The Evolution of Clinical Integration in Policy and Law

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Why Clinical Integration Can Help Solve Policy and Legal Issues

- The concept of clinical integration recognizes that single entities cannot pay themselves for referrals or conspire with themselves to restrain trade.
- This notion recognizes the importance of size and scale, but also the reality of multiple, diverse participants.
- It also accommodates both collaboration and competition.
- Examples of the application of this concept in current law and enforcement policy include the AMC exception to Stark, the employee exceptions to Stark and the anti-kickback laws, and antitrust guidance on clinical integration and joint ventures.
- Where true clinical integration is being sought and achieved, it is good for patients and society, institutional mission and public policy goals are advanced, and legal concerns should be lessened.

— Doug Hastings, “Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for a Rebuttable Presumption,” BNA’s Health Law Reporter, June 2009

Historical Legal Barriers to Provider Integration

- Federal and state regulatory schemes, particularly relating to antitrust, fraud and abuse and tax-exempt organizations
- These laws all evolved in an era in which provider separateness was assumed to be appropriate and financial incentives between providers generally were assumed to be improper
- Government as purchaser and regulator
  - Inherently, this dual role of government created a duality of interest
  - As purchaser, the goal was to pay less; as regulator, the goal was to require more
  - As purchaser, the goal was to encourage financial incentives to improve quality and reduce cost; as regulator, the result was to view incentives with suspicion and declare some incentives illegal
  - As purchaser, the goal was to encourage innovation and efficiency; as regulator, the result often was to discourage innovation and efficiency in an attempt to control behavior

The Current Case for Payment and Delivery Reform

- The problem: fragmented care; uneven, unsafe practices; unsustainable costs
- Quality = Care that is safe, effective, effective, patient-centered, timely and equitable

  — Institute of Medicine, Crossing the Quality Chasm, 2001
- "Our fee-for-service system, doling out separate payments for everything and everyone involved in a patient's care, has all the wrong incentives: it rewards doing more over doing right, it increases paperwork and the duplication of efforts, and it discourages clinicians from working together for the best possible results."

  — Atul Gawande, "Testing, Testing," The New Yorker, 12/14/09
- The Triple Aim — organizing care to: improve the health of the population; enhance the patient experience of care (including quality, access, and reliability); and reduce, or at least control, the per capita cost of care.

  — Institute for Healthcare Improvement at: http://www.ihi.org/IHI/Programs/StrategicInitiatives/TripleAim.htm

The ACA Timeline for Accountable Care

- 2011 Programs Announced and/or Implemented
  - Extension of Physician Group Practice Demonstration and Gainsharing Demonstration
  - State Option to Provide Health Homes for Enrollees with Chronic Conditions
  - National Strategy for Quality Improvement in Health Care
  - Plans for Value-Based Purchasing Program for Ambulatory Surgical Centers
  - Community-Based Care Transitions Program
  - Hospital Value-Based Purchasing Program Regulations
  - Plans for Value-Based Purchasing Programs for Skilled Nursing Facilities and Home Health Agencies

The ACA Timeline for Accountable Care

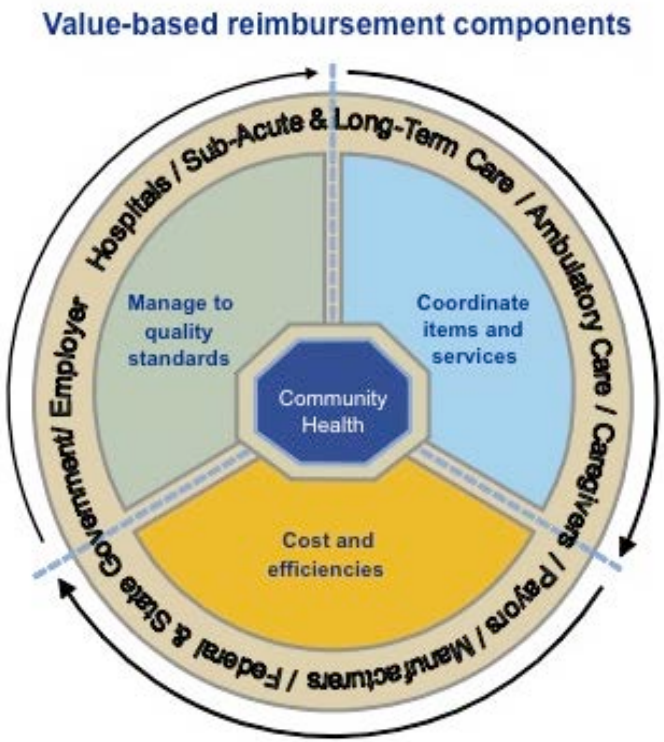
- Federally Qualified Health Center Advanced Primary Care Practice Demonstration Project
- Pioneer ACO Program
- Multi-payer Comprehensive Primary Care Initiative
- Bundled Payment Initiative
- Medicare Shared Savings Program Final Rule
- Innovation Advisors Program
- Advance Payment ACO Model
- Health Care Innovation Challenge
- FQHC Advanced Privacy Care Practice Demonstration

