Structuring Clinically Integrated Networks: Legal Considerations for Hospitals, Health Systems and Physicians

Navigating Organization and Governance Issues, Complying with Regulatory Requirements, and Negotiating Key Provisions

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Today’s faculty features:

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Bruce A. Johnson, Shareholder, Polsinelli, Denver
Michael Strilesky, Senior Manager, Dixon Hughes Goodman, Hudson, Ohio

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Structuring Clinically Integrated Networks: Legal, Regulatory, Financial and Practical Considerations for Hospitals and Physicians

Andrea Ferrari, Esq., MPH, Healthcare Appraisers, Inc.
Michael Strilesky, DHG Healthcare
Bruce Johnson, Esq., Polsinelli PC
Purposes of the Program:

1. De-Mystify the “buzzwords” of the year, including distinguishing them from one another
   - Clinically Integrated Network (“CIN”)
   - Accountable Care Organization (“ACO”)/Accountable Care Entity (“ACE”)
   - Hospital Efficiency Program
   - Co-Management Arrangement
   - Gainsharing/Shared Savings Arrangement
Purposes of the Program:

2. Provide an in depth discussion of the business, regulatory, financial and practical considerations of CINs, focusing on physician contributions and payments and the necessity, methods and pitfalls of determining their fair market value
Why Do We Think These Purposes Are Worth 90 Minutes of Your Time?

1. Increased attention on the quality, efficiency and value of health care is fueling more vigorous interest in the legally-permissible ways for payors, hospitals and health systems to engage and/or work with physicians to manage care costs and improve the quality and efficiency of health care delivery.
   • options vary depending on variety of financial, cultural and infrastructure issues
Why Do We Think These Purposes Are Worth 90 Minutes of Your Time?

2. “Clinical Integration” and “Clinically Integrated Networks” are becoming a popular means to pursue the cost, quality and value objectives of post-ACA health care delivery. However:

• Formation of a CIN is typically a large undertaking that requires consideration of myriad legal, regulatory and financial factors.
• Important for stakeholders to understand not only the theoretical goals of CINs, but also the practical aspects of achieving those goals via a CIN, including how and why CINs are similar to and different from other strategies for achieving provider alignment toward common goals.
Disclaimers:

• This slide deck:

• Is the result of collaboration of your panelists.
• May not be covered in its entirety in the course of the webinar. Some slides are merely for general reference and to help provide context for the interactive discussion that we have planned.
• May contain statements that are controversial and not espoused by colleagues or employers.
• Does not contain legal advice or legal opinions; it is just a collection of ideas.
• Is the second in a planned series on the general topic of CINs, and will provide a more in depth look at some of the issues raised in the first webinar presentation.
The “Good Old Days”: Fragmented Delivery System and Relationships
The New Trend: CINs/ACOs

Key Attributes:
- Patient Centered
- Coordinated Care
- Quality and Cost Focus
- Information Sharing
- Aligned Incentives

Financing and Insurance

Clinically Integrated Network

Consumers/ Patients

CIN/ACO

Accountable Care Organization
# De-Mystifying Alignment Strategies

<table>
<thead>
<tr>
<th>Alignment Method</th>
<th>Defined</th>
<th>Primary Purpose/Focus</th>
<th>Initial Investment/Financial Risk by Stakeholders</th>
<th>Longevity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gainsharing</strong></td>
<td>Sharing of cost savings from improved hospital or program efficiency</td>
<td>Hospital or program cost management, usually with simultaneous quality safeguards or improvements</td>
<td>Low to Moderate</td>
<td>Limited, unless new targets are identified</td>
</tr>
<tr>
<td><strong>Service Line Management and Co-Management</strong></td>
<td>Contractual or JV arrangement to enlist physicians to assist a hospital in cost and quality management of a specific service line</td>
<td>Hospital service line quality and efficiency</td>
<td>Moderate</td>
<td>Limited, unless new tasks and goals are identified</td>
</tr>
<tr>
<td><strong>Clinically Integrated Network (CIN)</strong></td>
<td>Collaborative venture directed at enhancing quality and value of health care for one or more specific populations/clients</td>
<td>Population health management and cost and quality improvements for healthcare payors and providers</td>
<td>Usually High (Dependent on infrastructure in place to support tracking of services and outcomes)</td>
<td>Indefinite</td>
</tr>
<tr>
<td><strong>Accountable Care Organization (ACO)</strong></td>
<td>Collaborative venture (sometimes a CIN) for the express purpose of enhancing quality and value of care for an assigned population of Medicare beneficiaries</td>
<td>Population health management and cost and quality improvements for the Medicare program and its beneficiaries, with similar benefits for providers</td>
<td>Moderate to High (Dependent on infrastructure in place to support tracking of services and outcomes)</td>
<td>Indefinite (Minimum of 3 years of participation in the Medicare Shared Savings Program)</td>
</tr>
<tr>
<td><strong>Accountable Care Entity (ACE)</strong></td>
<td>Collaborative venture (sometimes a CIN) for the express purpose of enhancing quality and value of care for an assigned population of Medicaid or other patients</td>
<td>Population health management and cost and quality improvements for the subject health care coverage program</td>
<td>Moderate to High (Dependent on infrastructure in place to support tracking of services and outcomes)</td>
<td>Indefinite (If a Medicaid ACE, there may be a state-imposed minimum time for participation)</td>
</tr>
<tr>
<td><strong>Combinations of Above</strong></td>
<td>Alignment methods may co-exist, subject to certain safeguards against duplication of services and compensation</td>
<td>Transitional and/or multipurpose goals</td>
<td>Variable (Depends on combinations)</td>
<td>Longevity of each alignment method is generally the same as if each existed independently</td>
</tr>
</tbody>
</table>

