 Patient experience 2 Population health 3 Reducing per capita costs of health

VOLUME-BASED BUSINESS PRACTICES
Currently in Play

- **Abandoning too quickly resulting in decreased sales and profits**
  - ✓ Fee-for-service
  - ✓ Site of service incentives
  - ✓ Selected packaging
  - ✓ Quality metrics
  - ✓ Bonuses and penalties

EMERGING VALUE-BASED ENVIRONMENT
Testing in Demonstrations

- **Innovative payment mechanisms and value-based purchasing**
  - ✓ Payment bundles, per member per month, risk-sharing
- **Value-based pricing**
  - ✓ Mechanisms for suppliers and payers to negotiate the value of technologies
- **Value-based delivery support programs**
  - ✓ Delivery solutions to support medication therapies: education & adherence tools

Population Health

Shifting to Value-Based Paradigms: Identifying Opportunities for Value-Based Pricing

Evaluating a Drug Candidate for Value-Based Pricing

- Drug product is a major determinant of health

- Costs associated with the arrangement justify the effort
- Target chronic conditions that are high cost

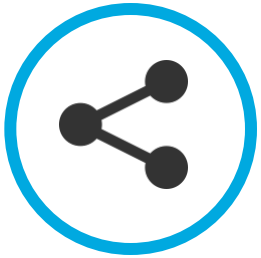
- Clear definitions of problem, value, objectives
- Evaluation plan that can rely on existing administrative and data collection capabilities
- Governance and management plan

- Partner is truly a partner and willing to share real risk and reward

National payers have experience and infrastructure – IDS/ACOs are early in the learning curve and will be looking for partners to implement value-based programs

Key Points for Pharmaceutical Manufacturers

Manufacturers will need to **maintain expertise** in **volume-based requirements** while developing business and legal expertise in **value-based paradigms**.



For certain products, especially those involving high expense and uncertain or debatable outcomes, **risk-sharing agreements** are likely to be **key to product adoption**.

Manufactures will need to engage in **development of appropriate value metrics** to proactively offer ways to share risk and decrease the probability of access issues.

Organizations that are early in the learning curve when it comes to **value-based partnerships** should consider providing **medication-related program delivery support services.**

1. Are you currently in dialogue with a **commercial payer** to develop a **value-based pricing arrangement**?

   A. Yes, currently in dialogue

   B. No, but plan to in 2014

   C. No, but have plans to do so in next 3 years

   D. No, we are not planning to make such arrangements

   E. Don't know

2. Are you currently in dialogue with an **accountable care organization or some other type of integrated delivery system** to develop a **value-based pricing arrangement**?

A. Yes, currently in dialogue

B. No, but plan to in 2014

C. No, but have plans to do so in next 3 years

D. No, we are not planning to make such arrangements

E. Don't know

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The New Sheriff in Town – Centrality of States

TRADITIONAL MEDICAID

- Currently Medicaid programs are required to cover all drugs for which manufacturers enter into **rebate agreements**
- States may try to **exclude drugs** that do not have a therapeutic advantage over other drugs on formulary