The ACA Timeline for Accountable Care

- 2012 Programs Scheduled
  - Demonstration Project to Evaluate Integrated Care Around a Hospitalization
  - Pioneer ACO Program
  - Medicare Shared Savings Program
  - Independence at Home Demonstration Program
  - Comprehensive Primary Care Initiative
  - Models 2, 3, and 4 of Bundled Payment Initiative Applications
  - Hospital Value-Based Purchasing Program
  - Hospital Readmissions Reduction Program

Value-Based Purchasing: The Market is Moving Away from Utilization Reimbursement

- There is movement to “Accountable Care Capable” entities
  - Improving access to primary care resources
  - Increasing patient satisfaction and engagement
  - Increasing disease management and preventive care programs
  - Strengthening continuity-of-care
  - Building clinical management and care coordination capabilities
  - Being able to track and report on quality measures and outcomes
  - Improving cost-efficiency
- The goal is improved provider integration and engagement of patients/members in health improvement
- Moving from utilization based reimbursement to value based reimbursement



What Will it Take to Succeed?

- Participants with high quality standards and a focus on patient centered care
- Participants that can manage additional cost reduction
- Participants with medical management, care management, risk management competencies
- Participants that are “financially sound” with a “war chest” available to cover at risk amounts and required investments
- Participants that already have the physician and other network relationships
- Those who believe in the “spirit of the rule” vs. “another reimbursement game”
- Participants with robust information technology and monitoring capabilities
- “Meaningful Users” of EHR and other clinical technologies will fair better
- Participants with a stable primary care patient base
- Participants that have standardized on clinical processes and protocols
- Participants with strong governance and change management structures

Changing Financial and Care Delivery Models Go Hand in Hand

	The industry implication	The question	The challenge
Financial	▪ Shifting reimbursement/funding ▪ Challenged healthcare margins ▪ Provider consolidation ▪ Relationship development	▪ How will you address the "shrinking balloon?"	▪ Healthcare "cost" is revenue for somebody
Health & wellness	▪ Enhanced consumer engagement ▪ Transition to wellness & prevention ▪ Changing clinical acuity and shifting levels of care	▪ How will you be compensated for "health" and "wellness?"	▪ Transition of care management to greater individual responsibility (e.g., "consumerism" in the new paradigm)? ▪ Population based care management focus
Care delivery model	▪ Disruptive new market entrants ▪ Changing sites of service ▪ Client-centered care ▪ Use of health information technology and data analytics	▪ Where do you fit in the shifting intersection of risk and reward?	▪ Where/how does "risk" shift? Who gets paid to remediate, mitigate, and/or assume? ▪ As risk shifts, who can truly influence amount of and variability of risk? ▪ What are the "intelligent information" requirements? Is quality a driver of economic reward?

Provider Alignment is Essential

- Provider alignment strategies are necessarily focused on the "brave new world" of health care delivery and payment reform.
- The shift from volume-based payment models to value-based payment models will change hospitals' and physicians' financial incentives, and how they will deal with one another.
- Aligning those incentives is difficult, but essential.
- Emerging payment arrangements will demand, and reward, effective clinical and financial integration among providers across the continuum of care, and punish the failure to do so.

Goals of Financial and Clinical Integration are Aligned

- Financial Integration
  - Shared financial risk and reward
  - Mutual dependency on financial outcomes
  - Aligned financial incentives among providers
- Clinical Integration
  - Shared data and patient relationships
  - Mutual dependency on clinical outcomes
  - Aligned clinical incentives among providers

What's in a Definition?

Clinical Integration → Coordinated Care → Accountable Care → ?

Evolving Definitions of Clinical Integration

"(Provider) network joint ventures that do not involve the sharing of substantial financial risk may also involve sufficient integration to demonstrate that the venture is likely to produce significant efficiencies. Such integration can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies."

— U.S. Department of Justice and Federal Trade Commission. Statements of Antitrust Enforcement Policy In Health Care. Statement 8: Enforcement Policy on Physician Network Joint Ventures, August 1996

Evolving Definitions of Clinical Integration

"Clinical integration refers to the capacity of an organization to provide most of the services that patients with chronic illnesses will need over the duration of the illness, be it a period of months or years. Clinical integration sharpens the focus on value, and the evidence strongly suggests that patients are not receiving the best value. Clinically integrated systems of care are better positioned to design safe, effective, and efficient longitudinal care processes for patients with chronic conditions. With clinical integration, performance measurement and improvement can extend across each entire patient focused episode and can help inform and redesign the whole care process."

— Janet Corrigan and Dwight McNeill, "Building Organizational Capacity: A Cornerstone Of Health System Reform Achieving Breakthroughs in Health Care Value Requires New Organizational Models," Health Affairs, January 2009

Evolving Definitions of Clinical Integration

"So what does this mean? There is no single way to structure a clinically integrated network. This flexibility is an asset. Rather than a "one size fits all" approach, clinically integrated networks can conform to the demands and requirements of their respective communities and the other legal restrictions faced by providers, while also staying within the broad bounds of the antitrust laws. While there is no "cookie cutter" structure, in the Guidelines the FTC and DOJ do provide guidance on the structural pillars that clinically integrated networks often have."

