

Clinically Integrated Networks; The PHOs of the Twenty-First Century?

a presentation for

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Agenda

- Why Clinically Integrated Networks (CINs) Are Needed?
- How Are CINs Similar to PHOs/ How They Differ?
- What's In It for Physicians/ for Hospitals/ Others?
- How Are CINs Organized and Governed?
- What Tools Are Needed for CINs to Be Successful?
- What Are the Major Regulatory Hurdles?
 - Antitrust
 - Fraud & Abuse
 - Tax
 - HIT- Meaningful Use
 - Insurance and Other State Law Issues
- Case Study



The New Realities: Physician Employment vs. Independent Practice

- Growth in hospital employment of physicians
- Co-existence with independent medical practices
- As reimbursement changes under reform, these two camps will need to work together more than ever
- Hospitals are seeking alternative strategies for doctors who don't want to give up private practice
- The “mixed medical staff” has re-awakened an interest in building hospital-physician networks similar to the PHOs of the 80s and 90s



Why Many PHOs Failed to Achieve Their Objectives

- PHOs rarely had the infrastructure to manage the risk they assumed under contracts with MCOs
- In particular, health information technology was in its infancy, so essential data was often hard to come by
- Non-risk bearing PHOs attracted the scrutiny of payers and regulators because they were neither financially integrated nor clinically integrated
- The hey-day of the PHO was brief, but some survived and went on to become what might now be viewed as the antecedent of the ACO



Doctors Still Desire What PHOs Promised But Failed To Deliver

- Higher reimbursement
- More efficient claims administration
- Improved health information technology
- Ability to deliver better care and get paid for it



The Hurdles Faced By Independent Practitioners Getting Ready For Reform

- Lack of capital and management expertise
- Fee-for-service medicine acts as a disincentive to improving quality and cost-efficiency
- Existing medical staff structures provide no incentives for improvement
- Commercial payers are not waiting for ACOs to blossom – they want to contract with providers who will collaborate to keep costs low and improve outcomes



Why Hospitals Are or Should Be Interested in a Network Strategy

- Not getting the cooperation of physicians in controlling costs and improving quality
- Not being attractive to third party payers who are willing to do bundled payments, P4P, shared savings and other performance-based contracts
- Losing the loyalty of physicians to competitors who have such contracts
- In the post-ACA environment, hospital-physician alignment will require a common vehicle for managing patient care and getting paid fairly



What Are Clinically Integrated Networks (“CINs”) and How Do They Differ From PHOs, Etc.?

- CINs are arrangements (usually separate legal entities) sponsored by hospitals but led by physicians who assemble the resources required to manage care for defined patient populations
- Like PHOs, CINs are “membership” organizations requiring doctors to meet strict criteria
- Unlike PHOs, they are under-inclusive (think of the hospital’s “A” team)
- They may evolve into ACOs, but don’t need to



Ultimate Purpose of a CIN Is to Allow Providers to Engage in Joint Contracting

The most effective networks require:

1. Every physician to participate in every contract
2. Adherence to common set of quality, safety, cost-effectiveness measures
3. Ability to share in incentive funds
4. Infrastructure (e.g., governance, IT, training) to support CIN objectives
5. Ability to achieve market recognition



Ultimate Purpose of a CIN Is to Allow Providers to Engage in Joint Contracting

Providers who are not economically integrated (such as independent physicians) may not engage in “single signature” third-party contracting unless they become clinically integrated (more on this later)



What Benefits Do CINs Provide to Payers and Patients?

- Ability to deliver progressively improved quality outcomes from:
 - Incentives for positive results
 - Collaborative education for physicians and staff
 - Standardized practices and protocols
 - Specific disease clinics to support practitioners
 - On-line resources
 - Disease registries that track outcomes and recall patients when needed



What Benefits Do CINs Provide to Payers and Patients?

- Ability to make progressively greater use of health information technology:
 - Access test results and discharge data
 - Track patients with chronic disease
 - Fill prescriptions with prompts that identify opportunities for generic substitution
 - Generate report cards on physician performance
 - Electronic data interchange (EDI) to submit bills to payers and receive expedited payment



Who Else Benefits From CINs?

