

Practical Approaches to Managing Conflicts of Interest and Gifts Issues

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INTRODUCTION

The government agencies and public scrutiny of health care providers' conflicts of interest with industry vendors, referral sources, and other related associates is expected to only increase with newly enacted disclosure laws and increases in government enforcement resources.¹ Prior studies first highlighted that gifts and other relationships between health care providers and industry affiliates may impact clinicians' decision-making. Now, more recent reports began to directly link such relationships to a delivery of lower quality of care.² If future reviews and reports continue to demonstrate that a patient's quality of care is impacted by such arrangements, the health care provider industry can expect to see more regulations to monitor such relationships.

This document provides a brief summary of some recent industry guidance and key laws that address the possible impropriety that can result when gifts are provided to physicians and other clinicians. A comprehensive review of each applicable statute or industry guidance given the breadth of this topic is beyond the scope of this paper. This paper will focus primarily on laws and industry guidance regarding the relationships between health care providers and industry vendors such as pharmaceutical and medical device companies ("Industry"), but the paper also will comment on other laws which can impact health care providers' conflicts of interest policies with other related business partners and patients. For purposes of this paper, gifts are construed broadly to include several different types of arrangements and items. Among other items, gifts include branded

¹ See generally Ailsa Chang, *Physicians on Pharma's Payroll: Educators or Marketers?*, Nov. 18, 2010, available at <http://www.wnyc.org/articles/wnyc-news/2010/nov/18/physicians-pharmas-payroll-educators-or-marketers/>; John Carreyrou and Tom McGinty, *Top Spine Surgeons Reap Royalties, Medicare Bounty*, *The Wall Street Journal*, Dec. 20, 2010 available at <http://online.wsj.com/article/SB20001424052748703395204576024023361023138.html>.

² See Journal of the American Medical Association, January 19, 2000 Physicians and the Pharmaceutical Industry – Is a Gift Ever Just a Gift? *JAMA*, 2000; 283:373-380; Journal of the American Medical Association, January 25, 2006 Health Industry Practices that Create Conflicts of Interest – A Policy Proposal for Academic Medical Centers *JAMA*, 2006; 295:429-433. See also Kevin B. O'Reilly, *Drug rep visits rarely result in better prescribing, study says*, Nov. 11, 2010, *amednews.com* available at <http://www.ama-assn.org/amednews/2010/11/08/prsf1111.htm>. See also David S. Hilzenrath, *Some medical sales reps work along side doctors, even in operating rooms*, *WASHINGTON POST*, Dec. 27, 2009, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/24/AR2009122403368.html>.

company items (e.g., pens, calculators), meals, cash, gift cards, drug samples, entertainment, honorariums, consulting fees, and grants.

UPDATE: HEALTH CARE PROVIDER AND VENDOR RELATIONSHIPS

As reflected in industry studies, medical articles, and government guidance, there is a growing concern regarding the influence of pharmaceutical and medical device sales on clinical decision-making. Despite existing rules and regulations most physicians still accept Industry gifts according to a national survey recently published in the *Archives of Internal Medicine*.³ The survey found that about 84% of United States physicians reported some type of relationship with Industry during the previous year – although it was noted to be a significant decrease from 2004.⁴ For example, physician accepting drug samples decreased from 78% in 2004 to 63% in 2009 and the acceptance of cultural/sporting event tickets decreased from 7% in 2004 to 1% in 2009.⁵

Notwithstanding, new studies and industry developments continue to reinforce existing literature in prominent medical scholarly journals that Industry's remuneration has the ability to negatively influence physicians' prescribing practices despite regulatory and industry reform measures.⁶ For example, one recent medical journal study found that pharmaceutical promotion through Industry sale representative visits, medical journal advertisements and other Industry sponsored meetings rarely result in higher quality prescribing.⁷

At the same time, Congress remains concerned about Industry relationships with health care providers despite the recent enactment of the Physician Payments Sunshine provisions which will require Industry to begin recording any physician payments that are worth more than \$10 in 2012 and report them in 2013.⁸ Senators Grassley and Kohl

³ Eric G. Campbell et al, *Physician Professionalism and Changes in Physician-Industry Relationships from 2004-2009*, ARCHIVES OF INTERNAL MEDICINE Vol. 170, No. 20, Nov. 8, 2010, p.1820-1826, available at <http://archinte.ama-assn.org/cgi/reprint/170/20/1820>.

