Anytime you structure a transaction involving healthcare providers, you must beware federal and state statutes unique to the healthcare industry, including laws prohibiting illegal kickbacks or referrals. Those laws may affect any transactions between health care providers, including employment or service contracts, group compensation structures, joint ventures, leases for space or equipment, professional courtesies, free or discounted items or services, and virtually any other exchange of remuneration. Violations may result in significant administrative, civil, and criminal penalties. The Affordable Care Act (ACA) dramatically increased exposure for violations by expanding the statutory prohibitions, increasing penalties, and imposing an affirmative obligation to repay amounts received in violation of the laws. The following are some of the more relevant traps for the unwary.

**Anti-kickback statute (AKS)**

The federal AKS prohibits anyone from knowingly and willfully soliciting, offering, receiving, or paying any form of remuneration to induce referrals for any items or services for which payment may be made by any federal health care program unless the transaction is structured to fit within a regulatory exception. An AKS violation is a felony punishable by a $25,000 fine and up to five years in prison. Thanks to the ACA, violation of the AKS is also an automatic violation of the federal False Claims Act, which exposes defendants to additional civil penalties of $5,500 to $11,000 per claim, treble damages, and private *qui tam* lawsuits. The AKS is very broad: it applies to any form of remuneration, including kickbacks, items or services for which fair market value is not paid, business opportunities, perks, or anything else of value offered in exchange for referrals. The statute applies if “one purpose” of the transaction is to generate improper referrals. It applies to any persons who make or solicit referrals, including health care providers, managers, program beneficiaries, vendors, and even attorneys.

Despite its breadth, the AKS does have limitations. First, it only applies to referrals for items or services payable by government health care programs such as Medicare or Medicaid. If the parties to the arrangement do not participate in government programs or are not in a position to make referrals relating to government programs, then the statute should not apply. Second, the statute does not apply if the transaction fits within certain regulatory exceptions. For example, exceptions apply to employment or personal services contracts, space or equipment leases, investment interests, and certain other relationships, so long as those transactions satisfy specified regulatory requirements. Third, interested persons who are concerned about a transaction may obtain an Advisory Opinion from the Office of Inspector General (OIG) concerning the proposed transaction. Past Advisory Opinions are published on the OIG’s website, www.hhs.oig.hhs.gov/fraud. Although the Advisory Opinions are binding only on the parties to the specific opinion, they do provide guidance for others seeking to structure a similar transaction.

**Ethics in patient referrals act (Stark)**

The federal Stark law prohibits physicians from referring patients for certain designated health services to entities with which the physician (or a member of the physician’s family) has a financial relationship unless the transaction fits within a regulatory safe harbor. Stark also prohibits the entity that receives an improper referral from billing for the items or services rendered per the improper referral. Unlike the AKS, Stark is a civil statute: violations may result in civil fines ranging up to $15,000 per violation and up to $25,000 per year. The following are some of the more relevant traps for the unwary.
Idaho Code § 41-348 prohibits paying or accepting payment from others to refer claimants to healthcare providers, or to provide services to a person knowing that the person has been referred in exchange for payment of a fee.
requires covered entities and business associates to implement certain administrative, technical and physical safeguards to protect electronic PHI. HIPAA violations may result in fines of $100 to $50,000 per violation; violations involving “willful neglect” are subject to a mandatory fine of $10,000 to $50,000 per violation. To make matters worse, covered entities and business associates must voluntarily self-report breaches of unsecured PHI to affected individuals and the government, thereby increasing the potential for HIPAA sanctions.

If you are handling a transaction involving covered entities and/or their business associates (e.g., services contracts, sales contracts, practice acquisitions, etc.), chances are you will need to consider and address HIPAA requirements in your transaction. Among other things, covered entities must execute business associate agreements (BAAs) with their business associates that require the business associate to comply with HIPAA conditions; the BAAs themselves must contain required terms. Similarly, business associates must execute BAAs with their subcontractors. Accordingly, BAAs have become ubiquitous in the healthcare industry. They even apply to lawyers who receive PHI in the course of providing services for clients. Failure to properly structure BAAs or other PHI-related transactions expose your clients — and you — to unanticipated HIPAA liability.

