

Legal Issues for Medical Home Formation and Operation

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Medical Home – Legal Construct

There is no particular structural model—

A medical home is defined by an approach to providing clinical care (i.e., *operational* characteristics), not by contractual relationships and exchange of payments

Medical Home – What Defines It?

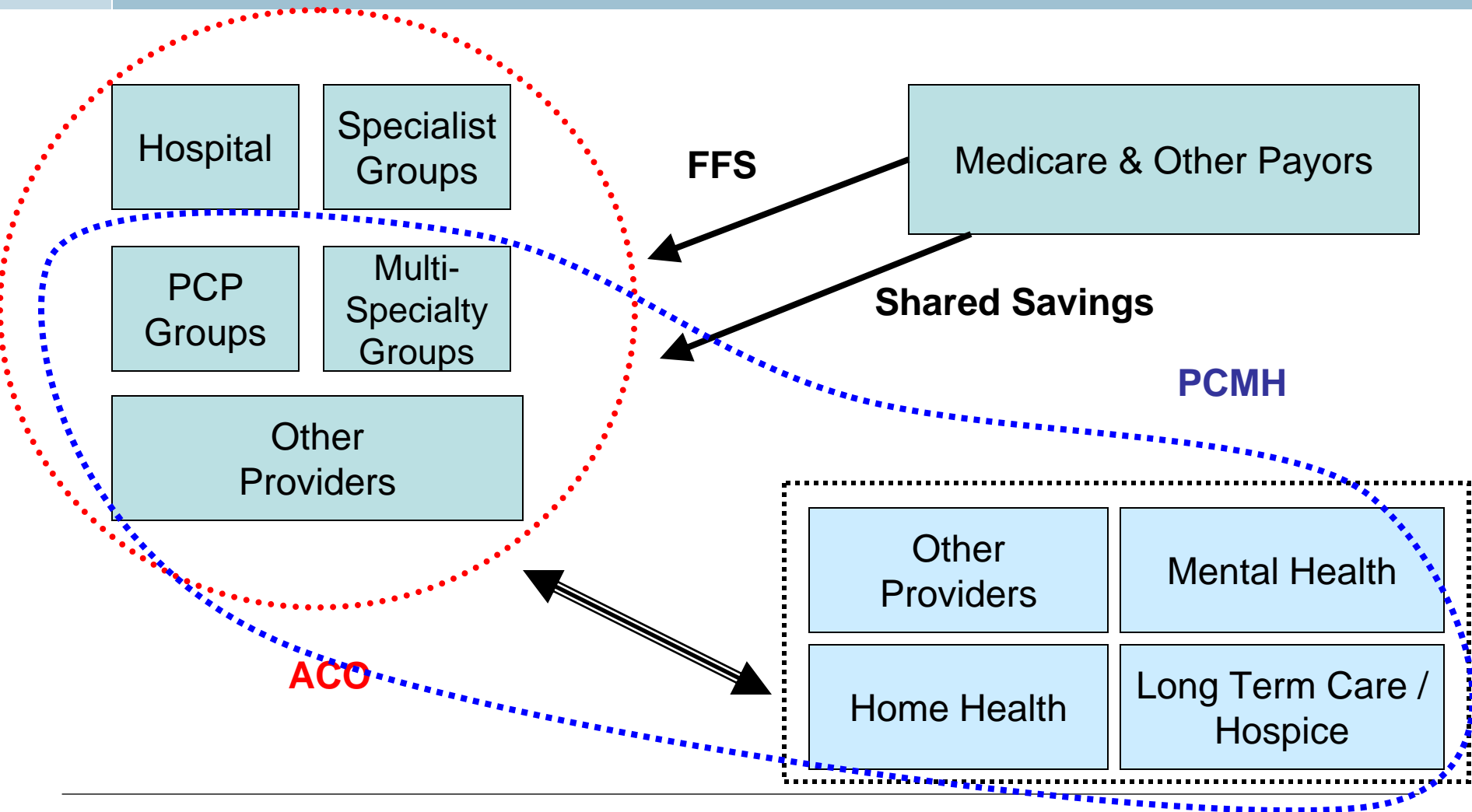
- **Personal physician** - each patient has an ongoing relationship with a personal physician.
- **Physician directed medical practice** – the personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients.
- **Whole person orientation** – the personal physician is responsible for providing for all the patient's health care needs or taking responsibility for appropriately arranging care with other qualified professionals. This includes care for all stages of life; acute care; chronic care; preventive services; and end of life care.
- **Care is coordinated and/or integrated** – patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.
- **Quality and safety** are hallmarks of the medical home.
- **Enhanced access** to care is available through systems such as open scheduling, expanded hours and new options for communication between patients, their personal physician, and practice staff.
- **Payment** appropriately recognizes the added value provided to patients who have a patient-centered medical home.

Source: American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, and American Osteopathic Association (2007 Mar.), "Joint principles of the patient-centered medical home"

Medical Home – Organizational Structures

- Primary Care Practices
- Multi-Specialty Care Practices
- Networks of Physicians
- Networks of Physicians + Other Providers
- Medical Groups
- Clinics
- IPAs/Networks

Medical Home & ACOs – Macro View



Medical Home – Formation Issues

- **Entity Formation**
 - Type of Entity (or Entities)
 - Equity
 - Governance Structure
 - Membership (Getting them in – Getting them out)
- **Creating a Network of Physicians/Providers**
 - Exclusivity / Non-competition
 - Scope of Services / Geographic Market
- **Allocation of Payments among Physicians**
 - Based on Equity
 - Based on Participation (numbers of physicians or performance)