⁴ *Id.* See also Kris B. Mamula, *Pennsylvania, Pittsburgh doctors get millions from drugmakers*, July 26, 2010, PITTSBURGH BUSINESS TIMES, available at <http://www.bizjournals.com/pittsburgh/stories/2010/07/26/story1.html>.

⁵ *Id.* at 1823. See also Kevin B. O'Reilly, *Drug industry ties to doctors weaken as disclosure, gift rules spread*, Nov. 29, 2010, *amednews.com*, available at <http://www.ama-assn.org/amednews/2010/11/29/pr111129.htm>.

⁶ *Id.* See also *Physicians and the Pharmaceutical Industry – Is a Gift Ever Just a Gift?*, JAMA. 2000; 283:373-380 January 19, 2000; *A National Survey of Physician-Industry Relationships*, N ENGL J MED 2007; 357:507-508, Aug 2, 2007.

⁷ Kevin B. O'Reilly, *Drug rep visits rarely result in better prescribing, study says*, Nov. 11, 2010, *amednews.com* available at <http://www.ama-assn.org/amednews/2010/11/08/prsf1111.htm>. See also David S. Hilzenrath, *Some medical sales reps work along side doctors, even in operating rooms*, WASHINGTON POST, Dec. 27, 2009, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/24/AR2009122403368.html> (states that Endovascular Technologies plead guilty to federal charges that it covered up malfunctions of a device during surgery with the help of sales representatives).

⁸ Arlene Weintraub, *New Health Law Will Require Industry to Disclose Payments to Physicians*, KAISER

recently expressed concern that there was not enough guidance to ensure consistent reporting from all parties under the new law and requested that HHS designate an agency to oversee this reporting process.⁹ The reporting process is further complicated by different disclosure requirements in proposed and existing National Institute of Health and Food and Drug Administration regulations which may lead to inconsistent reporting.¹⁰ The United States Senate Committee on Finance also recently issued a report alleging inappropriate and potentially harmful cardiac stent procedures were performed by a physician in Maryland.¹¹ The report and newspaper articles highlighted Abbott Laboratories' relationship with the implanting physician at a hospital. For example, Abbott Laboratories disclosed during the Committee's review that it reimbursed an Abbott employee \$1,235 for a barbeque dinner at the physician's home -- two days after the physician set the single day implant record.¹²

Likewise, government enforcement agencies' remain committed to continue to vigorously pursue inappropriate relationships between health care providers themselves and also Industry. From January 1, 2010 to date, the website of the Civil Division of the Justice Department lists seven settlements totaling over \$2.5 billion with drug and medical device manufacturers that mention improper promotional agreements with physicians.¹³

Also, the government continues to pursue other pharmaceutical and medical device vendors regarding similar alleged arrangements.¹⁴ For example, ELA Medical Inc. recently agreed to pay the government approximately \$9.2 million to settle allegations that it violated the False Claims Act by giving kickbacks to cardiologists who bought the medical company's pacemakers. ELA Medical Inc. was accused of paying illegal kickbacks to physicians who bought the medical company's pacemakers.¹⁵ Accordingly to the settlement agreement, the alleged kickbacks given to the cardiologists included

HEALTH NEWS, Apr. 26, 2010, available at

<http://www.kaiserhealthnews.org/Stories/2010/April/26/physician-payment-disclosures.aspx>.

⁹ Allison Cohen and Leah Voigt, *Teaching Hospital Update – Lawmakers Want More HHS Leadership on Streamlining Doc “Sunshine” Disclosures*, AHLA Practice Group Teaching Hospital Update, Nov. 15-19, 2010.

¹⁰ Gelvina Stevenson, *Financial Conflicts of Interest: The March Towards Greater Transparency*, AHLA Connections, Vol. 14, Issue 12, Dec. 2010.

¹¹ Staff Report on Cardiac Stent Usage at St. Joseph Medical Center, COMMITTEE ON FINANCE, UNITED STATES SENATE, December 2010, at 6-8, available at <http://finance.senate.gov/library/reports/committee/>.