MEDICAID EXPANSION

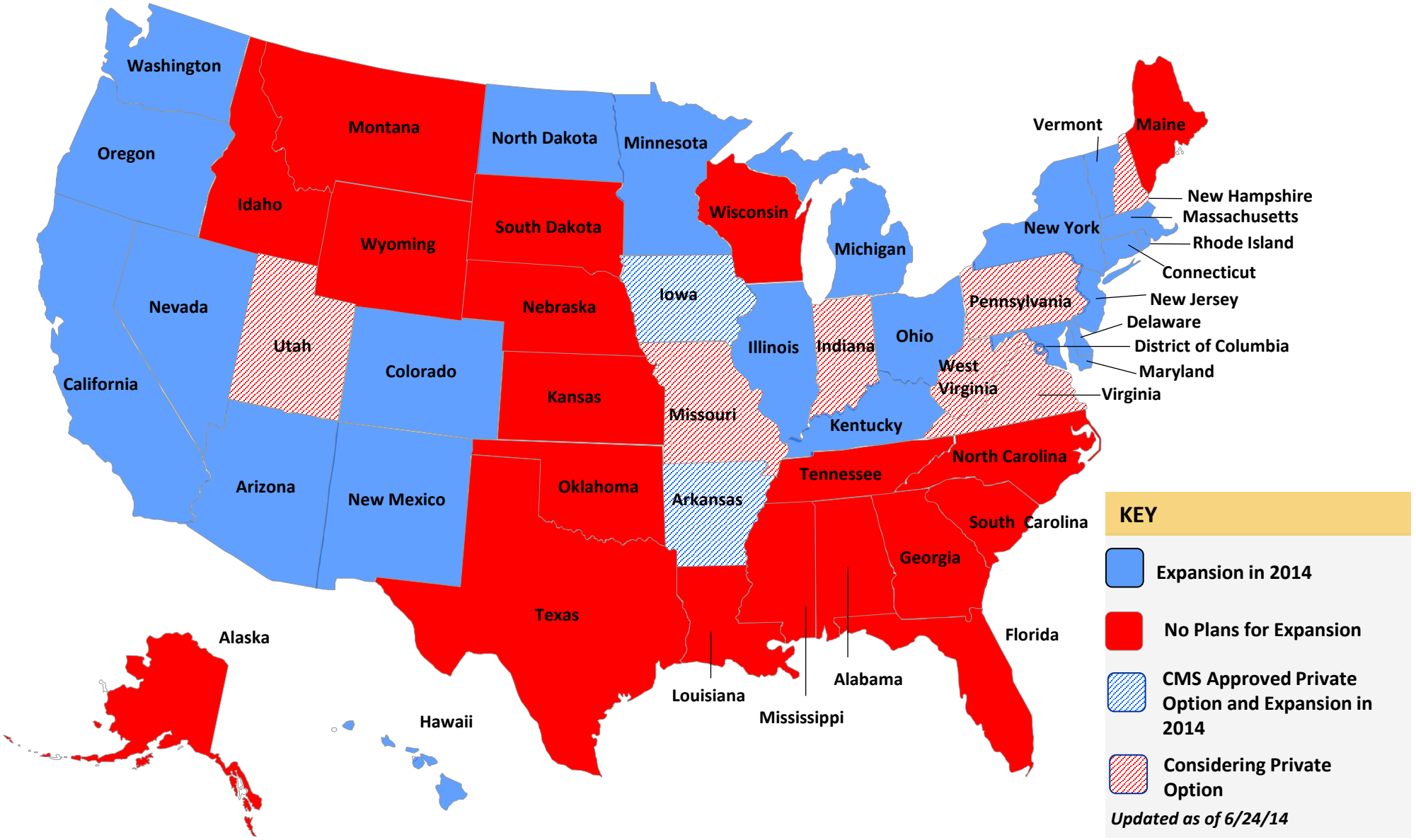
- Drug coverage may differ depending on what kind of Medicaid benefit a patient has
- ABPs - states only need to cover the greater of one drug per category and class or number per category and class in EHB benchmark plan

MEDICAID MANAGED CARE

- States expand programs to cover higher risk populations
- ACA extension of rebates to drugs dispensed by Medicaid managed care
- More states will add Rx benefits into MC packages
- Enhanced use of utilization mechanisms

