APPLICATION OF HEALTH CARE FRAUD AND ABUSE LAWS TO PHARMACEUTICAL MARKETING

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I. PHARMACEUTICAL COVERAGE AND PAYMENT UNDER MEDICARE AND MEDICAID

A. Medicare

1. Title XVIII of the Social Security Act (SSA), enacted in 1965.

2. Federal program of health benefits for individuals age 65 and older, certain disabled individuals, and end stage renal disease patients.

3. Part A
   a. Inpatient hospital services and post-hospital nursing home care.
   b. Administered by private contractors (fiscal intermediaries) under regulations and policies issued by Centers for Medicare & Medicaid Services (CMS).
   c. Inpatient reimbursement is prospective based on diagnosis related groups (DRGs).
   d. Drugs administered to inpatients are included in DRG payment, not separately reimbursed.

4. Part B
   a. Voluntary program covering physician, hospital outpatient, ambulatory surgical, and other non-inpatient services.
   b. Administered by private contractors (regional carriers) under regulations and policies issued by CMS.
c. Limited coverage of prescription drugs. Covered drugs include:

(1) Drugs administered incident to physicians’ services (in office or hospital outpatient settings) that are not generally self-administered.
   
   (a) Generally injectables, e.g., chemotherapy agents and pain management drugs for cancer patients; arthritis therapies; radiopharmaceuticals and other diagnostic imaging agents.

(2) Drugs used with durable medical equipment (DME) (non-disposable medical equipment used in the home).
   
   (a) E.g., respiratory drugs used with nebulizers.

(3) Other drugs specifically identified in statute.
   
   (a) Antigens

   (b) Pneumococcal, influenza, and hepatitis B vaccines

   (c) Blood clotting factors for hemophilia patients

   (d) Immunosuppressive therapy drugs for organ transplant patients

   (e) Erythropoietin for dialysis patients

   (f) Self-administered oral cancer drugs

d. Payment for drugs used in hospital outpatient setting:
Balanced Budget Act of 1997 required the establishment of a prospective payment system (PPS) for hospital outpatient services. CMS implementation of the hospital outpatient PPS took effect August 1, 2001. Most Medicare reimbursable drugs administered in the hospital outpatient setting are included in global PPS payment based on ambulatory patient classifications (APCs), but certain drugs are paid separately
under their own APCs. Additional transitional “pass-through” payments are available for from two to three years for drugs that were not paid for as a hospital outpatient service as of December 31, 1996 and whose cost is “not insignificant” (as defined in 42 C.F.R. § 419.64(b)) in relation to the prospectively determined payment for the service involved. In CY 2009, most Part B hospital outpatient drugs that are reimbursed under a separate APC are reimbursed at 104 percent of Average Sales Price (see (e), below), and drugs eligible for pass-through payments are reimbursed at 106 percent of ASP.

**e. Payment for Part B drugs outside the hospital outpatient setting:** The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed reimbursement rates under Part B. For 2004, reimbursement for drugs was generally limited to 85 percent of the reported average wholesale price (AWP) as of April 1, 2003.

For 2005 and subsequent years, reimbursement for single source drugs is 106 percent of the Average Sales Price (ASP) or 106% of WAC, whichever is lower. ASP, which is reported quarterly to CMS by drug manufacturers, is the weighted average of prices to all customers, excluding sales that are excluded from the determination of best price under the Medicaid Drug Rebate Program. For multiple source drugs, reimbursement is 106 percent of the weighted average of ASPs for the same multiple source drug.

The MMA required CMS to establish a competitive acquisition program (CAP) through which physicians may obtain certain Part B covered drugs designated by CMS without purchasing them. Contractors under the CAP purchase drugs, provide them to physicians, and bill Medicare directly at an amount established under a bidding process. Physicians are required to elect to obtain Part B drugs either through the CAP or through traditional purchasing and billing. CMS established a CAP in July 2006, but announced on November 10, 2008 that it was suspending the CAP program for 2009, and will be seeking feedback from stakeholders before reestablishing the program.
5. Part C

a. Medicare Advantage programs (formerly Medicare+Choice program) (revised by the MMA).

b. Voluntary program in which beneficiaries may enroll in additional types of plans other than traditional fee-for-service Medicare.

c. Beneficiary can choose among private HMOs, preferred provider organizations (PPOs), provider sponsored organizations (PSOs), or private fee-for-service plans that have risk-sharing contracts with CMS.

d. Benefits must include at least the items and services included in Medicare Parts A and B, but may include additional benefits, including outpatient prescription drug coverage under Part D (see 6, below).

6. Part D

a. Outpatient prescription drug coverage was added as Part D by the MMA, effective January 1, 2006.

b. Benefits are provided by prescription drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs). Plans submit a bid to CMS specifying the expected cost of providing prescription drug coverage to enrollees. Medicare reimburses the Plan based on the bid amount, but is also at risk for additional payments if the Plan’s cost of providing prescription drugs exceeds the estimated amount by a specified percentage.

c. PDPs are pharmacy benefit managers and other managed care organizations experienced in administering pharmacy benefits based on formularies.

d. Drug prices/rebates are negotiated between drug manufacturers and PDPs. The government is statutorily prohibited from interfering in price negotiations.
B. Medicaid

1. Title XIX of the SSA, enacted in 1965.

2. Jointly funded federal-state health benefit program for low-income individuals.

3. CMS establishes minimal requirements, but states have considerable latitude to establish benefits, eligibility requirements, payment rules and rates, and procedures.

