ACCOUNTABLE CARE ORGANIZATIONS

Steven N. Beck sbeck@fredlaw.com

Laurie E. Hartman lhartman@fredlaw.com

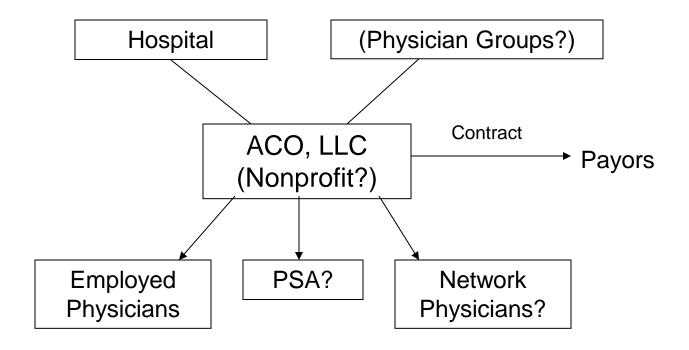
Fredrikson & Byron, P.A. Minneapolis, MN 55402 (612) 492-7000



Two Kinds

- Medicare Shared Savings Program ("MSSP")
- "ACO"s that contract with commercial insurers

GENERIC ACO MODEL



ACO Entity and Governance

- If a separate legal entity will be formed:
 - Nonprofit or for profit?
 - Tax exempt or taxable?
- Reserved powers of the health system
 - Approval of Board members selected by a nominations committee
 - Amendments to governing documents
 - Sale, merger, dissolution
- Accountability of ACO officers
 - Will the CEO and CFO report to the ACO board or to health system executives (or both)?
 - Selection and removal a possible reserved power of the health system
- Consider impact of peer review and movement of peer review protected information between ACO and health system



Legal Barriers to ACO Integration

Federal:

- Antitrust Law
- Antikickback Statute ("AKS")
- Stark Law
- Civil Monetary Penalties ("CMP")
- Nonprofit/Tax Exemption

Legal Barriers to ACO Integration (cont.)

State:

- Insurance laws
- Managed care laws
- Antikickback laws
- Self-referral laws / "Mini-Stark" laws
- Fee splitting
- Corporate practice of medicine
- Antitrust
- Securities laws



Antitrust

- Competitors prohibited from cooperating to set prices.
- If creating a new, integrated product, arguably not price fixing.
- FTC Antitrust Guidelines -- rules for determining whether integration (financial, clinical) is sufficient.
- 30% non-exclusive, 20% exclusive.
- If a joint venture (due to sufficient integration), a balancing test is still applicable.



Applying the Balancing Tests

- Shared savings
- Capitation
- Bundled payments



AKS Basics

- Intent-based
- Greber test
- Presumptions by regulators
- Managed care
- Special waiver may be available



Stark Basics

- Intent irrelevant
- Non-FMV payment deemed to take into account volume or value
- Managed care exception
- Special waiver may be available

CMP Basics

 Payments to physician to reduce or limit services

Nonprofit / For Profit

- Most hospitals are nonprofit entities under state law.
- Generally, nonprofit entities cannot distribute profits to members, except other nonprofits.

Tax Exemption

- Many hospitals are tax exempt ("501(c)(3)").
- Prohibited from sharing profits, or paying in a manner that gives rise to private inurement, private benefit, disqualified transactions.
 Tax consequences for unrelated business income.
- No exemption in law.
- Insurance companies are not permitted to be exempt under 501(m) of the Code.

How Can ACOs Pay?

- Distributing risk may create insurance law problems.
- Payments to independent contractor physicians may create problems under Medicare and tax exemption laws.

Commercial ACO Payments

- Care management / administration
- Quality improvement
- TCOC incentive shared savings
- Individual cost incentives
- Down-side risk
- Withhold
- Bundled payments
- Capitation



Legal Issues Implicated by Distribution

- Medicare Fraud and Abuse
- Antitrust
- Insurance
- Tax Exemption



State Insurance Laws

- States regulate entities engaged in the business of "insurance"
 - Defined by state statute and case law
 - Assumption of financial risk of loss
- Allocation of risk vs. contract for services: What is the primary purpose of the arrangement?
 - Pricing of own services typically okay.
 - Risk on another's services, pooling patients to manage risk, fixed payment unrelated to utilization: more likely to = insurance.