Medicaid Transformation from Welfare Space to Health Insurance Market

Medicaid Expansion Decisions for 2014



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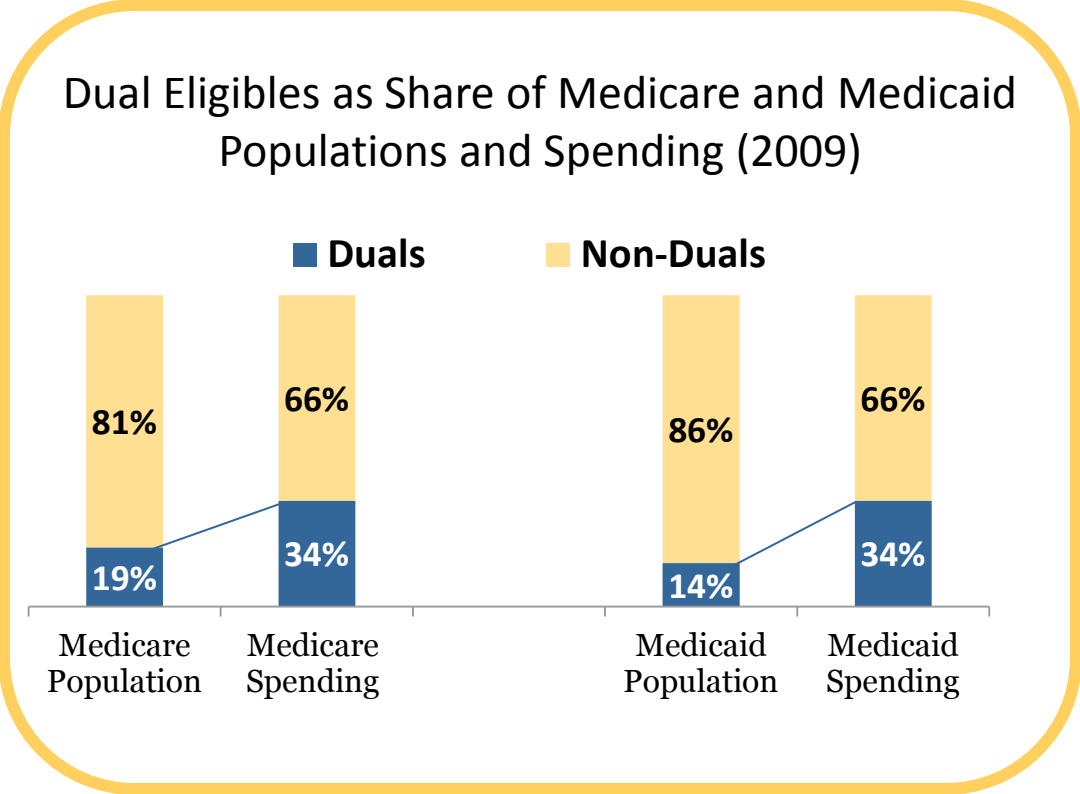
Dually Eligible Beneficiaries: Small Population – High Cost

Dual Eligibles account for a disproportionate share of both service utilization and program spending in Medicare and Medicaid

- The majority of duals remain in FFS
- Many states exclude duals from Medicaid managed care
- Mandatory enrollment in managed care for Medicare services is prohibited
- Population complexity raises concerns regarding ability to provide care through limited network
- Dual Eligible demonstrations or alternatives are growing and combine Medicare Part D with Medicaid formulary requirements



Expect efforts to blur lines between Medicare and Medicaid with the goal of accessing Medicaid's drug price savings

Key Points for Pharmaceutical Manufacturers

State reimbursement of **pharmaceutical costs under Medicaid is changing** due to implementation of ABPs for newly eligible adults, the extension of drug rebates in Medicaid Managed Care, and new efforts to manage high need Medicaid patients and dually eligible populations.

Convergence between public and private markets – driven by alternative approaches to Medicaid expansion, as well as efforts to align market influence across Medicaid, purchasing of health insurance for employees, and in some states state-based marketplaces – will drive efforts to **reduce pharmaceutical expenditures**.

3. What development do you believe will impact access to prescription drugs **the most** for traditional Medicaid patients?