- Primary care physicians can be given an elevated status in a CIN, i.e., their role in governance
- Patient-centered medical homes can also be given an important role in a CIN
- Patients can get greater accessibility through:
 - e-visits
 - group sessions
 - use of APNs



Who Else Benefits From CINs?

- Hospitals can use CINs to address community health needs, improved patient safety, greater use of hospitalists, cost reduction, and strengthening physician loyalty
- Post-acute providers and ancillary service providers can be beneficiaries of network case managers directing patients to more appropriate sources of care, e.g. home health agencies



How Are CINs Organized and Governed?

- Choice of Entity/ Organizational Structure
 - Separately organized entities, but form may vary
 - Essentially a membership organization, typically an LLC or non-profit corporation
 - Allow multiple classes of membership
 - For profit forms are available, but in most cases pass-through taxation to CIN's members is desired
 - By themselves, CINs are unlikely to qualify for tax exemption; however, they may be positioned in an exempt system to promote population health and serve other charitable purposes



How Are CINs Organized and Governed?

- Mutual Dependency of Physicians and Hospitals
 - Physician seek:
 - Access to facilities and technology
 - Access to capital
 - Professional administrative leaders
 - Support for clinical care re-design
 - Access to health information technology
 - Structure for shared decision making
 - Common interface with multiple health plans



How Are CINs Organized and Governed?

- Mutual Dependency of Physicians and Hospitals
 - Hospitals seek:
 - Stable professional staff
 - Loyal and engaged physicians
 - High quality clinical supervision
 - Encouragement of cost-effective practices
 - Adoption of health information technology
 - Medical leadership
 - Strategic positioning for health reform



How Are CINs Organized and Governed?

- Physician Membership
 - CINs must be more concerned about the quality of their physician membership than their size
 - Physicians must be committed to:
 - Compliance with credentialing standards
 - Sharing of clinical data electronically with the CIN and their peers
 - Active participation in the clinical improvement process
 - Submission to CIN's authority within certain parameters
 - Participation in CIN's managed care contracts once the CIN achieves clinical integration
 - Avoidance of conflicts of interest



How Are CINs Organized and Governed?

- Physician Membership
 - CINs may require a participation fee but unlike other ventures they do not expect physicians to contribute substantial capital
 - Although the CIN may distinguish between employed and independent physicians, it is advisable to diminish the importance of who a doctor works for
 - Embracing a diverse physician membership supports the CINs clinical and business objectives




How Are CINs Organized and Governed?

- Role of the Hospital or Health System
 - Typically the sponsor of the CIN, but physician-only examples do exist in some markets
 - Balancing hospital and physician interests is key
 - Hospitals bring capital, HIT and administrative support, but at a price – they expect certain reserved powers (especially if tax exempt) and a place “at the table”
 - That being said, most CIN boards are dominated by practicing physicians




How Are CINs Organized and Governed?

- **Boards, Committees and Officers**
 - Multiple layers of governance are common
 - Board of directors (or equivalent) reflects the “balance of power” but is usually physician-led
 - Class voting, super-majority voting requirements and reserved powers are combined to forge a sustainable compact between the hospital and physicians
 - Boards set policy and make strategic decisions, but committees are where most work is done
 - Officer positions are shared among different interest groups, but usually tip in favor of physicians




What Tools Do CINs Need to Improve Clinical and Financial Outcomes?

- Comprehensive Physician Performance Data Sets
 - EMRs
 - Billing Records
 - Scheduling Records
 - CMS Core Measure Reports
 - Joint Commission OPPE reports
 - Co-Management Reports




What Tools Do CINs Need to Improve Clinical and Financial Outcomes?

- What Can Be Learned From Comprehensive Physician Performance Data Sets?
 - General performance (LOS, cost per case, patient volumes)
 - Hospital utilization (pharmacy, imaging, lab, supplies)
 - Quality outcomes (readmissions rates, complication rates, mortality rates)
 - Hospital charges vs. rates
 - Other performance measures (e.g., patient satisfaction, comparison with evidence-based medical protocols)




What Tools Do CINs Need to Improve Clinical and Financial Outcomes?