Note: All terms used to refer to alignment methods are, to some degree, terms of art that may have varying meaning based on context and circumstances.
# De-Mystifying Alignment Strategies

<table>
<thead>
<tr>
<th>Alignment Method</th>
<th>Typical Funds Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gainsharing</td>
<td>Third Party Payors ► Hospital ► Physicians</td>
</tr>
<tr>
<td>Service Line Management and Co-Management</td>
<td>Hospital ► Management Entity ► Physicians</td>
</tr>
<tr>
<td></td>
<td>Or</td>
</tr>
<tr>
<td></td>
<td>Hospital ► Physicians</td>
</tr>
<tr>
<td>Clinically Integrated Network (CIN)</td>
<td>Third Party Payors (which may include hospital employee health plan) ► CIN (of which Hospital may be sole or JV owner) ► Physicians</td>
</tr>
<tr>
<td>Accountable Care Organization (ACO)</td>
<td>CMS (MSSP) ► ACO/CIN (of which Hospital may be sole or JV owner) ► Physicians</td>
</tr>
<tr>
<td>Accountable Care Entity (ACE)</td>
<td>Medicaid or other third party payor ► ACO/CIN (of which Hospital may be sole or JV owner) ► Physicians</td>
</tr>
<tr>
<td>Combinations of Above</td>
<td>Variable (Depends on combinations)</td>
</tr>
</tbody>
</table>

*Note: Funds Flow varies based on circumstances. These are examples only.*
# De-Mystifying Alignment Strategies

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gainsharing</td>
<td>Yes (Financial relationship must meet an exception)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (no private inurement or excess benefit)</td>
<td>Often, yes Examples: physician self-referral law, anti-fee splitting laws</td>
<td>Depends on circumstances</td>
</tr>
<tr>
<td>Service Line Management and Co-Management</td>
<td>Assume Yes (Compliance with an exception may be required)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (no private inurement or excess benefit)</td>
<td>Often, yes Examples: physician self-referral law, anti-fee splitting laws, other antikickback laws</td>
<td>Depends on circumstances</td>
</tr>
<tr>
<td>Clinically Integrated Network (CIN)</td>
<td>Assume Yes (Compliance with an exception may be required)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes (no private inurement or excess benefit)</td>
<td>Often, yes Examples: physician self referral, state antitrust laws, insurance/any willing provider laws</td>
<td>Yes</td>
</tr>
<tr>
<td>Accountable Care Organization (ACO)</td>
<td>Assume Yes (Stark implicated, but waivers available for MSSP ACOs)</td>
<td>Assume Yes (AKS implicated, but waiver available for MSSP ACOs)</td>
<td>Assume Yes (CMP commonly implicated, but waiver available for MSSP ACOs)</td>
<td>Yes (no private inurement or excess benefit)</td>
<td>Often, yes Examples: physician self referral, state antitrust laws</td>
<td>Yes (But MSSP ACOs generally deemed clinically integrated)</td>
</tr>
<tr>
<td>Accountable Care Entity (ACE)</td>
<td>Assume Yes (Compliance with an exception may be required)</td>
<td>Assume Yes</td>
<td>Assume Yes (no private inurement or excess benefit)</td>
<td>Examples: physician self referral, anti-fee splitting, state antitrust laws</td>
<td>Depends on circumstances</td>
<td></td>
</tr>
<tr>
<td>Combinations of Above</td>
<td>Depends on combination</td>
<td>Depends on combination</td>
<td>Depends on combination</td>
<td>Yes</td>
<td>Yes</td>
<td>Depends on circumstances</td>
</tr>
</tbody>
</table>

*Content of this chart is generalizations only. Application of specific laws may vary based on circumstances.*
Alignment Strategies ... Various Models
Components of a Clinically Integrated Network

- Structure & Governance
- Clinically Integrated Network
- Physician Leadership
- Performance Objectives
- Participation Criteria
- Information Technology
- Distribution of Funds
- Contracting
- Infrastructure & Funding

Components of a Clinically Integrated Network:

1. **Structure & Governance**
2. **Physician Leadership**
3. **Performance Objectives**
4. **Participation Criteria**
5. **Information Technology**
6. **Distribution of Funds**
7. **Contracting**
8. **Infrastructure & Funding**

These components work together to create a clinically integrated network.
## Structure & Governance
What is the optimal governance model? How do physician leaders participate in governance and decision-making?

## Infrastructure & Funding
Is there a distinct entity that has the vision, leadership & infrastructure to truly succeed at creating value for physicians & payors?

