

WHAT YOU DON'T KNOW MAY HURT YOU: LAWS AFFECTING HEALTH CARE TRANSACTIONS

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To protect the integrity of the practice of medicine as well as the government health care budget, federal and state statutes limit arrangements between medical referral sources. Those laws and regulations potentially affect any transactions between health care providers, including service contracts, compensation structures, ownership interests, investments, leases for space or equipment, joint ventures, acquisitions, gifts, donations, discounts, and virtually any other exchange of remuneration. Violations may result in significant administrative, civil and criminal fines. The new health care reform law dramatically increased exposure for violations by expanding the statutory prohibitions, increasing penalties, and broadening the government's power to prosecute violations. Lawyers and other professionals must beware the laws and regulations as they advise health care clients and structure transactions.

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.¹ The AKS is a criminal statute: its violation is a felony and may result in a \$25,000 fine and/or imprisonment for up to five years.² In addition, the new Patient Protection and Affordable Care Act makes a violation of the AKS also a violation of the federal False Claims Act,³ which exposes the defendants to additional civil penalties and private qui tam actions.⁴ The AKS is very broad—it applies to any form of remuneration, including kickbacks, free or discounted items or services, 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.⁵ It applies to any



persons who are in a position to make or influence referrals, including health care providers, management, program beneficiaries, vendors, and even attorneys. In *U.S. v. Anderson*,⁶ for example, physicians, hospital administrators, and outside attorneys were indicted for entering contracts with physicians to provide medical director services as a way to generate referrals from the physicians and business for the hospital.

Despite its breadth, the AKS does have limitations. First, it applies only to referrals for items or services payable by government health care programs such as Medicare or Medicaid.⁷ 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, because of its potential breadth, the federal government has issued statutory exceptions and regulatory safe harbors which offer protection if the transaction fits all the specified requirements.⁸ For example, exceptions and safe harbors apply to employment or personal services contracts, space or equipment leases, investment interests, etc., so long as those transactions meet regulatory requirements.⁹ 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.hhh.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

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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.¹⁰ Stark also prohibits the entity that receives the improper referral from billing for the items or services rendered per the improper referral.¹¹ Unlike the AKS, Stark is a civil statute: violations may result in civil fines ranging up to \$15,000 per violation and up to \$100,000 per scheme in addition to payments received for services rendered per improper referrals.¹²

Also unlike the AKS, Stark is a strict liability statute; it does not require intent.¹³ Additionally, Stark applies only to referrals by physicians, i.e., M.D.s, D.O.s, podiatrists, dentists, chiropractors, and optometrists,¹⁴ or with members of such physicians’ families; it does not apply to transactions with other health care providers. Finally, unlike the AKS, Stark applies only to referrals for certain designated health services, (DHS), payable by Medicare and Medicaid;¹⁵ it does not apply to referrals for other items or services.

However, like the AKS, Stark is very broad—it applies to any type of financial relationship between physicians (or their family members) and a potential provider of DHS, including any ownership, investment, or compensation relationship.¹⁶ Thus, the statute applies to everything from ownership or investment interests to compensation among group members to contracts, leases, waivers, discounts, professional courtesies, medical staff benefits, or any other transaction in which anything of value is shared between the parties. If Stark applies to a financial relationship, then the parties must either structure the arrangement to fit squarely within one of the regulatory safe harbors¹⁷ or not refer patients to each other for the designated

health services covered by the statute and regulations.

Civil Monetary Penalties Law: (CMP)

The CMP prohibits certain transactions that have the effect of increasing utilization or costs to federally funded health care programs or improperly minimizing services to beneficiaries.¹⁸ For example, the CMP prohibits offering or providing inducements to a Medicare or Medicaid beneficiary that are likely to influence the beneficiary to order or receive items or services payable by federal health care programs.¹⁹ This law may affect health care provider marketing programs as well as contracts or payment terms with program beneficiaries.²⁰ Similarly, the CMP law prohibits hospitals from making payments to physicians to induce the physician to reduce or limit services covered by Medicare.²¹ Thus, the CMP law usually prohibits so-called "gainsharing" programs in which hospitals split cost-savings with physicians.²² Finally, the CMP law prohibits submitting claims for federal health care programs based on items or services provided by persons excluded from health care programs.²³ As a practical matter, the statute prohibits health care providers from employing or contracting with persons or entities who have been excluded from participating in federal health care programs.²⁴ Violations of the CMP statute may result in significant penalties ranging from \$2,000 to \$50,000 per violation.²⁵