- Practice Protocols, Performance Metrics and Other Standards
 - Need to encourage physicians to adopt protocols, etc. that minimize variation in care
 - Physicians need a better understanding of the clinical and economic forces that impact care and be willing to collaborate with others
 - Protocol development should be placed in hands of those physician leaders who exemplify “best practices”
 - The organizational structure of the CIN must empower developers of evidence-based protocols
 - Need to invest in training physicians and other clinicians




What Tools Do CINs Need to Improve Clinical and Financial Outcomes?

- Performance-Based Incentives
 - Outcome-based compensation is still uncommon, but that's about to change
 - Even in FFS environment, a CIN has the ability to encourage best practices
 - Use of incentive funds is the best way to overcome the deficiencies of the traditional FFS system
 - Until these funds are paid by third parties, hospitals may need to fund performance improvement



What Tools Do CINs Need to Improve Clinical and Financial Outcomes?

- Performance-Based Incentives: Key Questions
 - How much incentive is needed to change behavior?
 - What is proper balance between group and individual rewards?
 - How frequently should CIN measure effectiveness?
 - What process is needed when incentives don't work?
 - How should regulatory issues be addressed?
 - Also consider non-monetary incentives:
 - Awards/ recognition for clinical excellence
 - Research opportunities
 - Improved administrative/ technical support



What Tools Do CINs Need to Improve Clinical and Financial Outcomes?

- Preparing for New Reimbursement Methods
 - The strongest reason for building a CIN is to allow providers to engage in joint contracting for the purposes of receiving performance-based compensation
 - As a precursor to new forms of compensation, some CINs have chosen to be “narrow networks” that drive volume to their members. There is, however, risk in this approach.
 - Skills needed for shared savings and other alternative payment methods:
 - Patient attribution
 - Chronic disease management
 - Transitioning patients to post-acute care settings
 - Improved patient communications



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Generally

- **Independent, competing providers' joint negotiation of fees** through a CIN may raise antitrust concerns.
- Federal Trade Commission ("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.



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Background on the Antitrust Laws

- Basis is Section 1 of the Sherman Act
- Two methods of analysis under Section 1 of the Sherman Act
 - **Per Se Rule**: certain conduct, including agreements by **horizontal competitors to fix prices and allocate markets**, is deemed so egregious and lacking in redeeming value that it is per se illegal; and
 - **Rule of Reason**: conduct is subject to a fact-intensive analysis that takes into account the reason for the restraint and its effects on competition, both pro-competitive and anticompetitive, resulting in a **balancing of the pro-competitive benefits of the arrangement against its anticompetitive results.**



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Background on the Antitrust Laws

- If a court identifies a particular restraint on trade, the arrangement will automatically be declared unlawful.
- Agreements to **fix prices or divide up a market among competitors** have been declared unlawful under the Per Se Rule.
- Section 2 of the Sherman Act **prohibits** monopolization, **attempts to monopolize and conspiracies to monopolize**.
- Section 7 of the **Clayton Act** prohibits acquisitions of stock or assets if their effect “may be substantially to lessen competition, or to tend to create a monopoly.”
 - This has been construed to **apply to the formation of joint ventures between actual or potential competitors**.



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Provider Network Statements, Analysis and Advisory Opinions

- **1996 Joint United States Department of Justice and FTC Statements of Antitrust Enforcement Policy in Health Care – Statements 8 and 9 (the “Statements”)**
 - **Clinical integration of physician or multi-provider networks could lead to significant enough efficiencies to obtain Rule of Reason treatment, despite the absence of sufficient financial risk sharing.**
 - **Risk-sharing networks and clinically integrated networks are automatically evaluated under the Rule of Reason.**



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Provider Network Statements, Analysis and Advisory Opinions

- Substantial **financial risk sharing factors** include:
 - **Capitated contracts** between the network and health plans;
 - Where the network creates significant **financial incentives** for its providers to **meet cost containment** goals;
 - Where provider reimbursement is based on a percentage of health plan premiums or revenues;
 - Where overall cost or utilization goals are established and subsequent financial rewards or penalties apply to those goals; and
 - Where the network has **global or all inclusive** case rates.



