THE NUTS & BOLTS OF ESTABLISHING
A CLINICALLY INTEGRATED
NETWORK

a presentation for the
American Health Lawyers Association
Physicians and Hospitals Law Institute
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I. Overview

- Clinically Integrated Networks Basic Legal Considerations
  - What is a Clinically Integrated Network (CIN)?
  - Types of CINs
  - Steps in CIN Formation

- Clinically Integrated Network Basic Financial Considerations
  - Financial Models of CINs
  - Tax Implications for Exempt Organization Participants
  - Valuation Issues Applicable to Joint Venture Investments
  - Compensation and Distribution Considerations
  - Value-Based Distribution Measures

- Questions & Answers
II. What is a Clinically Integrated Network (CIN)?

- Simply stated, a CIN is a network of providers that are **sufficiently integrated** at the clinical level that allows them to **contract jointly** with payers.
- Pursuant to DOJ and FTC Policy Statement (1996)
  - A provider network’s active and ongoing program to evaluate and modify practice patterns by the networks’ providers which create a high degree of interdependence and cooperation among the providers to control costs and ensure quality.
II. What is a CIN?

• What is the **Prime Objective** of a CIN?
  – **The Triple Aim**
    • A framework by which health care providers:
      1. Increase the **health** of a population
      2. Improve the **experience** of care
      3. Lowering per capita health care **costs**

http://www.hnhblhin.on.ca/Page.aspx?id=9158
II. What is a CIN?

• How do CINs Achieve the Triple Aim?
  – Standardized *practices* and *protocols* including:
    • Collaborative education programs including online education for physicians and staff
    • Specific disease clinics that assist practitioners
    • Disease registries that track outcomes and follows up with patients for additional services
    • Sets out unique clinical pathways in practicing
    • Incentive payments for positive results
II. What is a CIN?

- Why do providers want to join/form a CIN?
  - **CIN’s Ultimate Business Purpose**: Allow providers who are not otherwise economically aligned to engage in **joint contracting** with third party payers.
  - CIN providers may receive **enhanced reimbursement rates** from payers.
II. What is a CIN?

• Why do payers want to give enhanced rates to CIN participants?
  – Because of the **cost savings** created by the CIN’s **policies and protocols**.
  – CIN’s:
    • Establish and maintain mechanisms to monitor and control utilization of services which control costs and ensure quality of care
    • Selectively choose network providers who are likely to further efficiency objectives
III. Types of CINs

- CINs are more than Medicare Accountable Care Organizations
  - **Accountable Care Organization (ACO)**
    - Groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients
    - Medicare ACOs are subject to specific federal requirements
    - Not all ACOs are Medicare ACOs.
III. Types of CINs

- **Physician Health Organization (PHO)**
  - Joint ventures between a hospital (or more than one hospital) and physicians (or an IPA) who generally have admitting privileges there
  - Hospital and physician members sometimes contract jointly through the PHO with MCOs to provide care to a population of patients

- **Independent Practice Association (IPA)**
  - IPAs are networks of independent physicians that, among other things, may contract with MCOs and employers.
  - IPAs may be subject to various state reporting/inciporporation requirements, e.g., New York State requires the corporate name to include “IPA” and it must get Department of Health certification before formed.
III. Types of CINs

• Organized Delivery System (ODS)
  – Legal entities that contract with an insurance carrier for the purpose of providing or arranging for the provision of health care services to those persons covered under a carrier’s health benefits plan, but which is not a licensed health care facility or other health care provider
  – Broad types of entities. Preferred provider organizations (“PPOs”), PHOs, and IPAs all may fall within the definition of an ODS.
  – May be subject to licensure requirements with the state in which they contract.
III. Types of CINs

- Although many CINs are started by hospitals, there is no requirement for hospital involvement.
IV. Steps in CIN Formation

