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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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 “buzzwords”
   - Clinical Integration/Clinically Integrated Network ("CIN")
   - Accountable Care Organization ("ACO")/Accountable Care Entity ("ACE")
   - Hospital Efficiency Program
   - Co-Management Arrangement
   - Gainsharing/Shared Savings Arrangement

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 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 various financial, cultural and infrastructure issues
   • Legal and regulatory changes are continuously influencing the evolution of these issues
     - ACA implementation
     - MACRA/SGR legislation
     - 2016 PFS
     - Federal timeline for achievement of alternative payment models
     - Anti-fraud and abuse enforcement trends
       - OIG Advisory Opinions
       - OIG Fraud Alerts
       - False Claims Act litigation
       - Other government actions
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.

- Stakeholders need 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.
Why Do We Think These Purposes Are Worth 90 Minutes of Your Time?

“HHS has set a goal of tying 30 percent of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. HHS also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs....”

“Entities furnishing DHS face the predicament of trying to achieve clinical and financial integration with other health care providers, including physicians, while simultaneously having to satisfy the requirements of an exception to the physician self-referral law’s prohibitions if they wish to compensate physicians to help them.”
- CMS, Physician Fee Schedule Proposed Rule, July 2015
Disclaimers:

• This slide deck:

  • Is the result of collaboration of your panelists.
  • Will be the subject of interactive panelist discussion.
  • 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, business or valuation advice or opinions; it is just a collection of ideas.
  • Is the second in a 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

Financing and Insurance

Consumers/Patients

Health Care Providers
Replacing Today’s Fragmented Delivery System with The New Trend: CINs/ACOs

Key Attributes:
- Patient Centered
- Coordinated Care
- Quality and Cost Focus
- Information Sharing
- Aligned Incentives
# 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>Gainsharing</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>Service Line Management and Co-Management</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>Clinically Integrated Network (CIN)</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>Accountable Care Organization (ACO)</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>Accountable Care Entity (ACE)</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>Combinations of Above</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 ► <strong>Hospital</strong> ► <strong>Physicians</strong></td>
</tr>
<tr>
<td>Service Line Management and Co-Management</td>
<td><strong>Hospital</strong> ► <strong>Management Entity</strong> ► <strong>Physicians</strong> Or <strong>Hospital</strong> ► <strong>Physicians</strong></td>
</tr>
<tr>
<td>Clinically Integrated Network (CIN)</td>
<td>Third Party Payors (which may include hospital employee health plan) ► <strong>CIN</strong> (of which <strong>Hospital may be sole or JV owner</strong>) ► <strong>Physicians</strong></td>
</tr>
<tr>
<td>Accountable Care Organization (ACO)</td>
<td><strong>CMS (MSSP)</strong> ► <strong>ACO/CIN</strong> (of which <strong>Hospital may be sole or JV owner</strong>) ► <strong>Physicians</strong></td>
</tr>
<tr>
<td>Accountable Care Entity (ACE)</td>
<td>Medicaid or other third party payor ► <strong>ACE/CIN</strong> (of which <strong>Hospital may be sole or JV owner</strong>) ► <strong>Physicians</strong></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.
<table>
<thead>
<tr>
<th></th>
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<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</td>
<td>Yes (no private inurement or excess benefit)</td>
<td>Examples: physician self-referral, anti-fee splitting, state antitrust laws</td>
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<td>Combinations of Above</td>
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<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.
The Tipping Point – Volume to Value

1. Impact of Purchaser Pressure

2. When will our market tip?

3. How will you develop your Transformational Agility?

4. 

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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.

**WHAT IT’S NOT**

- Physician employment
- Hospital-led initiative
- Mechanism to gain negotiating leverage over payors
CINs: Key Components

**Contracting**
Multiple contract options secure rewards for better quality and demonstrated value.

**Structure & Governance**
Limited Liability Corporation, Non Profit Corporation, Health Care Authority

**Infrastructure & Funding**
Single CIN, multiple CINs, or super regional CINs with sustainable revenue and provider agreements.