— Brookings Institution ACO Toolkit, Part 6: "Legal Issues for ACOs", January 2011

Evolving Definitions of Clinical Integration

"Clinical integration means that independent providers such as hospitals or health systems, physician practices, individual providers, and outpatient diagnostic centers integrate their services through shared electronic health record systems, clinical guidelines, unified practice management, and other techniques. In optimal systems-based care, each patient's health care needs are evaluated and treated comprehensively as part of a "system" of care for that person."

— Doug Hastings et al., "A New Quality Compass: Hospital Boards" Increased Role Under The Affordable Care Act," Health Affairs, July 2011

Key Clinical Integration Elements

- Shared EHR
- Care coordination; clinical teaming
- Selective network
- Monitoring and controlling utilization
- Evaluating and modifying practice patterns
- Enforcing protocols and taking remedial action
- Investment in infrastructure
- Board oversight of quality compliance program
- Performance measurement and improvement
- Transparency – reporting performance to payers and public

Clinical Integration Summary Chart

Population Management

- Population profiling/segmenting
- Resource Planning
- Registries
- Access

Processes/Systems

- Patient communications
- Electronic Health Record
- Referral Management
- Compliance
- Medication reconciliation
- Patient Satisfaction

Venues

- Hospital/SNF
- Outpatient Clinics/ASCs
- Emergency/Urgent Care
- Home Health
- Physician Office
- Hospice

Culture

- Physician leadership
- Medical Home
- Patient engagement
- Clinical Teaming
- Un-blinded performance data

Structure

- Joint incentives
- Governance

Functions

- Case management
- Disease Management
- Wellness/Prevention
- Intercept/Intervention
- Medical Analytics/Modeling

Are Common Ownership and Employment Models More Effective?

- Only time will tell
- Antitrust enforcement will continue to challenge mergers deemed anti-competitive
- Evolving standards, including ACO final rule, provide guidance as to what independent providers must do together to be deemed “clinically integrated”
- There is the potential for new forms of contracting (rather than mergers) among providers, including in some cases high market share providers, working with payers, to accomplish accountable care goals through bundled and global payments to create antitrust-acceptable pathways (i.e., if payment is based on measurable value (quality over cost), where is the harm?)
- The private sector would benefit from greater payer-provider collaboration in this regard and acceleration of the movement to accountable care; failure to do so will put more onus on government to regulate the prices of both and to micromanage the contract provisions between them.

Proposed Elements for Rebuttable Presumption or Safe Harbor - 2009

- A virtual or entity-based organizational structure that features clinical integration and supports quality and cost-efficiency.
- Adoption of appropriate evidence-based measures with outside verification.
- Clear documentation of structure, measures, and operational processes.
- A virtual or entity board in place, including independent board members, to oversee operations.

— Doug Hastings, “Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for a Rebuttable Presumption,” BNA’s Health Law Reporter, June 2009

MSSP (ACO) Final Rule - 2011

- Organizational structure, governance and board oversight requirements
- Quality measurement and reporting requirements
- Management team and operational process requirements
- Compliance plan and other documentation requirements
- Legal protections for entities meeting CMS requirements

Coordinated Federal Agency Guidance

- The coordinated guidance issued with the ACO Final Rule from the DOJ, FTC, OIG and IRS shows a significant degree of inter-governmental agency cooperation and a respect for the substantial minimum requirements that CMS has established for ACOs.
- The guidance, taken together, suggests that a qualified – and effectively operating ACO – does gain a degree of legal protection under these regulatory schemes through waivers, safety zones and announced agency protocols.
- Particularly in the antitrust arena, there remain difficult issues to work through, particularly where the providers in an ACO have a high market share.
- But the recognition that legitimate ACO activities will be treated under the rule of reason and the identification of activities that may cause the antitrust agencies concern is helpful.
- The regulatory dialogue that has taken place around ACOs – how to distinguish "good" collaboration from "bad" – should be seen as progress, and we can expect that it will continue.

Clinical Integration Imperative - 2012

- The momentum of change is now mandating effective clinical integration, regardless of participation in Medicare ACOs
  - Clinical integration is a structured collaboration among providers in an active and ongoing program designed to improve the quality and efficiency of health care.
  - True clinical teaming between facilities and physicians, and among physicians
  - Agility to respond to quickly changing market and clinical requirements and opportunities
  - Connectivity across the delivery system to provide true care coordination and convenience
  - The ability to demonstrate value and outcomes to all key stakeholders
- It focuses on managing populations and patients based on:
  - A culture of patient-focused care
  - Systems and data which enable seamless coordination and continuity-of-care
  - Reinforcing aligned incentives
- The complementary nature of financial and clinical integration means that successful provider organizations can “do well by doing good”

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