Integrated Delivery Networks and What They Mean for Compliance

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Integrated Delivery Network (IDN) Goals

- Historically goals included:
  - Enhance physician/hospital alignment
  - Enhance quality of care and patient satisfaction
  - Control cost increases
  - Improve patient access to care
  - Integrate sufficiently to allow joint negotiation of payor agreements
IDN Goals (cont’d)

- “Triple Aim” of health care, summarized in 2008 article by Dr. Donald Berwick and two colleagues
- Improving the health care system “requires simultaneous pursuit of three aims:
  - improving the experience of care,
  - improving the health of populations, and
  - reducing per capita costs of health care.”

Physician/Hospital Alignment Strategies: Past and Present

- Clinical service line co-management agreements
- Joint ventures
- Acquisition, employment of physicians
- On-call arrangements
- Medical services, practice support agreements
- Physician recruitment
- Hospital assistance with physician liability insurance and joint ventures
Integrated Delivery Networks (IDNs)

- Known by many names, including
  - Accountable Care Organizations (ACOs)
  - Clinically integrated networks
  - Financially integrated networks
  - Physician hospital organizations (PHOs)
  - Patient centered medicine
  - Medical homes
  - Population (health) management

- Share similar goals

Key to Compliance Analysis: Follow the Money

- Financial issues
  - Payor contracting strategies
  - Direct contracting with employers
  - Who are the providers for billing purposes?
  - Who performs billing numbers?
  - What items and services can be billed?
  - How are funds distributed among providers?
Recent Evolution of IDNS: ACOs

- Major health care payment reform: Patient Protection and Affordable Care Act (ACA) enacted in 2010
- Many demonstration and pilot projects
- Major thrust: Accountable Care Organizations (ACOs) and Medicare shared savings program (SSP)

What is an ACO?

- An organization of physicians and health care providers (usually physician-led) providing care in a way that is intended to improve quality and reduce overall costs
- Many possible organizational models
- Specifically referenced in ACA for limited Medicare SSP and Medicaid pilot project only
- Other IDNs may possess many of ACO characteristics but decide not participate in SSP
Successful IDNs

- Have an enhanced ability to obtain and utilize data effectively to improve quality and reduce costs.
- New payment structures may/should result from effective development and operation of IDNs.
  - ACO may be physician-led and include a full range of providers.
  - Payment may move away from fee for service for individual items and services to reflect quality and cost goals.
  - Is payment reform a temporary trend or longer trend?

Achievement of Goals

- IDN must contain effective care integration and coordination programs.
- “Medical homes” that are patient-centered can be a very effective means to be the central coordinator of health care.
- Health information infrastructure is essential
  - Define the population
  - Define the source for data: electronic health records (“EHR”); or paid medical claims; access TPA claims
- “Clinical integration” is important to achieving IDN’s goals.
Questions/Decisions

- Should physicians and other providers form ACO to participate in Medicare and Medicaid programs under ACA?
- Should they form IDN to be able to benefit their market, payors, employer health plans?
- How much should be invested in forming IDN? How much investment is required?

Reimbursement Reform

- Today, fee-for-service payment of physicians (for real management of Medicare physician services in most situations)
- Trends:
  - Medicare SSP
  - Bundled payments/case rates
  - Global payments/partial cap
Bundled Payments/Episodes of Care

- One payment for an episode of care, combining hospital/physician and perhaps other services in one payment
- Secretary required to establish a pilot project for integrated care during an episode of care around a hospitalization

Antitrust Issues

- Is there a potential for IDN participants to jointly contract with payors? Issues include:
  - Single entity or multiple entities
  - Financial Integration
    - Capitation
    - Percentage of premium
    - Withholds
    - Bundled payments
  - Clinical Integration
  - Market Power
Antitrust

- Federal officials have recognized that clinical integration can achieve pro-competitive benefits
- May permit collective negotiation with payors where there is sufficient integration
- Also consider direct IDN negotiation with self-insured employers
- Ability of IDN to restructure formula for payments

Antikickback/Stark/CMP Law

- Federal laws designed to regulate fraud and abuse in fee-for-service health care financial relationships
  - Antikickback Statute (AKS) (42 U.S.C. 1320a-7b(b))
  - Stark Law (Stark) (42 U.S.C. § 1395nn)
  - Civil Monetary Penalty Law – Limiting hospital payments to reduce or limit provision of medical care (CMP Law) (42 U.S.C. § 1320a-7a(b)(1))
ACO Waivers

- ACO Pre-Participation Waiver
  - Waiver is designed to allow potential ACOs and ACO participants to share resources to start ACOs
  - Waives fraud and abuse laws for start-up arrangements that meet all conditions

- ACO Participation Waiver
  - Arrangement between the ACO, one or more ACO participants, and/or ACO providers/suppliers, is not a violation of the fraud and abuse laws, if all conditions are met
ACO Waivers

- **Shared Savings Distribution Waiver**
  - Waives fraud and abuse laws with respect to the distribution or use of shared savings earned by the ACO under the MSP, provided all conditions are met.

