McDermott Will & Emery

Hospital-Physician Clinical Integration

HFMA Physician Hospital Alignment Relations Program

November 15, 2010

Daniel F. Gottlieb

312.984.6471

dgottlieb@mwe.com

www.mwe.com

Boston Brussels Chicago Düsseldorf Houston London Los Angeles Miami Milan Munich New York Orange County Rome San Diego Silicon Valley Washington, D.C.

Strategic alliance with MWE China Law Offices (Shanghai)

© 2010 McDermott Will & Emery LLP. McDermott operates its practice through separate legal entities in each of the countries where it has offices. This communication may be considered attorney advertising. Previous results are not a guarantee of future outcome. The following legal entities are collectively referred to as "McDermott Will & Emery," "McDermott" or "the Firm": McDermott Will & Emery LLP, McDermott Will & Emery/Stanbrook LLP, McDermott Will & Emery Rechtsanwälte Steuerberater LLP, MWE Steuerberatungsgesellschaft mbH, McDermott Will & Emery Studio Legale Associato and McDermott Will & Emery UK LLP. These entities coordinate their activities through service agreements. This communication may be considered advertising under the rules regulating the legal profession.

Topics

McDermott Will & Emery

- Clinical Integration Before and After Health Care Reform
- Clinical Integration Strategies
  - Physician practice and ancillary service acquisitions
  - Service Line Co-Management
  - Pay-for-quality compensation models
  - Shared savings arrangements
  - Physician-owned medical device distributors
  - Accountable Care Organizations

Hospital-Physician Clinical Integration Before Health Care Reform

McDermott Will & Emery

- Characterized by:
  - Shared interest in increasing volume of profitable acute inpatient interventions
  - Shared interest in increasing volume of profitable ambulatory/ outpatient services paid on a fee-for-service (FFS) basis, e.g., ambulatory surgery, leading to
    - Competition
    - Joint ventures
  - Limited incentives for collaboration in reducing costs and improving quality

Health Care Reform Drives Integration

McDermott Will & Emery

- Medicare P4P, i.e., value-based purchasing program (Sec. 3001)
- Pilot for bundled payments for courses of treatment (Sec. 3023)
- Payment adjustments for readmissions (Sec. 3025)
- Financial penalties for hospital-acquired conditions (Sec. 3008)
- Extension of gain-sharing demonstration project (Sec. 3027)
- Center for Medicare and Medicaid Innovation (Sec. 3021)
  - development of medical homes, chronic care management, home-based primary care, IT-enabled networks, medication therapy management, and other quality, cost-effectiveness and evidence-based medicine initiatives.

Effect of Health Care Reform on Hospital Economics

McDermott Will & Emery

- Medicare and Medicaid payment cuts
- More insured lives (reduced bad debt and uncompensated care)
- Under new payment schemes, poor quality and inefficiency will have economic consequences
- “Expanding the DRG” – making hospitals the centerpiece of new payment and delivery models that go beyond the acute care hospital stay

Effect of Health Care Reform on Physician Economics

McDermott Will & Emery

- Medicare cuts (especially for specialists)
- Health reform emphasis on reducing Medicare Advantage premiums, leading to reduced payments to providers
- Shift of $ from specialists to primary care
- Higher practice costs
  - Health Information Technology (HIT)
  - Quality data reporting
  - Increased regulation
- Shifting payment from FFS to bundled payments, capitated payments, and shared savings payments involving broader swath of the care continuum, i.e., more financial risk for providers

Hospital-Physician Clinical Integration <u>After</u> Health Care Reform

McDermott Will & Emery

- Increasingly focused on:
  - Acquiring or otherwise gaining control of physician practices and other ambulatory/outpatient services, e.g., Ambulatory Surgery Centers
    - Employing physicians
    - Leasing physicians
  - Service Line Co-Management Agreements
  - Incentive compensation arrangements with physicians to comply with, and benefit from, commercial and governmental payor value-based purchasing initiatives
  - Creation of Accountable Care Organizations (ACOs) and other coordinated care organizational initiatives designed to benefit from new payment models

Practice and Ancillary Service Acquisitions

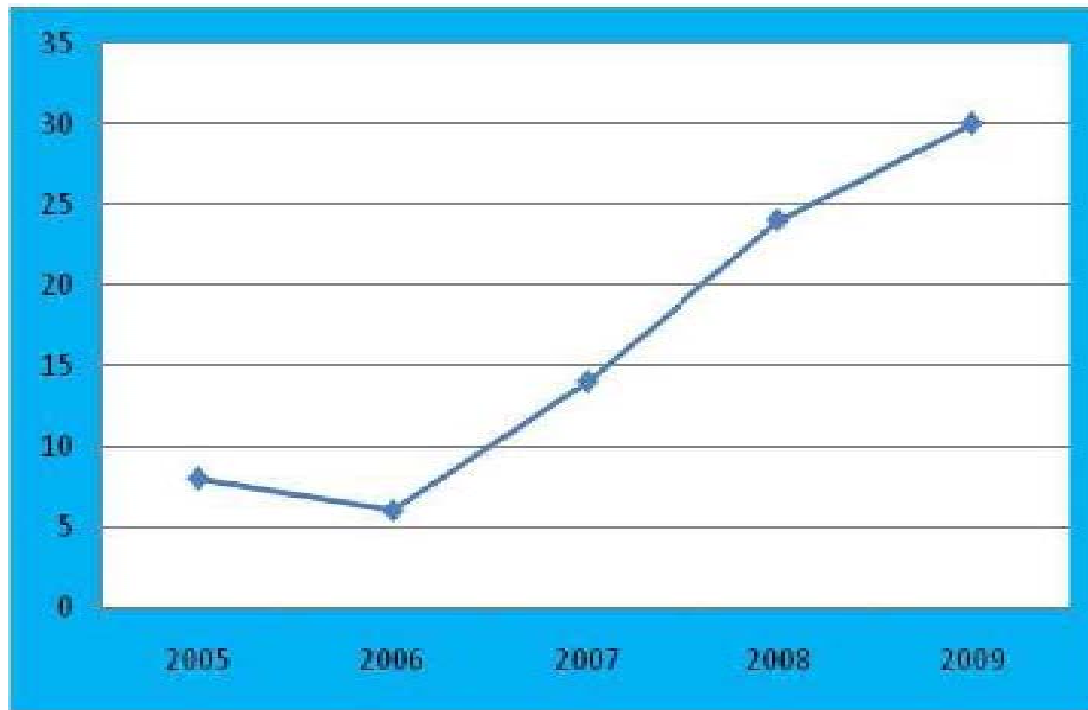
McDermott Will & Emery

- Hospitals buying physician practices and physician-owned hospitals, ASCs, diagnostic testing facilities, rehab facilities, chemo-infusion facilities, and other ancillary services