How will the costs of building the infrastructure be offset? What potential revenue sources exist and what is the plan to capture that revenue?

## Participation Criteria
How will you decide which physicians to employ, align or integrate?

## Performance Objectives
Do your physicians have experience in leading performance initiatives? How do you plan to proactively enact a cultural change towards value?

## Physician Leadership
How do your physicians participate in leadership functions today? What kind of empowerment do they have within the organization? What plans do you have to develop physician leadership competencies?

## Information Technology
What IT systems are in place to monitor and track utilization, quality, efficiency, and value? How mature is the technology platform and how effectively is it currently used?

## Distribution of Funds
How are providers compensated across the organization? What methodology exists for distributing value-based funds to providers? How does the model mature with the market and organizational capabilities?

## Contracting
How urgent and ready is your market (payors and employers) to move toward value-based contracts? How prepared are providers to pursue value-based contracts and/or joint contracting?
Overview: Other than an employment-only model, a CIN usually is structured as a joint venture or subsidiary Physician Hospital Organization, or an Independent Practice Association (IPA).
Organizational Structure: Joint-Venture LLC

**Key Characteristics:**
- Physicians can elect Board Members
- Participation Fees will be different for Owners than for Participants
- All physicians will sign the same Membership Agreement
- Active participation is required to achieve performance goals
- Profit distribution to owners only, based on company’s profits
- Performance rewards will be available to Owners and Participants based on performance
Organizational Structure: Subsidiary LLC

Key Characteristics:
- Physicians can nominate Board Members, that are approved by Health System
- Participation Fees are typically the same for all Physician Participants, assuming all physicians sign the same Participation Agreement
- Active participation is required to achieve performance goals
- Distribution pool developed at the discretion of Health System, factoring in overhead costs for the network
- Networks can create rewards to physicians
# Common Reasons to Join a CIN

## ADVANTAGES FOR PHYSICIANS

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Benefit Range (Per Physician)</th>
<th>Low</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Improvement / P4P Incentives</td>
<td></td>
<td>$300</td>
<td>$4,000</td>
</tr>
<tr>
<td>Shared Savings</td>
<td></td>
<td>$1,500</td>
<td>$8,000</td>
</tr>
<tr>
<td>Leadership Participation Incentives</td>
<td></td>
<td>$50</td>
<td>$1,500</td>
</tr>
<tr>
<td>Capitalize on Payer Relationships</td>
<td></td>
<td>2%</td>
<td>10%</td>
</tr>
<tr>
<td>Narrow Network Participation</td>
<td>Belongs to <strong>Exclusive access to patients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care Management Resources (IT, Staff, Case Management)</td>
<td>Belongs to <strong>Shared network resources</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group Purchasing</td>
<td>Belongs to <strong>Reduction in expenses</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## ANNUAL CI INCENTIVES FOR ADVOCATE PHYSICIAN PARTNERS

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Total</th>
<th>Per physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Improvement / P4P Incentives</td>
<td>$12.4 M</td>
<td>$3.9 K</td>
</tr>
<tr>
<td>Shared Savings</td>
<td>$16.7 M</td>
<td>$5.2 K</td>
</tr>
<tr>
<td>Leadership Participation Incentives</td>
<td>$25.0 M</td>
<td>$8.6 K</td>
</tr>
<tr>
<td>Capitalize on Payer Relationships</td>
<td>$30.0 M</td>
<td>$9.4 K</td>
</tr>
</tbody>
</table>

Source: Advocate Physician Partners
Overview: The CIN is a separate business entity with a distinct identity, mission, and vision, dedicated leadership and staff, sustainable sources of revenue, and participating provider agreements with physicians that create potential value for both physicians and payors.

The CIN will need to offset costs of building the network (Infrastructure) and eventually provide returns through various revenue sources depending on the maturity of the network.
## Performance Objectives

**Overview:** CINs identify metrics and targets designed to meaningfully impact the clinical practice of all network physicians, and to align their conduct with hospital initiatives, so as to improve quality and demonstrate value across the entire continuum of care.

### Examples of Performance Improvement

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
</table>
| **Variance & Cost Reduction**   | Minimize variable physician performance not related to patient characteristics | • Minimize orthopedics supply chain cost  
• Staffing and productivity opportunities |
| **Unnecessary Care Reduction**   | Reduce avoidable, unproductive and duplicative services                      | • Prostate cancer screenings for elderly patients  
• Reduce Readmissions                   |
| **Clinical Restructuring**       | Ensure treatment in most optimal setting with most appropriate level of provider | • Early step down from an IP to SNF bed  
• Partnerships with a local retail clinic to offer non-urgent care |
| **System Optimization**          | Shift focus to upstream, preventative care with emphasis on CI and population health | • Disease-based medical homes  
• Patient engagement strategies using telehealth |

Source: Sg2 Analysis
Physician Leadership

**Overview:** Health systems must empower physicians to have an influence on the future direction of the network. This can represent a significant cultural transformation for many health systems, as physicians are integrated into the direction of the strategy for the network. If the network is successful, it will in turn have a significant impact on the future direction of the health system.