ACO Waivers

- **Compliance With the Stark Law Waiver**
  - Waives the AKS and Gainsharing CMP with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Stark Law, provided all conditions are met.
ACO Waivers

- Waiver for Patient Incentives.
  - Waives application of the Beneficiary Inducement CMP and the AKS for items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair-market value if all conditions are all met

ACO Waivers

- Waivers are limited to SSP, and they generally do not extend to demonstration programs approved by the Center for Medicare and Medicaid Innovation.

- No specific waiver for commercial ACOs, but the waivers do offer some flexibility. For example, CMS/OIG note that the Participation Waiver does not turn on the source of funds, and many commercial shared savings arrangements may qualify for the Stark Compliance Waiver.
ACO Waivers

- Patient Incentives Waiver is intended to allow arrangements to engage patients in better managing their own health care. The exception does not include financial incentives such as waiving or reducing cost sharing amounts, the provision of free or below-cost items, or service by manufacturers or other vendors.

- CMS/OIG intend to monitor ACOs through June 2013 and indicate that they may narrow the Waivers if they find they are used to shelter abusive arrangements.

ACO Antitrust “Waiver”

- Unlike the Fraud and Abuse waivers, the FTC/DOJ Policy Statement does not set forth a waiver of antitrust laws.

- Rather, the Policy Statement is a “statement of antitrust enforcement policy.” The Policy Statement reduces antitrust scrutiny of providers and suppliers that form and operate an ACO, based upon the individual facts and circumstances. The Policy Statement also gives additional guidance regarding how the Agencies’ will view joint contracting with payers and clinical integration.
ACO Antitrust “Waiver”

- Antitrust laws must be analyzed notwithstanding the exemption of certain activity from the antitrust laws by regulations issued at the time the proposed ACO rules were promulgated.
- There is still potential antitrust risk to assess regarding whether the ACO possesses sufficient market power to raise concerns regarding increased anti-competitive effect on the relevant market.
- This risk can arise both with respect to vertical integration (because of the presence of most types of health care providers) and horizontal integration.

If the ACO and its members engage in anti-competitive actions, in particular collective negotiation of managed care agreements with non-Medicare payors, then risk is raised if the members are competitors.

- As a general rule, competitors cannot negotiate terms such as price or division of the markets without a legitimate antitrust defense.
- In recent years, providers who are competitors have obtained favorable FTC advisory opinions if they can show that they are sufficiently clinically integrated and/or financially integrated.
- Messenger model has questionable remaining usefulness.
Securities Laws

- Federal securities laws and state Blue Sky laws should be analyzed with respect to the offering and sale of ownership interests in the ACO entity.
- In most cases there will be applicable exceptions or exemptions.
- There should be consideration given to whether such laws require documents to be signed by the prospective members of the ACO.
  - It may be useful to have the documents reflect that the members have certain status, such as a sophisticated investor, that is necessary to meet an exemption.

Other Laws

- State laws generally regulate entities that assume insurance risk.
  - Most states have not considered an ACO-type entity when enacting their insurance laws and regulations.
  - Health maintenance organizations and health insurers are subject to state regulation.
  - A preferred provider organization ("PPO") may be regulated depending on the nature of the organization and the specifics of state law.
  - ACOs are not the same as HMOs, insurers or PPOs. If the ACO assumes insurance risk, a state law may require some kind of regulatory compliance or at least an opinion from the relevant administrative agency.
Other Laws

- Federal and state tax laws
  - Federal tax exempt status
  - State nonprofit status
  - Unrelated business income
  - Lobbying compliance
  - EMR
  - Providing technology to physicians for low or no cost
- Compliance with HIPAA and state laws for confidentiality of patient medical records
- Will state law protect peer review (and similar) records from disclosure?

Risk Management

- Arrangements for insuring/self-insuring various risks of IDNs are still in development stage
- Can hospital insurance be extended to other providers in the IDN?
- Indemnification issues
Current Laws Principally Address

- Potential for overutilization in our fee-for-service payment system
- Removal of financial considerations from medical decision-making
- No payments for referrals
- Unfair competition
- In Hospital PPS system: avoid stinting on care (underutilization of necessary care)

Conclusion

- Pressure to increasingly align all providers, and particularly physicians, will continue.
- As gains in quality and cost control are demonstrated, pressure to form IDNs will increase.
- ACOs are both an opportunity and a threat.
- How will achieving these goals be balanced against goals of applicable laws?