Physician Practice Acquisitions

McDermott Will & Emery

Acquisitions of Large (50+) Medical Groups by Hospitals



Source: Irving Lewin Associates and Cain Brothers

Acquisitions

McDermott Will & Emery

- Hospitals having been buying practices and ancillaries for years? What's different?
  - In response to health care reform, and the need for integrated delivery systems to manage risk, the pace is increasing, i.e., more deals
  - More of a buyers' market; fewer hospitals paying for the "good will" (intangible asset value) of the practices
  - Physician compensation is productivity based, with indirect benefits for hospital performance
  - Ancillary service lines facing diminishing revenues or more restrictive regulation of physician ownership; physician-owners want to cash-out while there is still value
  - Hospitals are generally paid substantially more for the ambulatory/outpatient services than physician-owned entities

Service Line Co-Management Arrangements

McDermott Will & Emery

- Changes to the Stark Law have caused hospitals and physicians to look to alternative arrangements to allow physicians and hospitals to align around clinical initiatives
- Hospital and physician group co-manage a hospital service line
- Participating physicians are compensated for their efforts in developing, managing and improving quality and efficiency of a particular hospital service line
- Services include: medical director services; budgeting; strategic planning; patient satisfaction; development of clinical protocols; and case management

Service Line Co-Management Arrangements

McDermott Will & Emery

- Legal Considerations
  - As this activity increases, hospitals and physicians must be cautious and ensure that there are substantial clinical and business justifications for each arrangement
  - Moreover, it will be critical that any such arrangement involve only those physicians for whom the service line (to be managed) utilize those services as an “extension” of their respective practices and are not merely as passive referral sources
  - Compensation formulas and valuations of compensation also are critical components of these transactions

Incentive Compensation

McDermott Will & Emery

- Emerging FFS payment models making hospital reimbursement contingent on achievement of quality and/or cost performance metrics
- Hospitals need to change medical staff clinical behavior and care processes to achieve the quality or cost metrics
- Key incentive compensation models:
  - Pay-for-Quality Model
  - Shared Savings Model

“Pay for Quality” Model

McDermott Will & Emery

- Physicians create a legal entity to be owned by all physicians who have been on the active medical staff in relevant departments for at least one year (PO)
- Each physician makes an equal capital contribution to provide for the PO’s working capital
- The physician-investors commit to practice in compliance with certain protocols calculated to assist hospital in meeting quality performance metrics

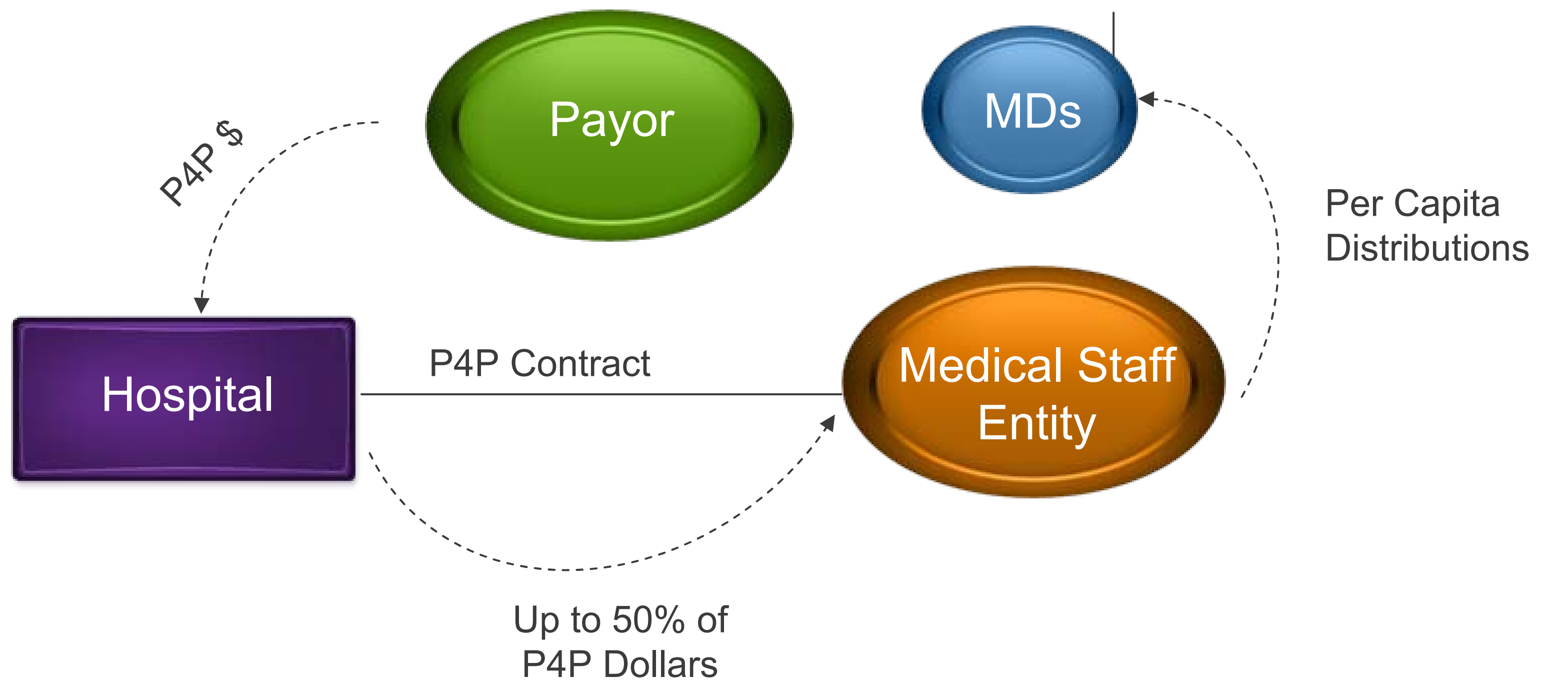
"Pay for Quality" Model

McDermott Will & Emery

- The PO contracts with the hospital and agrees to:
  - Cause its physicians to make the changes in clinical behavior calculated to assist hospital in achieving quality metrics
  - provide management services related to the quality initiative
- Hospital payment to the PO is based on percentage of pay for performance dollars earned by the hospital (up to 50%) and then distributed to the physicians on an equal or per capita basis

"Pay for Quality" Model

McDermott Will & Emery



"Pay for Quality" – Legal Issues

McDermott Will & Emery

- Anti-Kickback Statute (AKS) means:
  - PO investment should only be offered to physicians who have been on the medical staff for at least one year
  - Hospital should have the ability to monitor case-mix severity of each physician and have ability to terminate participation by any physician for whom changes in the case-mix severity suggest patient "cherry-picking"
  - Physician investment and distributions should be uniform; no disparate treatment based on value or volume of referrals
  - Incentive pool should be capped based on historical patient admission volume
  - Quality performance payments should be capped at 50% of incentive payment from payor

“Pay for Quality” – Legal Issues

McDermott Will & Emery

- Stark Law means:
  - Physician investment and distributions should be uniform; no disparate treatment based on volume or value of referrals
  - Incentive pool should be capped based on historical patient admission volume