4. Federal government and states share costs on matching fund basis. Federal share (federal financial participation, or FFP) may range from 50% to 83%, depending on state per capita income.

5. Prescription drug coverage and payment

   a. Inpatient prescription drugs: incorporated into payment rates for hospital inpatient services, generally based on per diem, DRGs, or other prospectively determined rate, depending on the state.

   b. Outpatient prescription drugs

      (1) Though optional service under statute, coverage is provided by all 50 states and D.C.

      (2) Reimbursement

         (a) Levels established by states -- level varies from state to state.

         (b) Single source drugs

            i) Generally, pharmacies are reimbursed either average wholesaler price (AWP) minus a specified percentage plus a dispensing fee, or wholesaler’s acquisition cost (WAC) plus a specified
percentage plus a dispensing fee, or the lower of the two.

ii) AWP generally based on First Data Bank listing.

(c) Multiple source drugs

i) For multiple source drugs for which at least 3 products are A rated (i.e., rated as bioequivalent) in FDA’s Orange Book, CMS publishes “federal upper limit” (FUL), which equals 150% of the lowest price listed for the drug in the above compendium.

ii) Where FUL has been established, state reimbursement may not exceed, in the aggregate, the FUL plus a dispensing fee. “Dispense as written” scripts are exempted from FUL.

iii) Under amendments enacted under the Deficit Reduction Act of 2005, state Medicaid payment for a multiple source drug may not exceed 250% of the lowest Medicaid Rebate Average Manufacturer Price (AMP) among the versions of the multiple source drug. This change was to have gone into effect on January 1, 2007, but was postponed until at least October 1, 2009 pursuant to section 203 of the Medicare Improvements for Patients and Providers Act of 2008. CMS regulations to implement the new FUL provisions were also enjoined by the court in National Association of Chain Drug Stores v. U.S. Department of Health and Human Services, Civ. No. 1:07cv02017 (RCL) (D.D.C.) in an order issued on December 19, 2007.
(3) Pharmaceutical manufacturers must pay quarterly rebates to each state on outpatient drugs dispensed in state to Medicaid beneficiaries. Rebate for NDA drugs equals greater of 15.1% of average manufacturer price (AMP) or difference between AMP and single best price to non-federal customer. Rebate for ANDA drugs equals 11% of AMP. SSA § 1927, 42 U.S.C. § 1396r-8.

(4) A number of states have required pharmaceutical manufacturers to pay supplemental rebates in order for their drugs to be included on the state preferred drug list (PDL). Drugs not on the PDL are subject to prior authorization. See, e.g., Fla. Stat. § 409.912.

II. THE FEDERAL HEALTH CARE PROGRAM ANTIKICKBACK LAW
(42 U.S.C. § 1320a-7b(b))

A. Prohibited Conduct

1. Knowing and willful

2. Solicitation/receipt or offer/payment

3. Of “any remuneration”
   a. including kickback, bribe, or rebate
   b. in cash or in kind

4. To induce a person to
   a. refer an individual for an item or service; or
   b. purchase, lease, or order – or arrange for the purchase, leasing, or ordering of – an item or service.

5. Where the item or service is reimbursed in whole or in part by a “Federal health care program.”
a. “Federal health care program” is a health benefit program funded in whole or in part by the federal government, except the Federal Employee Health Benefit Program.

b. Includes, among other programs, Medicare, Medicaid, the Department of Veterans Affairs health network, TriCare, the Indian Health Service, the Maternal and Child Health Services Block Grant Program, the Social Services Block Grant Program.

B. Penalties

1. Criminal: felony punishable by up to five years imprisonment or $250,000 or both for an individual. Companies can be fined up to $500,000. 18 U.S.C. § 3571.

2. Civil monetary penalty (CMP)

a. $50,000 for each act plus 3 times the amount of illegal remuneration.

b. Added to statute by Balanced Budget Act of 1997, after government had sought CMP authority for kickback violations for several years. 42 U.S.C. § 1320a-7a(a)(7).

c. Permits government to prosecute in an administrative proceeding under burden of proof for civil cases (“preponderance of evidence”) instead of more difficult burden of proof for criminal cases (“beyond a reasonable doubt”).

3. Exclusion from federal programs

a. Kickback violations generally subject to mandatory exclusion for at least 5 years where criminal conviction; permissive exclusion where administrative finding of kickback violation. 42 U.S.C. § 1320a-7(a), (b)(7).

Effective October 2, 1998, exclusion can apply to “indirect” suppliers, such as drug and device manufacturers, that do not submit claims to federal programs. 63 Fed. Reg. 46676 (Sept. 2, 1998). Result of exclusion is denial of payment to
“direct providers” (e.g., pharmacies, hospitals) for the excluded manufacturer’s products.

(1) Exclusion results in denial of payment for all of manufacturer’s products, not just those associated with kickback activities.

(2) Providers will not be penalized under false claims laws for unknowingly submitting claim for excluded manufacturer’s product.

(3) Providers can use and bill for existing inventory of excluded supplier’s products up to 30 days after exclusion becomes effective.

