# ACOs: Navigating The Legal Minefield

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Accountable Care Organizations ("ACOs") hold great promise, but they are being placed upon a legal framework premised upon the fee-for-service health care payment model. This generates a number of challenging legal issues. Adaptations of the most problematic laws are promised. This last April, the same month the proposed regulations to implement the Medicare Shared Savings Program ("MSSP") were published in the Federal Register, guidance was issued on application to ACOs of the most potentially stifling bodies of law—the antitrust laws, Stark law, anti-kickback statute, and the Civil Monetary Penalties law. Unfortunately, the applicability is very limited. The documents basically address only ACOs participating in the MSSP, and reports are that virtually no ACOs will, absent major overhaul of the proposed regulations. Reference is made to the proposed MSSP regulations and the noted Federal Register postings, but because they do not provide current meaningful guidance, they will not be discussed further.[1]

In addition, ACOs raise a host of other legal issues because they often involve multiple parties and complex or novel business arrangements. Different ACO models will raise different sets of issues.

The following is an introduction to the principle bodies of law impacting ACOs:

**A.** **Antitrust** – Antitrust laws aim to protect consumers by promoting competition. The two agencies enforcing the federal antitrust laws, the U.S. Department of Justice ("DOJ") and the Federal Trade Commission ("FTC"), look to avoid unfair collusions of supposed competitors and monopolistic behavior. Health care has been regulated by the antitrust laws since 1974, and the agencies have developed expertise and guidance regarding which behaviors are not pro-competitive.

The federal antitrust laws are principally found in three key statutes: The Sherman Act, the Clayton Act, and the Federal Trade Commission Act.

Section 1 of the Sherman Act, 15 U.S.C. § 1, prohibits contracts, combinations and conspiracies which unreasonably restrain competition.

Section 2 of the Sherman Act, 15 U.S.C. § 2, prohibits monopolization, attempted monopolization and conspiracies to monopolize.

Section 7 of the Clayton Act, 15 U.S.C. § 18, prohibits mergers and acquisitions which may lessen competition or tend to create a monopoly.

[1] 76 Fed. Reg. 19528 (April 7, 2011); 76 Fed. Reg. 19655 (April 7, 2011); 76 Fed. Reg. 21894 (April 19, 2011).



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Section 7A of the Clayton Act, 15 U.S.C. § 18(a), known as the "Hart-Scott-Rodino Antitrust Improvements Act of 1976," requires parties to certain mergers, acquisitions, joint ventures and corporate and non-corporate formations to notify the FTC and DOJ about the transaction before the transaction closes.

Section 5 of the FTC Act, 15 U.S.C. § 45, prohibits unfair methods of competition. The FTC Act can also be used to challenge merger which are not technically covered under Section 7 of the Clayton Act. *See FTC v. Brown Shoe Co.*, 384 U.S. 316, 321 (1966). Only the FTC has jurisdiction to sue under the FTC Act.

While ACOs can provide a pro-competitive integrated method to raise quality and lower costs impossible for its component parts to delivery individually, it is also a collaboration of erstwhile competitors negotiating, collecting, and distributing significant dollars. The antitrust laws potentially apply to ACO through fee negotiations, market allocation within an ACO or among ACOs, exclusivity, boycotts, and undue market power. Detailed compliance analysis is beyond the purview of this overview, but the body of guidance provided by the DOJ and FTC will allow the ACO dedicated to providing greater value to be organized and operated successfully. Most noteworthy is the "clinical integration" exception.[2] The antitrust laws generally apply to private commercial health care, rather than to public payors.