TBD: What Risk is Allowed?

- Downstream Risk: many states do not regulate provider organizations when risk is assumed from a licensed insurance carrier.
- Some states regulate such risk bearing organizations under insurance/managed care laws
- Direct contracts with ERISA plans do not shield from insurance/hmo regulation

Applicability of Insurance/HMO/ Managed Care Licensing Laws

- Will depend on the state in which the ACO operates
- Multi-state operation?
- May depend on the particular payment structure:
 - Type of payment arrangement
 - Level at which state regulators conclude that the quantity or nature of transferred risk is sufficient to constitute "insurance"
 - Scope of services



How Can ACOs Take Real Risk?

- Meet requirements of insurance laws
 - Financial solvency & capital reserve requirements
 - Compliance with myriad insurance regulations
- Always contract with/via a regulated entity (unless state law says otherwise)

Other State Regulation?

- Third Party Administrator license
- Regulation of indirect provider contracting/network organizations
 - May affect structure of organization



ACO Participation Agreements

- What providers in the ACO network?
 - Eligible provider types, specific providers
- What type of payer arrangements will ACO pursue?
 - Delegation of rights to contract for any and all health services to ACO?
 - Or partial delegation of rights to contract only for incentive arrangements?
- All In vs Opt In
 - By payer? Plan type? Type of incentive arrangement?



ACO Participation Agreements (cont.)

Exclusive vs. non-exclusive

- Allow participation by providers in competing ACOs?
- Larger specialty groups in metropolitan areas may admit patients at hospitals in multiple systems; will they then participate in other ACOs with competing systems?
- Antitrust considerations
- State law limitations

Term and termination

- Allow termination without cause with advance notice?
- Continuity of care or payer obligations
- If a group terminates during the term, would incentives be paid (deficits owed)?



ACO Participation Agreements (cont.)

- Bind to terms of payer agreements
- Attribution of patients/lives
- Clinical management
- Data sharing
- Quality improvement and performance
- Reporting
- IT infrastructure/EHR/interoperability
- Payment



ACO Participation Agreements (cont.)

Ripple effects?

- What impact on reimbursement under the current payer agreements as new incentive arrangements are created?
 - Will health system reimbursement go down or be placed more at risk?
 - Potential antitrust concerns over price fixing
- Effect on physician compensation as new arrangements take effect (e.g., health system pays employed MDs based on wRVUs which are no longer aligned with new payment reforms)



Payer Agreements

- Which ACO network providers are included?
 - All in? Opt-in? Payer discretion?
 - Process for adding or terminating providers
 - Exclusivity requirements
- Agreement with ACO: in addition to or in place of provider network agreements?
- Scope of benefit plans/health insurance products included



- What membership included? (or eligible)
- Methodology for attribution/assignment
 - Can this be changed?
 - If so, how and when?
- Competition



- Data sharing & reporting: what, when, how
 - How much
 - Clinical reporting
 - Status updates; performance reports
- Sharing of PHI- HIPAA, state law
- Business Associate Agreements
- IT requirements



- How much transparency?
 - description of compensation arrangement / methodology
 - description of quality performance measures and requirements
 - How measured
 - How performance on quality measures affects payment(s)
- Other compensation: patient care management fee, administration

- Term and Termination
 - Impact of early termination on payment
- Process for resolving discrepancies

Should I Form an ACO?

- Expensive
- Little return on investment
- Sufficient population/attributed lives
- Change is hard

Can I Bring Value to an ACO?

- Population health
- Populations with behavioral health conditions
- Care management
- Protocols
- EHR data elements for behavioral health



Should I Join an ACO?

- Access to patients
- Enhanced reimbursement
- Participation in a model that may become more important
- Seat at the table



Questions?