(4) OIG will waive exclusion if necessary to protect patient health – e.g., if a drug is necessary/unique. No further guidance or criteria for waiver.

b. Procedure

(1) OIG proposes exclusion

(2) Hearing before ALJ

(3) Appeal to HHS Departmental Appeals Board

(4) Judicial review

C. Relevant Statutory Exemptions

1. Discount or other reduction in price, if properly disclosed in claims and cost reports.

2. Payments to bona fide employees.

3. Payments to group purchasing agents.

4. Waiver of Part B Medicare deductibles by federally qualified health centers for indigent individuals.
5. Remuneration between an organization and an entity providing items or services under a written agreement with the organization if
   a. The organization is a Medicare or Medicaid risk-contractor, or
   b. The agreement places the entity at substantial financial risk.

6. Reduction or waiver of cost-sharing amounts by pharmacies relating to beneficiaries under Medicare Part D if
   a. The reduction or waiver is not advertised or part of a solicitation;
   b. The reduction or waiver is not routine; and
   c. The pharmacy either makes a good faith determination that the patient is in financial need, or fails to collect the amount after making reasonable efforts to collect the cost-sharing amount.

7. Remuneration given to or received by a federally-qualified health center pursuant to a contract, lease, grant, loan or other arrangement if the arrangement contributes to the ability of the health center to serve a medically underserved population, or remuneration under a service agreement between a federally-qualified health center and a Medicare Advantage plan.

8. Remuneration protected under safe harbor regulations issued by the OIG. (See Sections E and F, below.)

D. Judicial Interpretations

1. The “One-Purpose” rule
(1) Physician who performed cardiac monitoring paid “consulting fees” to referring physicians for initial consultations and interpretation of cardiac monitors.

(2) Court held that violation occurred if one purpose of the payment was to induce referrals, even if payments were also intended to compensate for professional services.


(1) Ambulance company paid consulting fees to hospital official, who recommended that hospital give ambulance contract to the company.

(2) Court confirmed one-purpose rule, holding that even opportunity to earn reasonable payment for services can be an inducement to refer.

c. See also U.S. v. LaHue, 254 F.3d 900 (10th Cir. 2001), cert. denied, 122 S. Ct. 818 (2002); U.S. v. McClatchey, 217 F.3d 823 (10th Cir. 2000); U.S. v. Kats, 871 F.2d 105 (9th Cir. 1989). But see U.S. ex. rel. Villafane v. Solinger, 543 F.Supp.2d 678, 697-98 (W.D.Ky 2008), where the court rejected the one-purpose rule in construing a Stark Law exemption that excludes arrangements that violate the antikickback law.

2. No quid pro quo required: Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)

a. Exclusion case brought against clinical laboratory partnership and managing partners.

b. Government alleged Hanlester paid remuneration to physician investors to induce them to refer patients to Hanlester for laboratory tests.

c. Court held that no proof of an agreement to refer is necessary to establish a kickback violation.
3. Intent -- the meaning of “knowing and willful”

a. Courts differ in interpretation of mens rea requirement.

b. Intent to induce

Pre-1995 case law, without specifically addressing meaning of “knowing and willful,” held that only intent to induce referrals is necessary for conviction. See, e.g., Bay State Ambulance, 874 F.2d 20.

c. Knowledge of antikickback law violation

Hanlester Network v. Shalala, 51 F.3d 1390 (see Section D.2, above)

Court held that “knowingly and willfully” requires that the defendant (i) know that the antikickback statute prohibits the offer of remuneration to induce referrals, and (ii) have the specific intent to violate the statute.

d. Knowledge of unlawfulness

(1) U.S. v. Starks, 157 F.3d 833 (11th Cir. 1998)

Eleventh Circuit held that government must prove only that defendant acted with knowledge that his conduct was unlawful, and not that defendant knew about the antikickback law and intended to violate it. Hanlester cited as a contrary case. Court relied on Bryan v. U.S., 118 S. Ct. 1939 (1998), in which Supreme Court construed the term “willfully” in a statute governing firearms dealers to mean knowledge that the conduct is unlawful.

The Court followed the Bryan and Starks cases in applying an intent standard that required knowledge of unlawfulness of the conduct.

e. Knowledge of wrongfulness


The Eighth Circuit rejected the Hanlester standard, holding that the government must prove only that defendant knew his conduct was “unjustifiable and wrongful,” not that he intentionally violated a known legal duty.


f. As a result of differing interpretations, mens rea standard will vary depending on where case is brought. Hanlester standard is extremely difficult for government to meet. OIG opposes the Hanlester decision, and has stated that it will “vigorously oppose its application in other circuits.” However, the government did not seek Supreme Court certiorari review of Hanlester.

E. Safe Harbors -- General Considerations

1. Recognizing that the extremely broad prohibition of the statute could encompass many common and non-abusive practices, Congress in 1987 directed the OIG to establish safe harbor regulations describing activities protected from prosecution.

3. Safe harbors are extremely narrow.

4. OIG has agreed that an arrangement that potentially falls under more than one safe harbor need only meet the requirements of one safe harbor, not both. Negotiated Rulemaking Committee on the Shared Risk Exception, Committee Statement (Jan. 22, 1998) at 12 (hereinafter “Negotiated Rulemaking Committee Statement”).