Corporate Practice of Medicine Doctrine (CPOM)

Some states impose the so-called “corporate practice of medicine” doctrine by statute or case law, i.e., only certain licensed health care professionals (e.g., physicians) may practice medicine; corporations may not employ physicians to practice medicine due to the risk that such an arrangement would improperly influence medical judgment. The Idaho Supreme Court recognized the CPOM in Worlton v. Davis, a case from 1952. Although the rationale of Worlton seems to have been undermined by the changing healthcare industry and intervening legislation, the Idaho Board of Medicine has periodically used Worlton as a basis for threatening physicians who are employed by certain corporations.

Although the rationale of Worlton seems to have been undermined by the changing healthcare industry and intervening legislation, the Idaho Board of Medicine has periodically used Worlton as a basis for threatening physicians who are employed by certain corporations.

Corporate Practice of Medicine Doctrine (CPOM)

Some states impose the so-called “corporate practice of medicine” doctrine by statute or case law, i.e., only certain licensed health care professionals (e.g., physicians) may practice medicine; corporations may not employ physicians to practice medicine due to the risk that such an arrangement would improperly influence medical judgment. The Idaho Supreme Court recognized the CPOM in Worlton v. Davis, a case from 1952. Although the rationale of Worlton seems to have been undermined by the changing healthcare industry and intervening legislation, the Idaho Board of Medicine has periodically used Worlton as a basis for threatening physicians who are employed by certain corporations.

Conclusion

The foregoing is only a brief summary of some of the more significant laws and regulations that may affect common health care transactions. As in all cases, the devil is in the details (as well as the Code of Federal Regulations and CMS Medicare Manuals). Attorneys who represent healthcare providers should review the relevant laws and regulations whenever structuring a health care transaction, especially if that transaction involves potential referral sources or implicates federal health care programs.
Endnotes

1. 42 U.S.C. § 1320a-7k.
2. 42 U.S.C. § 1320a-7b(b)
5. See, e.g., 42 U.S.C. § 1320a-7a(5); 42 U.S.C. § 1320a-7(b)(7); 31.
10. 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952.
12. 42 C.F.R. § 411.353(b).
15. Id. at § 411.351.
16. The “designated health services” covered by Stark include clinical laboratory services; physical therapy, occupational therapy and speech-language pathology services; radiology and other imaging services; radiation therapy; durable medical equipment and supplies; prosthetics, orthotics, prosthetic devices and supplies; home health services; outpatient prescription drugs; inpatient and outpatient hospital services; and parenteral and enteral nutrients. Id. at § 411.351.
17. Id. at § 411.351. 18. Id. at § 411.355 to 411.357.
20. 42 U.S.C. § 1320a-7a(5).
22. 42 U.S.C. § 1320a-7a(b).
23. See, e.g., OIG Special Fraud Alert, “Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries” (July 1999).
24. 42 U.S.C. § 1320a-7a(1)(C) and (2).
25. OIG Special Advisory Bulletin, “The Effect of Exclusion from Participation in Federal Health Care Programs (Sept. 1999).”
26. See id. at § 1320a-7a(a) and (b).
27. I.C. § 41-327(1).
29. “Business associates” are generally those entities who create, maintain, use, access or transmit protected health information on behalf of a covered entity. 45 C.F.R. 160.103.
30. 45 C.F.R. 164.500 et seq. 31. 45 C.F.R. 164.300 et seq.
32. 45 C.F.R. 164.400 et seq.
33. 45 C.F.R. 164.400 et seq.
34. 45 C.F.R. 164.502(e) and 164.504(e).
35. Id.
36. 73 Idaho 217, 221, 249 P.2d 810, 814 (1952).

Kim C. Stanger is the chair of Holland & Hart’s health care practice group. He represents health care clients in regulatory, transactional and administrative matters, and is a frequent speaker and writer on health law-related topics. Mr. Stanger’s additional articles concerning health-law related issues may be accessed at https://www.hollandhart.com/healthcare.

What’s John Doing Now?

Since 1972

John Glenn Hall Company
PO Box 2683
Boise, ID 83701-2683
(208) 346-4120
www.jghco.com
jghall@jghco.com

Photography
Deposition Video
Depo Broadcasting
Medical Exam Video IME DME
Questioned Photo Video Examination

Mediation and Arbitration Services

D. Duff McKee

Practice limited to alternative dispute resolution services
Post Office Box 941
Boise, Idaho 83701
Telephone: (208) 381-0060
Facsimile: (208) 381-0083
Email: ddmckee@ddmckee.com

As in all cases, the devil is in the details (as well as the Code of Federal Regulations and CMS Medicare Manuals).