

Massachusetts Medical Society *Payment Reform Summit: Moving From Theory to Practice*

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The Continuous Evolution of the Massachusetts Health Care System

- CSHSC, September 2, 2010: Physician membership in physician organizations (POs) high and growing
 - Diminishing financial viability of small practices
- Alignment with hospitals
 - Physicians in academic medical centers with exclusive hospital arrangements
 - Community physicians joining POs and affiliating with one or more hospitals
- Benefits of alignment:
 - Payment
 - Technical support
 - Profit-sharing

National Policy of Practice Alignment Under Affordable Care Act

- Center for Medicare and Medicaid Innovation
 - Direct Medicare contracting with practice groups including risk-based comprehensive payment and salary payment
 - Care coordination between physicians and suppliers to move away from fee-for-service and toward salaried payment
 - Physicians integrated with community care teams
 - Fully integrated care for dual eligibles and medical home pilots
- Accountable Care Organizations and shared savings through provider/supplier groups
 - Independent groups and hospital based groups with the legal ability to receive and disburse payment
 - ACOs emphasizing primary care, panels of at least 5000 patients and overall clinical and practice management and integrated governance
- Authorization of necessary revisions to fraud and abuse laws to foster integrated practice
- Quality performance measurement methods that demand large patient panels
 - National quality strategy
 - Population-based performance standards for medical groups
- Technical complexities of practicing in a certified EHR environment

Legal Aspects of Practice Alignment

The Law Recognizes *Degrees* of Alignment

- Alignment through possible types of affiliations*
 - Informal handshake
 - Formal contracts between entities that retain separate corporate structure
 - Affiliation agreements and joint ventures
 - Contracts with a larger corporate structure, either with or without governance and management rights
 - A new corporate entity with management and governance powers

*Based on Affiliation Manual prepared by Feldesman Tucker Leifer and Fidell (2004)

The Handshake

- Maximum flexibility
- No enforceable expectations
- Risk of misunderstanding and disputes
- Is the output of the handshake legal?
 - Fee splitting
 - Collusive behavior
 - Kickbacks
 - Potential liabilities flowing from ambiguities and uncertainty

Distinct Contractual Relationships

- Specific to aims and goals
- Specified period of time
- Specified goods and services, space, equipment in exchange for payment or reciprocal provision of similarly valued services or goods
- Contracting parties retain corporate independence
- Joining a PO or sharing clinical or administrative services are both examples of specific contractual relationships
- Non-exclusive

Binding Affiliation Agreements

- Single umbrella agreement, multiple specific contractual relationships governing operations & financing
 - Specific implementing agreements
- Joint planning with priorities and timelines
 - Can be non-exclusive
 - Governed by confidentiality considerations during planning and development
 - Inclusive involvement with third parties
 - Right of first refusal with respect to future collaborations
 - Financial expectations
 - Right to modify terms
 - Dispute resolution
 - Grounds for modification/termination

Establishing a New Entity

- Examples
 - Practice management organizations
 - Management service organizations
 - Multi-purpose networks
 - Provider organizations
 - Managed care negotiating networks
- Types of entities
 - Limited liability corporations
 - New entities, joint governance
 - Full corporate integration/merger with fundamental change in corporate identity
- Key issues
 - Capitalization
 - Ownership and distributions
 - Control, governance, decision-making
 - In the case of nonprofit organizations, tax consequences of new entities (sec. 501(c)(3) or (c)(4) status) and revenue generating activities not in furtherance of exempt purpose

Legal Considerations in Alignment

- From a legal perspective, health care alignments and affiliations create new practice products for sale in the marketplace and raise both federal and state law legal considerations that reflect the federal and state law tiers of the American legal system
- Federal
 - Medicare and Medicaid payment incentives and cost reporting
 - Antitrust principles
 - Anti-kickback and Stark self-referral rules
 - Tax consequences
- State
 - Licensure
 - Corporate practice of medicine
 - Liability
 - Anti-kickback and Stark self-referral
 - Liability
 - Fee splitting
 - Tax consequences

Antitrust and Anti-Kickback Considerations

Antitrust Considerations

- Purpose of antitrust law: to promote competition and prohibit anticompetitive activities that unreasonably restrain trade
 - To prevent competitors from collective and concerted action that results in unlawful market power in the relevant market
- Two types of conduct
 - Rule of reason: joint ventures, mergers, consolidations and other collaborative arrangements that involve a level of clinical and financial integration.
 - Analysis in rule of reason case: what purpose is served by the new activity or business? Balance anti-competitive harms against pro-competition benefits
 - Per se unlawful: price fixing, boycotts, market allocation among non-integrated competitors (*Arizona v Maricopa County Medical Society*, 457 U.S. 332 (1982))

FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care

- Issued in wake of *Maricopa County* in order to permit integrated activities to proceed
- Unchanged by the Affordable Care Act
- *Original Statement 8*:
 - Express safety zone for clinical entities that share substantial risk, lack market power and can thus demonstrate a pro-competitive effect. Analyzed under the Rule of Reason
- *Expanded Statement 8*
 - Recognizes entities that achieve clinical integration without substantial financial risk, provided no market power. Analysis also utilizes Rule of Reason analysis to identify a level of clinical integration sufficiently strong to permit collective bargaining even in the absence of substantial financial risk.
 - Key: an agreement that improves quality and efficiency and an “active and ongoing program to evaluate and modify practice patterns by the group’s physician participants and create a high degree of interdependence among physicians to control costs and ensure quality.” (*Statements*)

Indicia of Clinical Integration

- Analysis of FTC/DOJ advisory opinions and judicial rulings* shows that certain elements are considered highly relevant:
 - Multiple diagnoses and diseases to be addressed
 - In-network referrals
 - Networks that include specialty and primary health care
 - Physician financial investment
 - Technology that enables physicians to share patient/practice information
 - Streamlined record-keeping and clinical management; use of EHRs
 - Enforceable performance standards and ability to enforce performance through adequate staffing
 - Non-exclusivity
 - Joint contracting in order to align practice with a broad array of conditions subject to quality improvement through clinically integrated performance as well as to performance measurement
 - Reporting of results
- Cannot be a loose network of competitors: must achieve integration; at same time, antitrust law sees this as “putting a toe in the water” of full integration**

*Taylor Burke and Sara Rosenbaum, Accountable Care Organizations: Implications for Antitrust Policy, BNA Health Law Reporter 19:10 (March 13, 2010)

**tim Greaney, Thirty Years of Solicitude, Hous. Jour. Health Law and Policy 7: 189-226 (2007)

Other Permissible Activities for Providers That Lack Sufficient Clinical Integration

- Joint purchasing of supplies, equipment and services used to execute and manage collaboration, provided:
 - collaborators do not possess market power and
 - the conduct does not facilitate price fixing or reduce competition
- Collecting and sharing fee-related information and participating in fee surveys as long as
 - data are collected by 3d party,
 - are more than 3 months old,
 - are presented in aggregate form, and
 - activity does not involve collective communication about future payments
- Collecting and using non-fee information provided neither collaborators nor their representative use the information to boycott a payer or purchaser

Messenger Model Arrangements for Collaborations Not Considered Clinically Integrated

- For providers that lack clinical integration
- Provider network entity serves as negotiator with payers and an intermediary between providers and purchasers
- No specific safety zone, but recognized by DOJ/FTC
- Key considerations
 - Independent and unilateral decisions by providers regarding contract terms
 - Non-exclusivity
 - Messenger barred from
 - divulging contract terms among the providers (but messenger can develop minimum terms and separately communicate with each provider who acts independently)
 - Sharing information about provider decision-making
 - Collective negotiations
 - Binding the providers as a group

Other Antitrust Considerations

- It is acceptable to:
 - Discuss potential collaboration and share historical data that in turn enable participants to make decisions
 - Develop and share information management systems for clinical and administrative data that would be necessary to execute and manage an affiliation
 - Establish joint patient tracking as long as patients are not allocated
- State action immunity doctrine permits anti-competitive activity to proceed under federal and state law if the state
 - *Clearly articulates in state law* that certain types of conduct are permissible and describe the conduct in detail while fully acknowledging the value of the activity even if anti-competitive (e.g., conduct aimed at promoting greater physician collaboration)
 - Actively supervises the conduct including ongoing review and regulation to assure that the activity of private parties is of the nature sanctioned under state law
 - State Health Care Collaboration Statutes promoting voluntary cooperation

Anti-Kickback Considerations

- Federal anti-kickback law purpose: to prevent abusive arrangements that result in higher cost or undermine the quality of care
- The law prohibits arrangements under which any entity or person
 - knowingly or willfully
 - solicits or receives (or offers to pay)
 - anything of value (remuneration)
 - directly or indirectly, overtly or covertly, in cash or in kind
 - In exchange for making or inducing patient referrals or the purchase or lease of goods, services, or equipment (other businesses generated by the parties)
 - Any of which are paid for in whole or in part by federal health care funds
- Agreements, collaborations and sharing arrangements can run afoul of the law if undertaken with the intent of inducing referrals or to generate business financed by health care funds
- States have similar laws reaching other funds

Anti-Kickback Safe Harbors

- Multiple safe harbors designed to foster integration
 - Personal services and management contracts
 - Space and equipment rental agreements
 - Discount arrangements
 - Referral arrangements for specialty care
 - Sale of practice
 - Managed care safe harbor for risk-sharing arrangements
 - Employment arrangements
 - Group purchasing
 - Investment in group practices and joint ventures
- Each safe harbor subject to multiple requirements
 - E.g. specialty referral agreements must reflect clinical appropriateness on the part of both parties and cannot split a single global fee unless both the primary care professional and specialist are members of the same group practice