CLINICALLY INTEGRATED NETWORKS: BUSINESS AND LEGAL CONSIDERATIONS

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Agenda

BUSINESS CONSIDERATIONS
How Fast are Markets Moving Toward Provider Networks?

OVERVIEW & EVOLUTION OF NETWORKS
What is an Integrated Provider Network and Why is the Market Moving?

LEGAL CONSIDERATIONS
How is a CIN Unique?
A Clinically Integrated Network (CIN) is a selective partnership of physicians collaborating with hospitals to deliver evidence-based care, improve quality, efficiency, and coordination of care, and demonstrate value to the market.

**BENEFITS TO STAKEHOLDERS**

**Physicians**
- Preserving private practice model through alignment
- Enhanced reimbursement through contracting for demonstrated network quality
- Improved communication, coordination, transparency, accountability

**Hospitals**
- Align independent, employed, and specialist physicians in one organization
- Enhanced reimbursement under FTC guidelines for demonstrated quality

**WHAT IT’S NOT**
- Physician Employment
- Hospital Initiative
- Mechanism to gain negotiating leverage with payors
## Network Value Proposition

### HOSPITALS & HEALTH SYSTEMS
- Improved coordination, efficiency, satisfaction, transparency and information
- Response to market pressures
- Provide right care in the right setting
- Alignment with independent and employed PCPs and specialists
- Enhanced reimbursement for demonstrated quality

### PHYSICIANS
- Improved coordination of patient care
- Access to patient information and transparency across the continuum
- Implementation of data-driven clinical best practice guidelines
- Increased input and decision making
- More attractive payor contracts
- Share in performance based incentives

### PAYORS & EMPLOYERS
- Reduced cost and enhanced value
- Better management of high-cost chronic patients
- Increased collaboration between patients and providers
- Shift of risk to providers

### PATIENTS & COMMUNITIES
- Improved coordination and efficiency of care
- More information and control of care
- Higher satisfaction
- Improved quality and outcomes
- Lower cost and higher value
• Increased focus on the quality, efficiency and value of health care is driving increased interest in clinical integration.

• Payers, hospitals and health systems to engage physicians to manage costs and improve the quality and efficiency of health care delivery.
• “Clinically Integrated Networks” are a popular means to pursue the cost, quality and value goals of post-ACA health care delivery.

• Forming a CIN is a major undertaking involving complex strategic, legal and business issues.
Fragmented Delivery System and Relationships

- The “Good Old Days”:

Financing and Insurance

Health Care Providers

Consumers / Patients
Models of Strategic Alignment

- **TACTICAL**
  - Pay for Call
  - Directorship
  - IT Deployment
  - Co-Marketing

- **STRATEGIC**
  - Joint Venture
  - Physician Hospital Organization
  - Gainsharing
  - Management Services Organization
  - Physician Advisory Council
  - Co-Management

- **TRANSFORMATIONAL**
  - Accountable Care Organization
  - Clinically Integrated Network
  - PCMH
  - Foundation
  - Hospital Efficiency Program
  - Employment
  - Institute
  - Professional Services Arrangement

**Degree of Alignment**

- **Resources Required**
  - LOW
  - HIGH

- **Degree of Alignment**
  - LOW
  - HIGH
Emerging Models

CINs/ACOs

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

Financing and Insurance

Consumers/Patients

Clinically Integrated Network

Accountable Care Organization
Evolution of a Network

- Enhance Care Coordination
- Eliminate Waste and Inefficiencies
- Standardize Protocols and Care Pathways
- Reduce Variance
- Define, Measure and Report Quality
- Manage Utilization
- Preserve / Improve Market Position

Legislative Reform

Payment Reform

Traditional Model

Integrated Provider Network

CMS, PAYORS, EMPLOYERS, EXCHANGES

Hospital(s) and Health Systems

Post-Acute Facilities

AMBULATORY
Community Facilities

Community-Based Care

Acute Care
Market Pacers: How fast? How much?

Local Market Conditions will Impact Timing of Network Development

1. When will our market tip?
2. What percentage of our net revenue will be tied to performance metrics?
Key Questions

1. What is the **urgency** for key stakeholders in the market to pursue risk and network formation?
   - Is there a burning platform to move away from the status quo?
   - Is a focus on quality, efficiency and performance driving consolidation?
   - Do new payment models represent a significant business opportunity?

