Agenda

Health System, Physician, and Payer Collaborations

Context: reform impacts that are driving increased collaboration across industry segments

Industry response: models at play in the market as the shift from volume to value accelerates

Compliance implications: new guidance and old pitfalls to consider
Context

Context: three big challenges—access, quality, and cost (but cost is the most pressing!)

Access
The number of Americans without health insurance coverage is high and climbing higher
Uninsured in the U.S., 1990-2010 (in millions)

Cost
The US spends significantly more per capita on health care than other industrialized nations
Health care spending per capita, 2010, Comparison of OECD countries

Quality
Despite higher US spending, our nation lags behind benchmark countries in measures of health care outcomes
U.S. & OECD average comparison of key health indicators, 2010

<table>
<thead>
<tr>
<th>OECD Average</th>
<th>United States</th>
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<tbody>
<tr>
<td>Health care expenditure % of GDP</td>
<td>9.5%</td>
</tr>
<tr>
<td>Average life expectancy at birth</td>
<td>79.8</td>
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<tr>
<td>Public financing % of health care</td>
<td>72.2%</td>
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<tr>
<td>Prevalence of obesity</td>
<td>22.2%</td>
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<tr>
<td>Birth by Caesarean section, per 1,000</td>
<td>261</td>
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Sources: OECD, CMS, 2012
Context: the Affordable Care Act (ACA) and related laws

ACA of 2010
Children’s Health Insurance Program Reauthorization Act (CHIPRA)
Health Insurance Portability and Accountability Act (HIPAA)
State-based reforms

American Recovery and Reinvestment Act (ARRA): Health Information Technology for Economic and Clinical Health (HITECH)
New Clinical Coding Standards (ICD-10) per the ACA
Consolidated Omnibus Budget Reconciliation Act (COBRA) Expansion

Source: Patient Protection and Affordable Care Act (P.L. 111-148)

Regulatory forces are driving the industry toward a “New Normal”

- Health Plans
  - 2011: Minimum Medical Loss Ratio and Rebates
  - 2012: Reduced rebates to Medicare Advantage plans
  - 2012: Medicare Advantage Star Quality Based Payments
  - 2013: Administrative Simplification
  - 2017: Exchanges open for large employers
  - 2018: Excise tax on “Cadillac” plans

- Providers
  - Fall 2011: PCORI Established
  - 2012: Supreme Court upholds ACA
  - 2012: CMS ACOs begin
  - 2013: Episode based payments begin
  - 2014: Physician Self Referral
  - 2014: ICD-10 Go Live for Hospitals
  - Fall 2014: HITECH penalties begin

Financial penalties require immediate focus on quality, safety, transparency and outcomes
The new normal: Two major changes—financing, delivery

**Delivery system changes**
- Increased linkage between performance (outcomes, costs) and payments/incentives
- Increased integration of physicians, hospitals and long term care providers
- Increased access to health services by under-served populations
- Increased alignment of coverage with evidence

**Insurance system changes**
- Elimination of pre-existing condition, lifetime and annual limits for insurance plans
- Required coverage of preventive health services without co-payments
- Creation of health insurance exchanges in each state to facilitate access to affordable insurance and manage subsidized purchases by individuals and employers
- Federal-state regulation of insurance plan coverage, premiums, and medical expenditures

**Consumerism**
Engaged, accountable

**Preventive health, individual insurance, PHR**

**Primary Care 2.0**
The front door and “home”
Home monitoring, retail medicine, LTC, medical homes, retail medicine, medical homes, health coaching

**Comparative Effectiveness**
What works best, at what cost?
Personalized medicine, bundled payments, provider adherence/performance-based payments liability reforms

**Health Information Technology**
Information driven health: cost, quality, safety
Electronic medical records, health information exchanges, fraud detection, administrative simplification, clinical data warehousing, ICD-10

**The Anticipated “New Normal” Delivery System**

Source: Congressional Budget Office, 2012

Industry response
The pharmaceutical industry faces a critical need for change

The unsustainable trajectory of health care spending and a wave of regulatory reforms have triggered forces that are transforming the pharmaceutical landscape.

Future market will be increasingly driven by...

- Big data
- Health economics
- Comparative effectiveness

Pharma companies are trying to address these challenges with traditional strategies such as reloading product pipelines through mergers and acquisitions.

Health plan segment is seeing fewer players with wider reach

The insurance industry is heavily regulated and capital intense; the margins in its core business — managing health — are thin.