“Pay for Quality” – Legal Issues

McDermott Will & Emery

- Civil Monetary Penalty (CMP) Law
  - Prohibits a hospital from making payments, directly or indirectly, to a physician as an inducement to reduce or limit services to a Medicare or Medicaid patient
  - Concern? Risk of underutilization; stinting on care
  - HHS Office of Inspector General (OIG) interprets broadly –
    - Not just payments to reduce lengths of stay or readmission rates
    - Also payments to comply with clinical protocols that could place a limitation on the quantity of health care services furnished to a hospital patient

“Pay for Quality” – Legal Issues

McDermott Will & Emery

- CMP Law means that the hospital should:
  - Not use clinical protocols or elements of clinical protocols that could reduce or limit the quantity of health services that a patient receives;
  - Expressly grant physicians the freedom to depart from these protocols or the problematic elements of a protocol when clinically directed; or
  - Seek an advisory opinion from the OIG

Shared Savings Model

McDermott Will&Emery

- Hospital pays physicians a percentage of the savings realized by the hospital from a reduction in costs attributable to changes in the physicians' utilization of hospital resources
- Important to margins of hospitals who are paid a flat, case rate regardless of the patient length of stay or costs incurred
- What about the CMP Law?
- In 1999, OIG said shared savings programs are illegal
  - Rejected argument that law is limited to payments to reduce/limit the provision of medically necessary services
- Since 2001, OIG has issued favorable advisory opinions to at least 12 requestors

Shared Savings Model

McDermott Will & Emery

- OIG Advisory Opinions (AOs) limited to surgical/procedural supply costs
  - Cardiac surgery services: AOs 05-1, 05-3, 05-6, 06-22 and 07-21
  - Invasive cardiology: AOs 05-2, 05-4, 05-5, and 08-15
  - Invasive peripheral vascular: AO 08-21
  - Spine fusions: AO 08-9
  - Anesthesiology: AO 07-22
- AOs address AKS and CMP Law, but not Stark Law analysis since CMS administers the Stark Law

What does OIG look for?

McDermott Will & Emery

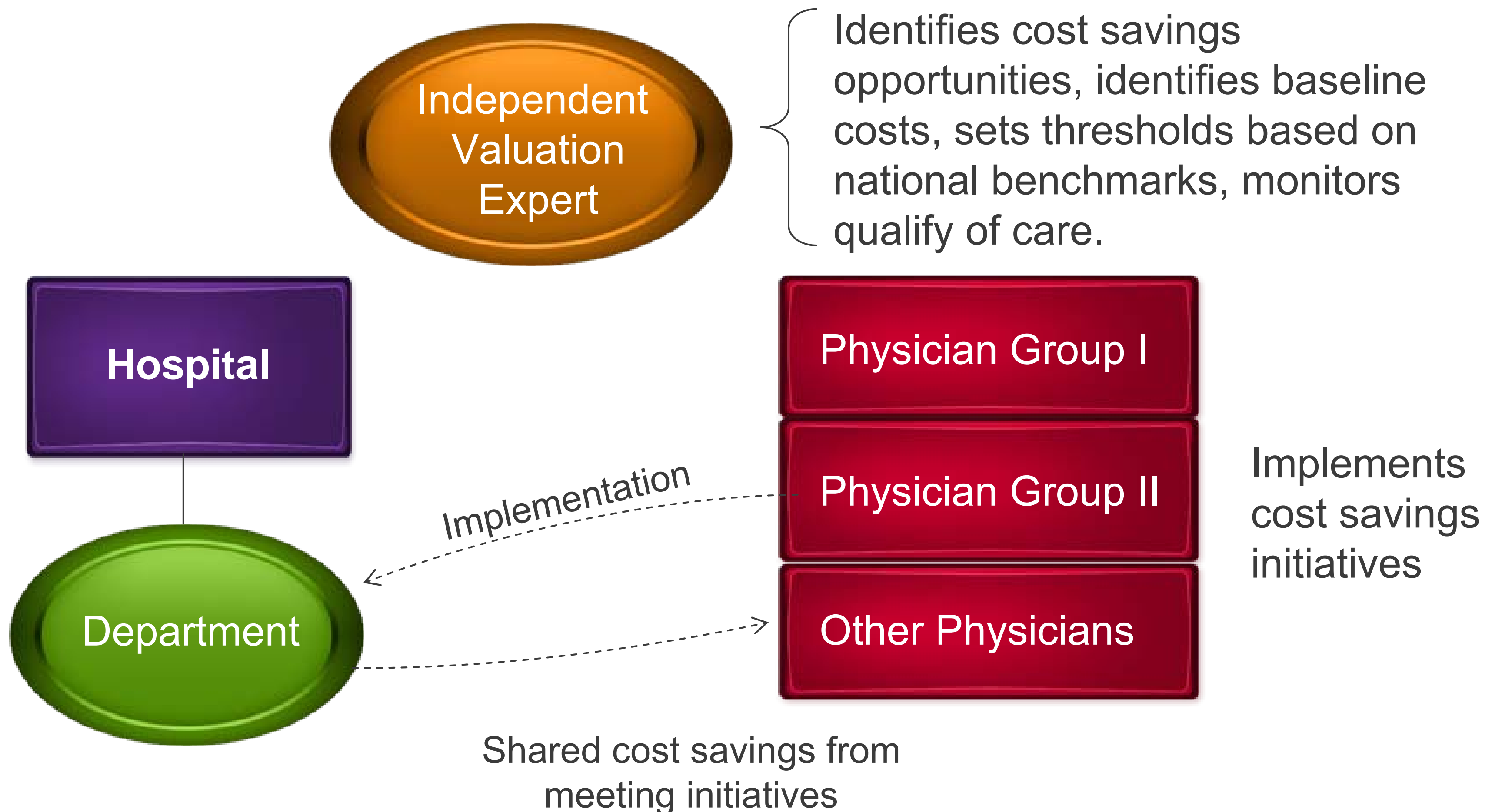
- The shared savings arrangements blessed by the OIG included the following elements, among others:
  - Credible evidence that quality of care is not adversely affected
  - Physician has discretion to depart from standardized product/supply; other products are still available
  - Portion of savings distributed to physicians is reasonable and distributed on a per physician basis and not based on referral volume
  - Duration of programs usually limited to one year
  - Physician referral patterns are unchanged
  - Cost-savings actions and resulting savings are clearly and separately identified, i.e., transparent
  - Arrangement is disclosed to patients

Shared Savings Model

McDermott Will & Emery

- Congress and Centers for Medicare and Medicaid Services are exploring, and seemingly recognize potential value of, shared savings programs
  - Two shared savings demonstration projects launched in mid-00's
  - Accountable Care Act extends one of the shared savings demonstration projects (report to Congress not due until 2012)
  - Participants in the demonstration projects exempted from the CMP Law, Kickback Law and Stark Law
  - CMS proposed Stark exception for shared savings/incentive payment programs in 2008, but still not finalized
    - excludes any payment for reduced lengths of stay

