An Evolving Lens: The Intersection of Real World Evidence, Payer Policy and Reimbursement

SLA PHT Spring Meeting 2014

Mitch DeKoven, MHSA, Principal – Health Economics and Outcomes Research, IMS Health
Agenda

**Hallmarks of payment reform**
- The birth of real world evidence
- Intersection: case studies
## Hallmarks of Payment Reform

The most promising strategies require a move away from the current fee-for-service model

<table>
<thead>
<tr>
<th>Strategy</th>
<th>% change in costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utilize bundled payment</td>
<td>-5.9% to -0.1%</td>
</tr>
<tr>
<td>Institute hospital all-hospital rate setting</td>
<td>-3.9% to 0.0%</td>
</tr>
<tr>
<td>Institute rate regulation for academic medical centers</td>
<td>-2.7% to -0.2%</td>
</tr>
<tr>
<td>Eliminate payment for adverse hospital events</td>
<td>-1.8% to -1.1%</td>
</tr>
<tr>
<td>Increase adoption of health information technology</td>
<td>-1.8% to 0.6%</td>
</tr>
<tr>
<td>Institute reference pricing for academic medical centers</td>
<td>-1.3% to -0.1%</td>
</tr>
<tr>
<td>Expand scope of practice for nurse practitioners and physician assistants</td>
<td>-1.3% to -0.6%</td>
</tr>
<tr>
<td>Promote growth of retail clinics</td>
<td>-0.9% to 0.0%</td>
</tr>
<tr>
<td>Create medical homes</td>
<td>-0.9% to 0.4%</td>
</tr>
<tr>
<td>Decrease resource use at end of life</td>
<td>-0.2% to -0.1%</td>
</tr>
<tr>
<td>Encourage value-based insurance design</td>
<td>-0.2% to 0.2%</td>
</tr>
<tr>
<td>Increase use of disease management</td>
<td>-0.1% to 1.0%</td>
</tr>
</tbody>
</table>

Multiple payment models are possible, with substantial implications for provider economics, risk, and incentives.

<table>
<thead>
<tr>
<th>Description</th>
<th>Current FFS payment</th>
<th>Enhanced FFS payments</th>
<th>Blended FFS/care mgmt fee</th>
<th>Episode-based payment</th>
<th>Global payment/capitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment for each unit of service provided</td>
<td>Enhanced FFS payments to support coordination and management</td>
<td>Monthly payment for patients to compensate for non-encounter-based activities</td>
<td>Single payment covers all products and services associated with episode of care</td>
<td>All upside for the practice</td>
<td>Single monthly risk-adjusted payment per enrolled patient for all services</td>
</tr>
<tr>
<td>N/A</td>
<td>All upside for the practice</td>
<td>Partial capitation for some activities, but underlying FFS model remains largely intact</td>
<td>Capitation element reduces incentive to oversupply services per episode</td>
<td>Transforms current FFS-based model into one in which provider holds significant risk</td>
<td></td>
</tr>
</tbody>
</table>

Impact on Practice:
- Low
- High

Impact on existing practice revenue model

Hallmarks of Payment Reform
Movement away from the FFS model involves transferring more risk to providers

Our research suggests that there are four “hallmarks” that will characterize the transformation of the prevailing payment model in US.

1. **Reduced profitability of the FFS model**
   - Providers seek to augment revenue
   - Providers seek scale and better risk management capability

2. **Increased use of pay-for-performance, pathways, and related incentives**
   - Larger settings take on more outcome risk
   - Patients increasingly seek quality for their premiums

3. **Consolidation and adoption of new organizational forms**
   - Patients trade “choice” for coordination

4. **Transformation of patient “choice”**
   - Transformation of patient “choice”
The first hallmark is the reduction of the profitability of the prevailing FFS model

1. Reduced profitability of the FFS model

- Reduced reimbursement rates (ASP+4%, etc.)
- Elimination of payments for readmissions
- Growing experimentation with episode-based payments and capitation forms
- Reduced volume of ASP-reimbursable business
- Mandatory vendor imposition
Faced with margin and cash flow pressure, providers will seek to augment practice revenue.