In 2011, 20 managed care M&A transactions took place, totaling nearly $8 billion.
Many physicians foresee increased consolidation of physicians into larger organizations

Percent responding very likely/likely that physicians and hospitals will become more integrated in the next 1-3 years

66% of all physicians

Source: Deloitte Survey of U.S. Physicians, 2013

Hospital and health system consolidation continues

Acute sector consolidation is likely to accelerate as hospitals seek sustainability

The acute sector is under stress

- Increased margin pressures
- Increased regulatory compliance costs
- Increased responsibility for public transparency
- Increased operational integration
- Payment reforms
- Increased implementation of clinical improvements

Acute hospital deal flow 2007–2012

Source: Data from Modern Healthcare, January 28, 2013.
The result: Stakeholder roles are blurring

- Health care providers are creating health plans and expanding their clinically integrated networks
- Health plans are buying and building clinical delivery capabilities
- Life sciences companies are creating closer collaboration with providers and health plans to generate real world evidence

Many of these collaborations are not just for scale or to grow market share but for closing capability gaps in a health care system transitioning from *volume to value*

<table>
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<th>New technologies</th>
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<td>New solutions</td>
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<td>New approaches</td>
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What is Volume to Value?

**Volume**

**What is Volume?**
- More services leads to more money for providers with limited incentives for high quality, integrated, and coordinated care

**Payment Structure:**
- Providers are paid a fixed fee for every service they deliver, in most cases with no limits on those services and without regard for results

**Incentives:**
- This model rewards volume – more tests, scans, specialist examinations, surgeries, etc., encouraging higher costs

**Interaction between Providers and Plans:**
- Transactional interaction, with some tension

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**Value**

**What is Value?**
- Value means different things for different players including improved health outcomes and lowering costs

**Payment Structure:**
- Providers are compensated for the patient as a whole, taking quality, and outcomes into account, not just for specific services provided

**Incentives:**
- This model rewards value – defined as patient health outcomes/dollar spent, encouraging higher quality at a lower cost

**Interaction between Providers and Plans:**
- Relational interaction, requires collaboration

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How does the journey from volume to value change over time?

- **Unit Cost Leadership**
  - Use scale and select partnerships to lower the cost of service, while maintaining superior quality

- **Utilization Management & Alternative Care Delivery Models**
  - Utilize integration to improve health, reduce need for care / use of expensive resources, and assume risk for delivering value based care

- **Population Management & Revenue Diversification**
  - Leverage brand, reputation and relationships to extend into new products and services

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What approaches are emerging?

Health care stakeholders are testing out various approaches to value based care

<table>
<thead>
<tr>
<th>Value-based network configurations</th>
<th>Provider incentives &amp; risk sharing</th>
<th>Vertical integration with providers</th>
<th>HIE / data exchange &amp; connectivity</th>
<th>Analytical services provider</th>
</tr>
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<tbody>
<tr>
<td>Tailor network strategy to reinforce value-based care by limiting the providers within the network to low cost / high value options</td>
<td>Shared payer-provider risk and reward model in which physicians are tasked with collaboratively improving care to reach cost and quality targets set by the payer</td>
<td>Purchasing of physician groups and hospitals to create a closed-loop, integrated delivery system and finance model</td>
<td>Enables electronic record sharing between hospitals, physicians, health plans, etc. to improve documentation of care and coordination</td>
<td>Clinical, cost and outcomes data is analyzed to identify opportunities to lower costs and improve outcomes</td>
</tr>
</tbody>
</table>

What are the vehicles organizations are using to gain Value Based Care experience and capabilities?

- National Systems
- Regional Systems
- Academic Medical Centers
- Community Hospitals
- Physician Groups
- Life Sciences

Vehicles to develop core competencies:
- Medical Home
- Bundled Payment
- Private Label Plan
- P4P/P4Q/VBP
- Self-Insured Employee ACO
- Medicare Advantage
- CMS ACO

On-ramp to Value Based Care

Clinical Integration & Assumption of Performance Risk

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Where are you on the path from volume to value?

To help pace strategy execution with capability development, the intent should be to allow the organization’s clinical integration strategy to evolve over time.

**EXPLORE**
- Analyze market opportunity
- Identify the opportunity
- Consider long term strategic roadmap
- Define initial population(s) and vehicle(s)
- Assess capabilities
- Evaluate potential partners
- Evaluate financial feasibility

**DESIGN**
- What do I need to deliver?
  - Define capabilities required
  - Establish legal entity (where necessary) and define operating model, decision rights, and governance
  - Build and design products, networks, contracts, and care model
  - Acquire customers
  - Deploy platforms and technology services

**OPERATE**
- How do I achieve results?
  - Run and manage operations
  - Manage care and outcomes
  - Engage consumers
  - Administer population health management strategies
  - Deliver clinical effectiveness
  - Optimize clinical efficiency and cost reduction

**SCALE**
- How do I expand and grow sustainably?
  - Operate fully functioning value based care model
  - Leverage brand, reputation and relationships to extend into new products and services
  - Capitalize on sales opportunities

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Changing the paradigm: The possibilities of innovation through value based collaborations

- Better care
- 24-hour 7-day a week health care system
- Patient care moving to the internet
- Increasing access
- Reducing costs
- Growth in the use of health information technologies

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But ... Collaboration is not without risk

The journey from volume to value is bringing a broad spectrum of collaboration structures and transactions

- Joint Ventures
- Mergers
- Clinically Integrated Networks
- IPA / PHO v2.0
- ACOs
- Affiliation Agreements
- Shared Savings Contracts
- Exclusivity Deals

The most challenging aspect of convergence in health care ...

