The Impact of the Fraud and Abuse Laws on Pharmaceutical Advertising and Marketing Compliance: A Manufacturer’s Perspective

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The intersection between the health care fraud and abuse laws and pharmaceutical marketing practices in the U.S. raises interesting compliance issues for pharmaceutical manufacturers, particularly in light of the newly enacted federal health care reform legislation. The legislation includes significant anti-fraud measures as well as additional funding to fight fraud and abuse. Such increased scrutiny on pharmaceutical promotional practices requires manufacturers to pay close attention to and comply with the health care laws, regulations and guidelines. Compliance is the only clear path to minimizing exposure to potential liability.

1. Anti-Kickback and False Claim Laws

Under the federal health care program anti-kickback law, it is illegal for any individual to offer to pay to induce a person to:

1. refer an individual to a person for any item or service for which payment may be made under a federal health care program;
2. purchase or order such an item or service; or
3. arrange for or recommend purchasing or ordering such an item or service.

Illegal payments include, directly or indirectly, kickbacks, bribes, rebates, cash or “in kind” remuneration. A person need not have actual knowledge of the anti-kickback statute or a specific intent to violate the anti-kickback statute.

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1 The health care reform legislation consists of H.R. 3590, the Patient Protection and Affordable Care Act, and H.R. 4872, the Health Care and Education Reconciliation Act of 2010.
2 An additional $10 MM/year for 2011-2020 and an additional $200 MM/year for 2011-2016 (H.R. 3590, Sec. 6402 and Sec. 1304, respectively).
3 42 U.S.C. §1320a-7b.
4 A federal health care program is a health benefit program funded in whole or in part by the federal government and includes Medicare, Medicaid, and the VA health network, among others.
Violations of the anti-kickback statute are deemed “federal healthcare fraud offenses” and are punishable under the U.S. criminal code by prison terms and fines, as well as civil consequences of no small magnitude. The current civil penalties for violation of the federal anti-kickback law vary depending upon the illegal conduct and include, for example, a penalty of up to $50,000 for each improper act as well as three times the amount of remuneration at issue. With respect to the criminal exposure, the violator (corporate or individual) faces a felony conviction with imprisonment up to five years, a $25,000 fine, or both. The government may proceed civilly, criminally, or both ways against companies.

Violation of the anti-kickback law can also result in exclusion from participation on any federal health care program, for over 10 years, depending on the nature of the offense and the violator’s prior compliance history. During the exclusionary period, pharmacies and hospitals will not be reimbursed for the excluded manufacturer’s products, thereby influencing the manufacturer’s bottom line by removing a large marketplace for those products.

In addition, other federal criminal and civil laws prohibit individuals from submitting false information or claims for payment to the government. For example, the Federal False Claims Act (“FCA”) prohibits the offer or payment to a Medicare or Medicaid beneficiary of remuneration that the offeror knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular healthcare practitioner or supplier. Under the new healthcare legislation, claims resulting from violations of the anti-kickback laws constitute false claims subject to the FCA.

While many pharmaceutical manufacturers generally don’t submit claims to government programs such as Medicaid or Medicare, they can also be subject to liability under the FCA for a variety of activities. Pharmaceutical companies often provide advice on specific reimbursement coding to use for a drug. Drug companies must be careful to avoid claims that they improperly gave coding advice to healthcare providers, which resulted in the submission of false claims. Improper manipulation of average warehouse price (“AWP”) is another area of concern. The federal government, some states, private individuals and health plans have brought lawsuits challenging drug company practices of increasing customer profit by increasing government reimbursement and then marketing the spread” to prospective customers. Underpayment of Medicaid rebates is yet another area of concern; that is, where improperly reported AWP lowers the rebate the company is required to submit (23.1% for brand drugs under the new health care legislation) causing profit to the drug company.

Those who violate the FCA are liable to a mandatory civil penalty of not less than $5,000 and not more than $10,000 per false claim, as adjusted upward by inflation – plus costs and three times the amount of the government’s damages. Moreover, private citizens can use the FCA as a vehicle to bring a “qui tam” action and recover the ill-gotten gains, as well as reasonable attorneys’ fees.