**Distribution of Funds**
Flow of funds distributes rewards based on measurable performance.

**Participation Criteria**
Provider agreements outlining expectations/requirements for participation in the CIN.

**Information Technology**
Architecture to monitor and track utilization, control costs, ensure quality and demonstrate value.

**Physician Leadership**
Physicians empowered to have an influence on future direction of the network.

**Performance Objectives**
Metrics and targets that impact the clinical practice of all providers to improve care and demonstrate value.
Typical CIN Board & Committee Structure

**BOARD COMPOSITION**

Physician Chair

**MANAGING BOARD**

**COMMITTEES**

Chaired by Physicians

- Finance and Contracting
- Clinical Quality
- Membership and Operations
- Communication and Education
- Information Technology
Organizational Structure: Joint-Venture LLC

**Observed 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
Observed 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
Regardless of the Model, each Network will typically ensure the following:

1. **Health System maintains “Reserved Powers” that include…**
   
   *Budget, Capital, Dissolutions or Mergers, Not-for-Profit Status*

2. **Critical issues have support of the Physicians**
   
   *Ex. No contract should be approved unless the physicians agree it’s a good idea*

3. **Committees and Management to support Activities of the Network**
   
   *Management (along with Executive Committee) will be accountable for day-to-day operations*

4. **Physicians are meeting Participation requirements for Network Activities**
   
   *Failure to meet network requirements, and associated penalties are the same in either model*
## 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>
</table>
| **Clinical Quality** | **Sample Measures**  
CAD Mgt: An LDL-C test performed for CAD patients during the measurement year.  
COPD Mgt: % of COPD patients that had an annual physician visit.  
Diabetes HbA1C testing: % diabetic members 18-75 who had at least one HbA1C testing within 12 months.  
Preventative Care: Breast Cancer Screening (40-69 years old).  
Preventative Care: Colorectal Cancer (50-75 years old) | 40              |                 |
| **IT Adoption**      | Internet Access  
Email Address  
Install Patient Registry (MedVentive) | 15              |                 |
| **Credentialing**    | Meets NCQA standards for credentialing | 15              |                 |
| **Patient Satisfaction** | CMS metrics | 5               |                 |
| **Education**        | Completion of required educational programs | 15              |                 |
| **Leadership**       | Committee involvement | 10              |                 |

**Total Score** 100
3 “Bands” of a Distribution Model

Network Infrastructure Costs / Provider Distributions
A percentage of network revenue is typically allocated to pay for elements of the network infrastructure, prior to the distribution to the hospital, Primary Care and Specialty physicians.

Percentage Allocation to Major “Buckets”
Revenue is then allocated to major categories, based on the key areas the network determines warrant physician reward.

Metric Performance
Based on individual / group performance against set targets, payments will be distributed to participants, either based on performance relative to a target or relative to their peers.
Selecting the Contracting Approach for Your Organization

FFS Focus

Value-Based Focus

- Physician Engagement
- Health System Engagement
- Interoperable Capabilities
- Cost and Quality

Leverage
Reputation
Limited Alternatives
Value-based Contracting Options

**Definition:** A provider agreement with a payer or employer with the following characteristics:

1. A clear set of goals and indicators
2. Organized efforts to collect data on the progress of the selected indicators
3. Rewards or penalties based on performance

### Medicare and Medicaid

- **85%** of traditional Medicare FFS payments will be tied to quality or value by 2016.

  - HHS, 2015

### Commercial Payers and Employers

- **75%** of a members’ business will shift to incentives for health outcomes, quality and costs management by January 2020.

  - Modern Healthcare, 2015

*In reference to The Healthcare Transformation Task Force which includes Ascension, Aetna, Caesars Entertainment Corp. and Pacific Business Group.*
Align CMS criteria to other performance-based contracts

Rewards and/or penalties are linked to each program

Scope of services and requirements are already defined

Workflow changes for CMS programs will directly impact on other patient populations.