Shared Savings Model



Physician-Owned Distributors

McDermott Will & Emery

- In some areas, surgeons are organizing medical device distributors and distributing devices to the hospitals at which they implant or otherwise use the devices
- Like shared savings arrangements, the effect is to transfer a portion of the savings from medical device standardization to the surgeons through their return on investment in the distributor
- Distributors can be structured to satisfy the Stark indirect compensation arrangement exception
- These arrangements do not satisfy an AKS safe harbor and present a substantial risk under the AKS
- OIG has declined to say that they are per se illegal under the AKS despite urging of large medical device manufacturers

ACOs

McDermott Will & Emery

- An ACO is:
  - an organization of physicians, group practice, a hospital that employs physicians, or a hospital/physician organization
  - held accountable for the overall care of traditional fee-for-service Medicare beneficiaries assigned by CMS to an ACO
- By January 1, 2012, HHS must establish a shared savings or other payment model that:
  - promotes accountability for a patient population;
  - coordinates provision of items and services under Medicare parts A and B; and
  - encourages investment in infrastructure and care processes designed to ensure high quality and efficient service delivery
- CMS plans to propose ACO regulations in the fall of 2010

ACOs - Requirements

McDermott Will & Emery

- ACOs must:
  - Have defined processes to promote evidence-based medicine, report on quality and cost measures, and coordinate care
  - Enter at least a 3-year agreement with HHS and have at least 5,000 Medicare beneficiaries, without engaging in risk selection, e.g., avoiding sicker patients
  - Demonstrate that it meets the defined criteria for "patient-centeredness," including:
    - Use of individualized care plans
    - Patient and caregiver assessments
  - Be accountable for the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to ACO

ACOs – Payment Model Options

McDermott Will & Emery

- Shared Savings
- Partial Capitation
- Bundled Payment/Episode of Care (a pilot program)

ACOs – Payment Models

McDermott Will & Emery

- Shared savings
  - All of the physicians and facilities treating the ACO's assigned Medicare population are paid on a traditional FFS basis
  - The ACO receives a share of the savings Medicare realizes relative to cost benchmarks established by CMS for the ACO's assigned Medicare population by the ACO if the ACO:
    - Meets quality performance metrics; and
    - Exceeds the cost reduction benchmark
  - The ACO redistributes the shared savings payment to its constituent physicians and facilities

ACOs – Payment Models

McDermott Will & Emery

- Partial Capitation
  - ACO assumes financial risk for <u>some</u>, but not all, of the Part A and Part B services furnished to the ACO's assigned Medicare population
  - ACO paid a risk-adjusted per beneficiary, per month payment for the capitated services
  - Those Part A and Part B services not covered by the partial capitation payment are paid on a traditional FFS basis
  - The ACO presumably passes the risk and capitation payment through to the constituent physicians or facilities in a position to manage the utilization and quality of the capitated services

ACOs - Payment Models

McDermott Will & Emery

- Bundled Payment/Episode of Care
  - Affordable Care Act mandates a pilot program
  - Single payment for all professional and facility component services rendered during an episode of care involving a hospitalization
  - Episode of care includes:
    - 3 days prior to hospitalization
    - during length of impatient stay
    - 30 days post discharge
  - The Secretary of HHS must select up to 10 clinical conditions
  - No requirements to date as to how the ACOs would redistribute the bundled payment to the care providers

ACOs – Act Now

McDermott Will&Emery

- Providers should not wait for new Medicare ACO regulations to become effective
  - Should immediately begin creating, or converting existing managed care integrated delivery systems (e.g., PHOs; contractual risk-sharing affiliations) into, ACOs
  - Medicare, Medicaid, HMOs, PPOs and other insurers, including Self-funded Employers/Union Trust Funds, will want to contract with ACOs
  - Providers should use the next few years to build the HIT and other managed care-infrastructure necessary to thrive, and not just survive, oncoming payment reform

Significant Unanswered Questions About ACOs

- How will beneficiaries be assigned to the ACO?
- How will the ACO control costs when the patients are free to go outside the ACO for care?
- What level of savings below historical Medicare costs will trigger a shared savings payment?
- Will the potential incentive payments be enough to incentivize physicians to participate?
- How will the Secretary of HHS exercise her authority to waive application of the Kickback, Stark, and CMP Laws for the new payment models?
  - OIG not likely to support a broad waiver
  - Restrictive OIG safe harbors and Stark exceptions?
- Will CMS prescribe how shared savings and bundled payments must be redistributed?

