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Health Care Transactions: Beware Stark, Kickbacks, and More

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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.[1] 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.[2] An AKS violation is a felony punishable by a $25,000 fine and up to five years in prison.[3] Thanks to the ACA, violation of the AKS is an automatic violation of the federal False Claims Act[4], which exposes defendants to additional civil penalties of $5,500 to $11,000 per claim, treble damages, and private qui tam lawsuits.[5] 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.[6] It applies to any persons who make or solicit referrals, including health care providers, managers, program beneficiaries, vendors, and even attorneys.[7] 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.[8] 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 regulatory exceptions.[9] 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.[10] 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 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.[11] Stark also prohibits the entity that receives an improper referral from billing for the items or services rendered per the improper referral.[12] 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 repayments received for services rendered per improper referrals.[13] Repayments can easily run into thousands or millions of dollars. Stark is a strict liability statute; it does not require intent, and there is no "good faith" compliance.[14] Stark applies only to financial relationships with physicians, i.e., M.D.s, D.O.s, podiatrists, dentists, chiropractors, and optometrists[15], 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;[16] it does not apply to referrals for other items or services. If triggered, Stark applies to any type of direct or indirect financial relationship between physicians or their family members and a potential provider of DHS, including any ownership, investment, or compensation relationship.[17] 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 harbors[18] or not refer patients to each other for DHS covered by the statute and regulations.

Civil Monetary Penalties Law ("CMP"). The federal 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.[19] 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, including free or discounted items or services, waivers of copays or deductibles, etc.[20] This law may affect health care provider marketing programs as well as contracts or payment terms with program beneficiaries.[21] The CMP also prohibits hospitals from making payments to physicians to induce the physicians to reduce or limit services covered by Medicare.[22] Thus, the CMP usually prohibits so-called "gainsharing" programs in which hospitals split cost-savings with physicians.[23] Finally, the CMP prohibits submitting claims for federal health care programs based on items or services provided by persons excluded from health care programs.[24] 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.[25] Violations of the CMP may result in administrative penalties ranging from $2,000 to $50,000 per violation.[26]

State Anti-Kickback, Self-Referral, or Fee Splitting Statutes. Many states have their own versions of anti-kickback[27] or self-referral laws[28] that must also be considered. State versions vary widely; they may or may not parallel federal versions. In addition, most states also prohibit fee splitting or giving rebates for referrals, which might also apply to some transactions between referral sources.[29] Providers should check their own state statutes to ensure compliance.

Medicare Reimbursement Rules. The Centers for Medicare & Medicaid Services ("CMS") has promulgated volumes of rules and manuals governing reimbursement for services provided under federal health care programs. 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 in which such services may be performed to be reimbursable. 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 or maximize their reimbursement under such programs.

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 influencing medical judgment.[30] There are often statutory exceptions, e.g., professional corporations or employment by hospitals or managed care organizations. In those states that apply or enforce the CPOM, transactions may need to be structured around the CPOM, including services contracts with physicians or other healthcare providers.

Certificates of Need ("CON"). Finally, to avoid over-saturation and resulting overcharges, some states require that providers obtain a certificate authorizing the construction or expansion of certain types of facilities, e.g., hospitals, ambulatory surgery centers, or skilled nursing facilities.[31]

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). Providers and their advisors 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).
[3] 42 U.S.C. § 1320a-7b(b)(2)(B).

[4] 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*.
[5] *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).
[6] *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).
[7] *United States v. Anderson*, Case No. 98-20030- 01/07 (D. Kan. 1998).
[8] *See* 42 U.S.C. § 1320a-7b(b)(2)(B).
[9] 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952.
[10] 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952.
[11] 42 U.S.C. § 1395nn; 42 C.F.R. § 411.351 *et seq*.
[12] 42 C.F.R. § 411.353(b).
[13] 42 U.S.C. § 1395nn.
[14] *See* 42 C.F.R. § 411.353(a)-(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.
[19] 42 U.S.C. § 1320a-7a.
[20] 42 U.S.C. § 1320a-7a(a)(5).
[21] 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).
[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(a)(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] *See, e.g.*, Colorado Revised Statutes ("CRS") § 25.5-4-305; Idaho Code ("IC") § 41-348(1); Nevada Revised Statutes ("NRS") 439B.420; New Mexico Statutes Annotated ("NSMA") §§ 30-41-1 to -3, and 30-44-7(A)(1); Utah Code § 26-20-4.
[28] *See, e.g.*, CRS § 25.5-4-414; NRS. 439B.425; New Mexico Administrative Code ("NMAC") 439B.5205-.5408; NMSA §§ 24-1-5.8(C)(6); NMAC 7.7.2.8(B)(3) and 7.7.2.8(N); Utah Code §§ 58-67-801, 58-68-801, 58-69-805.
[29] *See, e.g.*, CRS §§ 12-36-125 and 12-36-126; IC § 54-1814(8)-(9); NMSA §§ 61-6-15(D).
[30] *See, e.g.*, CRS §§ 12-36-117(m) and 6-18-301 *et seq.*; *Worlton v. Davis*, 73 Idaho 217, 221, 249 P.2d 810 (1952).
[31] *See, e.g.*, NRS 439A and NAC 439A.

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