A. Expansion of Medicaid Managed Care?

B. Expansion of Dual-Eligible alignment Initiatives?

C. Approval of Medicaid waivers to implement delivery system incentive payment reforms?

D. Expanded use by States of their authority to exclude drugs that do not have therapeutic advantage?

E. Other?

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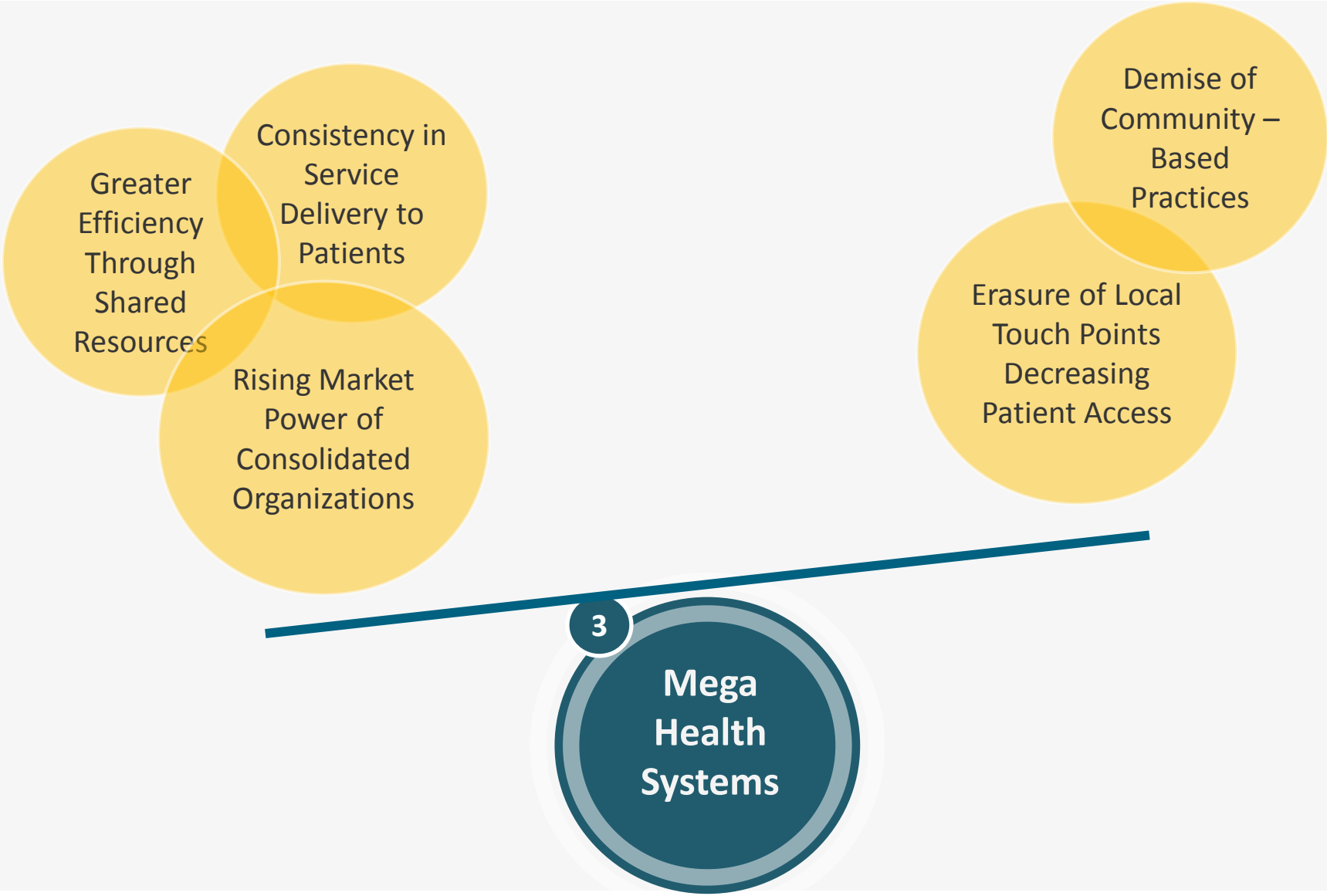
Big is Bigger



IDS and Payers:
More Information for Management of Large Patient Populations

Large Health Systems Will be Looking for Ways to Manage Drug Budgets

INTEGRATED DELIVERY SYSTEMS

- Clinical systems will share information with payers to manage services and costs
- Interested in program delivery support services for high cost patient populations
- Alignment of health records for better patient outcomes as well as data source for negotiations with manufacturers and payers
- Higher prices for centers of excellence

COMMERCIAL PAYERS

- Reconfigure coverage and benefit designs to contain costs and improve quality
- Integrated information systems to better estimate OOPC to identify opportunities to create limited networks that do not include high cost providers
- Reference pricing and point-of-service cost sharing incentives with patient responsible for cost above reference price our out-of-network cost-share

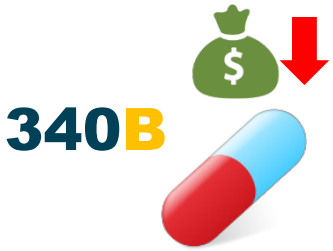
Mega health systems improve negotiations with payers – payers deploy tools to incentivize cost containment and improved quality

Industry Anticipation for Issuance of Proposed 340B Mega-Rule

Number of participating facilities has doubled between 2001-2011

One third of all hospitals participate

Expanded eligibility to include: critical access hospitals, sole community hospitals, rural referral centers, free-standing children's hospitals, and free-standing cancer hospitals



With the development of ACOs, hospitals purchased more physician practices & moved drug administration from physician offices to the hospital outpatient setting

Expansion of 340B prices will increase pressure to have drug launch prices account for mandated discounts and will encourage other payers to negotiate comparable rates

Key Points for Pharmaceutical Manufacturers

Downward pressure on drug pricing will emerge as a result of the **growing negotiating power of mega health systems** and pressures on these systems from payers to improve quality while saving costs.