What is stopping you from creating the same type of performance-based contracts with commercial payers and employers?
Value-based Contracting Alternatives

Level of integration required

- FFS Reimbursement Reductions
- Penaltly Avoidance and Pay for Performance
- Bundled Payment (BPCI)
- Capitation, Shared Savings (MSSP)
- Fee-For Service
- Pay-for-Performance
- Bundled Payments
- Shared Savings
- Hospital Efficiency Program
Value-based contracting options

Hospital Efficiency Program

A **Hospital Efficiency Program** is an agreement between the hospital and an integrated legal entity to improve quality and reduce costs within the hospital. Payments and targets are defined in advance and if achieved are allocated back to the legal entity for distribution to network providers. Areas of focus are defined via a set of initiatives and metrics, each with its own predefined baseline and performance targets.

**Performance Management**

**Hospital Efficiency Program**

- HEP Contract (1-3 Years)
- Shared Savings Distribution
- Health System
- $ $ 
- Integrated Legal Entity
- HEP Initiatives
  - Supply costs
  - Pharmacy Costs

**How You Win:**

- Align internal cost savings initiatives with mandatory/voluntary Medicare and Medicaid programs
- Define quality metrics as a prerequisite for achievement of any cost savings goals
- Align performance targets between physicians and administration
- Distribute performance across key metrics on a regular basis (as close to real-time as possible)
- Engage employed and independent providers into the program
- Use this program to “practice” value-based contracting competencies prior to engaging a third-party
Value-based contracting options

Pay-for-performance based contracts

**Pay-for-performance** (or per-member-per-month PMPM) contracts are typically defined by a select number of evidence-based guidelines that have direct payments for compliance. They typically involve process-based metrics, which identify gaps in care for defined populations.

### Performance Management

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Target</th>
<th>Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body Mass Index</strong></td>
<td><strong>Defined population:</strong> Assigned members between 18-74 years of age who had an OP visit&lt;br&gt;<strong>Criteria:</strong> Organization must calculate and document patients height, weight and BMI in the patient’s chart and submit a claim with the specific diagnosis code indicating such services were provided</td>
<td>&gt; 61%</td>
<td>$3.00 PMPM</td>
</tr>
<tr>
<td><strong>Breast Cancer Screening</strong></td>
<td><strong>Defined population:</strong> Assigned female members from 40-69 years of age&lt;br&gt;<strong>Criteria:</strong> Organization must ensure that each eligible woman has had a mammogram during the measurement year or the prior year to screen for breast cancer</td>
<td>&gt; 70%</td>
<td>$2.50 PMPM</td>
</tr>
</tbody>
</table>

### How You Win:

- Utilize an integrated legal entity as the vehicle for change
- Define the patient population that your organization is managing
- Identify the high-risk patients that represent performance metrics
- Agree to receive clear, simple and accurate dashboards with third-party on a regular basis
- Align incentives with all providers involved in the care for the defined patient population
Medicare Bundled Payments, formally called Bundled Payments for Care Improvement (BPCI) has been gaining popularity since inception in 2011; currently more than 6,000 organizations are participating or evaluating participation today. BPCI makes a single provider responsible for Medicare expenditures for an episode of care, including expenditures by any Medicare providers.
Commercial bundled payments share principles in common with Medicare bundled payments, including taking episodic risk beyond a providers’ direct sphere of responsibility, financial incentives/disincentives, and quality measurements.

The best episode of care from a commercial insurers’ perspective is **an episode that never happens.** It is avoided by identification, treatment, and management.
Value-based contracting options

Shared Savings

Shared savings contracts are regularly scheduled FFS payments in addition to opportunities for bonus payments based on the achievement of quality targets and decreased expenditures.