**B.** **Stark Law** – Stark Law is the federal physician self-referral law. The law reflects Congress' fear that patient referrals are often unduly influenced by a profit motive, thereby undermining utilization, patient choice, and competition among participants in the federal healthcare programs. A government concern in the ACO context occurs when physician referrals are "controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price."[3]

Stark Law has two basic prohibitions: a referral prohibition and a billing prohibition. Under the referral prohibition, a physician may not refer certain services to an entity where payment for that a designated health service ("DHS") is made under Medicare and where the physician (or a family member) has a financial relationship with the entity.[4] The term "financial relationship" is defined in the Stark Law to include both compensation arrangements and interests in investment and/or ownership. Under the billing prohibition, a healthcare provider may not bill for improperly referred services.

Congress and CMS have created dozens of exceptions to mitigate the breadth and strict liability harshness of the law. ACOs generally will need to navigate the Stark Law and regulations by determining if there is a "physician" making a "referral" to an "entity" for the "furnishing" of a "DHS" covered by Medicare. Next, if so, does the physician (or immediate family member) have a "financial relationship" with the entity? Next, if so, does this arrangement qualify under one of the exceptions? Although there are myriads of ACO referral scenarios, it is highly probably that there will be a Stark Law triggering "referral" and "financial relationship," especially if a hospital is involved in the ACO. If the source of funds is not a participating hospital or passes through the hospital, chance of applicability is much reduced.

[2] *The Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care* (1998), Statement 8, Physician Network Joint Ventures.
[3] Stark II, Phase II Proposed Regulations (Preamble), 63 Federal Register 1659, 1662 (1998).
[4] 42 U.S.C. §1395(n)(n).


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In July 2008, CMS proposed a new exception covering Shared Savings. In addition, the employment, personal services, fair market value, and indirect compensation arrangement exceptions may apply to typical ACO arrangements.

**C. Anti-Kickback Law** – There are both federal and state anti-kickback laws. The federal Anti-Kickback Law is related to Stark Law and it prohibits one person from "knowingly and willingly" giving "remuneration" to another if the payment is intended to "induce" the recipient to (1) refer an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under a federal healthcare program; (2) purchase, order or lease any covered item or service; (3) arrange for the purchase, order or lease of any covered item or service; or (4) recommend the purchase, order or lease of any covered item or service. In short, the law prohibits any payment intended for referrals where payment for services is made under a federal healthcare program.[5] Unlike the Stark Law, however, the federal Anti-Kickback Law is an intent-based statute with both criminal and civil liabilities. Also, the Stark Law's prohibitions apply only to Medicare; the Anti-Kickback Law covers all federal health care programs (with the exception of the Federal Employee Health Benefits Program).

The federal Anti-Kickback Law is so broad that it covers many common and non-abusive arrangements. Recognizing this over-breadth, the U.S. Department of Health and Human Services Office of Inspector General—the agency charged with enforcing the Anti-Kickback Law—has established a large number of statutory exceptions and regulatory safe harbors. Several exceptions/safe harbors may apply to the ACO model, including Personal Service Arrangements, Fair Market Value Compensation, and Indirect Compensation arrangements. The safe harbors, however, are fairly narrow, especially in the face of the breadth of the Anti-Kickback Law.

To augment the protection provided by the safe harbors, the Office of Inspector General has implemented an "advisory opinion" program through which organizations and arrangements apply for a waiver. Pursuant to this program, organizations may submit proposed arrangements to the agency and request, in effect, a "case-specific" safe harbor. The Office of Inspector General has issued over two hundred advisory opinions.

An ACO would analyze applicability of the Anti-Kickback Law as follows: Was there "remuneration" flowing from a person or entity in a position to benefit from a referral of a federal health care program patient to the potential referral source? If so, was it intended to induce conduct in violation of the Act? If so, is it protected by a safe harbor? If not, is there a material risk of an abuse sought to be prohibited by the Act?

To mitigate risk, ACOs should not be making arrangements with this intent and should have safeguards in place.

**D. Civil Monetary Penalties Law** – The Civil Monetary Penalties ("CMP") Law provides that if a "hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals" who are (1) entitled to Medicare or Medicaid benefits and

[5] 42 U.S.C. §1320a-7b(b).