5. Effect of failure to comply with safe harbor

a. Effect of safe harbor is to shelter activity from liability “even though unlawful intent may be present.” 62 Fed. Reg. 7350, 7351 (Feb. 19, 1997) (OIG interim final rule on advisory opinions). Failure to meet conditions of safe harbor means only that the arrangement does not have guaranteed protection. Arrangement that does not fall within a safe harbor is not necessarily unlawful or suspect. See, e.g., Advisory Opinion No. 98-2 (April 8, 1998) (generic drug firm’s rebates to wholesalers do not qualify for discount safe harbor but are nevertheless lawful).

b. Arrangements that “drift from a safe harbor out to sea” will be examined by OIG on a case-by-case basis to determine whether the statute has been violated in such a way as to warrant prosecution. 56 Fed. Reg. at 35979 (preamble to final safe harbor regulations).

c. Criteria identified by OIG for determining whether an arrangement is abusive include:

   (1) Increased cost to federal programs (due to overutilization of items and services).

   (2) Effect on quality of care.

   (3) Effect on patient freedom of choice.

   (4) Effect on fair competition in the health care marketplace.
See, e.g., 56 Fed. Reg. at 35956.

6. “Sham” transactions

a. In 1994, the OIG proposed a rule under which compliance with a safe harbor would be disregarded when the government determined that an arrangement was entered into for the purpose of appearing to fit within a safe harbor and the substance of the transaction is not reflected by the form. 59 Fed. Reg. 37202, 37208 (July 21, 1994).

b. OIG decided in November 1999 to withdraw this proposed rule but cautioned that OIG will continue to deny safe harbor protection where the form of an agreement does not reflect the substance (e.g., where parties enter into a service agreement with no intent that the service actually be performed). 64 Fed. Reg. at 63530.

F. Summary of Pertinent Safe Harbors

1. This section summarizes only the six safe harbors of most interest to drug manufacturers.

2. Discounts (42 C.F.R. § 1001.952(h))

a. Relationship of safe harbor to statutory exemption for price reductions

(1) OIG has taken the position that discount safe harbor and statutory exemption for price reductions are coextensive. Thus, according to OIG, failure to meet conditions of the safe harbor means there is no protection under the statutory exception. See, e.g., 64 Fed. Reg. at 63527.

(2) However, in U.S. v. Shaw, 106 F. Supp. 2d 103 (D. Mass. 2000), court held that safe harbor and statutory exception are not coextensive, although interpretation of the statutory exception may be informed by safe harbor.
Court noted that it was not bound by OIG interpretation of safe harbor in interpreting statutory exception. Thus, failure to meet safe harbor conditions does not preclude protection under statutory discount exemption.

b. The discount safe harbor was revised by a regulation published on November 19, 1999 (64 Fed. Reg. 63518). Noteworthy changes were made to the safe harbor, including:

(1) Reporting obligations were changed for charge-based and fee-schedule based providers (e.g., pharmacies)

(2) End-of-period rebates to non-cost reporters permitted

(3) Bundled discounts permitted where items reimbursed under same methodology

(4) Addition of a new category of entity on which requirements are imposed -- the offeror

(a) An offeror is an individual or entity which is not a seller but promotes the purchase of an item or service by a buyer at a discount.

(b) For example, where a manufacturer sells a product to a wholesaler which, in turn, sells the product to an end user, and the manufacturer offers a discount to the end user, the wholesaler is the seller and the manufacturer is the offeror.

c. Analysis of whether arrangement falls within discount safe harbor involves two steps:

(1) Does it fall within definition of “discount”?

(2) What type of purchaser? This determines what the reporting obligations are for the buyer, seller, and offeror.
d. Definition of discount: reduction in amount a buyer (who buys either directly or through a wholesaler or GPO) is charged based on arms’ length transaction.

(1) Definition excludes

(a) Cash or cash equivalents, but rebate checks are permitted.

(b) Combination or “bundled” discounts – i.e., providing one good or service free or at reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed under the same Federal health care program using the same methodology, and the reduced charge is fully disclosed to the Federal health care program and accurately reflected “where appropriate, and as appropriate,” to the reimbursement methodology.

(c) Reduction in price offered to one payor but not to federal program.

   i) Exclusion applies to arrangements where discounts are offered on items or services for private pay patients to induce referrals of federal program beneficiaries. 64 Fed. Reg. at 63528. See Advisory Opinion No. 99-13 (Nov. 30, 1999) (laboratory discounts offered for private pay patients but not Medicare patients are excluded from safe harbor).

(d) Routine reduction or waiver of copayments owed by a beneficiary.

   i) Other discounts to a beneficiary besides routine waivers are permissible if they
otherwise comply with the safe harbor.  

(e) Warranties

(f) Personal or management services

(g) Other remuneration not expressly included in definition of discount.

(2) Prompt-pay discounts are not prohibited.

(3) Not all price reductions are discounts subject to the antikickback law. In Klazak v. Consolidated Medical Transport, 458 F.Supp. 622, 678-679 (N.D. Ill. 2006), the court rejected plaintiff’s theory that any reduction from a seller’s retail price was a “discount” subject to the antikickback law. The court reasoned that a discount exists only where the price offered is less than fair market value, which is determined by comparison of the seller’s price with prices that competitors are charging.

e. Definition of rebate: discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase subject to discount, but which is not given at time of sale.