Hallmarks of Payment Reform

2. Increased use of pay-for-performance, pathways, and related incentives

- Increased use of pathways with compensation tied to adherence
- Differential payments based on adherence performance
- Rising share of physician compensation based on quality or adherence performance
- Transition from process to outcomes measures
Quality, Pathways, and Pay-for-Performance initiatives create opportunities for providers to augment revenue while reducing variation in treatment.

As part of the effort to shift the US system away from paying for volume, a range of initiatives have been introduced to incentivize the achievement of specific quality and outcomes objectives.

**Pay-for-Performance (P4P)**
- Pay-for-performance (P4P) programs offer financial incentives to health care providers who achieve, improve, or exceed their performance on specified process benchmarks.
- Performance measures include structure, process, and outcomes.
- Payments may be made at the individual, group, or institutional level.

**Pathways**
- Pathways are designed to decrease variability in treatments, improve quality of care and decrease costs.
- Pathways present a narrow, standardized pool of treatment choices based on clinical evidence.
- Physicians rewarded for adherence to treatment “on-pathway.”
Pathways programs have successfully reduced costs and treatment variation, while generating good physician participation with only modest incentives. 

- Pathways reduce costs through reduced variance from optimal treatment strategies.
- Lowered risk of denied or delayed reimbursement reduce providers’ administrative costs.
- Pathway adoption can contribute to cost-savings of 20%-35% per year.
- Physicians have been successfully incentivized to prescribe on-pathway drugs through a $5,000 incentive bonus if a 70%-80% compliance level is met at year end.

Source: Cost Effectiveness of Evidence-Based Treatment Guidelines for the Treatment of Non–Small-Cell Lung Cancer in the Community Setting; *J Oncol Pract.* 2010 January; 6(1): 12–18; Citi research.
Additionally, providers will continue to consolidate in order to achieve greater scale and to better manage risk.

### Consolidation and adoption of new organizational forms

- Continuing consolidation of smaller practices into larger groups
- Continued hospital consolidation and purchase of practices
- Expansion of accountable care organizations
Providers have also sought to offset declining margins through consolidation and new organizational forms

Consolidation and New Organizational Forms

In response to reforms and the evolving healthcare environment, providers are consolidating and taking on new organizational forms to meet the demands of shifting risk and emergence of new payment models

Provider Consolidation

- Significant consolidation has occurred in recent years: hospitals are merging and acquiring practices and physicians increasingly likely to be employed by a hospital or payer
- Within a hospital system, a clinician has no direct economic benefit associated with selection and administration of treatment intervention

Accountable Care Organizations

- In an ACO, provider groups accept responsibility for the cost and quality of care delivered to a specific population of patients, fostering coordinated care anchored by primary care physicians
- Payments initially maintain the FFS model, but layer on an asymmetric shared savings program (SSP); may shift to partial/full capitation and P4P
Deteriorating practice economics, administrative burdens, and superior compensation drives migration of community physicians to hospital and managed care employment

- The majority of US physicians are now employed or affiliated with a hospital group or an insurer
- Between 2010-2011, there was a 40.6% increase in practice mergers and hospital acquisition combined

Source: Citi Research, Physician Compensation and Production Survey, Medical Group Association, 2003-2009
Continued cost pressure on patients facilitates a transformation in choice, leading to thinner benefits and acceptance of higher “control”

• Growth in OOP burdens and premiums continue to crowd out wage growth
• Restrictions on copay cards and other programs heightens patient cost sensitivity
• Patients willing to exchange “choice” for lower cost benefits
• Exchange-based benefits introduce lower cost options
• Patient demand for lower cost options drives innovation and competition in commercial market
The patient response to changes in healthcare delivery and benefit designs will play a crucial role in the success of payment reform.

There is an important question about the tradeoff between care coordination and patient choice, and healthcare insurance exchanges (HIX) will facilitate the consumer ability to make informed choices.

**Choice vs. Cost**
- Historically patients have been unwilling to forego "choice" in return for only modest savings.
- Coordinated care leads to better outcomes at lower costs, but it also conflicts with the notion of unfettered patient choice of provider at the point of service.

**Impact of HIX**
- The availability of various exchange plan options will allow patients to purchase lower cost options with thinner coverage.
- As employees are pushed to the exchanges, greater innovation and competition is expected.
- HIX increases transparency of OOP max, deductibles, and other costs, as well as provider quality.