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(2) "under the direct care of the physician," then the hospital and physician are subject to a Civil Monetary Penalty of $2,000 for each individual with respect to whom the payment is made.[6] The CMP Law only applies to payments from hospitals to physicians. The key to the law is that if the hospital is paying or administering ACO-related payments (*i.e.*, incentives to physicians), *the goal cannot be to limit care to necessary services*. The CMP Law recognizes that hospitals have a legitimate need to eliminate "unnecessary care;" however, there is no explicit distinction made in the law between "necessary" and "unnecessary" care.

There is inherent tension between the CMP Law and the ACO model. In reality, the efficacy, efficiency and lowered costs of ACOs depend on the incentives of gainsharing and value-based reimbursements. However, bundled payments, gainsharing and capitated arrangements (in which the hospital keeps the remainder of payments not distributed to the physicians) all may implicate the CMP Law. The Patient Protection and Affordable Care Act includes an amendment to the CMP Law for remuneration that promotes access to care and poses a low risk of harm to participants.

Note that the CMP Law only applies to Medicare or Medicaid payments from hospitals to physicians. However, if it is, "reduce or limit" services has been interpreted quite broadly. There have been a number of advisory opinions from the OIG. If the narrower CMP Law is applicable, an ACO either refrains from the conduct or undertakes it consistent with the OIG's guidance and/or the PPACA amendments to mitigate, but not eliminate, the risk.

**E. Tax Exemption and Inurement** – The first tax exemption question is whether the newly-created ACO entity might qualify for tax exemption? Early indications are that a properly structured one can. The next question is whether the shared savings and other payments among tax-exempt members of the ACO are consistent with their tax-exempt status? A related question is whether, for example, payment from a hospital's ACO to a member of its medical staff is an improper "inurement?"

**F. HIPAA and Other Health Information Privacy and Security Laws** – The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") established standards and requirements for healthcare providers and health plans to protect confidential patient information. HIPAA's privacy standards (impacting covered entities and individuals) can be organized into four major areas: (1) Administrative and training requirements; (2) the requirement for policies, procedures, and forms regarding how patient information is used and disclosed; (3) certain requirements regarding patient access to their own information; and (4) the requirement for agreements and policies regarding how business associates keep information confidential.

For health information privacy and security law, the critical sections are the Privacy Rule and the Security Rule of Title II of HIPAA. The HIPAA Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes. The Security Rule complements the Privacy rule and specifies

[6] 42 U.S.C. §1320 a-7a(b)(1)


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a series of administrative, physical, and technical safeguards for covered entities to assure the confidentiality, integrity, and availability of electronic protected health information.

HIPAA sets the federal "floor" of health privacy protections. There are other, more stringent, health information privacy laws, both at the state and federal level. For example, Part 2 of Title 42 of the Code of Federal Regulations regulates the privacy restrictions on information regarding substance abuse. For example, health information privacy laws related to mental health and communicable diseases are prescribed by the state in North Carolina. HIPAA privacy regulations generally do not preempt state laws that are more stringent than the HIPAA privacy standards regarding patient confidentiality or reporting.

HIPAA was amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH" Act), which was enacted as part of the American Recovery and Reinvestment Act of 2009. HITECH enacted expansive changes to HIPAA aimed at encouraging the sharing of electronic health information. It also provides funding assistance and incentives to encourage implementation of electronic health records. It expanded business associate responsibilities and liability (discussed below) and expanded patient rights.

The well-known compliance considerations for HIPAA and related laws are generally the same regarding health information exchange within and among ACOs.

**G. Professional Liability Common Law** – Malpractice is a cause of action that by its nature differs from other liability theories in ways that make it less susceptible to sudden change. A professional liability, or malpractice, claim must generally demonstrate that harm arose from a departure from the "standard of care." The standard of care must be established by medical expert testimony and the harm for which the plaintiff seeks damages must proximately arise from a breach of the standard of care.