(1) OIG has objected to rebates paid prior to the sales they apply to.

(a) OIG Advisory Letter re “Up-front Rebates,” “Prebates,” and “Signing Bonus” Payments (July 17, 2000): up-front payments to group purchasing organizations implicated antikickback statute because they were made prior to any purchase and not attributable to
identifiable purchases of items or services.


(c) U.S. v. Schering-Plough (2004) (interest on prepaid rebates was remuneration intended to induce managed care organization to maintain product on formulary). See Section V.F.4, below.

f. Requirements by type of buyer

(1) Risk-based Medicare HMO under SSA § 1876(g) or Medicaid HMO under SSA § 1903(m).

(a) Buyer need not report discount to government except as required by the risk contract.

(b) Seller need not report discount to the buyer.

(c) Offeror need not report discount to buyer.

(2) Buyer that reports costs (e.g., hospital, nursing facility)

(a) Buyer’s requirements

i) Discount must be earned from purchases of the same good bought within a single fiscal year of buyer.

ii) Buyer must claim the benefit of discount in the fiscal year earned or following year.
iii) Buyer must fully and accurately report discount in its cost report.

iv) At government request, buyer must provide seller’s invoices and (if applicable) reconciliation report and offeror’s information (see below).

(b) Seller’s requirements

i) Fully and accurately report discount on invoice.


ii) Inform buyer of its reporting obligations.

iii) If value of discount is not known at time of sale (i.e., end-of-period rebate),

   a) Report existence of discount program on invoice;

   b) Inform buyer of its reporting obligations “in a manner reasonably calculated” to give notice to buyer;

   c) When amount of discount becomes known, provide buyer with reconciliation statement documenting how discount was calculated;

   d) Refrain from impeding buyer’s ability to meet its obligations.

iv) Seller not liable for reporting omissions of buyer. 64 Fed. Reg. at 63527.
v) Even if an arrangement does not meet all the conditions of the safe harbor, accurate reporting of the net price and a notice informing the customer of its obligation to report discounts could defeat a government attempt to prove a “knowing and willful” violation of the antikickback law. See U.S. ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141 (D. Mass 2000).

(c) Offeror’s requirements

i) Inform buyer of its reporting obligations.

ii) Refrain from impeding buyer’s ability to meet its obligations.

(3) Other buyers (i.e., those paid based on reasonable charge or fee schedule amount, such as physicians and pharmacies)

(a) Buyer’s requirements

i) Discount must be made at time of sale, or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale.

ii) At government’s request, buyer must provide seller’s invoices and reconciliation statements (if any) and information provided by offeror.

iii) Discounts need not be reported in claims. 64 Fed. Reg. 63527.
(b) Seller’s and offeror’s requirements

Same as for cost-reporting buyers – see (2)(b) and (c), above.

3. Personal services and management contracts (42 C.F.R. § 1001.952(d))

a. Designed to ensure that payments for personal services are not made to induce referrals or purchases.

b. Can protect consulting, service, or grant agreements between drug companies and entities who provide services but are also purchasers/prescribers/formulary managers.

c. This safe harbor was revised by the November 19, 1999 regulation (64 Fed. Reg. 63518), which added conditions (3) and (8), below.

d. Requirements

(1) Agreement must be in writing.

(2) Agreement must specify services to be provided.

(3) Agreement must cover all of the services to be provided during term of agreement.

(4) If services are part-time or sporadic, agreement must specify the intervals and length of and charge for each.

(5) Terms of agreement may not be changed within one year. 56 Fed. Reg. at 35973.

(6) Compensation must be set in advance and be consistent with fair market value, and must not take into account referrals or business generated between the parties.

(7) Services must not involve promotion of activity that violates federal or state law.
(8) Aggregate services contracted for must not exceed what is “reasonably necessary to accomplish the commercially reasonable business purpose.” 64 Fed. Reg. at 63552.

4. Group purchasing organizations (42 C.F.R. § 1001.952(j))

a. Definition of GPO: entity authorized to act as purchasing agent for group of providers that are not corporate affiliates of the agent.

b. Requirements

(1) GPO must have written agreement with each member either

(a) Providing that the maximum fee paid by vendors to GPO will be 3% of price of vendor’s goods; or

(b) If fee will exceed 3%, specifying the amount or maximum amount of the fee paid by each vendor (either a fixed sum or percentage of sales).

(2) GPO must give provider members annual statement disclosing amount received from each vendor for purchases on behalf of the member.


5. Employees (42 C.F.R. § 1001.952(i))

a. Protects remuneration paid by employer to bona fide employee.

b. Employee must be “employee” as defined in Internal Revenue Code (26 U.S.C. § 3121(d)).
c. Volume-based commissions paid by drug companies to employee sales representatives are protected. Commissions paid to sales representatives who are independent contractors are not protected. See e.g., Advisory Opinion No. 98-1 (Mar. 25, 1998) (percentage compensation paid by device company to non-employee marketing personnel was deemed potentially abusive).