Mega health systems are likely to have an interest in **delivery support programs**, especially non-branded solutions, to **improve appropriate medication** use and adherence within patient populations served by the system.

If requirements are tightened, the future of the **340B drug discounting program** may create additional pressure to the bottom line of mega health systems.

4. Are you currently in dialogue with an **accountable care organization or some other type of integrated delivery system** to develop a **delivery support program or solution** (e.g. patient education, tools to improve appropriate medication use and adherence)?

A. Yes, currently in dialogue

B. No, but plan to in 2014

C. No, but have plans to do so in next 3 years

D. No, we are not planning to make such arrangements

E. Don't know

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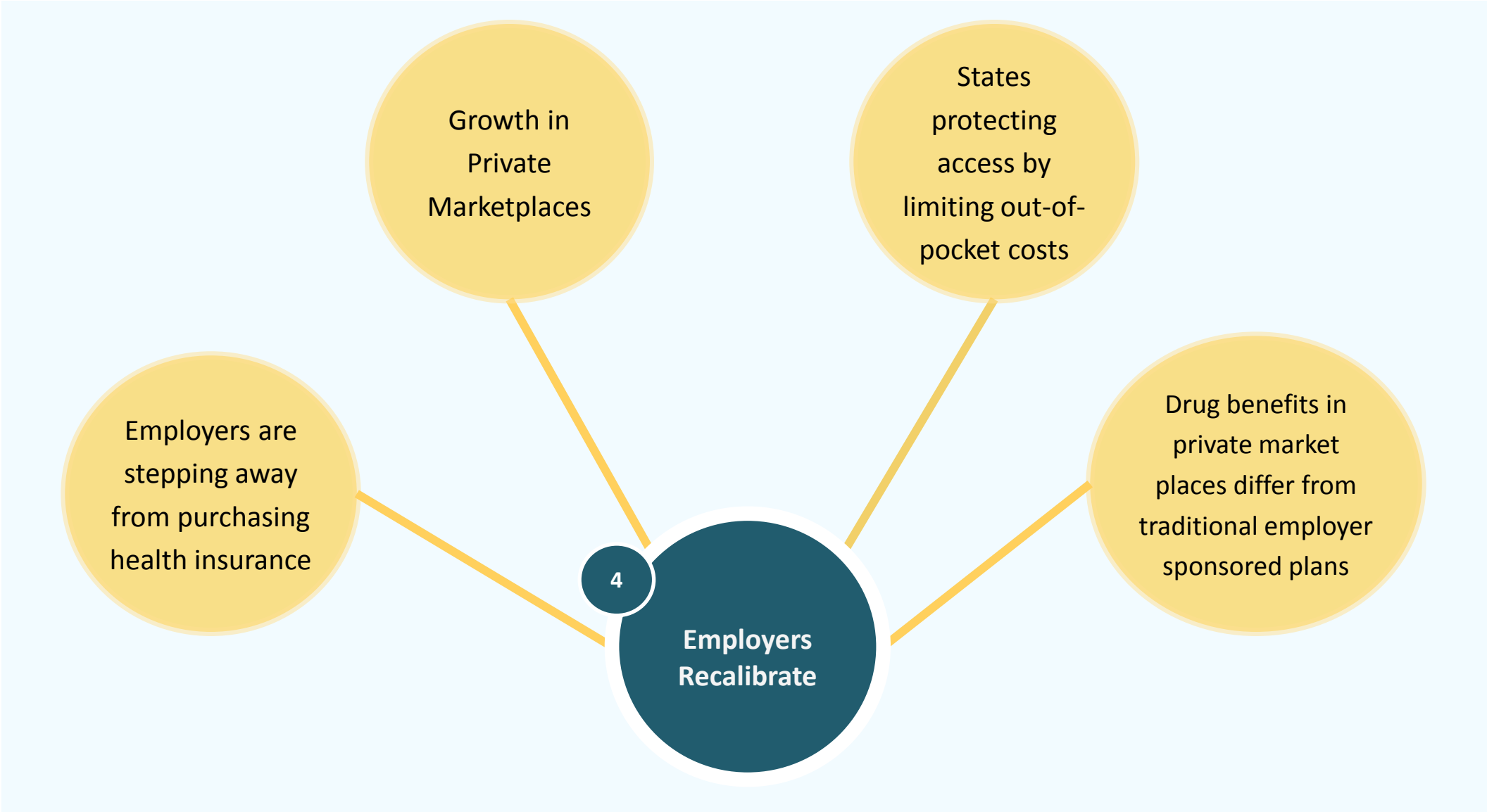
Change in the HR Office – Employers Recalibrate