¹² *Id.* at 8. See also *Abbott Labs hired cardiologist barred from hospital*, Dec. 6, 2010, available at <http://chicagobreakingbusiness.com/2010/12/abbott-labs-hired-cardiologist-barred-from-hospital.html>.

¹³ UNITED STATES DEPARTMENT OF JUSTICE, available at www.justice.gov/civil/press.

¹⁴ John Commins, *Feds File Suit Against J&J for Alleged Kickback Scheme*, HEALTHLEADERSMEDIA, Jan. 10, 2010, available at <http://www.healthleadersmedia.com/content/LED-245011/Feds-File-Suit-Against-JJ-for-Alleged-Kickback-Scheme.html##>. See also Jeanne Whalen, *Novartis Case Underscores Increased Scrutiny of Drug Marketing*, THE WALL STREET JOURNAL, Jan. 29, 2010, at B3.

¹⁵ Jesse Witten, *Device Manufacturer ELA Medical, Inc. Settles False Claims Act Case Premised on Alleged Anti-Kickback Statute Violations for \$9.2 Million*, AHLA Fraud and Abuse Practice Group Email Alert, November 5, 2010.

gifts, meals, entertainment, tickets to sporting events, travel to medical conferences, travel to Costa Rica, fishing and boating trips, and payment of travel expenses for the physicians' spouses.¹⁶ Also, a recent False Claims Act complaint alleged that Johnson & Johnson made various kickback payments to Omnicare in the form of grants and educational funding even though their alleged true purpose was to induce Omnicare to recommend Johnson & Johnson drugs.¹⁷ Another recent example of the government's enforcement that focuses on Stark and anti-kickback laws was a 2010 settlement where the U.S. Department of Justice collected \$108 million from an Ohio hospital for unlawful payments to physicians in exchange for cardiac patient referrals.¹⁸

SELECT LAWS AND GOVERNMENT GUIDANCE IMPACTING CONFLICTS OF INTERESTS AND GIFTS

The Federal and State Anti-kickback Statutes

Gifts and other potential conflicts of interest can give rise to potential criminal liability under the federal Anti-Kickback Statute (AKS), which prohibits the payment or receipt of any "remuneration" that is intended to induce the purchasing, leasing or ordering of any item or service that may be reimbursed, in whole or in part, under a federal health care program.¹⁹ The AKS has been interpreted by courts to cover any arrangement where "one purpose" of the remuneration was to obtain money for the referral of services or to induce further referrals even though there may have been other legitimate reasons for the remuneration.²⁰

The OIG also can pursue violations of the AKS under a provision of the Civil Monetary Penalties Law.²¹ In the past, the OIG has taken issue at even gifts of a relatively low monetary value. For example, two Florida physicians paid approximately \$65,000 and \$57,000 for allegedly accepting Miami Dolphin football tickets and other similar gifts from a durable medical equipment supplier in exchange for patient referrals.²²

¹⁶ *Id.*

¹⁷ John Commins, *Feds File Suit Against J&J for Alleged Kickback Scheme*, HEALTHLEADERSMEDIA, Jan. 10, 2010, available at <http://www.healthleadersmedia.com/content/LED-245011/Feds-File-Suit-Against-JJ-for-Alleged-Kickback-Scheme.html##>.

¹⁸ THE UNITED STATES DEPARTMENT OF JUSTICE, OFFICE OF PUBLIC AFFAIRS, Justice News, The Health Alliance of Greater Cincinnati and the Christ Hospital to Pay \$108 Million for Violating Anti-Kickback Statute and Defrauding Medicare and Medicaid, May 21, 2010, available at <http://www.justice.gov/opa/pr/2010/May/10-civ-602.html>.

¹⁹ 42 U.S.C. §1320a-7b.

²⁰ *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).

²¹ 42 U.S.C. §1320a-7a(a)(7).

²² U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, Kickback and Physician Self Referral Archive, 02-16-2006, available at http://oig.hhs.gov/fraud/enforcement/cmp/kickback_archive.asp.

Due to the breadth and scope of the statute, Congress created several statutory exceptions to the AKS and delegated to the OIG the responsibility of creating safe harbor regulations to the AKS.²³ Conduct that falls outside a safe harbor does not mean an individual or entity automatically has violated the AKS. However, compliance with the safe harbor requirements will protect an arrangement from AKS scrutiny by the OIG and the United States Department of Justice.