**Performance Management**

<table>
<thead>
<tr>
<th>Quality and Efficiency Metrics</th>
<th>Baseline</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Day Readmission Rate</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>HEDIS Measures</td>
<td>%</td>
<td>%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cost Metrics</th>
<th>Baseline</th>
<th>Target 1</th>
<th>Target 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admissions Trend</td>
<td>#</td>
<td>1% Reduction</td>
<td>3% Reduction</td>
</tr>
<tr>
<td>Total Payout</td>
<td>$50,000</td>
<td>$100,000</td>
<td></td>
</tr>
<tr>
<td>ER Visits</td>
<td>#</td>
<td>1% Reduction</td>
<td>3% Reduction</td>
</tr>
<tr>
<td>Total Payout</td>
<td>$50,000</td>
<td>$100,000</td>
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**How You Win:**

- Utilize an integrated legal entity as the vehicle for change
- Define the patient population that your organization is managing
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- Agree to receive clear, simple and accurate dashboards with third-party on a regular basis
- Align incentives with all providers involved in the care for the defined patient population
## CINs: Advantages

### 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
- Demonstrate quality for patient satisfaction and enhanced reimbursement

### 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
Large-Scale Network Objectives

1. ACCESS TO PATIENTS
   - **Geography**
     - Secure referral markets
     - Coordination of patients
     - New market growth / penetration
   - **Payer Contracts**
     - Enhance value with comprehensive services
     - Mitigate reimbursement rate pressure
     - Large “buyers”
   - **Marketing**
     - Leverage brand & reputation
     - Local presence with big market access
     - Strength & expertise through scale

2. SHARE COSTS & CAPABILITIES
   - **Information Technology**
     - Platform to build population health analytics
     - Expand Data over continuum of care
   - **Skilled / Scarce Resources**
     - Clinicians (recruitment & outreach)
     - Leadership & oversight
     - Care management teams
     - Payer & population health expertise

3. STANDARDIZE
   - **Operational**
     - Promote best practice adoption
     - Accelerate innovation
     - Benchmark & measure
   - **Clinical**
     - Consolidate duplicative services
     - Drive patient care coordination
     - Enhance quality
   - **Finance**
     - Improve each organization’s cost structure
# Legal Issues Affecting Alignment Structures and CINs

<table>
<thead>
<tr>
<th>Issue</th>
<th>Concerns</th>
</tr>
</thead>
</table>
| Antitrust – Market Concentration and Integration | Impact on competition by:  
• Too many providers/exclusivity in market  
• Competitor joint action without integration |
| Federal Fraud and Abuse – Stark, Antikickback and Civil Monetary Penalties | • Physician financial and referral relationships  
• Hospital incentives/payments 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 provisions  
• Medical practice and licensure  
• Peer review  
• Business of insurance and any willing provider  
• Form of entity and tax considerations |
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 initiatives
  - 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

CIN Governance – Board and Committees
CI and other contracts funds
Payers
FFS

CIN/ACO Entity (New)
Governing Board
IT
Quality
Finance
Other

Participation Agreements (provider services)

Dr./Groups
Group
Hospital
Other Prov.

CI Services
HIE, Portals, Messaging, Care Management, Credentialing

MSO
“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
Clinical Integration – Blended Operational and Legal Definitions

- Clinically Integrated Networks involve arrangements in which:
  - Physicians participate in active and ongoing programs to evaluate and modify practice patterns
  - Create a high degree of 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](http://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 tax-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

• State and local tax exemption issues
  • Cautionary Tale - AHS Hospitals v. Town of Morristown
    • Morristown Community Hospital could lose local property tax exemption
    • June 2015- Judge ruled against AHS/Morristown Community Hospital on account of hospital’s support of for-profit ventures, high executive compensation, compensation for employed physicians, and cost savings initiatives that were viewed by the judge as disguised profit sharing
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 fair market value 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
  - Multiple voluntary safe harbors have fair market value and commercial reasonableness requirements; if an arrangement does not fit within a voluntary safe harbor, it will be subject to case specific analysis and fair market value compensation and a commercially reasonable arrangement could be important for establishing that remuneration is legitimate and not a payment for referrals (see OIG Supplemental Compliance Guidance for Hospitals)

- **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” – note: recent changes in provisions and government guidance regarding CMP

- 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 targets/metrics, and amount (i.e., FMV, reasonableness and other standards)
Revenue Source and Funds Flow Illustration

Clinically Integrated Network

- Operating Capital
- Budget and Business Plan

Hospital/Health System

- Mgmt. Agmt.