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Provider Network Statements, Analysis and Advisory Opinions

- Substantial **clinical integration** factors:
 - Establishing mechanisms to manage utilization and to control costs and ensure quality;
 - Selectively choosing network participants who are likely to further efficiency objectives; and
 - Investments in resources needed to realize the network's efficiencies.



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

MedSouth Independent Practice Association (“IPA”) Advisory

Opinion: although the participating physicians constituted over 50% of the physicians with admitting privileges at the hospitals in the service area, the FTC concluded that the network would be unlikely to raise antitrust concerns due to the non-exclusive nature of the network and the presence of other efficiencies.

- **3 goals of MedSouth IPA:**

- Coordinate its participants’ delivery of care services;
- Implement a clinical resource management program with clinical information sharing, development and implementation of clinical protocols, and oversight and monitoring of performance against pre-established benchmarks; and
- Negotiate with payors as a network of collaborating physicians to improve quality and integrate physician services and efficiency tools.

- **Tools**

- A web-based clinical data record system;
 - Create, adopt, implement and monitor clinical practice protocols;
 - Impose performance goals on participants relating to service quality and utilization. Each physician would be required to
- **Contracting:** Negotiate fee-for-service rates with commercial managed care payers on a non-exclusive basis.



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Greater Rochester IPA Advisory Opinion: the FTC concluded that the proposed IPA would involve **substantial integration** among the physician participants that had the potential to produce significant efficiencies and that joint contracting, even if it resulted in higher rates, was reasonably related to the IPA's planned integration and efficiencies.

- Implemented practice guidelines and quality benchmarks.
- Monitored individual and collective performance in applying the guidelines and achieving benchmarks.
- Used an electronic clinical-information system through which participants would share clinical information related to their common patients, order prescriptions and lab tests electronically, and access patient information from hospitals and ancillary providers throughout the community.



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

TriState Health Partners Advisory Opinion: the FTC approved a clinical integration program established by a physician-hospital organization.

- Although participation was generally very open to physicians, the number of requirements imposed on participants appeared to be designed to limit participation to those who would be fully committed to the network.
- Substantial investment of time and effort and some, although modest, financial investment in the network by participants was present.
- Infrastructure was put into place to foster increased interaction and cooperation among participants to achieve efficiencies including a health information technology system, clinical practice guidelines, monitoring of physician performance targets and policies and procedures related to utilization management, case management and disease management.
- Measurement and evaluation of physician performance was deemed important, although the FTC noted that the network's systems for doing so had yet to be fully developed.



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

It is important to note that there is **no specific antitrust guidance for CINs**, but should Consider:

Final Statement of Antitrust Enforcement Policy Regarding ACO Participating in the Medicare Shared Savings Program

- Although ACOs and CINs are not exactly the same, they **share many characteristics** for antitrust analysis purposes that some guidance for CINs may be gleaned from the Final Statement.
- Participants in CINs should not share competitively sensitive information.
- Exercise caution with exclusivity arrangements with CIN participants especially in light of high participation by providers in the applicable market



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Other Considerations:

- CINs should aim to **improve quality of care and access** to high quality of care while at the same time reducing costs
- Do not assume that participation thresholds % in the Statements are absolutely binding under all circumstances (must look at the relevant markets).
- If there is high participation, the CIN may need to justify why high participation is necessary to achieve its objectives
- Generally, the pro-competitive efficiencies of the CIN must **outweigh** the potential anticompetitive effects



What Are the Major Regulatory Hurdles to CIN Development? ANTITRUST

Other Considerations:

- Quality improvement should not just be an objective, but measures should be employed to document and show the improvement.
- Employ clinical practice guidelines for participants
- Participants should collaborate on patient and treatment information and implement health information technology systems to achieve collaboration
- Require participants to be active in achieving the objectives of the CIN by taking part in developing the actual measures used to satisfy those goals
- Monitor participant performance and engagement in the CIN
- Inject significant capital into the infrastructure to be utilized to build the CIN



What Are the Major Regulatory Hurdles to CIN Development? Fraud and Abuse

1. The Federal Healthcare Program's Anti-Kickback Statute (“AKS”) 42 U.S.C. §1320(a)-7b

- Relevant Safe-Harbor Regulation: Electronic Health Records Items and Services Safe Harbor 42 C.F.R. §1001.952(y)