When advising clients it is best to try to structure a transaction to meet the requirements of a statutory exception or safe harbor. The AKS provides criminal and civil penalties for violations of the statute and parallel laws.²⁴ Violations of the AKS are punishable by: criminal fines up to \$25,000 per offense, and/or five years imprisonment; administrative fines and automatic exclusion from the Medicare and Medicaid programs; and civil monetary penalties of up to \$50,000 plus damages of three times that amount.²⁵ In addition, many states have adopted state anti-kickback statutes that have similar elements and penalties.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (“PPACA”) also included more expansive provisions of the AKS which will make it easier for enforcement agencies to bring actions against individuals and entities.²⁶ For example, claims that include items or services resulting from an AKS violation also now constitutes false or fraudulent claims under the False Claims Act. Also, the new law makes clear that an individual may violate the AKS without actual knowledge of or specific intent to violate the AKS.²⁷ As a result, organizations and individuals need to proceed with even more caution as it will be easier for the government to pursue inappropriate arrangements.

Federal and State False Claims Act Laws

The majority of the government’s recent large settlements against manufacturers under the AKS were initiated by the filing of *qui tam* lawsuits under the federal False Claims Act (FCA) in which a whistleblower can receive as much as 30% of the amounts recovered.²⁸ These prior *qui tam* cases expanded the use of the FCA; they allege that otherwise non-fraudulent claims breached the FCA due to violations of other federal regulatory statutes such as the AKS. As discussed above, PPACA now mandates that such AKS cases can be brought under the FCA.²⁹ Under the FCA, a person or entity is

²³ See 42 U.S.C. §1320a-7b; 42 C.F.R. §1001.952.

²⁴ *Id.*

²⁵ 42 U.S.C. §1320a-7a(a)(7).

²⁶ PATIENT PROTECTION AND AFFORDABLE CARE ACT, Pub. L. 111-148, 124 Stat. 119, § 6402(f), March 23, 2010.

²⁷ *Id.*

²⁸ See generally Duff Wilson, *Drug Makers Are Paying Big Settlement*, NYTIMES.COM, December 16, 2010, available at <http://prescriptions.blogs.nytimes.com/2010/12/16/drug-makers-are-paying-big-settlements/?partner=rss&emc=rss>; 31 U.S.C. § 3729.

²⁹ See *id.* at 21.

liable for treble damages in addition to penalties up to \$11,500 for each false claim.³⁰ Several states have enacted similar false claims act laws that establish liability for the submission of false or fraudulent claims to a State's Medicaid program.³¹

The Physician Payments Sunshine Provisions - PPACA Section 6002

In addition to enforcement laws, new disclosure laws will make it easier for the government to identify improper arrangements between Industry and health care providers. As part of PPACA, section 6002 requires pharmaceutical, medical device, biological, and medical supply manufacturers to begin recording any payments to physicians and teaching hospitals that are worth more than \$10 in 2012 and to report them on March 31, 2013.³² The Secretary is required to publish all reported payments and ownership interests to the public on the Internet beginning September 1, 2013 and each June 30th thereafter. Manufacturers and group purchasing organizations also must report any ownership or investment interests by physicians and their immediate family members.

Items Required to be Reported

Section 6002 requires disclosure of payments whether cash or in kind transfers to all covered recipients including: compensation; food, entertainment or gifts; travel; consulting fees; honoraria; research funding or grants; education; stocks or stock options; ownership or investment interest; royalties or licenses; charitable contributions; direct compensation for serving as faculty or as a speaker for a medical education program, and any other transfer of value as described by the secretary.³³ Payments related to clinical trials or product development agreements for new products are allowed a publication delay of four years or until product approval, whichever comes first. Product development agreements for "new applications" of existing technologies are also allowed this publication delay.³⁴

Items Excluded from Reporting

A number of items are excluded from the reporting obligation including: payments under \$10 unless the aggregate amount paid to a covered recipient exceeds \$100 per year; educational material provided for the benefit of patients; rebates and discounts; loans of covered devices; items or services provided under warranty; dividend or investment

³⁰ 31 U.S.C. § 3729.