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Progress Report on Private Exchanges

March 2014 report by Aon Hewitt shows growth from 150,000 members in 2013 to 600,000 in 2014

- 75% surveyed felt that they chose the plan that offered the best value for them
- 87% surveyed liked the ability to choose between multiple carriers

Formularies in exchanges appear to be less generous than those in employer sponsored plans

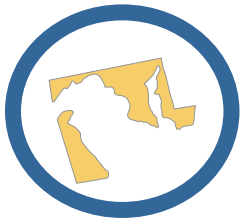
- Twice as likely to experience UM controls compared to employer based plans
- Silver plans nearly four times more likely to have combined deductible for pharmacy and medical benefits
- Enrollee cost sharing is 38% higher employer plans

State Efforts to Establish Legislation to Limit Out-of-Pocket Costs

State Response to Low Marketplace Premiums Masking High Patient OOPC

CA: Proposed bill to limit cost-sharing for covered prescription drugs at 1/24th of the annual EHB out-of-pocket limit for a 30 day supply

LA: Proposed bill to limit copay or coinsurance for specialty drugs to $150 per month for a 30 day supply while requiring an exceptions process for non-formulary drugs



DE/MD: Legislation caps out-of-pocket costs for specialty drugs

Federal: Protects largest employers from state legislative oversight by ERISA. Legislative efforts are not likely to have an impact on the law. Also unlikely that government will attempt to regulate private marketplaces

Key Points for Pharmaceutical Manufacturers

Employers may **delegate insurance role to Marketplaces** (e.g., Federally-sponsored, state, private); hence, formularies in Marketplaces will take on new and growing importance.

The traditional role of employers in providing generous **drug benefits** with low cost sharing will erode.

States are moving to rein in **cost-sharing** but these efforts may have limited impact.

Marketplaces are a new "customer" for drug makers.

Polling Question #5

5. What priority does your entity place on understanding the role of state laws that would establish requirements for formularies or pharmacy benefits (e.g. out-of-pocket cost limits, restrictions on formulary tiers, chemotherapy oral parity laws)?