Medicare reimbursement rules

The Center for Medicare and Medicaid Service, (CMS), has volumes of esoteric rules that apply to reimbursement for services provided under government health care programs that are buried in federal regulations and program manuals. For example, the rules govern such items as when a health care provider may bill for services provided by another entity, supervision required for such services, and the location that such services may be performed. In addition, the amount of government reimbursement may differ depending on how the transaction is structured, e.g., whether it is provided through an arrangement with a hospital or by a separate clinic or physician practice. The rules concerning reimbursement and reassignment should be considered in structuring health care transactions if the entities intend to bill government programs for services.

Idaho Anti-Kickback Statute

Idaho has its own, little-known version of the federal AKS. Idaho prohibits

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health care providers from paying others to make referrals to the provider or from providing services to someone who was referred in exchange for a payment for the referral.²⁶ In addition, the statute also prohibits health care providers from engaging in a regular practice of waiving, rebating, giving, paying, or offering to waive, rebate, give or pay all or a part of a person's health insurance deductible.²⁷ Persons who violate the statute may be subject to a \$5,000 fine.²⁸ The Idaho statute is potentially broader than the federal AKS or Stark in that it is not limited to items or services covered by government health care programs. Nevertheless, the statute does contain some potentially significant limitations. First, the statute was passed by insurance companies that were attempting to limit inducements for services covered by health insurance. To that end, the statute applies to services provided to "claimants,"²⁹ which presumably means those patients who submit claims to health insurance; it is not clear to what extent the statute would apply to others. Second, by its express terms, it only applies to the "treatment of physical or mental illness or injury arising in whole or substantial part from trauma."³⁰ Arguably, it would not apply to treatment for other conditions.

Idaho Medical Practices Act

Idaho's Medical Practices Act and similar licensing statutes prohibit "fee-splitting", i.e., the dividing of fees or gifts received for professional services in exchange for referrals, or giving or receiving rebates for services provided.³¹ It also prohibits offering rebates for such services. The violation of the statute could result in professional discipline and loss of licensure.³² Although there do not appear to be any reported Idaho cases directly interpreting or applying the statute, the statute may apply in any situation between physicians and potential referral sources where some benefit is conferred in exchange for referrals.³³ To that end, it is potentially broader than the federal AKS. The Idaho Board of Medicine has

used the Medical Practices Act to challenge arrangements in which physicians share ownership or control of a practice with non-physicians.

Corporate Practice of Medicine Doctrine (CPOM)

Under the corporate practice of medicine doctrine, 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 influencing medical judgment. It is not clear to what extent the CPOM doctrine applies in Idaho. In *Worlton v. Davis*, the Idaho Supreme Court declared (arguably in dicta):

It is well established that no unlicensed person or entity may engage in the practice of the medical profession through licensed employees; nor may a licensed physician practice as an employee of an unlicensed person or entity. Such practices are contrary to public policy.³⁴

Worlton appears to be an anomaly in Idaho law: there do not appear to have been any Idaho CPOM cases preceding it, and *Worlton* has been largely ignored since it issued. Idaho statutes expressly or impliedly authorize hospitals, managed care organizations, (MCOs), and certain other licensed health care entities to make health care available through employed physicians, and the corporate code allows physicians and other health care providers to practice through professional service corporations and associations.³⁵ Accordingly, hospitals and other health care entities commonly employ physicians and other health care professionals. Nevertheless, the Idaho Board of Medicine has periodically cited the Medical Practices Act³⁶ and *Worlton* to warn that certain physician employment arrangements (outside the scope of hospitals, MCOs, and other licensed health care entities) may violate the Medical Practices Act if they unduly

interfere with the physician's independent medical judgment.³⁷ Health care providers should at least consider the possibility of CPOM issues when structuring employment relationships with physicians.