³¹ U.S. DEPARTMENT OF HEALTH AND HUMAN RESOURCES, OFFICE OF INSPECTOR GENERAL, State False Claims Act Reviews, available at <http://oig.hhs.gov/fraud/falseclaimsact.asp>.

³² PATIENT PROTECTION AND AFFORDABLE CARE ACT, Pub. L. 111-148, 124 Stat. 119, § 6002, March 23, 2010. See also *Physician Payment "Sunshine Provisions" Signed into Law as Part of Health Care Reform Legislation*, Ropes and Grey, Health Reform Matters Alert, Mar. 30, 2010.

³³ PATIENT PROTECTION AND AFFORDABLE CARE ACT, Pub. L. 111-148, 124 Stat. 119, § 6002, March 23, 2010.

³⁴ *Id.*

interests in a publicly-traded security or mutual fund; in-kind items used for the provision of charity care; non-medical professional services; self insurance from manufacturer for employees; and payments made to a physician who is a patient, or an employee of the reporting company. Prescription drug samples are also exempted from section 6002, but a separate section of PPACA requires reporting of information on samples.³⁵

Preemption of State Laws

Some states already have enacted similar disclosure laws relating to Industry payments to physicians. Effective January 1, 2012, this law will preempt state disclosure laws except for state requirements to collect other types of data not captured or excluded from the federal physician payment sunshine reporting requirements.³⁶

Penalties

The penalties for each failure to report are fines ranging from \$1,000-\$10,000, not to exceed \$150,000 annually. For each knowing failure to report, fines ranging from \$10,000-\$100,000 will be applied, not to exceed \$1,000,000 annually.³⁷ Some pharmaceutical companies have already begun to voluntarily disclose payments to physicians on their websites before the timeframe set forth in section 6002.³⁸ Hospitals should consider checking internal physician disclosures against the available sites now to help detect potential conflicts of interest issues.

Proposed Rule

On December 19, 2011, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule (i.e., Transparency Reports and Reporting of Physician Ownership of Investment Interests) to implement PPACA Section 6002.³⁹ The purpose of the proposed rule is to help provide for transparency in the financial relationships between covered recipients (e.g., physicians and teaching hospitals) and applicable manufacturers as well as group purchasing organizations. Comments on the proposed rule were due on February 17, 2012. In general, the proposed rule largely followed the PPACA statutory provisions, but it also provided significant clarification to several areas. A full discussion of the proposed rule is beyond the scope of this document. The final rule is expected to be released later in 2012.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ Duff Wilson, *Data on Fees to Doctors Is Called Hard to Parse*, New York Times, Apr. 12, 2010, available at <http://www.nytimes.com/2010/04/13/business/13docpay.html>.

³⁹ *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests*, 76 Fed. Reg. 78742 (Dec. 19, 2011) available at <http://www.gpo.gov/fdsys/search/pagedetails.action?granuleId=2011-32244&packageId=FR-2011-12-19&acCode=FR>.

State Gift Disclosure Laws

As discussed above, some states have recently enacted or proposed laws that also require pharmaceutical companies and some medical device companies to annually report the amount of gifts they provide to physicians annually.⁴⁰ For example, a proposed law in New Jersey went as far as prohibiting physicians from accepting gifts from pharmaceutical sales representatives and publicly disclosing any Industry payments of more than \$200 as conditions of licensure.⁴¹ While some of these laws will be preempted by PPACA, it is important for attorneys and compliance officers to assess whether any state laws are applicable to your organization.

Joint Commission Leadership Standard - LD 04.02.01

In 2009, the Joint Commission included a new conflict of interest requirement in its Leadership Chapter to further regulate potential Industry conflicts of interest that could impact patient care.⁴² Under this standard, leaders are required to address any conflict of interest involving licensed independent practitioners and/or staff that affects or has the potential to affect the safety or quality of care, treatment, and services. Among other requirements, leaders have to develop a written policy that defines how the organization will address such conflicts.⁴³

A hospital also has to make available on request its policies, procedures, and information about the relationship between care, treatment, and services and financial incentives to all patients and individuals who work in the hospital. For example, this standard requires a physician to disclose any royalties the physician would receive from the use of the device he/she is recommending to his/her patients. The hospital also has to review its relationships with other care providers, educational institutions, manufacturers, and payers to determine whether conflicts of interest exist and whether they comply with the law.⁴⁴ This new standard will force more hospitals to develop more robust conflicts of interest procedures to detect arrangements that may impact patient care.