Medical Home – Formation Issues

- **Contracting with Payors**
 - Medicare
 - Medicaid
 - Commercial
- **IT Issues – Procurement, Privacy**
 - Adequate IT for data collection, measurement & reporting?
 - Financing strategies – donation / meaningful use
 - Harmonizing systems / interoperability
 - Practice redesign
 - HIPAA / State Privacy Laws
- **Liability to Third Parties / Liability to Participants**
 - Creation of New Standards of Practice?
 - Medical Staff Interface

Medical Home – Legal Issues

Primary Regulatory and Other Concerns

- Antitrust
- Stark Law
- Anti-kickback Statute
- CMP/Physician Incentive Plan Law
- State Law Issues
- HIPAA
- Malpractice Liability

Legal Issues - Antitrust

Key Antitrust Considerations

- **Internal structure of provider network within the PCMH**
 - Organization cannot be a means for individual competitors to act as a single entity

- **Interplay of multiple PCMHs within a market**
 - Organization cannot use market position to adversely affect competition (i.e., unlawfully exclude competitors through exclusive contracts)

Legal Issues - Antitrust

Key Antitrust Considerations

- **Financial Integration** – “share financial risk in such a way that each member has an economic incentive to ensure that the group as a whole produces material efficiencies that will benefit consumers”¹
 - Agreement by provider network to provide services at a capitated rate
 - Agreement by provider network to provide designated services or classes of services for a predetermined rate
 - Use by a provider network of significant financial incentives for participants, as a group, to achieve specified cost-containment goals

- **Clinical Integration** – “comprehensive, coordinated program of care management designed, and likely, to improve quality and cost-effective care”; “use of IT systems, practice guidelines, care protocols, referral policies and quality benchmarks . . . to align efforts to improve [patients’] health and delivery of services”²

1. Christine A. Varney, Assistant Attorney General, Antitrust Division, U.S. Dept. of Justice, Remarks as prepared for the ABA/AHLA Antitrust in Healthcare Conference, 5/24/10

2. Id.

Legal Issues – Stark Law

Stark Law prohibits a physician (or immediate family member) with a “financial relationship” with an “entity” from making a “referral” to that entity for “designated health services”, for which payment is made by Medicare, absent an applicable exception

- No intent requirement; strict liability for Stark violations
- Any financial relationship (equity or compensation) between a physician and a recipient of a referral for certain services will trigger Stark

Possible exceptions for a number of financial relationships; however, limits flexibility in physician compensation modeling, and physician participation in equity

Creates limitations for entity formation and flow of funds / compensation

Legal Issues – Stark Law

CMS proposed a “shared savings” and incentive payment exception to the Stark regulations in 2008, but there are no stated plans to finalize it (73 Fed. Reg. 38502)

Three essential elements of the proposed exception:

- (1) transparency
- (2) quality controls
- (3) safeguards against payments for referrals

Legal Issues – Anti-kickback Statute

Prohibits someone from “knowingly and willfully” giving (or offering to give) “remuneration” to another person if such payments is intended to “induce” referrals for the furnishing of health services, or to induce the purchase, order, lease or recommendation of items covered by Medicare

- Intent requirement; without requisite intent, no violation
- Even without requisite intent, best practice is to structure the arrangement under a safe harbor, if possible

Creates limitations for entity formation and flow of funds / compensation

Legal Issues – Physician Incentive Payment Prohibition (CMP Law)

Hospital may not knowingly make a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals who—

- are entitled to benefits under Medicare part A or part B or to medical assistance under a State plan, and
- are under the direct care of the physician

Applies only in the fee for service context

Limits “gainsharing” – i.e., payments from hospitals to physicians for achieving cost savings

- Insurance: Medical Homes with full or partial capitation or other risk-bearing arrangements may be subject to state insurance regulations
 - State insurance regulations may require licensure, minimum financial reserves, financial reporting, or other requirements
- Corporate Practice of Medicine: CPOM laws prohibit a lay entity to practice medicine or to employ a physician to provide professional medical services
 - CPOM prohibitions may limit an organization's structure, governance or function

Legal Issues – Privacy & Risk Management

Medical Homes must effectively act as a conduit for health information exchange among their stakeholders – same issues arise as in HIEs

Organizations require:

- Policies to promote efficient and consistent operation; compliance with federal and state privacy laws and regulations
- Policies to promote trust among participants, trust by patients/consumers and the community
- Uniform Participation Agreements
- Uniform information exchange policies
- Structure emphasizing cooperation among participants
- Flexible arrangements permitting change as circumstances change and electronic health information exchange matures

- Consider insurance coverage and other measures to limit risk exposure related to the implementation of practice protocols

Medical Home – Governance Issues

- Medical Homes must determine how governance decisions (e.g., allocation of shared savings) will be made and the type of organization that will best facilitate that governance
- “Best” governance structure will vary from organization to organization
 - Size, network, and the needs of the organization and the individual participants will determine governance
 - Committee structure and design to be created
- Will the feds or evolving state law require specific structural or operational components?
- How are payments allocated among participants – what are the implications?

- Will the Medical Home be focused on Medicare patients only? Medicaid only? Commercial only? Mixed payor? – What is the scope?
- How to populate the organizational Board? How much, if any, lay, community, and clinical leadership?
- What functions will be delegated to the Board, and what will be a function of any operating committees?
- Who will staff and manage the administrative functions of the organization?
- How to pick organizational and individual partners?

Medical Home – The Devil's in the Details

- Financial Model for Clinical Integration?
- Financial Model for Financial Integration?
- Coordinate financial relationships and establish flow of funds among all participants
- Entity organizational documents
- Develop Mechanisms to Track and Report Financial Data
- Develop Mechanisms to Track and Report Clinical Data
- IT Infrastructure
- HIPAA compliance for shared PHI
- Exit strategy or termination events
- More to Come...

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