... compliance in an ever-changing regulatory environment.¹

¹ Based on responses from 1,450 participants in Sept 2013

Compliance implications
Legal and Regulatory Compliance: General Areas of Consideration

- Meeting the definition of clinical integration
- Anti-trust considerations
- Compliance with requirements of MSSP Final Rule
- ACO waivers
- Legal considerations on commercial side
- Audit preparation

Clinical Integration

To build a successful clinically integrated program, organizations entering into these arrangements need to understand the regulatory environment

Legal/Regulatory Considerations

- The FTC has acknowledged that joint contracting may be necessary to create value for clinically integrated programs
- Statements and advisory opinions issued by the FTC and DOJ have provided frameworks for clinical integration requirements
- Pay-for-performance and other at-risk contracting are supported under certain circumstances
- The FTC has described four primary characteristics of clinical integration:
  - The ability to achieve significant clinical and economic efficiencies
  - Broad physician representation and physician investment
  - A well-developed care management program that uses evidence-based guidelines
  - A data management system that enables extensive data collection, information sharing, and utilization review
Antitrust Considerations

The FTC and DOJ have identified several factors to be used when determining whether a proposed alignment or integration plan is likely to achieve quality and cost improvements that justify joint contracting.

Key Questions

- Is the program selective in choosing network physicians who are likely to further the program’s efficiency objectives?
- Are the participating physicians investing both monetary and human capital into the program?
- Will the structural and operational elements of the program foster significantly increased interaction among the participating physicians in the treatment of patients?
- Is there adequate information regarding how the program will be evaluated over time?
- Does the participation of the hospital create an inherent conflict in terms of the hospital’s need to fill beds?

Sample Review Criteria

- Adequate number of diagnoses and diseases covered by clinical integration
- Agreement by physicians to refer in-network
- Both specialists and primary care physicians in-network
- Financial investment by physicians
- Human resource investment by physicians
- Technology that enables multiple physicians to gain access to and share patient information
- Streamlined recordkeeping and operations, including the use of electronic lab orders and prescriptions
- Enforceable performance standards and a demonstrated capacity to enforce the standards through adequate staffing
- A non-exclusive arrangement
- Joint contracting that aligns with a broad array of conditions and diagnoses subject to clinical integration performance measurement and improvement
- Upward reporting of results, in terms of both aggregate and individual physician performance

MSSP Final Rule Requirements: Organizational Structure

- Entity formation documents/amendments (own EIN, shared governance, distribute shared savings, etc.)
- State licensing (if necessary, e.g., risk bearing)
- Org charts with position descriptions/reporting (Background checks? Exclusion screening? COI?)
MSSP Final Rule Requirements:
Organizational Structure (Cont’d.)

- Compliance Officer – independent; reporting relationship – direct access to the top; COI
- Patient/Consumer Advocate
- Network participation agreements
- Clinical/administrative systems to: promote evidence-based medicine and patient engagement; quality measures reporting; care coordination across continuum; patient-centeredness (e.g., individual care plans)
- Senior level medical director (board certified) – clinical oversight, part of ACO

MSSP Final Rule Requirements:
Compliance

- Compliance Training (Centralized? At Participant Level?)
- Code of Conduct
- Compliance officer (see Slide 2)
- Mechanism for reporting issues (Hotline?)
MSSP Final Rule Requirements:
Compliance (Cont’d.)

- Report suspected violations to law enforcement (part of policies)
- Compliance Program (can leverage existing programs)
- Compliance Policies and Procedures (NPP; access to PHI; patient complaints, retention/disposal of PHI/records; COI; licensure and verification; training/education; patient incentive waivers for in kind - preventive care/advance clinical goal, e.g., blood pressure monitor)
- Monitor CMS claims to ensure opt-outs’ data not flowing?