1. Non-Disclosure Agreement

• Non-Disclosure Agreement (NDA)
  – All potential members enter into an NDA which limits disclosure of information provided to other parties
  – Key Issues:
    • Definition of Confidential Information
    • Return of Confidential Information
    • Non-Solicitation/Standstill
    • Limit disclosure of payer contracting information
IV. Steps in CIN Formation

1. Non-Disclosure Agreement

- Sample Payer Confidentiality Language:
  - **Confidential Information Not to be Disclosed.** The parties do not intend to exchange, divulge or share information concerning the prices or fees charged for professional or technical services, or to otherwise agree, collude, conspire or otherwise act so as to fix prices for services, engage in group boycotts or take any other actions which are prohibited under applicable anti-trust laws. **ACCORDINGLY, NONE OF THE PARTIES NOR ANY OF THEIR OWNERS DIRECTORS, MANAGERS, OFFICERS, EMPLOYEES, CONTRACTORS OR AGENTS WILL SHARE, EXCHANGE, DIVULGE, REVEAL OR DISCLOSE TO EACH OTHER ANY INFORMATION THAT PERTAINS TO THE FEES CHARGED FOR SERVICES RENDERED BY A PRACTICE, OR TO THE MEANS OF DETERMINING SUCH FEES, OR TO THE AMOUNTS OF REIMBURSEMENT FOR ANY SUCH SERVICES BY THIRD PARTY HEALTH INSURERS.**
IV. Steps in CIN Formation

2. Retain Professionals

- Accountants
- Lawyers
  - Regulatory
  - Anti-Trust
  - Corporate
- Insurance Brokers
- Consultants
IV. Steps in CIN Formation

3. Due Diligence

- Licensure Requirements
  - Review state law regarding licensure requirements
  - Examples:
    - **New York**: IPAs must obtain a Consent from the Commissioner of the Department of Health prior to filing a certificate of incorporation, (or, in the case of a limited liability company, articles of organization) with the Secretary of State.
    - **New Jersey**: ODSs may be required to be licensed with the New Jersey Department of Banking and Insurance if they assume financial risk as defined by N.J.A.C. 11:22-4.2.
IV. Steps in CIN Formation

3. Due Diligence

- **Stark and State Self-Referral Laws**
  - Analyze each aspect of the CIN, with particular attention to policies surrounding network referrals under the Stark Law and its state equivalent, if applicable.
  - Multispecialty CINs which limit referrals only to in network participants need to carefully consider whether the group practice exception is applicable or attainable.
  - Contracts with providers should be structured in a way that they comply with Stark exceptions including:
    - **Direct Compensation Exception**: FMV and not take into account referrals
    - **Indirect Compensation Exception**: FMV and not take into account referrals
IV. Steps in CIN Formation

3. Due Diligence

- Federal and State Anti-Kickback Concerns
  - Analyze each aspect of the CIN with regard to federal and state anti-kickback laws, if applicable
  - Particular attention should be directed to CIN purchasing drugs and medical equipment and incentive payments made directly to CIN providers, which may raise anti-kickback concerns
  - Payments from the CIN should be constructed to fall into one of the safe harbors such as:
    - Employment safe harbor (payments to W-2 for medical services); or
    - Personal services safe harbor (set in advance at fair market value)
IV. Steps in CIN Formation

3. Due Diligence

- HIPAA and HITECH
  - CINs share Protected Health Information (PHI) amongst providers
  - HIPAA, HITECH are applicable and arrangements under the CIN must be analyzed
  - Each procedure by which PHI is shared, must be carefully reviewed under HIPAA and HITECH and any state privacy law, if applicable

- It is recommended that Business Associate Agreements (BAAs) be in place for all parties dealing with the CIN
IV. Steps in CIN Formation

3. Due Diligence

- **Antitrust**
  - Generally, federal antitrust statutes **prohibit price fixing** and other **anticompetitive arrangements**
  - All CIN arrangements, especially those related to contracting with payers, should carefully analyzed under antitrust law
  - Independent, **competing providers’ joint negotiation of fees** through a CIN may raise antitrust concerns
  - FTC has not identified specific criteria to provide a safe harbor for providers clinically integrating and engaging in joint contracting, but has provided some guidance through statements and advisory opinions
### IV. Steps in CIN Formation