**Clinical Leadership**

- **Lead and participate on sub-committees supported by CIN or Health System personnel**
- **Provide clinical and operational input to the Health System**
Physician Leadership

**Overview:** Health systems must empower physicians to have an influence on the future direction of the network. This can represent a significant cultural transformation for many health systems, as physicians are integrated into the direction of the strategy for the network. If the network is successful, it will in turn have a significant impact on the future direction of the health system.

**Membership:**

- Hold physicians accountable for performance and compliance with network standards for quality
- Assist with the recruitment of new members within the network
- Assist physicians to improve, provide education and mentorship

**Finance and Contracting:**

- Determine the appropriate pace of change from FFS to other payment models
- Identify employers and payers that would be interested in contracting with the CIN
- Create a distribution and performance rewards methodology for the upcoming year
# Sample Physician Performance Dashboard

## PHYSICIAN DASHBOARD

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Potential Score</th>
<th>Physician Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Quality</td>
<td><strong>Sample Measures</strong>&lt;br&gt;<strong>CAD Mgt</strong>: An LDL-C test performed for CAD patients during the measurement year.&lt;br&gt;<strong>COPD Mgt</strong>: % of COPD patients that had an annual physician visit.&lt;br&gt;<strong>Diabetes HbA1C testing</strong>: % diabetic members 18-75 who had at least one HbA1C testing within 12 months.&lt;br&gt;<strong>Preventative Care</strong>: Breast Cancer Screening (40-69 years old).&lt;br&gt;<strong>Preventative Care</strong>: Colorectal Cancer (50-75 years old)</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>IT Adoption</td>
<td><strong>Internet Access</strong>&lt;br&gt;<strong>Email Address</strong>&lt;br&gt;Install Patient Registry (MedVentive)</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Credentialing</td>
<td>Meets NCQA standards for credentialing</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Patient Satisfaction</td>
<td>CMS metrics</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>Completion of required educational programs</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Leadership</td>
<td>Committee involvement</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td><strong>Total Score</strong></td>
<td></td>
<td><strong>100</strong></td>
<td></td>
</tr>
</tbody>
</table>
Distribution Funds

Overview: The CIN establishes an organized plan to link performance on defined gradients to eligibility for incentive payments.

- Cost Savings
- Efficiency Gains
- P4P Contracts
- Shared Savings
- Increased Rates
- Hospital
- Specialty
- Location
- Equal distribution
- Performance targets
- Educational event attendance
- Submission of Data
- Adoption of IT platform
Distribution Per Stakeholder – 2012 Distribution Results

**40% LOCAL NETWORK PERFORMANCE**

**20% GLOBAL NETWORK PERFORMANCE**

**40% INDIVIDUAL ACTIVITY / OUTCOME**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Distribution Per Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee Health Costs</td>
<td>$743</td>
</tr>
<tr>
<td>Global Network Performance</td>
<td>$537</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tier</th>
<th>Distribution Per Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>$0</td>
</tr>
<tr>
<td>1</td>
<td>$916</td>
</tr>
<tr>
<td>2</td>
<td>$1,373</td>
</tr>
<tr>
<td>3</td>
<td>$1,831</td>
</tr>
</tbody>
</table>

**Employee Health Costs**

**Employee Health Cost**

**Global Network Performance**

Physicians will receive between:

*$2,444 - $3,503

**Sample Range**

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Total Distribution per Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital A</td>
<td>$393</td>
</tr>
<tr>
<td>Hospital B</td>
<td>$249</td>
</tr>
<tr>
<td>Hospital C</td>
<td>$249</td>
</tr>
<tr>
<td>Hospital D</td>
<td>$393</td>
</tr>
</tbody>
</table>

*No Performance for Supply Costs and Pharmacy Costs Initiatives

---

All numbers are rounded for illustrative purposes

*This is an approximate amount and not a final range*
Contracting: Financial Risk & Investment Continuum

Maturity of Enterprise

Low
- Co-Management
- Employee Health Plan
- HEP

High
- Restrictive Network
- IP FFS + Shared Savings
- Managed PMPM Risk
- Capitation

Level of Infrastructure Investment
- Mix of Manual and Automated Reporting
- IT Supporting Population Health Management

Level of Risk
- Upside Only
- Risk / Reward

Internal Contracting

External Contracting
Internal Contracting through Hospital Efficiency Program

A Hospital Efficiency Program is an agreement between the hospital and a network of physicians to improve quality and efficiency within the hospital. Initiative and quality targets are defined in advance and if achieved, payments are made to the network for distribution to network physicians. Areas of focus are defined via a set of initiatives and metrics, each with its own predefined baseline and performance targets.

**BENEFIT TO STAKEHOLDERS**

**Physicians**
- Increased quality and efficiency through standardization
- Receive payment for demonstrated efficiencies and care coordination in various initiatives

**Markets and Hospitals**
- Reduce expenses in the “system” and gain efficiencies
- Establish a sense of urgency to reduce waste

**WHAT IT’S NOT**
- Traditional Gainsharing
Sequential Maturation Phase for CIN Development

- Clinical enterprise maturation can follow a systematic process paced to market opportunities, allowing the hospital and its physicians to prepare for the future while remaining focused on short-term initiatives.
- While the phases of maturity are sequential, unique local dynamics will dictate how a market approaches the progression (if appropriate) from each phase to another.