In January 2010, the federal government filed a civil action against a manufacturer and two of its subsidiaries under the FCA, for orchestrating a massive unlawful

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5 42 U.S.C. §1320a-7(a); 42 C.F.R. §1003.103.
6 42 U.S.C. §1320a-7b.
9 31 U.S.C. §3729. The present penalty range, as adjusted for inflation, is $5,500 to $11,000. 64 Fed. Reg. 47099 (Aug. 30, 1999).
pharmaceutical monetary kickback scheme. The scheme also involved a provider of healthcare services to nursing homes and long-term care facilities. The manufacturer is said to have violated the anti-kickback statute by entering into written agreements with the provider, whereby the manufacturer paid the provider rebates in return for the provider promoting and selling various manufacturer drugs to nursing homes. While the actions under the FCA were filed civilly, liability is predicated upon alleged violations of the anti-kickback statute. The provider was alleged to have received multiple kickbacks payments from the pharmaceutical manufacturers, and unlawful kickback payments from the provider to the multiple nursing homes that the provider was servicing, and settled with the government for $98 million. The civil case against the manufacturer has not yet been resolved. At this juncture, the government has chosen not to pursue criminal charges, but pharmaceutical manufacturers must be aware of the liability that can attach for unlawful financial arrangements. It behoves pharmaceutical companies to carefully examine their financial arrangements to confirm that they don’t contain any unlawful remuneration agreements.

Because the anti-kickback law is so broadly written that it encompasses many harmless arrangements, a number of statutory exceptions have been created to shield certain behavior from prosecution. These include properly disclosed discounts and price reductions, payments to *bona fide* employees, payments to group purchasing agents, waiver of certain Medicare deductibles by federally qualified health centers for indigent individuals, certain types of remuneration between Medicare or Medicaid risk contractors and entities providing services, reduction or waiver of cost sharing amounts to Medicare Part D beneficiaries in certain instances, remuneration to certain federally-funded health centers serving a medically underserved population, and remuneration protected by the safe harbor regulations discussed below.

Likewise, the Office of Inspector General (“OIG”) of Health & Human Services (“HHS”) has established regulatory safe harbors to shield remuneration paid by pharmaceutical companies. There are numerous safe harbors; the ones most applicable to pharmaceutical manufacturers include certain remuneration applicable to: discounts, personal services and management contracts, group purchasing organizations, employees, and risk-sharing arrangements. Arrangements that don’t fit within an exception or safe harbor are not *per se* illegal, but will be subject to scrutiny by OIG.

A number of states also have anti-kickback laws applicable to funds associated with government assistance, as well as gift disclosure laws that require pharmaceutical companies to disclose annually the value, nature and recipient of gifts to physicians or other healthcare providers. Certain of these states have limits on the annual value of gifts that can be given. For example, Vermont requires pharmaceutical companies to provide annual disclosures of payments by the company of $25.00 or more to physicians and other health care providers in Vermont in connection with detailing or other promotional activities. Minnesota law prohibits pharmaceutical companies from giving any gifts, with limited exceptions, to any practitioner in Minnesota exceeding, in total, $50.00 per year, and Massachusetts requires pharmaceutical companies to report annually any payment or gift of more than $50.00 to a health care professional. Washington, D.C.,

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11 Civil Action Nos. 07-10288-RGS and 05-11518-RGS (United States District Court, District of Massachusetts). Recent press suggests that the State of Virginia has joined the suit.


13 42 C.F.R. §1001.952.


West Virginia and Maine have similar laws. Moreover, under the Physician Payment Sunshine Act of the new healthcare legislation, pharmaceutical manufacturers must disclose all payments or other transfers of $10.00, or $100.00 in the aggregate, made to physicians or teaching hospitals.\textsuperscript{17} Failure to comply will subject manufacturers to civil monetary penalties of $1,000 to $10,000 with a ten-fold increase in fines if the manufacturer “knowingly” failed to report the payment(s).

2. Drug Promotion Under the Fraud and Abuse Laws

Drug promotion raises a number of potential problems under the fraud and abuse laws. In light of the myriad of enforcement actions for promotional activities, manufacturers should carefully conduct risk assessments prior to implementing any program.