Health System Self Insured

- CHI Shared Save

Commercial

- Comm.

Public / MSSP

- Medicare Etc.

- Operating Capital
- Budget and Business Plan

- 30% up to $1M
  60% Drs./10% Hosp.

- 60% Drs./10% Hosp.
  40% PCP
  60% Spec
  60% PCP
  60% Spec

- Up to $2M Based on Performance

- 40% PCP
  Equal./
  Perf.
  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./
  Perf.
  40% Spec
  Equal.

Indiv. Participant
OIG Advisory Opinion Guidance on Incentives

• Incentive Program Concerns:
  • Financial incentives to reduce or decrease patient care ("medically necessary" 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)
Clinically Integrated Network Financial Issues

• State Fraud and Abuse Laws, Including Prohibitions of Fee Splitting
  • Not waived by MSSP waivers; separate analysis required

• 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

• 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

• State/Local Tax Exemption Requirements
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.) a factor?
   iii. Is the risk that the arrangement will be viewed as prohibited remuneration for referrals:
      i. Based solely on whether the compensation is above fair market value?
      ii. Based solely on whether the compensation is below fair market value?
      iii. 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/operation for private benefit?
         ii. Trumped by other concerns, such as whether return is proportional to contributions?
         iii. Based on a definition of FMV that is different from the Stark definition of FMV?
     iii. Is bond counsel involved or required?
     iv. Are there state tax-exemption issues or requirements?
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 tax exemption issues
  ii. State physician self-referral laws
  iii. State antikickback and/or anti-fee splitting laws
  iv. State medical practice laws or regulations that restrict who can be paid how much and/or in what form for specific types of services in healthcare settings
• 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/distributions individual physicians or specific physician groups
  • Services/contributions/distributions for hospital participants
  • Operating or management expenses for the CIN, if funded by the hospital or health system
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/understanding the services
  • Appropriate valuation approaches for what is to be valued, taking into consideration applicable laws and regulations
    • Cost
    • Market
    • Income
  • Challenges in implementing specific valuation approaches under typical circumstances
    • Availability of appropriate data
    • Necessary assumptions
    • Uncertainty about legal “grey” areas and enforcement risk
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 - see grey areas below
      • Payments through different arrangements for the same services - see grey areas below
Fair Market Value Issues

• Selection of an Appropriate Valuation Approach
  • Potential Considerations and pitfalls:
    • Grey areas
      • Commercial reasonableness
        • Are opinions of what is “reasonable” changing?
        • Does commercial reasonableness affect FMV?
    • Stacking of compensation
      • Is it appropriate/reasonable?
      • Does it affect FMV for the subject services?
    • For purposes of determining incentives, is it necessary to differentiate between employed and independent contractor physicians?
    • If MSSP waivers apply, can/should valuater ignore Stark definition of FMV?
    • Patient safety/medical ethics considerations – do they affect FMV?
<table>
<thead>
<tr>
<th>Alignment Method</th>
<th>Payment Form(s)</th>
<th>Typically Reasonable Valuation Approaches</th>
<th>Other Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Gainsharing” (includes “gainsharing-like” arrangements)</td>
<td>Percentage of savings achieved in target efficiency improvement areas, or Fixed amount for achievement of specific efficiency goals</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>
</tr>
<tr>
<td>Clinically Integrated Network (CIN)</td>
<td>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</td>
<td>$ to CIN: market, cost, $ from CIN to physicians: market, cost, $ from CIN to hospital: market, cost, Operating costs of CIN: market, cost</td>
<td>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</td>
</tr>
<tr>
<td>Accountable Care Organization (ACO)</td>
<td>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)</td>
<td>$ from ACO to physicians: market, cost</td>
<td>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</td>
</tr>
<tr>
<td>Accountable Care Entity (ACE)</td>
<td>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)</td>
<td>$ from ACE to physicians: market, cost</td>
<td>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</td>
</tr>
<tr>
<td>Combinations of Above</td>
<td>Variable (Depends on combinations)</td>
<td>Variable</td>
<td>See above</td>
</tr>
</tbody>
</table>

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

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