**Physician Alignment and Engagement**
- Local committees formed to begin service line and market-focused growth strategies
- Committees foster shared vision across market
- Committees evaluate quality and cost opportunities
- Expectation is that stronger engagement and loyalty leads to sustainability under a FFS model while building the infrastructure to become risk-capable

**Quality, Efficiency and Standardization**
- Data collection allows definition of quality baselines and targets
- Physician-approved care protocols and processes drive standardization, cost reduction and quality improvement
- Typical models that accommodate this phase include co-management, shared savings with hospital employee health plan & HEP contracts

**Value-Based Contracting**
- Demonstrated improvement in quality and performance creates new value proposition for contract negotiations
- Value proposition positions hospital and physicians for enhanced reimbursement and narrow network opportunities
- Incentives from payers and/or employers shared with network participants
- Expectation is that new revenue through PMPM rates, P4P, VBP and shared savings reimbursement will offset costs of network development

**STRATEGIC OBJECTIVES**

- **Value-Based Contracting**
  - Lead Time: 18-24 Months*
- **Quality, Efficiency and Standardization**
  - Lead Time: 12-18 Months*
- **Physician Alignment and Engagement**
  - Lead Time: 6-12 Months*
### Defining the ROI of a Network Strategy (Hospital Perspective)

<table>
<thead>
<tr>
<th>Key Elements</th>
<th>Definition</th>
<th>Financial Components</th>
</tr>
</thead>
</table>
| **Costs and Capital**         | The hospital’s operating costs attributed to the implementation of the network. This assumes a joint-venture model.                                                                                      | • Hospital and Employed Physician Membership Dues  
• Health Plan Rate Increase and Network Premium  
• Overhead Allocation to CIN                                                                                                                                 |
| **Hospital Health Plan Cost Saving** | An initiative that formally aligns quality improvement, cost containment and operational efficiency efforts across each hospital and the network.                                                                 | • Net Impact of Shared Savings within the Employee Health Plan                                                                           |
| **Market Share Impact**       | Shifts in market share due to the introduction, performance and sustainment of Clinical Integration contracts with payers in the Hospital market.                                                              | • Payer Contracts that include; Employee Health Plan, major commercial payors                                                               |
| **Operating Cost Reduction**  | Shifts in operating costs that can be attributed to specific performance initiatives led by CIN providers.                                                                                                  | • Variable Cost Assumptions                                                                                                                  |
| **Service Line Impact**       | Shifts in volume attributed to improved coordination of care, reduced outmigration and leakage to non-Hospital provider facilities.                                                                        | • IP Contribution Impact  
• OP Contribution Impact  
• Readmission Penalty Impact                                                                                                                   |
### Legal Issues Affecting Alignment Structures and CINs

<table>
<thead>
<tr>
<th>Issue</th>
<th>Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antitrust – Market Concentration and Integration</td>
<td>Impact on competition by:</td>
</tr>
<tr>
<td></td>
<td>• Too many providers/exclusivity in market</td>
</tr>
<tr>
<td></td>
<td>• Competitor joint action without integration</td>
</tr>
<tr>
<td>Federal Fraud and Abuse – Stark, Antikickback and Civil Monetary Penalties</td>
<td>• Physician financial and referral relationships</td>
</tr>
<tr>
<td></td>
<td>• Hospital incentives/payments to reduce care</td>
</tr>
<tr>
<td></td>
<td>• Beneficiary inducement</td>
</tr>
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<td>Tax Exempt Organization Concerns</td>
<td>Use of charitable assets</td>
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<td>• Private inurement, private benefit</td>
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<td>• Excess benefit transactions</td>
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<td>HIPAA, Privacy and Confidentiality</td>
<td>• HIPAA privacy and security</td>
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<td>• State confidentiality and restricted records</td>
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<td>State Law Issues</td>
<td>• State/Medicaid fraud and abuse provisions</td>
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<td>• Medical practice and licensure</td>
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<td>• Peer review</td>
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<td>• Business of insurance and any willing provider</td>
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<td>• Form of entity and tax considerations</td>
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Keeping the End Game in Mind

• Future hospital and physician payment dependent upon new paradigm:
  • Quality control
  • Evidence-based care
  • Effective use of health IT
  • Patient-centered care
  • Patient engagement
  • Care coordination
  • Bundled services and payment systems
  • Managing total cost of care
  • Population health management

Clinical integration strategies directed at above
Hospital utilization **DECLINES** over time
Strategy and Structure Questions

- Participants -- Health system only; employed and/or independent physicians; others (e.g., non-Hospital hospitals, post-acute)

- Form of Participation -- Ownership, service relationship, or both

- Governance -- Formal (boards) and/or informal (advisory committees)

- Activities (funding source)
  - Medicare ACA initiatives (e.g., Medicare ACO, Bundled Payments, CMMI)
  - Commercial initiatives (e.g., commercial/self-insured plan, Medicare Advantage)
  - Hospital quality/efficiency
  - Desire and timing for collective negotiation of fees

- Infrastructure/Financial Systems
  - Capitalization, cash flow and use of existing resources
  - Flow of money/services, savings/proceeds from program

- Participation strategy – Medicare-specific (specific rules and waivers) or commercial/specific
CIN/ACO Legal, Relationship & Governance Structures
Clinical Integration – Operational Definition

“Clinical integration is defined as the extent to which patient care services are coordinated across people, function, activities, processes, and operating units so as to maximize the value of services delivered.