⁴⁰ Rich Daly, More States Explore Laws on Gifts to Physicians, PSYCHIATRIC NEWS, Vol. 45, No. 6, p. 7, Mar. 19, 2010 available at <http://pn.psychiatryonline.org/content/45/6/7.1.full>.

⁴¹ *New Jersey Targets 'Health Care Conflict of Interest,'* ConsumerAffairs.com Dec. 3, 2009, available at http://www.consumeraffairs.com/news04/2009/12/nj_doctor_payments.html.

⁴² Leadership in Healthcare Organizations, A Guide to Joint Commission Leadership Standards, A GOVERNANCE INSTITUTE WHITE PAPER, Winter 2009 at 28, available at http://www.jointcommission.org/assets/1/18/WP_Leadership_Standards.pdf.

⁴³ *Id.*

⁴⁴ *Id.*

Office of Inspector General for the U.S. Department of Health and Human Services (OIG)

The OIG has taken a multi-prong approach through education, audits and enforcement to help curb inappropriate conflicts of interest between Industry and health care providers.⁴⁵ In 2003, the OIG published the Compliance Guidance for Pharmaceutical Manufacturers (Guidance).⁴⁶ The Guidance is intended for companies that develop, manufacture, market and sell pharmaceutical drugs or biological products and addresses conflicts of interest issues among other topics. The Guidance also applies to medical device manufacturers. The OIG cites to the Pharmaceutical Research & Manufacturers of America (“PhRMA”) Code that was adopted by PhRMA in 2002 in its Guidance in its discussion of conflicts of interest. The OIG acknowledges that the PhRMA Code “provides useful and practical advice for reviewing and structuring these relationships and states that while compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the AKS, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”⁴⁷ As a result, the general health care industry relied upon the OIG’s citation of the PhRMA Code in its Guidance as an acknowledgment that following the PhRMA Code’s standards would be a reasonable approach to managing Industry relationships.

The OIG continues to examine the relationship between Industry and physicians.⁴⁸ Most recently, the OIG released, *A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse*, a guidance that comments on physicians’ relationships with vendors among other topics. In this guidance, the OIG asks physicians to evaluate proposed vendor relationships by asking: “(1) Does the company really need my particular expertise or input?; (2) Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?; and (3) Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?”⁴⁹ All health care providers need to carefully evaluate their contribution to such arrangements before entering into them.

⁴⁵ U.S. DEPARTMENT OF HEALTH AND HUMAN RESOURCES, OFFICE OF INSPECTOR GENERAL, Remarks as Prepared for Keynote Address Given by Daniel R. Levinson, Inspector General of the Department of Health & Human Services, to a Conference of the American Health Lawyers Association, *Trust, but Verify*, January 21, 2010, available at <http://oig.hhs.gov/testimony/docs/2010/IGCOIAHLA-1-2010.pdf>.

⁴⁶ 68 Fed. Reg. 23,731 (May 5, 2003) available at <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

⁴⁷ *Id.* at 23,737.

⁴⁸ U.S. DEPARTMENT OF HEALTH AND HUMAN RESOURCES, OFFICE OF INSPECTOR GENERAL, Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs, *Examining the Relationship Between the Medical Device Industry and Physicians*, Feb. 27, 2008, available at http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

⁴⁹ U.S. DEPARTMENT OF HEALTH AND HUMAN RESOURCES, OFFICE OF INSPECTOR GENERAL, *A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse*, available at http://oig.hhs.gov/fraud/PhysicianEducation/roadmap_web_version.pdf.

Industry Codes of Conduct

PhRMA represents the country's leading pharmaceutical research and biotechnology companies on public policy issues; whereas the Advanced Medical Technology Association ("AdvaMed") is the largest trade association for medical device, diagnostic products and health information systems companies. As stated above, PhRMA's Code is cited by the OIG as providing useful and practical advice in handling such issues. Both these associations have comprehensive Codes of Ethical Conduct that provide useful guidance to health care providers with regards to the standards of conduct their vendor members should be adhering to when interacting with health care providers.