6. Remuneration under risk-sharing arrangements (42 C.F.R. § 1001.952(t) and (u))
   b. Designed to protect remuneration common in managed care organizations (MCOs) that otherwise would be prohibited.
      (1) Providers offer discounted services to MCO in return for stream of patients. This is remuneration for referrals.
      (2) Compensation arrangements between MCOs and providers require providers to refer patients to other providers within the MCO’s network, or provide incentives/penalties to encourage prescribing on-formulary. This could also be construed as remuneration for referrals.
   c. Statute required HHS to develop implementing rule by negotiated rulemaking process.
   d. Arrangements with “eligible MCOs” (42 C.F.R. § 1001.952(t))
      (1) Safe harbor protects an arrangement between an “eligible MCO” and an entity providing items and services to program beneficiaries, or between an entity providing items and services (upstream entity) and its subcontractors (downstream entity).
(2) Examples:

(a) Medicare risk contractor (“eligible MCO”) contracts for pharmacy services with pharmacy chain, which subcontracts with drug manufacturers. Pharmacy chain is “first tier contractor.” Drug manufacturer is a “downstream contractor.”

(b) Medicaid HMO (“eligible MCO”) contracts with PBM to administer drug benefit; PBM subcontracts with pharmacies.

(c) Medicare Advantage plan (“eligible MCO”) contracts for disease management services with drug manufacturer, which subcontracts with nurses.

(3) “Eligible MCOs” include, among other things:

(a) Medicare Part C plans paid on capitated basis.

(b) Medicaid managed care organizations paid on a capitated basis.

(c) HMOs or Competitive Medical Plans with a risk or cost-based contract with Medicare under SSA § 1876.

(d) Programs for All Inclusive Care for the Elderly (PACE) paid on a risk basis.

(e) Federally qualified HMOs.

(4) “Items and services” include not only health care items (e.g., pharmaceuticals) but also items and services that are “reasonably related” to them, including patient education, social services, utilization review.

(a) Disease management not specified in rule itself but identified as “reasonably related” in
(b) Marketing services are not covered, but the preamble explains that the exclusion of marketing services is not meant to apply to value-added services for current enrollees. 64 Fed. Reg. at 63509.

(c) Does not exclude discounts on combinations of different items ("bundled discounts").

(5) Agreement between eligible MCO and first tier entity must

(a) Be set out in writing;

(b) Specify items and services covered;

(c) Specify that entity providing items or services may not seek payment from a federal health care program;

(d) Terms may not change within one year.

(6) Agreement between first tier contractor and downstream contractor or agreement between two downstream contractors subject to substantially the same requirements as agreement between eligible MCO and first tier contractor.

(a) Certain first tier contractors may seek payment from Federal health care program.

(b) Agreement between first tier contractor and downstream contractor or agreement between two downstream contractors not protected when the agreement between the eligible MCO and the first tier
contractor involves certain types of cost-based reimbursement.

(7) No “swapping”: Remuneration under arrangement may not be conditioned on referral of other business paid by federal program on fee-for-service basis, or otherwise increase payments claimed from federal program.

e. Substantial financial risk arrangements with MCOs (42 C.F.R. § 1001.952(u))

(1) Safe harbor protects an arrangement between a “qualified managed care plan” (not necessarily a Medicare/Medicaid contractor) and an individual or entity providing items and services, or between an upstream and downstream entity, where there is a risk sharing arrangement that puts the individual or entity at substantial financial risk (SFR) for the cost or utilization of the items or services.

(2) Examples:

(a) Blue Cross Blue Shield contracts with a physician hospital organization (PHO) paid on percentage-of-premium basis, which contracts with physicians paid on a capitated basis.

(b) HMO contracts with drug manufacturer to provide drugs and/or disease management on capitated basis.

(3) “Qualified managed care plan” is one that qualifies as a “health plan” under 42 C.F.R. § 1001.952(l)(2) and has certain attributes of managed care (e.g., a utilization review program and other reasonable checks against overutilization, a quality assurance program, and grievance procedures).

(4) “Substantial Financial Risk”: arrangement must meet one of two standards.
(a) **Payment methodology standard:** payment is either full capitation; percentage of premium (i.e., downstream provider is paid a percentage of premium paid to the health plan); or federal health plan inpatient DRGs.

(b) Capitation methodology is the only one that appears practicable for drug manufacturers.

(c) **Numeric Standard:** Difference between “target payment” and “minimum payment” is at least 20% for non-institutional providers and 10% for institutional providers.

i) “Minimum payment” is guaranteed payment to the provider.

ii) “Target payment” is payment the provider can receive by meeting utilization targets.

(d) Utility of numeric standard probably limited to MCO arrangements with physicians and possibly pharmacists; has questionable applicability to drug manufacturers and other suppliers.

(5) Agreement must meet requirements described above for agreements covered by 42 C.F.R. § 1001.952(t). See Section 6.d(5), above. In addition, it must:

(a) Specify the intervals at which distributions will be paid.

(b) Specify the formula for calculating incentives and penalties.

(c) Specify the methodology for determining compensation, which must be commercially
reasonable and consistent with fair market value established in an arms-length transaction.

(d) Require a quality assurance program that protects against underutilization and specifies patient goals.

(6) “Items and services” -- see 42 C.F.R. § 1001.952(t).

(7) No “swapping” -- see 42 C.F.R. § 1001.952(t).