Clinical integration includes both horizontal integration (the coordination of activities at the same stage of delivery of care as well as vertical integration the coordination of services at different stages).”

– Stephen Shortell, 1996

Focus: How care is furnished. Tools, techniques and activities of care delivery for a patient population
Clinical Integration – Legal/Antitrust Definition

• Concern with collective negotiation of fees by independent providers (hospitals, physicians, networks, etc.) who are not “integrated”

• Acceptable “integration” may be via:
  • Financial risk sharing (e.g., financial withhold or capitation) or
  • Through “clinical integration”

• Focus: Whether the network of providers is sufficiently “integrated” to permit collective negotiation of fees
Clinically Integrated Networks involve arrangements in which:
  • Physicians participate in active and ongoing programs to evaluate and modify practice patterns
  • Create a high degree interdependence and cooperation, in order to
  • Control costs and ensure the quality of services

• Agreements concerning price and other terms are reasonably necessary to obtain significant efficiencies

• Joint contracting is necessary to the end goal; not end of itself

Sources www.ftc.gov -- FTC/DOJ Statements of Antitrust Enforcement Policy; Tri-State Health Affiliates FTC Advisory Opinion
Progression to Accountable Care

“Clinically Integrated Network”
- Provider network
- The “team” for clinical integration

“Clinical Integration”
- What the CIN does
- Participants collaborate on care
- Game plan and rules
- Operational and legal concepts

“Accountable Care Organization”
- Market and payor engagement
- Clinical integration to achieve goals
- Population health management
- Shared savings and/or risk
Clinical Integration Criteria

- Key Elements from FTC Advisory Opinions:
  - Structural goal is care coordination with rigorous medical management of clinical practice
  - Development and implementation of evidence based or other clinical protocols
  - Performance reporting, corrective action procedures
  - Focused management of high cost, high risk patients
  - Health Information Technology/EHR use promotes network objectives
  - Data collection, evaluation and performance/outcome benchmarking
  - Provider financial and time commitment to program (e.g., committee service and staff training)
  - Ultimate ability to terminate non-compliant providers if remediation efforts are unsuccessful i.e., provider selectivity is important

- Valid plan to implement clinical integration can suffice . . . but the plan needs to be implemented.
  - Norman PHO FTC Advisory Opinion
Medicare Savings Program and Pioneer Accountable Care Organizations

- Affordable Care Act Section 3022 authorizes Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs)
  - “Shared savings” and other payment possibilities
  - Improve quality, improve patient experience and decrease cost for Medicare fee for service populations
  - Defined process and protocol to become MSSP ACO

- Concurrent guidance from other federal regulatory agencies
  - DOJ/FTC – Antitrust
    - MSSP ACOs effectively deemed clinically integrated
    - ACO market share protocol
  - CMS/OIG – Stark, AKS and CMP Waivers
    - Pre-participation Waiver
    - Participation Waiver
    - Shared Savings Waiver
    - Compliance with Physician Self-Referral Law waiver
    - Waiver of Patient Incentives
  - IRS – Exempt Organization “Notice and Fact Sheet”
Federal Tax-Exempt Organization Issues

- **Tax-Exempt Organization Concerns** –

- IRS § 501(c)(3) tax exempt hospitals are prohibited from engaging in inurement and private benefit
  - Allowing exempt income to unduly benefit private actors, including physicians
  - Conferring excessive “private benefit” upon such individuals or other “insiders”
  - Tax-exempt organization implications for CIN establishment, operations and funds flow. Examples:
    - Use of charitable assets from tax-exempt hospital to fund initiative in manner that only benefits participating physicians
    - Paying excessive compensation for physician services in connection with program
Federal Fraud and Abuse Laws

- **Stark Law** -- Forbids physicians having a broadly-defined financial interest in entities providing “designated health services” (including hospital services) from making patient referrals of Medicare or Medicaid-reimbursed patients to that entity, unless an exception applies
  - Common exceptions require compensation must be FMV and commercially reasonable

- **Antikickback Statute (AKS)** -- Forbids the payment of remuneration in exchange for referring or arranging the referral of governmentally-reimbursed health care services
  - Full or substantial compliance with safe harbor or AKS. No intent to influence referrals

- **Civil Monetary Penalties** Law (CMP) -- Prohibits hospitals from making payments to induce a physician to reduce or limit services provided to Medicare or Medicaid beneficiaries, and prohibits “beneficiary inducements”

- Fraud and abuse law implications for Clinically Integrated Network establishment, funds flow and operations. Examples:
  - Financial relationships between and among CIN participants
  - Funding of strategic, development and operational costs
  - Return on investment and compensation arrangements from CIN activities
  - Use of CIN/ACO to reward referrals and flow of funds
MSSP ACO Fraud and Abuse Waivers