There are a number of other Industry trade associations that also have guidelines with regards to Industry relationships and conflicts of interests. Depending upon the specific sector, it can be helpful for attorneys and compliance officers to understand the conflicts of interest standards for each Industry sector before advising a client to proceed with an arrangement. While Industry codes of conduct are not law and cannot immune a health care provider from government scrutiny, Industry sector codes of conduct can provide useful parameters.

Federal and State Stark Laws

While this paper's primary focus is on vendor relationships with health care providers, there also are laws that regulate gifts and other conflicts of interest between hospitals and referring community physicians. Federal and state Stark laws are intended to address the concern that financial incentives may negatively impact the medical decision-making of those providing care by causing an overutilization of services.

In short summary, the federal Stark Law is a civil strict liability law that prohibits a physician (or an immediate family member of a physician) from making referrals for certain designated health services ("DHS") payable by Medicare to an entity which he or she has a financial relationship (ownership, investment, or compensation) unless an exception is met.⁵⁰ It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for DHS furnished as a result of a prohibited referral.⁵¹ Some states also have state self referral laws.

Sanctions for violations of the Stark Law include denial of payment; refunds of amounts collected in violation; treble damages; a civil money penalty not to exceed \$15,000, and in certain cases not to exceed \$100,000 for each bill or claim for a service a person knows (or should know) is a service for which payment may not be made; and exclusion from

⁵⁰ 42 U.S.C. §1395nn.

⁵¹ *Id.* See also Jennifer Stamen, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, CONGRESSIONAL RESEARCH SERVICE CRS REPORT FOR CONGRESS, August 10, 2010, at p.5-6, available at <http://aging.senate.gov/crs/medicaid20.pdf>.

participating in the Federal health care programs.⁵² The two Stark exceptions which come up often with regards to gifts to medical staff are the non-monetary compensation and the medical staff incidental benefits exceptions.⁵³

Non-Monetary Compensation Exception

In accordance with the Stark law, the non-cash compensation a hospital may provide to referring physicians in 2012 is \$373 if: (1) the benefit is provided without regard to the volume or value of business generated; (2) the physician or his or her practice did not solicit the non-monetary compensation; and (3) the arrangement does not violate AKS or any Federal or State law or regulation governing billing or claims submission.⁵⁴ In addition, a hospital may provide one local medical staff appreciation event per year for the entire medical staff and the cost of this event will not count towards the \$373 annual limit; however any gifts or gratuities provided in connection with the staff appreciation event would be subject to the \$373 annual limit.⁵⁵

Staff Incidental Benefits Exception

Hospitals may also separately provide incidental benefits such as meals and parking to medical staff when used on the hospital's campus if certain requirements are met under the medical staff incidental benefits exception.⁵⁶ The incidental benefit must be: (1) offered to all members of the medical staff practicing in the same specialty; (2) cannot be cash or a cash equivalent; (3) less than \$31 per occurrence; (4) must be reasonably related to the provision of or designed to facilitate the delivery of medical services at the hospital; (4) must be provided by the hospital and used by the medical staff members only on the hospital's campus; (5) cannot take into account the value or volume of referrals; and (6) cannot otherwise violate the AKS or Federal or State law or regulation governing billing or claims submission.⁵⁷

The exception notes that identification of physicians on a hospital website or through advertising, or the provision of hospital pagers or two way radios meets the "on campus" requirements as long as the other requirements of this exception are met.⁵⁸ Also, other facilities and health care clinics that have bona fide medical staff may provide benefits under this exception on the same terms and conditions that apply to hospitals.⁵⁹

⁵² Jennifer Stamen, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, CONGRESSIONAL RESEARCH SERVICE CRS REPORT FOR CONGRESS, August 10, 2010, at p.5-6, available at <http://aging.senate.gov/crs/medicaid20.pdf>.

⁵³ 42 CFR §411.357(k) & (m).

⁵⁴ 42 CFR §411.357(k). See also http://www.cms.gov/PhysicianSelfReferral/50_CPI-U_Updates.asp#TopOfPage.

⁵⁵ *Id.*

⁵⁶ 42 CFR §411.357(m).