2. What is the **readiness** for key stakeholders to move quickly in the direction of risk and network formation?
   - How fast could the market move away from traditional fee for service reimbursement?
   - What are the barriers or accelerators that would pace the change in the market?
Responding to Market Dynamics

Market A: Slow Pace of Change
- System Assets
- Competitors
- Independent Physician Groups
- Payors
- Employers

Market B: Fast Pace of Change
- System Assets
- Competitors
- Independent Physician Groups
- Payors
- Employers
“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
Components of a Clinically Integrated Network

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

Bricker & Eckler
ATTORNEYS AT LAW
## Defining the ROI of a Network Strategy
**(Hospital Perspective)**

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

<table>
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<tr>
<th>Issue</th>
<th>Concerns</th>
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| **Antitrust – Market Concentration and Integration** | Impact on competition by:  
• Market power – too many providers  
• Competitor joint action without integration |
| **Federal Fraud and Abuse – Stark, Antikickback and Civil Monetary Penalties** | • Physician financial and referral relationships  
• Hospital incentives/payments to physicians to reduce care  
• Beneficiary inducement |
| **Tax Exempt Organization Concerns** | Use of charitable assets  
• Private inurement, private benefit  
• Excess benefit transactions |
| **HIPAA, Privacy and Confidentiality** | • HIPAA privacy and security  
• State confidentiality and restricted records |
| **State Law Issues** | • State/Medicaid fraud and abuse and physician-referral provisions  
• Medical practice and licensure  
• Peer review  
• Business of insurance and any willing provider  
• Form of entity and tax considerations |
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
- Health system typically controls certain key issues by member approval or supermajority of Board approval
- 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
Antitrust Concerns

Structure

• The CIN must be structured such that it avoids a *per se* violation of the antitrust laws and avoids overriding anticompetitive effects.

• The network must be “integrated” -- either financially integrated or clinically integrated.

• Financial integration requires all providers to share in significant financial risk, e.g. partial payment withholds; capitation.

• Clinical integration requires a structure such that the network of competing providers will result in a high degree of provider interdependence and cooperation to control health care costs and ensure quality health care through the CIN.

• Properly structured, the CIN will avoid a *per se* violation of price fixing, market allocation or agreement not to compete.
Key issue is whether joint price negotiations and any competitive restrictions within the CIN are "reasonably necessary" to further the legitimate purpose of the network.

- *i.e.*, Are the joint negotiations and restrictions necessary to achieve cost efficiencies and increased quality of care?

- Also, whether market power has been created as evidenced by high market shares or other indicators of market power such that the CIN can demand monopoly prices and/or eliminate competition. (This also applies to MSSP ACOs.)
Antitrust Concerns

Example of Clinically Integrated Multi-Provider Network Structure

• The goal is to implement an ongoing program to evaluate and modify practice patterns by the network’s providers to control costs and ensure quality.

• Creation of specialty advisory groups that are responsible for developing and updating clinical practice guidelines, with all physicians being required to actively participate.

• Development of clinical practice guidelines for disease-specific conditions.

• Creation of a quality assurance committee which includes physicians and quality assurance individuals to establish measures for individual and group performance.

• Development of measures to identify high-cost providers, inappropriate use of resources, and failures to comply with clinical practice guidelines.

• Development of electronic platforms for use by the CIN and its participating providers.

• NOTE: The actual structure and antitrust concerns will be specific to the proposed make-up of the network and to the character of the markets of the CIN.
Provisions to Reduce Antitrust Risks

- The providers enter into non-exclusive contracts with the network such that the providers can engage in contracting independently or through participation in a competing network.

- The providers agree to participate in all payer contracts entered into by the CIN. This increases the likelihood that the providers will actively participate to achieve the quality and efficiency goals.