"ACO is just another way to say HMO without having to say HMO." - Health Economist
Exchanges and other factors will transform the insurance landscape

**Healthcare Exchanges**

- Individuals shopping for coverage increasingly select thinner benefit designs and CDHPs, or trade “choice” for lower costs.
- Transparency provides buyers with clear data on cost and quality.
- Patients may forego “choice,” opting into higher-control settings, including HMOs and ACOs.

Source: Kaiser Family Foundation
Experience from Massachusetts suggests beneficiaries will adopt lower cost, thinner coverage.

The 5-year progress report of the Massachusetts healthcare reform law shows almost half of members choose the minimum level benefit (bronze).

The process of payment model transformation has begun – stay tuned

1. Reduced profitability of the FFS model
   - ASP+4 very likely
   - Capitation/bundles and SSP being piloted

2. Increased use of pay-for-performance, pathways, and related incentives
   - Oncology pathways gaining popularity
   - Provider consolidation to promote pathway and P4P

3. Consolidation and adoption of new organizational forms
   - Consolidation accelerated by reduced FFS profitability and rise of ACOs
   - SSP incentivizes coordination

4. Transformation of patient “choice”
   - Willingness to accept thinner coverage evident in MA
   - Impact of cost/quality transparency still emerging

Status: No progress ☐ ➔ Fully underway
The most far-reaching effects of the Affordable Care Act will come from 1) expansion of coverage and 2) payment reforms.

### Coverage Expansion
- Enrollment of the uninsured in health plans offered through state exchanges
- Expansion of Medicaid

### Payment Reforms
- Avoidable Readmission Penalties
- Value-based Purchasing Program
- Penalties for Hospital Acquired Conditions
- ACO Shared Savings Program
- Bundled payment pilots

### Mfr Implications?
- Increased demand
- Increased payer management
- Lower profit margins
- Emergence of integrated providers
- Focus on cost and quality in all settings of care
- Financial risk shifts from payers to providers
Pay-for-performance reforms are driving formation of comprehensive provider networks that are cost-sensitive, protocol-driven, and paid on quality.

**Hallmarks of Payment Reform**

- Comprehensive network and care coordination to manage total patient care across settings
- Protocols embodying best practices to guide physician decision making
- Infrastructure to accept and distribute payment on behalf of multiple providers
- HIT to enable physicians to manage patients and report on outcomes

**Under reform, the new provider needs to have:**

- **Comprehensive network and care coordination** to manage total patient care across settings
- Protocols embodying best practices to guide physician decision making
- Infrastructure to accept and distribute payment on behalf of multiple providers
- HIT to enable physicians to manage patients and report on outcomes

**To optimize payments under reforms, a central provider must be able to 1) ensure quality across settings of care, 2) control costs, and 3) accept reimbursements on behalf of multiple providers**
The ACO model, broadly defined, already covers about one-in-seven US lives, and the growth curve is steep.

*It's estimated that 37-43 million lives, or 14% of the population, already receive care through ACOs*

- **37 to 43 million** Americans currently receive healthcare through ACOs
  - **4M** Medicare lives are in Medicare ACOs
  - **25M** Commercial lives are in Medicare ACOs
  - **8-14M** Lives are part of non-Medicare ACOs

*The ACO Shared Savings Program is “training wheels” for providers to learn to coordinate care, control costs, and report on outcomes*

*Source: Oliver Wyman*
Health Exchanges expose payers to price competition, limits on profits, and rating restrictions that will drive them to shift risk.

**Commercial Payer’s Mindset:**

- Needs growth from Exchanges but fear risk.

- Needs to establish stable, predictable costs with limited swings toward loss or profit.

- Recognizes that capitation forces cost savings.

- Would like to set PMPM payments and performance standards and step away from care management.
Hailmarks of Payment Reform

In any region, evidence and endpoints must be tailored to resonate with the most sophisticated stakeholders.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Patient</th>
<th>Physician</th>
<th>Payer</th>
<th>Provider Network</th>
</tr>
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<tbody>
<tr>
<td>Care Discretion</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Cost Sensitivity</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Financial Risk</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
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At-risk provider networks will demand compelling clinical and economic evidence to demonstrate how new technologies improve cost-care equation.
In a changing landscape, a product’s value proposition must be tailored to appeal to all relevant stakeholders.