Free Goods and Services

Practices that shift a payment obligation from or provide free or goods or benefits to a healthcare practitioner, institution, pharmacy or formulary manager are problematic if they influence decisions to prescribe a particular drug. Conversely, there is no problem with providing free materials or services where there is no influence to choose or purchase particular drugs. In the same way, providing value-added items and services that eliminate an expense can be sticky. Recent enforcement actions in this area involve providing free goods, stocking allowances, and market share rebates. These types of practices should be avoided unless they involve an exchange of legitimate and necessary services for fair market value. Manufacturer patient assistance programs which provide discounted or free drugs to indigent patients, who are often recipients of government assistance via Medicare Part D, can also expose manufacturers to liability. This can be alleviated by offering patient assistance via independent charitable foundations, or patient assistance outside of Medicare Part D.

Discounts

Discounts can raise anti-kickback issues if not structured to fit within the any of the available safe harbors. A discount must be in the form of a rebate or other reduction in price given or set at the time of sale. Discounts do not include supplying one good for free or at a discounted rate to induce the purchase of another drug, a routine reduction or waiver of any coinsurance or deductible, services provided per contract, or any other remuneration not specifically defined as a discount. Companies likewise cannot offer discounts in return for the referral of business to the company or a related entity. Importantly, manufactures must ensure that they accurately track and report discounts under the various government pricing programs such as the Medicaid Drug Rebate\textsuperscript{18} program, Medicare Part B Average Sales Price\textsuperscript{19}, and the federal Ceiling Price.\textsuperscript{20} In light of the increasing number of enforcement actions brought against pharmaceutical manufacturers for discounting arrangements, all financial arrangements between providers and manufacturers should be carefully scrutinized.

Consulting Services

Consulting and services fee payments (e.g., for speaking engagements, advisory board memberships), in which the pharmaceutical manufacturer provides remuneration to providers or entities that are customers or potential customers may raise concerns if the manufacturer has no reason to enter into the consulting relationship other than to generate

\textsuperscript{17}42 U.S.C. § 1320a-7h.
\textsuperscript{18}42 U.S.C. § 1396r-8.
\textsuperscript{19}42 U.S.C. § 1395w-3a.
\textsuperscript{20}38 U.S.C. § 1826.
business. A safe harbor is available for fair arrangements that are set out in writing and signed by both parties, last for a duration of at least one year, and do not involve financial terms based on a volume of referrals. Consulting arrangements should be closely vetted, in particular, for anti-kickback compliance. If the arrangement does not clearly fit within the safe harbor, then steps should be taken to document the fair market value, the need and the purpose of the services provided. Recent enforcement actions focus on sham consulting arrangements, for example, where manufacturers paid physicians to prescribe certain drugs or to attend meetings at high-end resorts, high-end dinners and advisory board meetings where no consulting services were actually provided.

**Research Grants**

Research grants to providers and their institutions are another area of concern where they are linked to prescribing practices, research of questionable value, or are excessive in light of the work performed. Grants should not be unrestricted in return for certain benefits, i.e., exclusive formulary placement, nor should they comprise sham studies that induce physicians to prescribe certain drugs. Manufacturers should have written policies and procedures in place that describe the process by which research grants are awarded.

**Pharmacy and Pharmacy Benefit Managers (“PBM”) Payments**

Other areas of concern include payments to pharmacists and PBMs. Manufacturers that provide compensation to pharmacies for providing counseling, information or services related to a particular drug may improperly influence generic substitution decisions. Likewise, payments to induce pharmacists to call physicians to switch to the manufacture’s product run afoul of the fraud and abuse laws. Direct payments or rebates offered to PBMs for formulary access or position may implicate the fraud and abuse laws. Manufacturer activity should be structured to fit within the services contract safe harbor in the former instance. Payments for formulary access should be avoided with the latter.

3. **A Bit of Preventive Medicine**

**Pharmaceutical Compliance Programs**

In May 2003, the OIG issued a Compliance Program for Pharmaceutical Manufacturers that sets forth elements of an effective compliance program as well as specific risk areas for manufacturers. Risk areas include: (1) the integrity of data used to establish government program reimbursement; (2) kickbacks and other illegal remuneration which can arise with non-protected discounts, value-added items and services, manipulating AWP, fee-per-switch arrangements, consulting and advisory payments, entertainment, gifts, and continuing medical education funding; and (3) the distribution of drug samples. It is very important that companies carefully scrutinize all promotional activity falling within the risk areas for legal compliance.