A. High priority

B. Moderate priority

C. Low priority

D. Not relevant

E. Don't know

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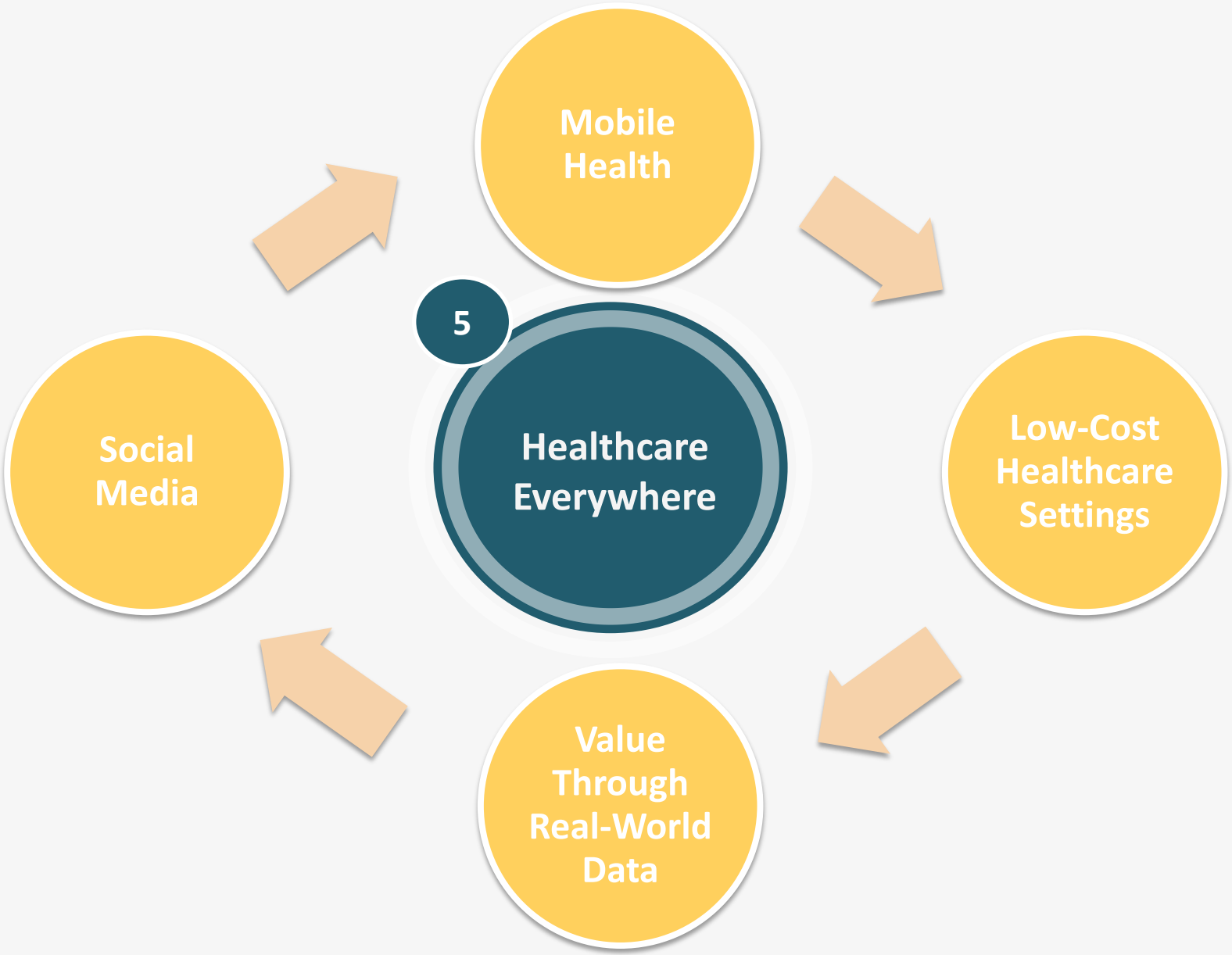
The Doctor's Not In the Office Now…



Pharmaceutical Manufacturers at the Nexus of Healthcare Everywhere

IMPLICATIONS FOR CLINICAL TRIALS

- **Increased demand for ability to access and analyze huge amounts of data**
- **Clinical and real-world clinical trial costs could drop dramatically**
  - ✓ New locations
  - ✓ Less expensive data collection methods
  - ✓ Ability to share data on utilization, effectiveness, and outcomes faster

EXPANSION OF RESPONSIBILITY TO INFORM

- **More transparency resulting in increased need to communicate benefits and risks of products**
- **Patient as a more knowledgeable consumer**
- **Expansion of sites of service resulting in more places that manufacturers will need to provide information and communication**
- **Current FDA regulations need to catch up**
  - ✓ Use of internet and social media
  - ✓ Use of cost-effectiveness data

Key Points for Pharmaceutical Manufacturers

The doctor's office and hospital will **lose their primacy** as the locus of healthcare delivery.

The ability to understand the changing places and **modes of delivery** will be a **core competency** of all healthcare organizations.

Partnering with **m-health** and other connected healthcare technology providers will provide pharmaceutical manufacturers with a leg up in understanding these changes and in getting ahead of them. Expanding manufacturers **social media platform** will be critical to reaching patients and providers.

6. What priority does your entity place on expanding the use of social media to communicate with potential customers or patients?