2. Federal Physician Self-Referral Law (the “Stark Law”) 42 U.S.C. §1395nn

- Relevant Stark Law Exception: Electronic Health Records Items and Services Exception 42 C.F.R. §411.357(w)



What Are the Major Regulatory Hurdles to CIN Development? Fraud and Abuse

Requirements to satisfy both AKS Safe Harbor & Stark Exception on Health Information:

Both regulations need specific **requirements** to be satisfied to gain protection under the applicable statute, the majority of which are identical:

1. The hospital and recipient physicians must be within the class of donors and recipients identified under each regulation.

- Donors. With regard to the Stark Law Exception, "entities" are permitted to be donors. Under the Stark Law, any entity that furnishes designated health services is an "entity." There are numerous designated health services, including inpatient and outpatient hospital services. With regard to the Anti-Kickback Safe Harbor, a "donor" is permitted to be **any individual or entity that provides services covered by a federal health care program and submits claims or requests for payment under that program.**
- Recipients. With regard to the Stark Law Exception, **physicians** are the only eligible "recipients" since the Stark Law covers only financial relationships with physicians. With regard to the Anti-Kickback Safe Harbor, eligible "recipients" include **any individual or entity engaged in the delivery of health care.**



What Are the Major Regulatory Hurdles to CIN Development? Fraud and Abuse

Requirements to satisfy both AKS Safe Harbor & Stark Exception:

- 2. Appropriate Scope of Items and Services. The items or services donated must be "software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records." Hardware, such as software with core functions other than as an EHR system, e.g., standalone practice management, is not included.
- 3. The software must be interoperable. Software will meet the definition of interoperable if, at the time of donation, the software is able to: (i) communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications and networks and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.



What Are the Major Regulatory Hurdles to CIN Development? Fraud and Abuse

Requirements to satisfy both AKS Safe Harbor & Stark Exception:

- 4. No Limitations on Donation by Hospital. The donor (or any person on the donor's behalf) may not take any action to limit or restrict the use, compatibility or interoperability of donated items or services with other electronic prescribing or EHR systems.
- 5. No Conditions on Receipt by Physician. Neither the recipient nor the recipient's practice (or any affiliated individual or entity) may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.



What Are the Major Regulatory Hurdles to CIN Development? Fraud and Abuse

Requirements to satisfy AKS Safe Harbor & Stark Exception:

- 6. **Eligibility Not Based on Volume/Value of Referrals.** The donor is permitted to select a recipient and/or the nature of the items or services, provided that the factors that are used do not directly take into account the volume or value of referrals or other business generated between the parties, including factors such as, the total number of prescriptions written by the recipient/physician, the size of the recipient/physician's medical practice, or whether the recipient/physician is a member of the donor's medical staff.
- 7. **Written Agreement.** The arrangement must be set forth in a written agreement that:
 - (i) is signed by the parties;
 - (ii) specifies the items and services being provided, the donor's cost of those items and services and the amount of the recipient's contribution; and
 - (iii) covers all of the EHR items and services to be provided by the donor (or any affiliate).



What Are the Major Regulatory Hurdles to CIN Development? Fraud and Abuse

Requirements to satisfy AKS Safe Harbor & Stark Exception:

- 8. No Knowledge of Equivalent Items or Services. The donor must not have actual knowledge, act in reckless disregard, or deliberate ignorance, of the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.
- 9. No Patient Restrictions. The regulations require that the items or services donated can be used for any patient without regard to payor status and prohibit the donor from restricting or taking any action to limit the recipient's right or ability to use the items or services for any patient.
- 10. Staffing/Relation to Clinical Operations. The regulations specifically prohibit the donor from contributing physician office staff or assistance in converting paper medical files to electronic medical records as part of the implementation process.