(8) Arrangements between an upstream and downstream provider only protected if both are paid on SFR basis. If one of them is paid on fee-for-service basis, neither is protected.

f. Utility for drug manufacturers

(1) 42 C.F.R. § 1001.952(t) could protect

(a) Agreements to supply drugs and/or related patient education, disease management services to beneficiaries of an “eligible MCO.”

(b) Rebates offered to an “eligible MCO” or a PBM that contracts with an eligible MCO. (Such rebates might not be eligible for protection under the discount safe harbor if the MCO or PBM reimburses, rather than purchases, drugs.)

(c) Incentive compensation arrangements between a PBM that contracts with an “eligible MCO” and pharmacies that contract with the PBM (e.g., bonuses/withholds for generic dispensing; dispensing on-formulary).

(2) 42 C.F.R. § 1001.952(u) could be useful for drug companies who offer drugs, patient education, and/or disease management services
to health plans (or their subcontractors) on an SFR basis.

7. Other safe harbors

a. Investment interests

b. Space rental

c. Equipment rental

d. Sale of practice

e. Referral services

f. Warranties

g. Waiver of beneficiary copay (for hospital inpatients and indigent patients of federally qualified health centers)

h. Health plan offers to enrollees

i. Price reductions by providers to health plans

j. Practitioner recruitment incentives in practitioner shortage areas

k. Obstetrical malpractice insurance subsidies

l. Returns on investments in group practices

m. Cooperative hospital service organizations

n. Returns on investments in ambulatory surgical centers

o. Referral agreements for specialty services

p. Ambulance replenishing
q. Electronic prescribing items and services and electronic health records items and services

r. Goods, items, services, donations, and loans provided to Federally-Qualified Health Centers

8. As mandated by HIPAA, the OIG began in December 1996, and must continue at least annually, to publish notices in the Federal Register soliciting proposals for new safe harbors and revisions to existing ones. The OIG is not required to adopt the proposals, but must report to Congress on proposals received, proposals rejected, and why they were rejected.

G. OIG Guidance on Compliance With Antikickback Law

1. Compliance Program Guidance


b. Elements of an effective compliance plan include:

(1) Written policies and procedures, comprising a general code of conduct and detailed substantive policies and procedures;

(2) Designation of a compliance officer;

(3) Education and training;

(4) Effective lines of communication to report complaints or ask questions;

1 These items and services are not eligible for safe harbor protection when offered by a pharmaceutical or device manufacturer. See 42 C.F.R. § 1001.952(x)(1) and (y)(1).
Compliance audits and monitoring;

Policies for disciplinary action for non-compliance; and

Policies for investigating non-compliance.

c. Specific risk areas:

The OIG identified the following risk areas that pharmaceutical manufacturers should address in their policies and procedures.

(1) Integrity of data used to establish government reimbursement under Medicare, Medicaid, and other programs, including Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC), Best Price, and Average Manufacturer Price (AMP) (See Sections V.E and V.F).

(2) Kickbacks and other illegal remuneration, including:

(a) Discounts and other terms of sale: The OIG stated that discounts can only be safe harbored if they are a reduction in the price of the good or service based on an arms-length transaction offered at the time of sale, or set at the time of sale even if finally determined subsequent to the sale (such as a rebate).

(b) Non-price terms of sale – i.e., value-added items and services – potentially implicate the antikickback statute because they can induce or reward referrals, and can distort the cost of the products with which they are associated.

Value-added items and services that are targeted to a potential referral source and that eliminate an expense the customer would otherwise have borne are likely to be problematic, according to the OIG. For example, “the anti-kickback
statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal healthcare program.” 68 Fed. Reg. at 23,735.

(c) Average Wholesale Price: The CPG states that a manufacturer’s purposeful manipulation of AWP to increase a customer’s profits by increasing government reimbursement implicates the antikickback statute. Moreover, “marketing the spread” is viewed as evidence of intent to violate the antikickback statute. The “spread” is defined in the CPG as the difference between the amount a customer pays for a product and the amount the customer receives in reimbursement from Medicare and state Medicaid programs. “Active marketing of the spread” includes promoting the spread between cost and reimbursement as a reason to purchase the product, or guaranteeing a certain spread.

(d) Switching Arrangements: The CPG warns against fee-per-switch arrangements (See, e.g., Section IV.E.3). Although the draft CPG suggested that “discounts and rebates based on movement of market share” raise antikickback concerns (67 Fed. Reg. at 62,062), this was deleted from the final CPG.

(e) Consulting and advisory payments.

(f) Entertainment, grants, gifts, CME funding, and other remuneration to healthcare practitioners. The CPG counsels compliance with, at a minimum, the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code). See section III.H.
(3) Drug Samples: In light of the TAP criminal and civil investigation, (see section IV.A.2.d) the CPG urges careful compliance with the Prescription Drug Marketing Act of 1987 (PDMA), including notifying sample recipients that samples are not to be sold or billed.