- The CIN provides a mechanism to avoid competing providers engaging in discussions and possible anticompetitive agreements outside of the legitimate business activities of the CIN, such as regular provider antitrust counseling.
Federal Tax-Exempt Organization Issues

Tax-Exempt Organization Concerns – General

- 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 Tax-Exempt Organization Issues

Tax Exempt Organization Concerns – Structure

• If the Health System is 501(c)(3) tax exempt, CIN typically must be operated for charitable purposes consistent with Health System mission

• Health System control over charitable issues and certain other key issues to ensure operated for tax exempt purposes

• Health System needs to ensure “investment” in CIN is reasonable

• Health System needs to ensure payments of benefits to physicians is reasonable in light of physician contributions or services to avoid private inurement, private benefit, and excess benefit transactions

• Medicare ACO IRS Notice helpful, but no clear IRS guidance on non-Medicare ACOs, CINs
Federal Fraud and Abuse Laws

- **Stark Law** – Prohibits physicians with a financial relationship with entities providing “designated health services” (including hospital services) from referring for Medicare or Medicaid-reimbursed services to that entity, unless an exception is met
  - Common exceptions require compensation must be FMV, commercially reasonable, and not vary with referrals
- **Anti-kickback Statute (AKS)** – Prohibits the payment of remuneration in exchange for referring or arranging referrals 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”
- **Implications for Clinically Integrated Network**
  - 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
Payments to physicians must not violate the Stark law or anti-kickback statute and similar state laws.

Stark compliance is highly dependent on the specific structure and Stark may not be implicated if the relationship with physicians is indirect (i.e., may not create a Stark “financial relationship”).

If Stark is implicated, possible exceptions to comply with: indirect compensation, personal services, shared risk.

Anti-kickback is intent-based:
- Ensure overall purpose is not to induce physician referrals
- Document appropriate business case
- Ensure payments are reasonable/FMV for physician’s participation
OIG Advisory Opinion Guidance on Incentives

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

- Safeguards from OIG Advisory Opinion involving hospital driven incentives (12-22, 08-16 and others)
  - Program auditing, monitoring and transparency
  - No limitations on selection/available care
  - Limits on total compensation and program duration/term and resetting
  - No clinical and referral practice changes (e.g., switching, stinting, cherry picking, etc.)
  - Fair market value compensation supported by valuation
  - Compensation does not vary with volume/value of referrals
  - Nationally recognized standards, specific 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
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
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 power concern in commercial markets
  - CMS/OIG – Stark, AKS and CMP Waivers
    - Pre-participation Waiver
    - Participation Waiver
    - Shared Savings Distribution Waiver
    - Compliance with Physician Self-Referral Law Waiver
    - Waiver of Patient Incentives
  - IRS – Exempt Organization “Notice and Fact Sheet”
MSSP ACO Fraud and Abuse Waivers

• Pre-participation Waiver
  – Applies to “start-up arrangements” that predate ACO’s MSSP contract 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 must determine arrangement is “reasonably related to the purposes of the MSSP”

• Participation Waiver
  – Operational arrangements after ACO has MSSP contract – “reasonably related to purposes of the MSSP”
  – Involving ACO, ACO participants, and outside providers and suppliers

• Other Waivers
  – Shared savings distribution waivers
  – Waiver for patient incentives
  – Stark self-referral exception compliance
Pre-Participation Waiver – 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
Provider Network Strategy Process

**DISCOVER**

- Project Planning & Management
- Market Briefing
- Project Communication, Education & Kickoff
- Market Readiness
  - Data Analysis
  - Interviews
  - Market Gap Analysis
- Organizational Readiness
  - Data Analysis
  - Interviews
  - Organizational Gap Analysis
- Strategic & Economic Impact Analysis
- Findings & Recommendations

**DEVELOP**

- Project Planning & Management
- Committee Formation
- Network Design
  - Structure & Governance
  - Infrastructure & Funding
  - Physician Leadership
  - Participation Criteria
  - Performance Objectives
  - Information Technology Design
  - Distribution of Funds
- Legal Document Creation
- Fair Market Valuation
- M, V, V & Identity Formation
- IT Screening & Selection
- Proforma & Business Planning
- Communication & Recruitment

**DEPLOY**

- Project Planning & Management
- Committee [Re]Formation
- PPM Development
- Membership Education & Enrollment
- Employer & Payor Contracting
- IT System Implementation
- Dashboard Creation
- Policies & Procedure Development
- Staffing Model Selection

**MARKET ASSESSMENT**

**NETWORK FORMATION**
Q & A

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