### Hallmarks of Payment Reform

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<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
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</table>
Promotional mix must shift toward stakeholders that control access to drugs across the care spectrum

**Challenges in this setting of care**

- Sales Reps will face increasing barriers to access to prescribers
- Prescribers face limited discretion under formularies and protocols
  
  *Manufacturer must tailor its approach*

- Provider Networks will be open to medical communications by MAMs about new information and data

- KAMs need to deliver B2B value to secure access

Local market understanding will be critical to developing the right mix of field personnel to succeed in a given market
Agenda

• Hallmarks of payment reform

• The birth of real world evidence

• Intersection: case studies
RWE is transforming the industry into a new era – The “Prove it Works” Era

The Birth of Real World Evidence

Product’s Lifecycle

External Scrutiny of Evidence

Early

Access Era

Arms Race Era

“Prove it Works” Era

LOE

ims consulting group™
The Birth of Real World Evidence

This is due to the fact that RWE provides insights not possible from clinical trials.
RWE extends across the product lifecycle
Historically Pharma were almost the exclusive custodians of data related to their products.
Whilst the data collected by Pharma has increased, governments/payers are generating their own data.

**Pre-launch**
- Increasingly sophisticated and extensive clinical trial program

**Post-launch**
- Manufacturer safety surveillance
- Manufacturer phase IV trials
- Non-pharma monitoring of appropriate use

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**Volume of Evidence**

- **Pharma RCT**
- **Pharma RWE**
- **Non Pharma RWE**

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**Product’s Lifecycle**

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**PRESENT**

**Conceptual**

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The Birth of Real World Evidence
In the future, these programs will develop further to include a wide range of metrics, outpacing data collection by Pharma.

**Pre-launch**
- Increasingly sophisticated and extensive clinical trial program

**Post-launch**
- Manufacturer safety surveillance
- Manufacturer phase IV trials
- Non-pharma collection and use of wide range of metrics

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**Volume of Evidence**

**Product’s Lifecycle**

- **Pharma RCT**
- **Pharma RWE**
- **Non Pharma RWE**
The Birth of Real World Evidence

Third parties are offering support to stakeholders across the spectrum in terms of both analytics...

Supporting Specialized Data Needs & Integrated Assets

Tools To Drive Broad Dissemination

Next Generation Analytic Tools

Bundled Analytic Services

Providing Flexible Support Models
The Birth of Real World Evidence

...and a vast array of available data
Certain types of evidence are preferred by stakeholders, but there are clear trade-offs

**Stakeholder perception of value...**

<table>
<thead>
<tr>
<th></th>
<th>Potential cost (€ mn)</th>
<th>Potential time (years)</th>
<th>Potential cohort size (patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RCT/pragmatic</strong></td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>1,000-100,000</td>
</tr>
<tr>
<td><strong>Prospective studies</strong></td>
<td>1-10</td>
<td>1-3</td>
<td>300-30,000</td>
</tr>
<tr>
<td><strong>Retrospective studies</strong></td>
<td>20-50</td>
<td>2-3</td>
<td>100-10,000</td>
</tr>
</tbody>
</table>

*The Birth of Real World Evidence*
In this environment, the application of inclusion/exclusion criteria against the relevant patient population is of the utmost importance...

Select best data source for your specific protocol

Health plan data
Pharmacy claims data
Oncology EMR data
Non-Oncology EMR data
Lab data
Medical pharmacy claims
Medical survey data
Oncology survey data

Feasibility - assess and optimize your I/E criteria

Country Allocation & Site Selection – find countries/sites with relevant patients
...as payers are using more sophisticated approaches to restrict access to products, including greater reliance on HTAs

Key stakeholders for access to pharmaceutical products

- **Regulatory approvals**
  - Examples: NICE & SMC (UK), TLV (SE), PBAC (Aus), CADTH (Can)

- **Payers**
  - Examples: CT (FR), DGFPS (SP), AIFA (IT)

- **HTA Agencies**
  - Primarily cost effectiveness focused HTA bodies
  - Primarily clinical value focused HTA bodies

In the past, payers imposed minimal restrictions for products, therefore regulatory approval was the main access hurdle for products.