ACOs are deeply involved in the aggregation of digital health information to be available at the point of care and in fostering best practices to influence physician medical decision-making. These activities raise interesting malpractice issues:

- The Duty to Consult Medical Records – Because the standard of care in medical malpractice cases is based upon medical expert testimony, it is an evolving, normative measure of physician performance. Failure to consult electronic medical records *may* not be negligent today, but as the standard of care evolves, failure to consult may constitute negligence in the future. Thus, a claim for malpractice involving failure to review an electronic health record ("EHR") would have to show that: (1) the standard of care included a duty to consult the medical record; and (2) the electronic technology involved was the medium dictated by the standard of care to access the medical record in question. However, the case law on the basic question of whether physicians have a duty to consult a medical record is inconclusive.


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- The Duty to Adopt New Technology – New technology is sought by an ACO to give physicians access to more records and tools to promote better health care. Should that new technology (such as a database allowing access to a patient's information) change the standard of care and thereby enhance medical liability exposure for laggard adopters of a given technology? However, expert testimony suggests that the standard of care involving a duty to use a particular technology changes rather slowly.

- Negligence in EHR Use – Malpractice risks may stem from improper data entry, with later reliance on that data resulting in patient harm. Even with good data entered, there could be user error or a system-wide EHR failure. There can be negligent documentation gaps caused by the interface between payor and electronic records. These risks can be mitigated by prudent system design, training, and monitoring.

- Corporate Negligence – ACOs may be subject to claims for corporate negligence, a claim for liability based upon an independent duty of care owed by a provider institution to its patients. Corporate liability involving HIE could be triggered by premature or inadequate deployment of EHRs or HIT that results in errors, such as inadequate staff training, erroneous data entry, flawed applications, or inadequate IT infrastructure. As with any technology, errors may occur.

- Bad Protocol as Proximate Cause – Another possible area of exposure would be adherence to an improper protocol that causes the physician to violate the standard of care (*i.e.*, all new mothers discharged within 24 hours of delivery).

To mitigate risk, larger ACOs should consider development of Patient Safety Organizations under new federal legislation.

**H. Corporate Practice of Medicine** – Many states have "corporate practice of medicine" laws. They generally prohibit the practice of medicine or employment of a physician by business corporations. One must be mindful that the administrative, financial, and practice parameter controls applied by a non-medical practice ACO are not viewed as crossing the line into the "corporate practice of medicine." A minority of states (California, Colorado, Iowa, Ohio, Texas, and possibly others) prohibit hospitals from employing physicians. Some flatly prohibit percentage billing arrangements. Depending on the state and desired structure, these statutes may have significant impact on the structure of an ACO.

**I. Insurance Laws** – If an ACO assumes financial risk for the provision of care, particularly if the arrangement is prepaid and the nature of the care needed is uncertain, it might be viewed as "insurance risk" subjecting the ACO to regulation by the state department of insurance as an insurance company. There is a significant body of law surrounding what is insurance risk. Generally, a shared savings model does not involve risk and is not considered the business of insurance. Other financial risk models for ACOs may be.


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**J.** **Intellectual Property** – ACOs create novel care pathways. Especially when "hardwired" into technology, this often results in valuable and protectable intellectual property. It is important to protect this "IP" at the beginning through the use of nondisclosure agreements and the like.

**K.** **State Self-Referral, Anti-Kickback, and Fraud and Abuse Laws** – Many states have self-referral, anti-kickback, and fraud and abuse statutes, which an ACO should consider when organizing.

**L.** **Business Laws** – Corporate, LLC, contract, state taxation, securities, conflicts of interest, unfair trade, and other laws also commonly will come into play during the organization of an ACO.

**Conclusion** – This overview is meant to provide a listing of the typical laws applicable to the formation and operation of ACOs. Space limitation does not permit a more considered analysis. Moreover, there is no "one-size-fits-all" application of the laws to the myriad of ACO possibilities. Experienced health law counsel will be able to navigate you through this legal minefield.


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