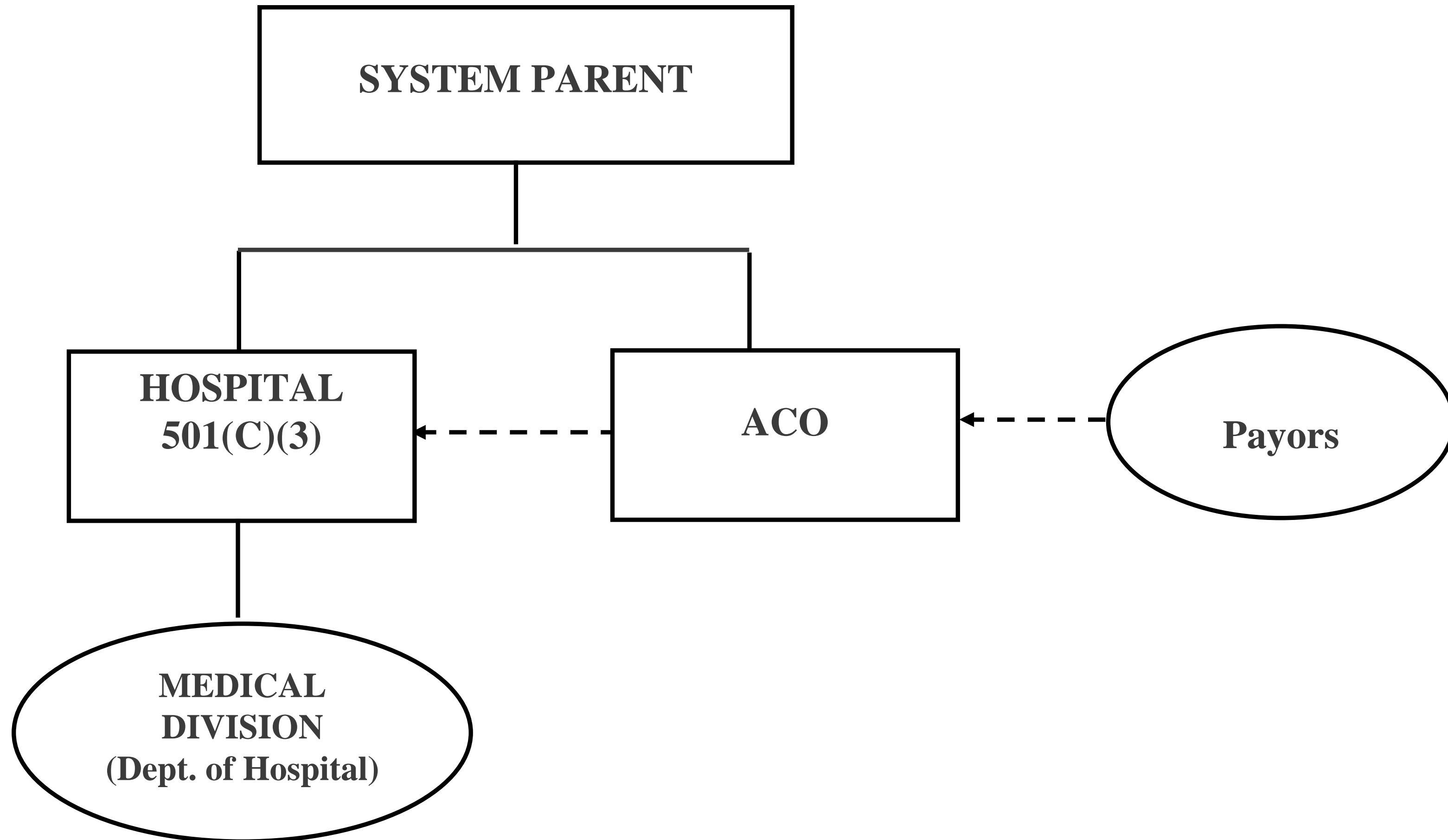
ACO Organizational Models

McDermott Will & Emery

- Direct Hospital Employment Model
- Hospital-Affiliated Group Practice Model
- Hospital-Affiliated Foundation Model
- Hospital/Physician Joint-Venture Group Practice
- PHO Model
- Contractual Affiliation Model

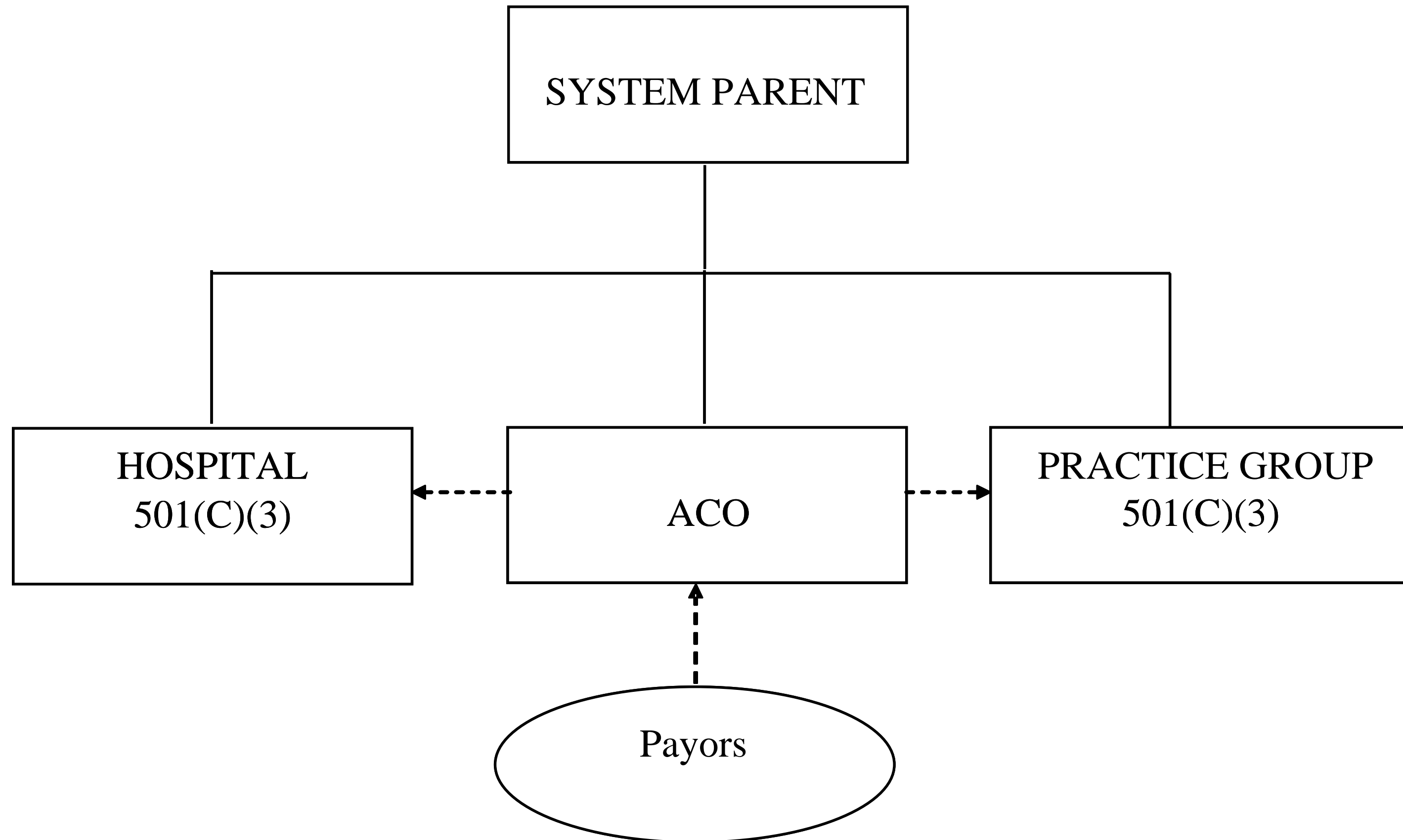
Hospital-Controlled Practice Model – Variation #1