MSSP Final Rule Requirements:
Beneficiary Opt Out/Data Sharing/Marketing

- Initial opt out notice; subsequent notice at time of visit
- Signage and written notices to explain data sharing and opt out right
- All subject to CMS’ marketing requirements – approval process
- CMS approval process – guard against coercion, misleading information
- Marketing materials defined broadly – when in doubt, submit for CMS approval
- ACO information publicly available on its website (Update regularly)
- If provider leaves – need to opt out or get patient consent, even though still aligned
MSSP Final Rule Requirements:
ACO Participants and Providers/Suppliers

- Medicare provider/supplier bills under ACO participant TIN (i.e., physician in large group practice which practice is in ACO as participant)
- Agreements in place – mandate compliance with ACO program compliance, but ACO ultimately responsible – distribute copy of agreement
- TIN/NPI list – correct? Notify CMS within 30 days of changes? Notify providers/suppliers 30 days prior to submission?
- Process to ensure not on exclusion list
- Termination issues/process? (consider: must maintain 5,000 beneficiaries)
- Business plan for selection of new participants and/or providers/suppliers?

MSSP Final Rule Requirements:
ACO Participants and Providers/Suppliers (Cont’d.)

- Compliance with beneficiary notification? Marketing?
- Quality reporting – accurate? Timely? Meeting targets? Performance improvement plan?
- Follow care management policies and procedures of ACO? Local policies with ACO reporting/oversight?
- ACO EHR access – for data analytics, quality improvement
Five CMS and OIG Fraud and Abuse Waivers – Laws Waived

1. Stark Law (Physician self-referral)
2. Federal Anti-Kickback Statute (criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business)
3. Gainsharing CMP (prohibits hospital payments to physician to reduce/limit care to Medicare beneficiary under his/her direct care)
4. Beneficiary Inducements CMP (prohibits inducements to Medicare beneficiary likely to influence choice of provider/practitioner/supplier)
5. Need to post on website (redact economic terms)

First Waiver
Pre-Participation Waiver

- ACO or its participants/providers/suppliers can fund ACO development services for benefit of all (i.e., hospital for referring physician); must be able to unwind; protects outside parties
- Does NOT include agreements for funding with home health agencies, DME suppliers, drug or device manufacturers
- Governing body must approve – reasonably related to CMS program purposes (i.e., triple aim)
- Prepare documentation of waived relationships at time of transaction; retain for 10 years; make available to CMS upon request
First Waiver (Cont’d.)

Pre-Participation Waiver

- ACO must be likely to participate by next application date
- Use once; waiver applies to pre-participation period only
- Waiver of Stark, Anti-Kickback, Gainsharing CMP
- Examples: Funding for IT, legal/consulting, staff hiring, capital contributions

Second Waiver

Participation Waiver

- Starts when agreement with CMS begins
- Protects all parties to the arrangement (must involve participant/providers/and/or suppliers; protects outside parties)
- Governing body approval – see pre-participation
- Document preparation – see pre-participation
- Generally ends when program participation ends
- Waiver of Stark, Anti-Kickback, Gainsharing CMP
Third Waiver

Stark Law Waiver

- Antikickback and Gainsharing CMP are waived for financial relationships among ACO/participants/providers and suppliers that implicate Stark Law
- Eligible if in good standing under ACO program; financial relationship is reasonable related to the ACO program; and financial relationship complies with Stark Law DHS, ownership/investment or compensation exceptions
- Generally ends when program participation ends

Fourth Waiver

Shared Savings Distribution Waiver

- Protects shared savings distribution methods (EXCEPT: hospital distribution to physician knowingly made to reduce/limit medically necessary services/items HOWEVER protects incentives for alternative evidence-based care that is medically necessary)
- No particular requirements must be met
- No particular duration
Fifth Waiver

Patient Incentive Waiver

- Waives Beneficiary inducements CMP and Kickback Law
- Applies to free/reduced items or services to beneficiaries
- Must be preventive care items or services or advance clinical goal (i.e., adherence to treatment/drug regime)

Legal Considerations for Commercial Arrangements

- Waivers – shared savings waiver not available BUT participation waiver is possibility per feds
- Data sharing – claims data with pricing/allowed costs and other sensitive information cannot get into wrong hands – go to actuary, data analytics provider ONLY – make sure NDA’s have this
- FISMA not applicable, but HIPAA is – leverage ACO policies/procedures
- Clinical integration FTC guidance is helpful (i.e., provider exclusivity, for example)
Legal Considerations for Commercial Arrangements (cont.)

- Do not share pricing information among participants; joint contracting for risk arrangements with shared savings/loss vs. negotiating fee for service
- Read the commercial contracts – understand cost targets, trend, minimum risk corridor, minimum savings rate, upside/downside caps, etc. Engage outside experts for assistance
- No mandatory antitrust review under CMS program – keep on radar for commercial lines (focus on shared savings/loss contracts to mitigate)

Audit Considerations

- CMS audit – review the slides on Final Rule requirements for general scope - address gaps now in your ACO
- Keep documentation (marketing materials, beneficiary forms, etc.)
- Update agreements as relationships change – maintain current documentation
- Ask for extension if needed – meet deadlines and communicate
- Project lead to ensure organized process – compliance/legal review suggested
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