A. High priority

B. Moderate priority

C. Low priority

D. Not relevant

E. Don’t know

Polling Question #7

7. Which megatrend has the most impact to your business?

A. From Volume to Value

B. Centrality of the States

C. Mega Health Systems

D. Employers Recalibrate

E. Healthcare Everywhere

Questions and Discussion:

What Trends Are Important for You?

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Education

- University of North Carolina, Gillings School of Global Public Health, Dr.P.H., 2011.
- Columbia University, Mailman School of Public Health, M.P.H., 2008.
- Hamline University, School of Law, J.D., 1995.
- University of California, Davis, B.A., English, 1991.

About

With over 18 years of experience advising pharmaceutical, biotechnology and medical device companies, Dr. McGee is widely known for her expertise in reimbursement issues, particularly helping clients create effective coverage and payment strategies and developing new offerings designed to address payer and patient access issues. She works with life sciences companies to identify opportunities and develop creative strategic and tactical approaches for specific products by analyzing healthcare policy, industry and distribution trends.

Prior to joining Manatt, Dr. McGee was Senior Vice President and Chief Operating Officer for Lash Group (AmerisourceBergen Corporation). In that role, she was an operational leader with P/L responsibility for an extensive portfolio of patient management programs and projects to help patients access new therapies. She led over 100 pharmaceutical, biotechnology and medical device manufacturer-sponsored patient access programs representing several hundred products.

Helen Pfister

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Education

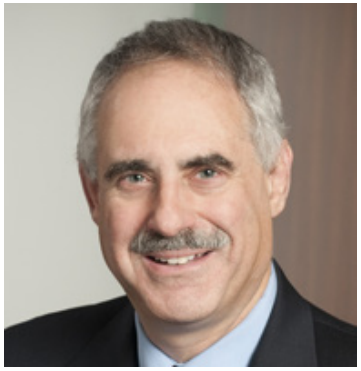
- **Boston University School of Law, J.D., magna cum laude, 1996.**
- **Cornell University, B.A., 1989.**

About

Ms. Pfister's practice focuses on advising healthcare providers and nonprofit organizations on legislative, regulatory and transactional matters. Ms. Pfister's clients include hospitals, pharmaceutical companies, community health centers, mental health facilities, substance abuse providers, nursing homes, home care agencies, health information exchange organizations and social service agencies. She has particular expertise representing federally qualified health centers and other organizations that serve medically underserved communities.

Ms. Pfister has extensive experience representing clients before state and federal regulatory agencies, including the NYS Department of Health and CMS, and in helping clients navigate the legal and political challenges of Medicare, Medicaid and other public health insurance programs. Her areas of expertise include licensure, reimbursement, fraud and abuse, and other regulatory issues. She also has a strong transactional background, and frequently advises clients on acquisitions, joint ventures, corporate governance, corporate finance and related matters. Ms. Pfister has been heavily involved in advising clients on the federal 340B prescription drug discount program.

Ms. Pfister is also involved in a range of projects involving the use of health information technology to facilitate the secure and timely exchange of health information to improve the quality and efficiency of healthcare delivery.



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Education

- New York University School of Law, J.D.
- Princeton University, Woodrow Wilson School of Public and International Affairs, M.P.P.
- Brandeis University, B.A.

About

Mr. Spatz provides highly experienced insights into ongoing health reform efforts, helps develop public and private strategies and guidance on a broad array of issues affecting health care providers and insurers, pharmaceutical companies, the consuming public and U.S. healthcare initiatives generally, as well as the development and implementation of communication and advocacy efforts at the federal and state levels. Among his areas of expertise are national healthcare policies and programs; pharmaceutical pricing, including Medicare and Medicaid; intellectual property protection; and policies related to the U.S. Food and Drug Administration's regulation of the research, approval, manufacturing and marketing of medicines.

Mr. Spatz is also the founder and principal of the policy consulting firm Rock Creek Policy Group, LLP. Before founding Rock Creek Policy Group, Mr. Spatz served for 15 years in increasingly responsible positions with Merck & Co., Inc. As Merck's Vice President for Global Health Policy, he directed U.S. public policy and related public affairs activities and represented the company before Congress, the Administration, and to the media. He also directed grassroots, employee communications and political action programs.

Manatt Locations

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Offices Nationwide