McDermott Will & Emery



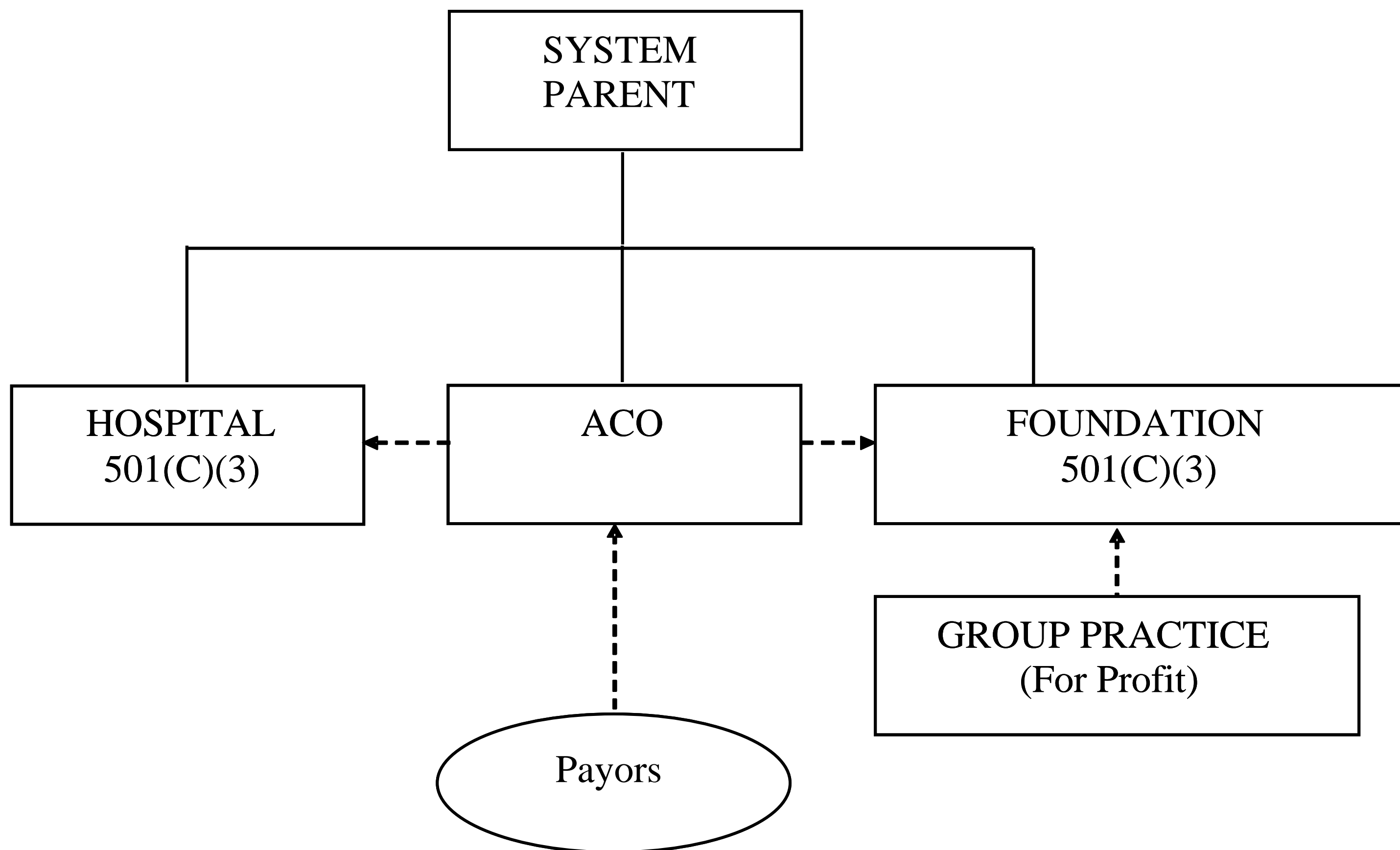
Hospital-Controlled Practice Model – Variation #2