#### 3. Due Diligence

- **FTC Norman PHO Advisory Opinion, February 13, 2013**
  
  **Facts**
  
  - Health system between the Norman Physicians Association (LLC of Physician members) and the Norman Regional Health System (Collection of Hospitals owned by the City of Norman and the Norman Regional Hospital Authority)
  
  - 280 Participating Physicians; 38 Specialty Areas
  
  - The PHO is managed by 11 representatives: 3 from the Health System and 8 elected physician members
  
  - Generated money from membership fees and dues
  
  - Began as a messenger model where PHO would contact with payers
  
  - Eventually the participating members would enter into joint contracting negotiations with payers
IV. Steps in CIN Formation

3. Due Diligence

- **How Norman PHO is Clinically Integrated?**
  - **Infrastructure:**
    - Multiple physician led advisory groups and committees that were responsible for developing the clinical practice guidelines (including protocols) on an ongoing basis
  - **Electronic Platforms and Interface**
    - Extensive electronic system including e-prescribing, EHR and electronic health interface system, which allowed the CIN to measure and evaluate physician performance and compliance with the clinical practice guidelines established by Norman PHO
• **How Norman PHO is Clinically Integrated?**
  
  – **Physician Involvement**
    • Each aspect of the CIN was guided or facilitated by the participating physicians
    • Each physician would make “meaningful contributions” to the CIN
  
  – **Payer Contracting and Non-Exclusivity**
    • Providers required to participate in all payer contracts of the CIN
    • Allowed to independently contract with any payers not in contract with the CIN.
IV. Steps in CIN Formation

3. Due Diligence

• FTC’s Antitrust Analysis
  – Applied the rule-of reason analysis to determine whether the CIN’s anticompetitive effects outweigh its overall efficiencies and pro-competitive effects of the CIN
  – Based on the clinical integration program components, the FTC opined that the Norman PHO would not pursue antitrust liability against the CIN
IV. Steps in CIN Formation

4. Choice of Entity

- **Choice of Entity**
  - **Limited Liability Company**
    - Certificate of Formation
    - Operating Agreement
  - **Limited Liability Partnership**
    - Certificate of Formation
    - Partnership Agreement
  - **Corporation (S Corp or C Corp)**
    - Certificate of Incorporation
    - Bylaws
    - Shareholders Agreement
  - **Partnership**
    - Certificate of Partnership
    - Partnership Agreement
IV. Steps in CIN Formation
5. Owners’ Agreement

- Operating Agreement/Stockholders Agreement/Bylaws
  (See Exhibit C in outline for sample provisions)
  - Business and Purpose
  - Owners/Members vs. Participants
    - Distinguish Owners/Members from Participants
    - Eligibility
    - Admission
    - Removal
    - Classes
    - Responsibilities
    - Participation Agreement
IV. Steps in CIN Formation

5. Owners’ Agreement

- **Management/Governance**
  - Board of Directors/Managers
    - Number
    - Term
    - Qualifications
    - Who elects?

- **Voting**
  - Managers vs. Owners/Members vs. Participants
    - Majority Matters
    - Supermajority Matters
      - Election/removal of managers
      - Election/removal of officers
      - Addition of additional classes of members
      - Amending company documents
IV. Steps in CIN Formation

5. Owners’ Agreement

• Committees
  – As was noted in the Norman advisory opinion, the FTC and OIG, when conducting an antitrust analysis, will focus on whether there are physician-led committees that establish the policies and protocols for the CIN.
  – Examples of CIN Committees
    • **Nominating Committee**: Charged with nominating and vetting physician members for leadership roles in the CIN.
    • **Initiatives Committee**: Responsible for identifying weaknesses of the CIN and formulating new initiatives to address these weaknesses.
    • **Measures Committee**: Charged with formulating processes and procedures by which the evidence and information from members is captured, processed, and analyzed.
    • **Payer Committee**: Responsible for crafting means and methods of contracting with payers
IV. Steps in CIN Formation

5. Owners’ Agreement

– Confidentiality
  • Who will have access to confidential information?
  • How will the CIN handle confidential information?
  • Will certain members/participants be required to take certain steps in protecting confidential information?
  • Will members/participants have to enter into business associate agreements?