What Are the Major Regulatory Hurdles to CIN Development? Fraud and Abuse

Requirements to satisfy AKS Safe Harbor & Stark Exception:

- 11. E-Prescribing Capabilities. Donated EHR software must contain an electronic prescribing capability either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system.
- 12. Cost Sharing. Before receipt of the items and services, the recipient must pay not less than 15% of the donor's cost for the items and services qualifying for the donation.
- This Section only considers Federal law. **State law needs to be independently considered.**



What Are the Major Regulatory Hurdles to CIN Development? Tax Implications of CINs

- **Furthering Charitable Purposes** -- IRC § 501(c)(3)-Broad discretion exists in defining what constitutes a "charitable" purpose.
 - Promotion of Health
 - Lessening the Burdens of Government
 - requires that a tax-exempt, charitable organization demonstrate the following:
 - that a governmental unit considers the activity in question to be a governmental burden; and
 - that participation in the activity lessens the governmental burden in some way.
- **Private Inurement**
 - No part of a tax-exempt, charitable organization's net earnings may inure to the benefit of private shareholders or individuals.
 - This prohibition targets non-fair-market-value transactions with so-called "insiders." "Insiders" are those persons who have an opportunity to control or influence an organization's activities because of their relationship with the organization.



What Are the Major Regulatory Hurdles to CIN Development?

Tax Implications of CINs

Excess Benefit Transactions: Non-fair-market-value transactions that result from the participation of a tax-exempt, charitable organization give rise to private inurement and result in an excess benefit transaction

- "Intermediate sanctions" imposes sanctions on the influential persons in charities who receive excessive economic benefits from the organization
- Persons who are insiders for purposes of the prohibition against private inurement are also disqualified persons..
- excise taxes on "disqualified persons" who receive benefits from § 501(c)(3) public charity that exceed the fair market value of the services that they provide in exchange for the benefits.
 - An initial excise tax equal to 25% of the excess benefit received
 - An additional 200% tax imposed if the disqualified person does not timely "correct" the excess benefit transaction.
 - Officers, directors, or other "organization managers" who knowingly approved the payment of the excessive benefits also incur excise tax liability equal to 10% of the excess benefit (up to \$20,000).
- - A "disqualified person" generally includes any person who is, or during the previous five years was, in a position to exercise substantial influence over the affairs of the exempt organization.



What Are the Major Regulatory Hurdles to CIN Development? Tax Implications of CINs

Private Benefit

- - A Tax exempt organization must be "**operated exclusively**" for one or more of the tax-exempt purposes and must serve a public, rather than a private, interest. It must not be operated for the benefit of private interests or persons controlled, directly or indirectly, by such private interests. This prohibition applies regardless of whether a person is an "insider" or a "disqualified person." As a result, IRC § 501(c)(3) organizations must demonstrate that their activities do not more than "incidentally" benefit private parties.

Impact of CIN Participation on Private Inurement, Private Benefit, and Excess Benefit Transactions

- -The IRS makes determinations regarding the existence of prohibited private inurement, excess benefit transactions, and impermissible private benefit **on a case-by-case basis** based on all the facts and circumstances of the transaction in question.



What Are the Major Regulatory Hurdles to CIN Development? Tax Implications of CINs

Unrelated Business Income

- defined as the gross income derived by an organization from any regularly carried on trade or business that is not related to its exempt purposes.
- in determining unrelated business taxable income, a tax-exempt organization that is partner in a partnership is considered to be directly carrying on its proportionate share of the partnership's activities and must include in unrelated business taxable income its share (whether or not distributed) of the gross income of the partnership.
- "unrelated trade or business" is defined as any trade or business the conduct of which is not substantially related



What Are the Major Regulatory Hurdles to CIN Development?

HIT Subsidies- Meaningful Use

- What are the Three Main Components of Meaningful Use?
 - 1. Use of certified EHR in a meaningful manner (e.g., e-prescribing)
 - 2. Use of certified EHR technology for **electronic exchange of health information** to improve quality of health care
 - 3. Use of certified EHR technology to **submit clinical quality measures (CQM)** and other such measures to be determined



What Are the Major Regulatory Hurdles to CIN Development? Patient Data Privacy and Security

- Participants in CINs need to access, analyze and share PHI to further the purposes of the CIN.
- HIPAA, HITECH and their regulations will apply to the operations of a CIN.
- CIN participants will fall under the definition of “Covered Entity.”