In keeping with the OIG Guidance, there are a number of steps that a company can take to demonstrate compliance with applicable laws and operation with the highest ethical standards. Companies should consider implementing a compliance program that addresses the risk areas identified above as well as reflect the unique and changing nature of their environment.

**Effective Pharmaceutical compliance programs should include, at a minimum:**

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A. Written Standards of Conduct. Basically, a statement of the ethical and compliance principles that guide daily operations.

B. Leadership. This means that companies should designate a senior member of their management team to serve as the company’s compliance officer. The compliance officer should be responsible for developing, implementing and refining the company compliance program. Importantly, the compliance officer must have independent judgment as well as the power to make necessary changes within the organization. Companies should also consider establishing a compliance committee to advise the compliance officer and to assist in the implementation of the compliance program.

C. Educate and Train. It is critical that organizations provide education and training of employees and agents on their legal and ethical obligations on the company corporate compliance program in addition to the obligations arising under the applicable federal health care program requirements.

D. Create Effective Lines of Communication. Employees and agents must know where and how to report suspected violations of any sort, with confidence that they will receive a meaningful response without fear of retribution.

E. Audit and Monitor. A compliance program should include monitoring, auditing and evaluation of compliance in relation to the program objective. This should include, as appropriate, efforts to monitor the activities of outside sales personnel.

F. Corrective Actions. Companies must have the ability to promptly respond to any potential violations of law or policy and take disciplinary action. In addition there must be means to assess whether these violations were due to gaps in policy or internal controls, and to take any necessary corrective measures.

G. Disciplinary Actions. Organizations should establish disciplinary programs that detail the consequences of violating the law or the company’s corporate compliance program.

Certain states have also enacted laws requiring pharmaceutical companies to implement compliance programs. California requires pharmaceutical companies to have compliance programs consistent with the OIG Guidance. Nevada has adopted the PhRMA Code of Conduct. The PhRMA Code on Interactions with Health Care Professionals, which is voluntary, sets out a number of do’s and don’ts for companies in their interactions with healthcare professionals. Under the PhRMA Code, companies cannot offer: items without educational value (such as pens, mugs, etc); meals outside of the hospital or doctor’s office setting; and entertainment and recreational outings. The PhRMA Code

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further requires companies to ensure that sales representatives have adequate training on health care laws and regulations, ensure responsible use of prescriber data, comply with specific requirements when hiring consultants, and disclose payment to health care professionals who are members of formulary committees or develop clinical practice guidelines. In addition, company CEO’s and compliance officers must provide annual certifications that they comply with the PhRMA Code. Compliance with the PhRMA Code is considered the “minimum acceptable level of conduct for pharmaceutical manufacturers” in the OIG Guidance. Like Nevada, Massachusetts has enacted laws that track the requirements of the PhRMA Code. 25

**Comply with the Anti-Kickback Law Safe Harbors**

Wherever possible, all monetary arrangements should be structured to fit within one of the safe harbors on the anti-kickback law. Arrangements that don’t fit squarely within a safe harbor should be reviewed on a case-by-case basis to determine if appropriate justification can be made, to support the activity. In any event, all decisions and activities should be supported by proper documentation.

### 4. Conclusion

As the government intensifies its efforts to prevent and punish fraud and abuse, pharmaceutical companies should make sure that they are effectively managing the risks associated with their marketing activities. Failure to oversee the details in marketing practices can lead to a number of negative consequences, including criminal liability. The savvy manufacturer will create a specific compliance program that covers each component of the anti-kickback laws – and then enforce that program. Those who don’t may regret that decision.

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**Validus Pharmaceuticals LLC** is focused on acquiring, reformulating and marketing prescription products relevant to the psychiatry and neurology markets. Validus seeks to acquire mature products that have well defined and accepted clinical utility relevant to today’s practice of medicine.

**Fox Rothschild LLP** is a national, general practice law firm with roughly 500 attorneys in 15 offices coast to coast. Approximately 150 attorneys practice in three New Jersey offices located in Princeton, Roseland and Atlantic City, making the firm one of the

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25 105 C.M.R. §970.000 et seq.
state’s largest. The firm has significant depth in the traditional practice areas most relevant to pharmaceutical clients.