– Conflicts of Interest
  • Under what instances does a conflict exist?
  • How will members/participants handle conflicts of interest?
  • What is the duty to disclose?
• **Protocols** are clinical methodologies developed through evidence based research

  – Protocols are unique to each CIN, for example:
    • Limiting the use of an expensive drug to circumstances where necessary.
    • Recommend that a child see a dentist to establish a dental home by age 1 or within six months from eruption of the first primary tooth.
• **Policies** are standards that providers must follow to be in the CIN, for example:
  
  – Providers must participate in the Clinical Integration program and allow the CIN **access to the data and information** necessary to track and report Physician’s performance in connection with the CIN.
  
  – Providers must maintain **active e-mail and high-speed internet** access while adopting a **single electronic medical record system** adopted by the board.
  
  – Assist the company in educating other members in **standard coding procedures** to be utilized for claims submission and clinical integration information technology.
IV. Steps in CIN Formation

6. Policies and Protocols

- Protocols should be in the hands of the physician led Board of Directors and Committees
- As noted in the Norman PHO Advisory Opinion, a focus of regulatory agencies is whether the physicians are actively involved in the crafting and evolution of the policies and protocols of the CIN
- These policies and protocols should not be delegated to an outside agency or management company
IV. Steps in CIN Formation

7. Participation Agreement

• **Participation Agreement** - governs the participating physician provider relationship with the CIN. It serves as the link between the providers and the CIN (See Exhibit B in outline for sample provisions)

  – **Physician Participants**
    • Qualifications?
    • Responsibilities?
    • Participation in other CINs?
    • Ability to compete?
IV. Steps in CIN Formation

7. Participation Agreement

- Development of the Clinical Integration Program (CI Program)
  - Participating providers responsibilities and duties in develop of the CI Program?
  - Will the participating providers have to share data with the CIN? To what extent?
  - Will the CIN be able to use the participating providers’ name?
  - How will the member/participant be made aware of changes to the CI Program?
  - What is the process for developing new policies and protocols?
IV. Steps in CIN Formation

7. Participation Agreement

• Financial Arrangements
  – How will owners/members vs. participants enter into financial arrangements with payers?
  – How will money flow through the CIN?
V. CIN Contracting

- Contract documents represent the glue that binds the parties
- Negotiating favorable managed care contract rates brings additional value to the CIN through improved revenues and better opportunities for provider distributions
- Rates include fee-for-service base rates, episodic (bundled) rates, risk arrangements, P4P arrangements, shared savings
- Trend toward employer health benefit plan and narrow network contracting
V. CIN Contracting

• Economic Provisions of Managed Care Contracts
  – Rate analysis
  – Cost analysis
  – Stop-loss provisions
  – Incentive bonus arrangement
V. CIN Contracting

• Non-economic Provisions of Managed Care Contracts
  – Patient attribution or covered lives
  – Contract term
  – Termination provisions
  – Exclusive contracting
  – Out-of-area coverage
  – Covered services
  – Audit rights
V. CIN Contracting

- Other Contract Terms
  - Reimbursement changes
  - Payer-required representations
VI. Financial Considerations

- Budgeting and Financial
  - Capital and operational budgeting
  - Market returns to equity investors
  - Reinvestment in infrastructure
  - Value-based distributions
VI. Financial Considerations

- Tax Implications for Exempt Organizations
  - Unrelated business income
  - Private inurement
  - Private benefit
  - Intermediate sanctions
  - Provisions applicable to Exempt ACOs participating in the Medicare Shared Savings Program (MSSP)
VI. Financial Considerations