What Are the Major Regulatory Hurdles to CIN Development?

The CIN and its Participants

The Privacy Rule:

- As the CIN is acting as a **Business Associate** for each participant, the CIN should have a **Business Associate Agreement**.
- **Caution must be taken** when one CIN participant seeks to disclose PHI to another CIN participant. Both are Covered Entities and such disclosures are restricted to instances where both Covered Entities have a current or prior relationship with the patient, the PHI to be disclosed relates to that relationship.



What Are the Major Regulatory Hurdles to CIN Development?

The CIN and its Participants

- Organized Health Care Arrangements (“OHCA”)
 - An arrangement whereby Covered Entity participants need to share PHI about their patients to manage and benefit a covered enterprise.
 - There are many types of OHCAs and a CIN may fit in one of these types.
 - A Covered Entity that participates in an OHCA may disclose PHI to another Covered Entity participant for any Health Care Operations of the OHCA.
- Certain Health Conditions may require **specific patient consent** under applicable state and federal laws.



What Are the Major Regulatory Hurdles to CIN Development?

Insurance Regulatory Oversight

- Participants in a CIN may be subject to the jurisdiction and oversight of the applicable **State's Division of Insurance** and could be **considered to have engaged in insurance business**.
- The question is whether the providers are considered to have engaged in the business of insurance without a **license** by assuming financial risk.
- Regulators are concerned when the financial risk (when providers accept financial responsibility for patients' future losses (i.e., the costs of future medical care of the patients) as opposed to costs in connection with identifiable and present medical needs of the patients (e.g., costs of episodes of care) exceeds the scope of provider risk and becomes insurance risk.



What Are the Major Regulatory Hurdles to CIN Development? Insurance Regulatory Oversight

- If a CIN is determined to be subject to state insurance laws, it will likely be required to obtain licensure or certification.
- This would require the CIN to meet:
 - financial solvency
 - capital reserve requirements and
 - reporting obligations.
- Compliance with insurance laws may be burdensome and costly for a CIN.



What Are the Major Regulatory Hurdles to CIN Development? Other State Law Issues

■ Corporate Practice of Medicine.

- Generally, this doctrine provides that only a licensed physician (or entities owned exclusively by them) may be permitted to provide medical services.
- The corporate practice of medicine doctrine essentially prohibits any person other than a licensed physician from owning or controlling or deriving the profits from a physician practice.
- Usually, the corporate practice of medicine doctrine does not apply in cases where there are rigorous licensure requirements for a health care facility. In addition, some states permit hospitals to employ physicians because hospitals are formed to treat patients and provide health care.
- In states with the corporate practice of medicine doctrine, CINs must be carefully structured to **avoid control of a physician by any other person or entity who is not a licensed physician**. This may prevent a true integration of providers and thus stunt the goal of CINs.



What Are the Major Regulatory Hurdles to CIN Development? Other State Law Issues

- **Anti-Kickback Laws.**

- Similar to the federal law, many states also have prohibitions on kickback arrangements.
- Safe harbors may not be available & may include the expansion of a state's kickback prohibition to include the referral of *any* patients (not just Federal health care program patients), as well as the absence of the federal law's intent requirement.

- **Self-Referral Laws.**

- State self-referral laws may be much broader than the federal Stark Law. Often, state laws prohibiting self-referrals apply to any health care service, not just the enumerated health services which implicate the Stark Law. In addition, state laws may apply to all payors and not just federal programs. Also, a state's self-referral law may not include the same exceptions as set forth by the Stark Law.



What Are the Major Regulatory Hurdles to CIN Development? Other State Law Issues

Fee Splitting Prohibitions.

- Many states have stringent fee splitting laws that prohibit the sharing of fees obtained from providing professional health care services with persons not licensed to provide the same or similar services.
- Each state varies regarding whether any such law exists and the scope of said laws. By way of example, fee splitting laws may prohibit a physician from sharing his professional fees with any other health care facility including a hospital or nursing facility. Some states only prohibit fee splitting when coupled with patient referrals.
- Since CIN participants may share savings, financial arrangements must be analyzed to ensure compliance with any state fee-splitting laws.