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

The Stark Law also has exceptions relating to providing compliance training and professional courtesy (i.e., discounted or free professional services) to medical staff.⁶⁰ It is expected that the government will be more aggressive in enforcing technical violations of the Stark Law in the future. Recently, two hospitals disclosed to the government some infractions of the Stark law because it was in non-compliance with some of requirements of the non-monetary compensation exception and other Stark exceptions to avoid scrutiny by regulators.⁶¹ It is important for hospitals to develop policies and procedures to mitigate the likelihood of any technical violations of the Stark law.

Beneficiary Inducement Law

In the past, hospitals were forced to follow narrow exceptions with regards to inexpensive gifts or services they provided to patients. The federal civil monetary penalty law (“CMP”) prohibits the offering of remuneration to beneficiaries of federal health care programs to influence the beneficiaries’ selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services. The OIG can pursue a CMP of up to \$10,000 for each wrongful act.⁶²

The OIG only previously permitted inexpensive gifts (other than cash or cash equivalents) that have a retail value of no more than \$10 individually and no more than \$50 in the aggregate annually per patient.⁶³ The OIG also allows providers to “offer beneficiaries more expensive items or services that fit within one of the five statutory exceptions: waivers of cost-sharing amounts based on financial need; properly disclosed co-payment differentials in health plans; incentives to promote the delivery of certain preventive care services; any practice permitted under the federal anti-kickback statute pursuant to 42 CFR §1001.952; or waivers of hospital outpatient co-payments in excess of the minimum co-payment amounts.”

PPACA Section 6402

Notwithstanding these prior exceptions, many “charitable and other innocuous” programs arguably violated this CMP because of the narrowly drawn exceptions. Section 6402 of PPACA significantly expands the exceptions to address this issue by creating new exceptions to the definition of remuneration under the CMP.⁶⁴ The exceptions are:

⁶⁰ 42 CFR §411.357(o) & (s).

⁶¹ See *Hospital Settles CMP Case After OIG Discovers No Problems in Referral Pattern*, REPORT ON MEDICARE COMPLIANCE, Vol. 18, No. 37, Oct. 19, 2009, available at http://www.lathropgage.com/files/upload/Ramirez_rmc101909.pdf; *Hundreds of MD Perks Trigger \$30M Settlement in Detroit Hospital Case*, REPORT ON MEDICARE COMPLIANCE, Vol. 20, No. 1, Jan. 10, 2011.

⁶² 42 U.S.C. § 1320a-7a(a)(5).

⁶³ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries, August 2002, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

⁶⁴ PATIENT PROTECTION AND AFFORDABLE CARE ACT, Pub. L. 111-148, 124 Stat. 119, § 6004(d)(2)(B),

- Remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs and designated by the Secretary under the regulations.
- The offer or transfer of the items or services for free or less than fair market value by a person if the items or services:
 - Consist of coupons, rebates, or other rewards from a retailer; are offered or transferred on equal terms to the general public, regardless of insurance status; and the offer is not tied to the provision of other items or services reimbursed by Medicare or Medicaid; or
 - Are not offered as part of any advertisement or solicitation; are not tied to the provision of other services reimbursed by Medicare or Medicaid; have a reasonable connection to the medical care of the individual; and are provided after the person determines in good faith that the individual is in financial need.
- The waiver by Prescription Drug Plan Sponsors and Medicare Advantage organizations offering an MA-PD plan under Part C of any co-payment for the first fill of generic drugs covered under Part D.⁶⁵

These exceptions should allow organizations much more flexibility in providing charitable and similar activities to patients. However, organizations should be cautious when relying upon the first exception related to activities that “promote access to care” until additional guidance is issued by the OIG.

Conclusion

Despite a reduction of inappropriate activities between Industry and health care providers, some inappropriate conflicts of interests still exist within the industry. While the government is taking a multi-prong approach to further curb problematic relationships, health care providers’ remain a possible enforcement target. This paper briefly covers some of the key laws health care attorneys and compliance officers should review before considering whether a relationship is appropriate between industry stakeholders.

March 23, 2010.

⁶⁵ *Id.*

While many industry activities fall within a grey area, it is important to consider industry benchmarks in addition to the law before proceeding forward with an arrangement. Even though certain activities may not be illegal, the proposed activity may not be in the best interests of the organization's mission. As new transparency disclosure laws go into effect in the future, health care providers need to be comfortable that any existing arrangement between industry partners could become a headline of a news story.