- Valuation Issues Applicable to Joint Ventures
  - Definition of Fair Market Value (FMV)
  - CMS Commentary on FMV
  - Valuation approaches and methodology
    - Asset-based approach
    - Income-based approach
    - Market-based approach
    - Valuation discounts
    - Synthesis and reconciliation
VI. Financial Considerations

• Compensation and Distribution Considerations
  – Physician service compensation
  – Value-based distributions
  – Valuation approaches and methodology applicable to compensation and distributions
    • Cost approach
    • Income-based approach
    • Market-based approach
    • Synthesis and reconciliation
VI. Financial Considerations

• Value-Based Distribution Measures
  – Attraction of the clinically integrated organizations lies in part in the diversity of its providers
    • Not all provider classes, and not all providers of the same provider class, contribute to the value proposition in the same manner
    • Because the way providers add value to the organization can be significantly different, rewards should ultimately be representative of the relative contributions of value.
VI. Financial Considerations

- Value-Based Distribution Measures
  - Pooling of distributable value by provider class
    - Provider classes ultimately share the reward system based on relative contribution toward overall value
    - Historically high-cost providers may not always represent the largest contributors to high quality at the lowest cost
    - Rewards are based on appropriate, high-quality, cost-effective care
    - Systems that encourage and distribute financial rewards based on the domains of cost-effective care, collaborative care, and clinical outcomes measures set the appropriate direction for the entire organization
VI. Financial Considerations

• Value-Based Distribution Measures
  – Selection of appropriate measures
    • Cost-effective care
      – Clinically integrated providers add value to the organization in different ways
        • Reducing hospital readmissions by post-discharge care management can reduce or eliminate reimbursement penalties while also reducing direct and indirect patient care cost
        • Improved screenings can improve patient wellness and reduce the high costs of catastrophic disease
      – Measures should be analyzed at both the individual provider and organization-wide levels
VI. Financial Considerations

• Value-Based Distribution Measures
  – Selection of appropriate measures
    • Collaborative care
      – Collaboration, coordination, and communication is essential for high quality, cost-effective care
      – Teamwork benefits the patient, individual providers, care teams, health facilities, and payers
      – Teamwork measures set goals for groups of providers in reaching the clinically integrated organization’s overarching objectives and foster the ideal environment for coordinated care
      – Transition along the fragmented points of care in the health care delivery model is essential to successfully managing care in the clinically integrated environment.
VI. Financial Considerations

• Value-Based Distribution Measures
  – Selection of appropriate measures

• Clinical quality
  – Employ nationally recognized, evidence-based best practices for care
  – Input from clinicians committed to the success of the project creates metrics that are adaptable to the applicable initiative and the associated providers and specialties.
VI. Financial Considerations

- Value-Based Distribution Measures
  - Weighting of measures
    - Clinician-leaders and C-suite leadership should give input into the selection and weighting of measures promotes unity, consistency, and transparency
    - Well-designed scoring system permit objective, dashboard-type reviews of provider performance and trends against targets and peers
    - Decisions are made during the planning stages regarding the relative importance that the domains of cost-effective care, collaborative care, and clinical outcomes factor into the success of the clinically integrated organization
VII. Data Analytics

- Twenty to 30 percent of health spending is “waste” that yields no benefit to patients
  - Therapies, care, diagnostic tests, and goods that are unnecessary or of no added value
  - Harmful, defective, or ineffective health care goods and services
  - Variation or inefficiency in delivery of health care goods and services
- CINs and providers must embrace new clinical behaviors and deploy systems to support these behaviors
VII. Data Analytics

- Using data to improve performance and outcomes
  - Process improvement begins with data capture to gather the clinical information needed to drive the measures and assimilation of data elements to drive the analysis
    - Electronic data warehouse systems extract pertinent information using common identifiers from EHR, billing, financial, administrative, patient satisfaction, and registries
    - Interpretation and action lead to improvements in efficiency, clinical processes, and care coordination across multidisciplinary teams
  - Dashboards yield useful information in the management of the clinically integrated organization
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