- **Pre-participation Waiver**
  - Permits subsidy for “start-up arrangements” involving items, services, facilities, goods etc. used to create or develop an ACO that are provided by ACO, ACO participants or ACO providers
  - Governing body determination arrangement is “reasonably related to the purposes of the MSSP”

- **Participation Waiver**
  - Start up and operational arrangements – “reasonably related to purposes of the MSSP”
  - Involving ACO, ACO participants, and outside providers and suppliers

- **Other Waivers**
  - Stark self-referral exception compliance
  - Shared savings distribution waivers
  - Waiver for patient incentives
Start-Up Arrangement Examples

- Infrastructure creation and provision
- Network development and management
- Care coordination mechanisms
- Quality improvement mechanisms
- Clinical management systems
- Creation of governance and management structures
- Performance-based incentives

- Staff (e.g., care coordinators, management, quality leadership, IT support, financial management, health information exchanges, data reporting systems (including all payers), data analytics)
- Consultant, legal and other professional support
- Organization and staff training costs
- Incentives to attract primary care physicians
- Capital investments
Clinically Integrated Network Financial Issues

- CIN Development and Operations (e.g., infrastructure, IT etc.)
- CIN Payer Initiatives – Funding Source and Purpose
  - Hospital and Health System
    - CIN Development, Operations and Management
    - Hospital-oriented Initiatives (e.g., Co-Management and Hospital Efficiency Agreements)
    - Health System Self-Insured Plan Shared Savings Arrangements
  - Commercial/Employer Self-Insured
  - Government – MSSP, Medicaid and other
- CIN Distribution Methodology, Incentive Metrics and Amount (i.e., FMV, reasonableness and other standards)
Revenue Source and Funds Flow Illustration

Hospital/Health System
- Mgmt. Agmt.

Health System Self Insured
- CHS Shared Save

Commercial
- Comm.

Public / MSSP
- Medicare Etc.

Clinically Integrated Network
- Operating Capital
- Budget and Business Plan

30% up to $1M
- 60% Drs./10% Hosp.
- 40% PCP Equal./Perf.
- 60% Spec Equal./Perf.

Up to $2M Based on Performance
- 60% PCP Equal.
- 40% Spec Equal.

50% Shared Save Linked to Quality Performance
- 60% PCP Equal.
- 40% Spec Equal.

50% Shared Save Linked to Quality Performance
- 60% PCP Equal.
- 40% Spec Equal.

Indiv. Participant

40% Spec Equal.
OIG Advisory Opinion Guidance on Incentives

- Incentive Program Concerns:
  - Financial incentives to reduce or decrease patient care
  - Hospital payments for physician referrals’ or for “cherry picking” or steering of patients
  - Overutilization and elimination of patient choice

- OIG Advisory Opinion 12-22, 08-16 and others involving hospital driven incentives
  - Program auditing, monitoring and transparency
  - No limitations on selection/available care
  - Limits on total compensation and program duration/term
  - No clinical and referral practice changes (e.g., stinting, cherry picking, etc.)
  - Fair market value compensation supported by valuation
  - Compensation not linked to volume/value of referrals
  - Recognized, evidence-based quality measures
    - Improvements from norms
    - Balancing of quality and cost (e.g., LOS and readmissions)
State Law and Other Considerations

- State Fraud and Abuse Laws
  - Not waived by MSSP waivers; separate analysis

- Corporate Practice of Medicine, State Licensure and Liability Concerns
  - Scope of practice limits and professional licensure requirements with service coordination across the continuum of care

- Prohibitions Against Fee-Splitting

- Business of Insurance -- Does arrangement involve acceptance of “insurance risk”?  
  - Entity licensure by State Division of Insurance and/or availability of exemptions (e.g., contracting with a licensed “upstream” carrier (indemnity insurer or HMO) from separate licensure requirements)  
  - Any Willing Provider law application to CIN and activities

- Peer review and protections
  - CINs focused on improvement of quality of care, data assessment etc. Application of federal and state peer review protections
  - Alternative strategies (e.g., Patient Safety Organizations) to provide protections
Fair Market Value Issues

• Is Fair Market Value Analysis Required, and If So, Why and How?
  • Sample Anatomy of Analysis

A. Does the Stark Law apply?
  i. If yes, what are the applicable exceptions?
  ii. Do(es) the applicable exception(s) have a fair market value compensation requirement?
  iii. Is the fair market value compensation requirement modified by additional requirements—e.g. not determined in a manner that takes into account the volume or value of referrals, set in advance, etc.?
Fair Market Value Issues

• Is Fair Market Value Analysis Required, and If So, Why and How?
  • Sample Anatomy of Analysis

B. Does the Federal Antikickback Statute apply?
   i. If yes, will compensation that is set at fair market value reduce the risk that the
      arrangement will be viewed as prohibited remuneration for referrals?
   ii. Is the form of compensation ($ for service, percentage, annual stipend, etc.) equally or
       more important to the risk than the amount?
   iii. Is the risk that the arrangement will be viewed as prohibited remuneration for referrals:
       a. Based solely on whether the compensation is above fair market value?
       b. Based solely on whether the compensation is below fair market value?
       c. Equally troublesome if the compensation is above or below fair market value?
Fair Market Value Issues