What Are the Major Regulatory Hurdles to CIN Development? Other State Law Issues

- **Licensure Requirements for Licensed Facilities.**
 - Licensed facilities are subject to stringent regulations governing many aspects of their operation. May range from certificate of need laws to general licensure rules to other administrative requirements. Some states also impose strict requirements on the governance and ownership of these licensed facilities.
- **State Security laws.**
 - A CIN will likely need to raise capital for its formation and operation. If the CIN intends to sell ownership interests to raise money, it must consider and comply with both federal and state security laws and regulations. If an offering is exempt under the federal securities laws, that does not necessarily mean that it is exempt from any of the state laws.



Case Study: “ApogeeCare Network”: FACTS

- The Apogee Health System is a non-profit, multi-hospital system in a large Midwestern city. Although it employs almost 200 physicians, over 80% of the members of its hospital medical staffs are independent physicians who have historically been resistant to Apogee’s integration efforts.
- Apogee’s primary competitor, BTF Healthcare, has been growing its market share by aggressively acquiring medical practices and smaller hospitals. BTF recently announced the development of an accountable care organization (ACO) and its plans to emerge as “the market’s leader offering high quality, low-cost care to payers”. BTF has been spending countless dollars on advertising this strategy.



Case Study: “ApogeeCare Network”: FACTS

- Apogee’s CEO, Carla Duke, has been charged by her board’s executive committee to come up with a strategy to compete with BTF before the Affordable Care Act is fully implemented. Carla began her career as a health executive running a physician-hospital organization during the 1990s. Although her PHO was disbanded following a threatened antitrust inquiry, she has always believed that joint contracting between hospitals and physicians provided a reasonable way to force efficiencies on the delivery system.



Case Study: “ApogeeCare Network”: FACTS

- Carla calls Edward Field, Apogee’s outside counsel looking for advice. She asks him if he’s familiar with a legally sound, patient-centric model that would be attractive to both Apogee’s employed physicians and to independent practitioners willing to work together to offer payers:
 - i) evidence-based care,
 - ii) performance transparency, and
 - iii) highly-coordinated care.
- In return, physicians would be promised meaningful, performance based incentives and access to the “best” third party contracts in Apogee’s market. Carla knows a little bit about the FTC guidelines for networks, so she tells Edward that financial integration is probably impossible at this stage. She wants to know how else she can form a PHO-like entity without running into antitrust trouble.



Case Study: “ApogeeCare Network”: Questions for Consideration

- Regardless of the organizational model recommended, how should Edward structure the network so that employed and independent physicians access the same contracts and have the same financial incentives to improve their clinical performance?
- Carla doesn’t want the network to be open to all members of her medical staffs because there are a significant number of older doctors who she believes will never change the way they practice. How can she legally exclude these physicians?



Case Study: “ApogeeCare Network”: Questions for Consideration

- Apogee has made a great deal of progress getting all of its employed physicians on a single IT platform, the independents have a variety of medical record and administrative systems. Carla wants to know if there’s way she can “just give” the independents the hardware and software they need to be a part of the network in exchange for complying with the network’s practice protocols?
- Carla knows that building the network (which she has tentatively named “ApogeeCare”) is going to be costly, both in terms of money and staff investment. Even though she believes this strategy is essential for the system’s survival, she knows that the independent physicians will be unwilling to share in the development costs. What advice should Edward give Carla on this point?



Case Study: “ApogeeCare Network”: Questions for Consideration

- Carla’s best friend from college, Ginger Hiatt, is the VP of Provider Relations for the Indigo Plus, the largest commercial payer in Apogee’s market. Over lunch a few weeks ago, Ginger let it slip that Indigo’s shareholders wanted the company to get out of the “risk” business by down-streaming most claims risk to providers and reinsurers. That got Carla to thinking... should ApogeeCare prepare itself to accept risk contracts, and if so, what regulatory hurdles would it face?
- Finally, Carla asked Edward to suggest any contract terms that would align the interests of the hospital system and the physicians. She said that she didn’t want to launch the network if it didn’t help everyone involved. What advice should Edward give?



QUESTIONS?



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