McDermott Will & Emery



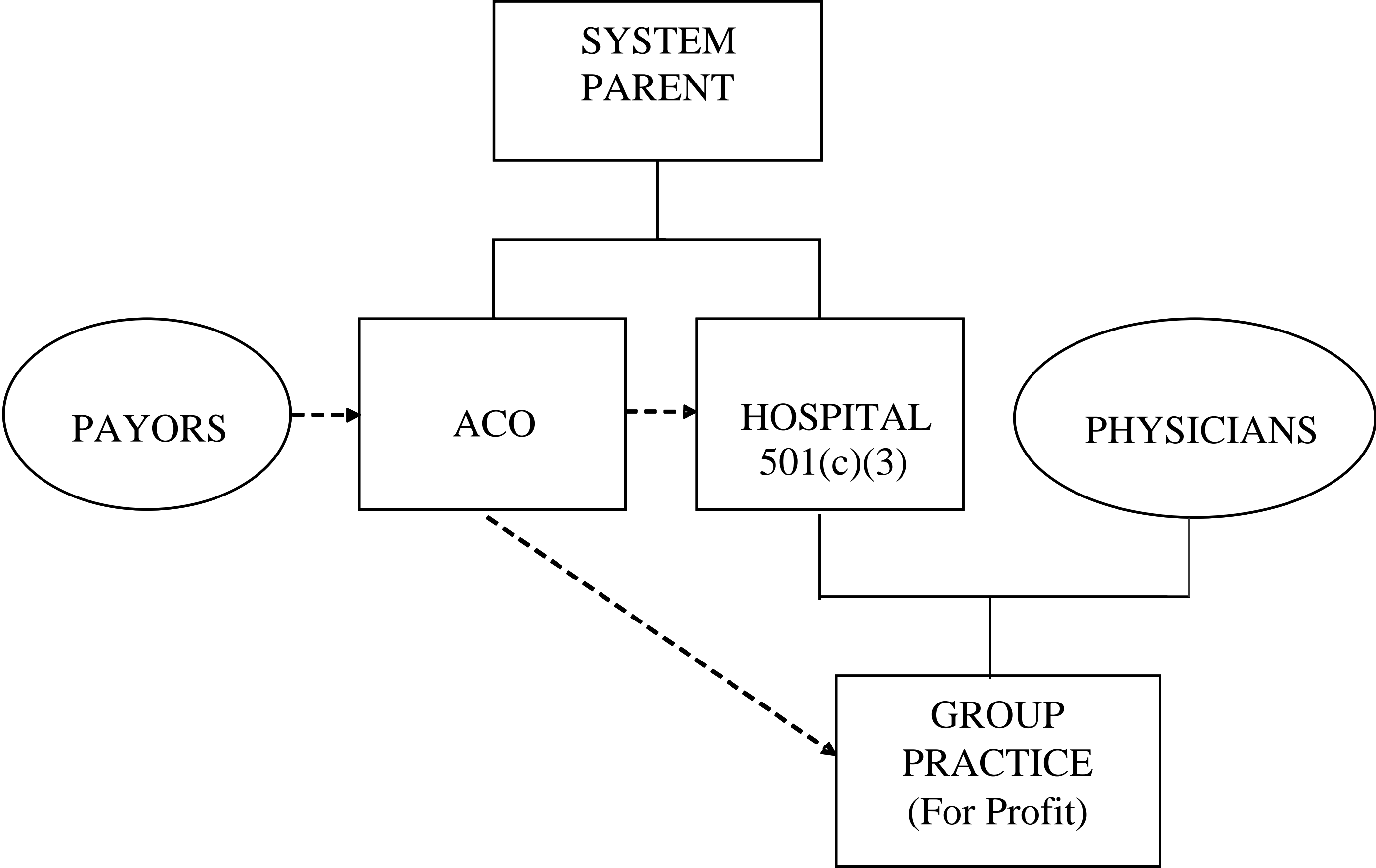
Foundation Model

McDermott Will & Emery



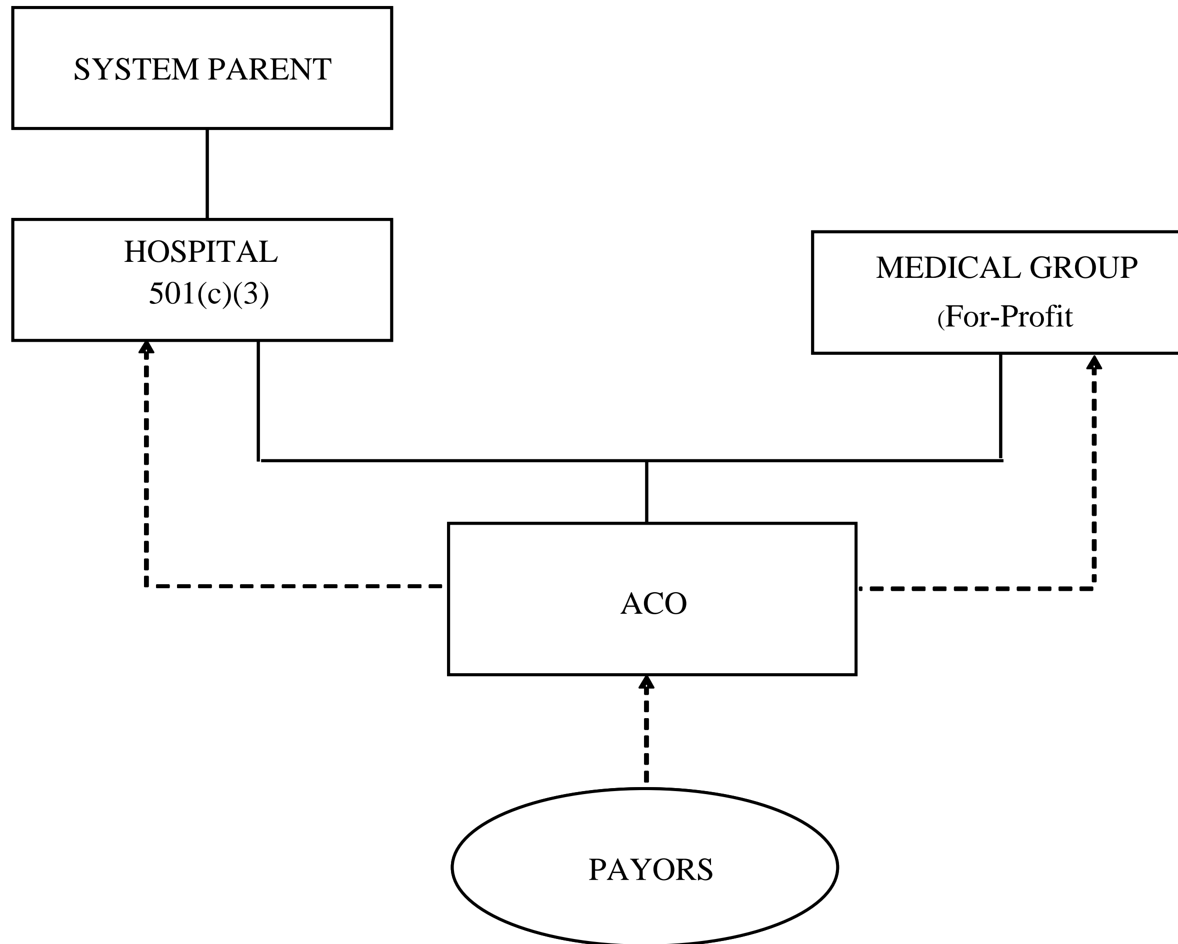
Joint-Venture Group Practice Model

McDermott Will & Emery



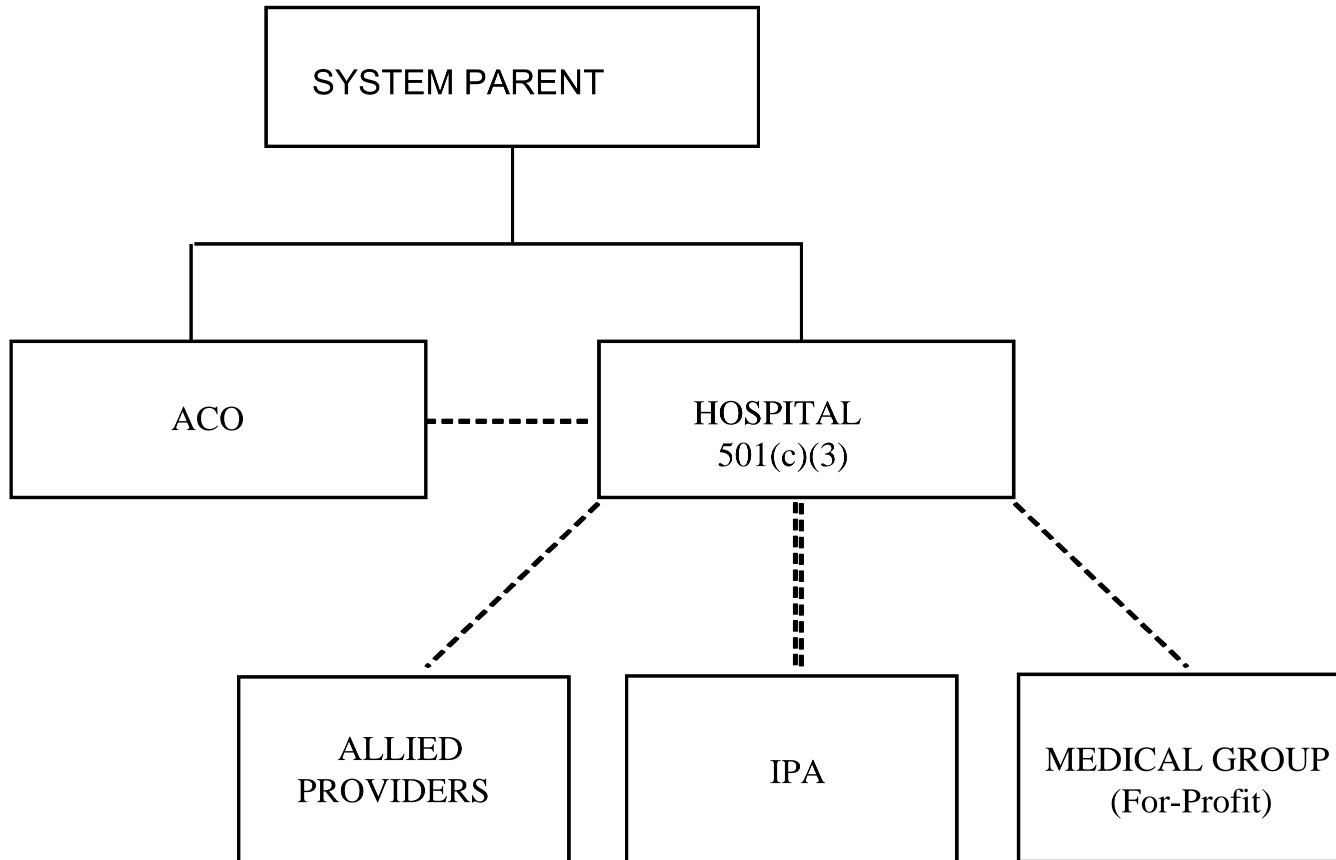
PHO Model

McDermott Will & Emery



Contractual Affiliation Model

McDermott Will & Emery



ACOs - Legal Issues

McDermott Will & Emery

- Antitrust Law
- Kickback Law
- Stark Law
- CMP Law
- Tax-exemption issues
- HIPAA compliance
- State law issues
  - HMO/Insurance
  - Corporate Practice of Medicine
  - Peer Review