P&MA decision makers, are increasingly relying on HTA’s as national, regional and local payers to impose access restrictions on products, and use HTA evaluations as evidence to justify their P&MA decisions.
The Birth of Real World Evidence

However, countries are at different stages in adopting real world evidence into their HTA decision making

<table>
<thead>
<tr>
<th>Geographical Examples:</th>
<th>Label</th>
<th>Price</th>
<th>Access</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMNOG ruling specifies that prices are to be reassessed post-launch</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observational data used in post-launch decision making</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug utilisation studies specified as a condition of market access</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Phase IV studies potentially influencing regional payer decisions</td>
<td></td>
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<td></td>
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<tr>
<td>Value Based Pricing consultation will potentially reassess price post-launch</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private payer attention to PCORI, private CER, FDAMA Sec 114</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

No Application   Limited Application   Application
The stakes are high! A product’s label, price, access and use are at continuous risk across the lifecycle...

We are moving from a “launch package” of data to an ever-expanding “lifecycle data file”
The Birth of Real World Evidence

...and stakeholders are tired of waiting

Are we at a tipping point?

- Rising health care costs
- Inefficiency of care
- Therapies failing to perform in practice
- Medical errors
- Conflicting data
- Increasing R&D costs
- Increasing patient awareness
- Increasing pipeline of undifferentiated treatment options
Agenda

- Hallmarks of payment reform
- The birth of real world evidence

**Intersection: case studies**
We continue to see RWE being used much more than what you might traditionally think is the case...

**Case Studies where RWE has Impacted Product Decisions**

_Total=104_

**Impact**

- **Ongoing access**
  - *WellPoint* moved Boniva to a non-preferred tier behind a step edit requiring failure of Fosamax or Actonel after Boniva ranked lowest on an analysis of 26,000 members.
  - RCT evidence indicates that inhaled corticosteroids (ICS) are more efficacious than leukotriene modifiers (LM) but Healthcore's analysis of *WellPoint* claims showed that patients on LM had better adherence and fewer events, leading *WellPoint* to keep LM on a preferred tier and removing associated PA.

- **BCBS Hawaii** tracked A1c levels for patients on Byetta versus other drugs and ultimately moved Byetta from a medical to a pharmacy benefit due to better results.

**Launch access**

- *United Healthcare* agreed to reimburse the list price of Genomic Health's Oncotype Dx test for breast cancer patients for 18 months while results of the test were tracked and clinical effectiveness verified.
...particularly given the increase in the number of global ‘risk sharing’ arrangements

<table>
<thead>
<tr>
<th>Country</th>
<th>Therapy Area</th>
<th>Brand</th>
<th>Brief Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Oncology</td>
<td>Taxotere</td>
<td>Sanofi-Aventis agreed to reimbursement the cost of Taxotere to provincial payers if an agreed upon responder level had not been reached (facilitating formulary listing at launch)</td>
</tr>
<tr>
<td>France</td>
<td>Diabetes</td>
<td>Glitazone</td>
<td>A conditional reimbursement price for Actos was provided on the basis that additional results from clinical or observational studies would be provided; if the results of the studies were negative, the manufacturer would be required to pay back the difference for past overpayments and would apply for future price reductions</td>
</tr>
<tr>
<td>Germany</td>
<td>Oncology</td>
<td>Avastin</td>
<td>Roche agreed to provide full or partial reimbursement for patients in which the Avastin and Taxol combination exceeded a specific total dosage in a study designed to test whether the combination of both medicines could extend patient survival in mBC and mRCC</td>
</tr>
<tr>
<td>Italy</td>
<td>Oncology</td>
<td>Afinitor</td>
<td>Novartis pays back 100% of the treatment cost of Afinitor in case of treatment failure after 3 month re-evaluation</td>
</tr>
<tr>
<td>Spain</td>
<td>Oncology</td>
<td>Iressa</td>
<td>Iressa was granted access in one hospital only, on the basis of outcomes collected as part of a contracting pilot project between AZ and Catalonia</td>
</tr>
</tbody>
</table>
In Sweden, demonstrating real-world cost offsets preserved market access and premium pricing

Large increase in sales of CNS drug led TLV to question its price and reimbursement

Retrospective Swedish RWE Study

Showed that initiating Product X in patients with a mental health condition significantly reduced overall health care costs

TLV have, as of this day, not restricted the reimbursement or reduced the price of Product X
Thank you.

Questions?

Mitch DeKoven, MHSA
Principal - HEOR
PH: (703) 837-5153
E: mdekoven@us.imshealth.com