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 and other professionals who advise health care 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.

About the Author

Mr. Stanger is a past President of the Health Law Section of the Idaho State Bar Association, past President of the Idaho Association of Healthcare Risk Managers; a founding member of the Idaho HIPAA Coordinating Council; past President and founding member of the J. Reuben Clark Law Society, Boise Chapter; and a mem-

ber of the American Health Lawyers Association and the Health Law Section of the American Bar Association. He is a recipient of the St. Luke's Regional Medical Center Certificate of Merit (2003).

Endnotes

- ¹ 42 U.S.C. § 1320a-7b(b) (year).
- ² 42 U.S.C. § 1320a-7b(b)(2)(B).
- ³ Patient Protection and Affordable Care Act Pub L. No. 111-148 § 6402(f)(1), 124 Stat. 119 (2010); see 31 U.S.C. § 3729 *et seq.*
- ⁴ See, e.g., 42 U.S.C. § 1320a-7a(5); 42 U.S.C. § 1320a-7(b)(7); 31 U.S.C. § 3729-3733, *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998).
- ⁵ *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied* 474 U.S. 988 (1985).
- ⁶ *United States v. Anderson*, Case No. 98-20030-01/07 (D. Kan. 1998).
- ⁷ See 42 U.S.C. § 1320a-7b(b)(2)(B).
- ⁸ 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952 (year).
- ⁹ 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952.
- ¹⁰ 42 U.S.C. § 1395nn, 42 C.F.R. § 411.351 *et seq.*
- ¹¹ 42 C.F.R. § 411.353(b).
- ¹² 42 U.S.C. § 1395nn.
- ¹³ See 42 C.F.R. § 411.353(a)-(b).
- ¹⁴ *Id.* at § 411.351.
- ¹⁵ 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.
- ¹⁶ *Id.* at § 411.351.
- ¹⁷ *Id.* at § 411.355 to 411.357.
- ¹⁸ 42 U.S.C. § 1320a-7a.
- ¹⁹ 42 U.S.C. § 1320a-7a(a)(5).
- ²⁰ See OIG Special Advisory Bulletin, "Offering Gifts and Other Inducements to Beneficiaries" (August 2002). OIG Special Fraud Alert, "Routine Waiver of Part B Co-Payments/Deductibles" (May 1991).
- ²¹ 42 U.S.C. § 1320a-7a(b).
- ²² 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).
- ²³ 42 U.S.C. § 1320a-7a(a)(1)(C) and (2). (I don't understand what this citation means: is it 7a(a)(2)?)
- ²⁴ OIG Special Advisory Bulletin, "The Effect of Exclusion from Participation in Federal Health Care Programs" (September 1999).
- ²⁵ See *id.* at § 1320a-7a(a) and (b).
- ²⁶ I.C. § 41-348(1).
- ²⁷ *Id.* at § 41-348(2).
- ²⁸ *Id.* at § 41-348(4).
- ²⁹ *Id.* at § 41-348(1).
- ³⁰ *Id.* at § 41-348(3)(a).
- ³¹ I.C. § 54-1814(8)-(9).
- ³² See *id.*
- ³³ See *Miller v. Haller*, 19 Idaho 345, 924 P.2d 607 (1996) (suggesting that the prohibition in the statute applies where the division of fees or money has changed hands in direct exchange for referrals). This citation needs pinpoint page numbers.
- ³⁴ 73 Idaho 217, 221, 249 P.2d 810 (1952). This citation also needs pinpoint page numbers.
- ³⁵ See, e.g., I.C. § 30-1301 *et seq.*
- ³⁶ I.C. §§ 54-1803-1804.
- ³⁷ See, e.g., Idaho Board of Medicine, "The Report" (Spring 2006); Memorandum from J. Uranga to Idaho State Board of Medicine, Corporate Practice of Medicine (February 26, 2007).



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