ACOs & Antitrust Law

McDermott Will & Emery

- Joint Contracting Issues
  - If providers in an ACO are considered a single entity, the ACO will not face price-fixing concerns under Section 1 of the Sherman Act
  - *See Copperweld Corp. v. Independence Tube Corp*, 467 U.S. 752 (1984) (holding that there can be no illegal conspiracy between a parent and a wholly-owned subsidiary by virtue of the parent's control over the subsidiary).
  - If providers in an ACO are not considered a single entity, then they must demonstrate sufficient financial and/or clinical integration to constitute a single entity for antitrust purposes, i.e., a legitimate joint venture

ACOs & Antitrust Law

McDermott Will & Emery

- **Financial Integration** (*see* Statement 9 of DOJ's and FTC's *Statements of Antitrust Enforcement Policy in Health Care* issued jointly in 1996) means providers sharing substantial financial risk:
  - Capitation payments to venture from payers
  - Percentage of premium for designated services from payors
  - Withholds or other financial incentives for achievement of quality and/or cost containment goals
  - Bundled payments for a complex or extended course of treatment

ACOs & Antitrust Law

McDermott Will & Emery

- **Clinical Integration** under antitrust guidance includes
  - Evidence-based practice guidelines and benchmarks intended to improve quality and reduce costs
  - An active and ongoing program that evaluates and modifies practice patters by the venture's participants and creates a high degree of interdependence and cooperation among venture participants to control costs and assure quality
    - In other words, clinical integration requires HIT
  - Four advisory opinions; three favorable

ACOs & Antitrust Law

McDermott Will & Emery

- Policy statements by federal officials recognize that clinical integration can achieve pro-competitive benefits
  - Efficiencies → cost savings passed to consumers
  - Improvements in **quality**
  - Expanding services beyond current offerings

ACOs & Antitrust Law

McDermott Will & Emery

- Joint negotiations must be reasonably necessary to achieve legitimate purposes of the ACO
- Market Power. FTC/DOJ will evaluate horizontal and vertical effects of the ACO on competition
  - Over-inclusion of providers could be construed as a group boycott
  - Exclusive arrangements with payors

ACOs and Anti-Kickback, Stark & CMP Laws

McDermott Will & Emery

- Three principal provisions of the Social Security Act regulate financial arrangements between hospitals (or other health care facilities and suppliers) and physicians
  - Anti-Kickback Statute (42 U.S.C. 1320a-7b(b))
  - Stark Law (42 U.S.C. § 1395nn)
  - Civil Monetary Penalty Law (42 U.S.C. § 1320a-7a(b)(1))

ACOs and Anti-Kickback, Stark and CMP Laws

McDermott Will & Emery

- Problem for ACOs?
  - Laws evolved in context of fee-for-service Medicare/Medicaid
  - Without safe harbors and exceptions these laws do not easily accommodate innovative hospital-physician ACO and other coordinated care models
  - ACOs need the same flexibility enjoyed by Medicare Advantage plans

ACOs and Anti-kickback, Stark and CMP Laws

McDermott Will & Emery

- Good News: Accountable Care Act gives the Secretary the authority to waive compliance with the Kickback and Stark Laws "as may be necessary to" conduct:
  - any payment model for ACOs that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, including:
    - A shared savings program for ACOs; and
    - Partial capitation payment model for ACOs
  - the bundled payment/episode of care pilot

ACOs and Anti-kickback, Stark and CMP Laws

McDermott Will & Emery

- <u>Outstanding Issues</u>:
  - Will the scope of the waivers be broad enough?
    - OIG will have a say; unlikely that ACOs will have carte blanche
  - Will the waivers be too broad, leaving hospital-ACOs vulnerable to unreasonable financial demands by physicians?
  - Will the OIG and CMS create limited safe harbors and exceptions as they have done for donation of HIT?
    - If so, will they only set up the industry for more “technical” Stark violations and qui tam plaintiff lawsuits?

ACOs and Tax Exemption

McDermott Will & Emery

Overview of Key concepts for tax exemption under IRC §501(c)(3):

- Must be organized and operated exclusively for charitable purposes [as defined by 501(c)(3)], including:
  - Limited private benefit (earnings may be distributed to private individuals or non-exempt entities, if qualitatively and quantitatively incidental to the public benefit achieved thereby); and
  - No private inurement to insiders e.g., board members (per se violation of tax laws; no de minimus exception)

ACOs and Tax Exemption

- Can a nonprovider ACO contracting entity be tax-exempt?
  - PHO analysis: More than incidental private benefit to participants, unless all participants are tax exempt

ACOs and Tax Exemption

McDermott Will & Emery

- Will participation in a taxable ACO jeopardize exempt status?
  - No, if:
    - ACO furthers charitable purpose (e.g., reduces costs, improves quality and safety)
    - Tax-exempt participants (e.g., hospitals) bear no more than their proportional costs
  - Depending on ACO funds flow model, could be subject to more restrictive IRS for-profit/non-profit joint venture rule

ACOs and HIPAA Compliance

McDermott Will & Emery

- ACO’s constituent providers should be able to share health information under exceptions for:
  - Affiliated Covered Entity
  - Organized Health Care Arrangement
  - Business Associate Agreements with MSOs

ACOs and Certain Representative State Law Issues

McDermott Will & Emery

- Corporate Practice of Medicine
- HMO/Insurance/Managed Care Contracting Laws
- Peer Review Laws

Recap

McDermott Will & Emery

- Hospital-physician alignment strategies should reorient both to the “brave new world” of health care delivery and payment reform
- 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
- Whether under acquisition/employment, or contractual affiliation, models, emerging payment arrangements will reward effective clinical and financial integration between hospitals and physicians across the continuum of care, and punish the failure to do so
- Key to any strategy is an EHR and other health information technology
- Develop and implement your strategy now!

McDermott Will & Emery

Hospital-Physician Clinical Integration

HFMA Physician Hospital Alignment Relations Program

November 15, 2010

Daniel F. Gottlieb

312.984.6471

dgottlieb@mwe.com

© 2010 McDermott Will & Emery LLP. McDermott operates its practice through separate legal entities in each of the countries where it has offices. This communication may be considered attorney advertising. Previous results are not a guarantee of future outcome. The following legal entities are collectively referred to as "McDermott Will & Emery," "McDermott" or "the Firm": McDermott Will & Emery LLP, McDermott Will & Emery/Stanbrook LLP, McDermott Will & Emery Rechtsanwälte Steuerberater LLP, MWE Steuerberatungsgesellschaft mbH, McDermott Will & Emery Studio Legale Associato and McDermott Will & Emery UK LLP. These entities coordinate their activities through service agreements. This communication may be considered advertising under the rules regulating the legal profession.

DM_US 26863915.1 T04540.0010