• Is Fair Market Value Analysis Required, and If So, Why and How?
  • Sample Anatomy of Analysis

C. Is one or more of the stakeholders tax exempt and subject to IRC §501(c)(3)?
  i. If yes:
     i. Is there IRS guidance regarding this type of arrangement?
     ii. Does IRS guidance indicate that fair market value is:
         i. Required, to the extent that it establishes that compensation is reasonable compensation for services and not private inurement?
         ii. Trumped by other concerns, such as whether return is proportional to contributions?
Fair Market Value Issues

• Is Fair Market Value Analysis Required, and If So, Why and How?
  • Sample Anatomy of Analysis

D. Are there state law issues that require consideration of the form or amount of compensation, including its fair market value?
   i. State physician self-referral laws?
   ii. State antikickback and/or anti-fee splitting laws?
   iii. State medical practice laws or regulations that restrict whom can be paid how much and/or in what form for specific types of services in healthcare settings?
Fair Market Value Issues

• Defining what needs to be valued: what (exactly) are the services and/or contributions for which fair market value analysis is needed?
  • Define the contributions of the various stakeholders to the arrangement

• Use answers to the questions on previous slides (“Is Fair Market Value Analysis Required, and if So, How and Why?”) to determine appropriate standards and focus for fair market value analysis
• Common fair market value topics for CINs:
  • Services/contributions by individual physicians or specific physician groups
  • Services/contributions by hospital participants
  • Operating or management expenses for the CIN
Fair Market Value Issues

• Selection of an Appropriate Valuation Approach
  • Potential Considerations and Pitfalls:
    • Why fair market value analysis is needed (legal and regulatory framework)
    • What is to be valued
    • Appropriate valuation approaches for what is to be valued
      • Cost
      • Market
      • Income
    • Challenges for implementing these valuation approaches under typical circumstances
      • Availability of appropriate data
      • Necessary assumptions
Fair Market Value Issues

• Selection of an Appropriate Valuation Approach
  • Potential Considerations and pitfalls:

  • Necessary assumptions and limiting conditions
    • Will the fair market value opinion be worth anything with all its disclaimers?
  • The co-existence of alignment methods (e.g. service line co-management, hospital gainsharing, and CIN)
    • Commercial reasonableness questions
    • Payments through different arrangements for the same services = payment in excess of FMV?
<table>
<thead>
<tr>
<th>Alignment Method</th>
<th>Payment Form(s)</th>
<th>Typically Reasonable Valuation Approaches</th>
<th>Other Considerations</th>
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</thead>
<tbody>
<tr>
<td>“Gainsharing” (includes “gainsharing-like” arrangements)</td>
<td>Percentage of savings achieved in target efficiency improvement areas, or</td>
<td>Market, Cost, Income</td>
<td>Nature of targets and measurement methods for achieving them, Context for gainsharing arrangement, including whether it is part of and/or co-exists with another alignment methods</td>
</tr>
<tr>
<td>Service Line Management and Co-Management</td>
<td>Typical: Fixed fee for performance of specific tasks, plus incentive compensation for achievement of specific goals</td>
<td>Fixed Fee: market, cost, Incentive: market, cost, Overall Compensation: market, cost</td>
<td>Nature and extent of duties and goals, Size and scope of service line, Context for arrangement, including whether it is part of and/or co-exists with other alignment methods</td>
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</tbody>
</table>
| Clinically Integrated Network (CIN) | Variable; examples:  
- Annual, per service or PMPM payments from third party payors and/or hospital(s) to CIN entity  
- FFS and/or fixed annual incentive payments from CIN to physician participants | $ to CIN: market, cost, $ from CIN to physicians: market, cost, $ from CIN to hospital: market, cost, Operating costs of CIN: market, cost | Structure and operational goals of CIN, Nature of duties and contributions of each stakeholder to the CIN, Existence of other alignment methods and potential overlap of contributions and value |
| Accountable Care Organization (ACO) | Variable; examples:  
- % of Medicare savings paid by CMS to ACO/CIN through MSSP  
- % of amounts received through MSSP paid by ACO/CIN to physicians or physician group(s) | $ from ACO to physicians: market, cost | Structure and operational goals of CIN, Nature of duties and contributions of each stakeholder to the CIN, Existence of other alignment methods and potential overlap of contributions and value |
| Accountable Care Entity (ACE) | Variable; examples:  
- % of payor savings paid by CMS to ACE/CIN through shared savings arrangement  
- % of amounts received through MSSP paid by ACE/CIN to physicians or physician group(s) | $ from ACE to physicians: market, cost | Structure and operational goals of CIN, Nature of duties and contributions of each stakeholder to the CIN, Existence of other alignment methods and potential overlap of contributions and value |
| Combinations of Above | Variable (Depends on combinations) | Variable | See above |

This slide contains generalizations of “typical” circumstances; considerations and valuation methods may vary based on circumstances.
Questions?

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