2. Advisory Opinions
   a. In February 1997, under the mandate of HIPAA, the OIG established procedures for requests for advisory opinions on, among other things, whether particular arrangements involve prohibited remuneration under the antikickback law, or satisfy the conditions of a safe harbor. 62 Fed. Reg. 7350 (Feb. 19, 1997) (interim final rule).

   b. Requestor must be party to actual arrangement. No hypothetical situations or anonymous requests by third parties.

   c. Request must contain complete description of facts. CEO or equivalent official must certify to accuracy.

   d. User fees required.

   e. OIG must respond within 60 days after acceptance of complete request.

   f. Submission of request will not bar investigation or prosecution if government views the arrangement to be unlawful.

   g. Few companies will want to submit requests for ongoing activities, since request may not be made hypothetically or anonymously and could draw investigation.

   h. A number of advisory opinions have addressed activities engaged in by drug manufacturers. Many of these are discussed in subsequent sections of this Outline.
3. Special Fraud Alerts

a. OIG periodically issues fraud alerts, which describe practices the OIG considers unlawful.

b. In August 1994, OIG issued “Special Fraud Alert on Prescription Drug Marketing Schemes,” which identified the following activities as ones that potentially warrant prosecution:

(1) Prizes (e.g., airline discounts), gifts, cash payments, and coupons offered to physicians, pharmacists, MCOs for prescribing or providing specific products.

(2) Benefits offered to pharmacists in exchange for performing marketing tasks, including sales-oriented “educational” or “counseling” contacts, physician- or patient-outreach.

(3) Grants to physicians for studies of drugs when the studies are of questionable scientific value.

(4) Payment to patient, provider, or supplier for changing (or recommending a change of) a prescription from one product to another, unless payment is safe harbored.

c. HIPAA requires OIG annually to solicit proposals for new fraud alerts in addition to safe harbors. 62 Fed. Reg. at 65049.

4. Settlement agreements and indictments are window on government’s view of abusive arrangements.

III. OTHER ANTIKICKBACK AND RELATED LAWS

A. Federal False Claims Act (see Section V)
B. Civil Monetary Penalty for Remuneration to Medicare or Medicaid Beneficiary (42 U.S.C. § 1320a-7a(a)(5))

1. Added to Social Security Act by HIPAA in 1996.

2. Prohibits offer or payment to a Medicare or Medicaid beneficiary of remuneration that offeror/payor “knows or should know” is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular provider, practitioner, or supplier.

3. Penalty is $10,000 for each item or service plus three times the amount claimed for the item or service, and/or permissive exclusion.

4. “Remuneration” includes “transfers of items or services for free or for other than fair market value.”

5. Selected exceptions\(^2\)
   a. Exception for incentives given to individuals to promote the delivery of preventive care.

      (1) OIG example: tee shirts, exercise videos, water bottles provided to beneficiaries for participating in post-cardiac care fitness program.

      (2) Preventive care must be a reimbursable service that is described in the current U.S. Preventive Services Task Force’s Guide to Clinical Preventive Services, or that is a prenatal service or post-natal well-baby visit.

      (3) Exception does not include cash or cash equivalents, or incentives of a value that is disproportionate to the value of the preventive service itself. \(\text{Id.}\)

      (4) Exception applies only to CMP provision and not to antikickback law. 63 Fed. Reg. at 64395.

b. Exception for waivers of coinsurance and deductibles if the waiver is not advertised and not routine, and a good faith determination of financial need has been made.


6. OIG has determined that drug manufacturers are not “providers, practitioners, or suppliers” for the purpose of the Civil Monetary Penalty, unless the manufacturer also owns or operates, directly or indirectly, pharmacies, PBMs, or other entities that file claims for payment under Medicare or Medicaid. Special Advisory Bulletin, 67 Fed. Reg. at 55,857. Therefore, CMP does not apply to samples, coupons, or other items provided broadly by drug companies for patients that might influence a patient to choose a particular drug.


1. Prohibits payment of kickback to any federal prime contractor or subcontractor to obtain favorable treatment.

2. One court has held that a hospital’s provider agreement with Medicare is a government contract, so that remuneration (in that case, an unsecured line of credit) provided by a company selling medical supplies under contract to the hospital was an illegal kickback. U.S. v. Warning, 1994 U.S. Dist. LEXIS 10402 (E.D. Pa. 1994).


3. Department of Justice has brought claims under this statute against PBMs administering drug benefit under federal employee health plans, alleging unlawful receipt of remuneration from drug
manufacturers in return for formulary position, prescription conversions, and other activities. See, e.g., Section IV. F, below.

D. Stark Anti-Referral Law (42 U.S.C. § 1395nn)

1. Prohibits physician from referring patients for designated Medicare- or Medicaid-reimbursable services to an entity with which the physician or his family member has a financial relationship, including a compensation arrangement.

   a. Designated services include “outpatient prescription drugs.”

   b. A “referral” includes a request by physician for, or ordering of a reimbursable item or service. 42 C.F.R. § 411.351.

2. Most arrangements between drug manufacturers and physicians are not subject to the Stark Law.

   a. If the prescribing of a drug were construed to be a referral for a designated health service, a physician might be prohibited from prescribing a drug manufactured by a company with which the physician had a compensation arrangement (e.g., a grant, consulting, or investigator arrangement).

   b. However, CMS has not construed the statute in this manner. CMS has stated that drug manufacturers are not entities that furnish designated services to patients. Therefore, the ordering or prescribing of a drug does not constitute a “referral” to the manufacturer of the drug that could potentially violate the Stark Law. However, manufacturer-owned or affiliated retail pharmacy operations or other health care providers may be entities that furnish designated services to patient, and thus a prescription could constitute a referral in that situation. 66 Fed. Reg. 856, 872 and 920 (Jan. 9, 2001).

E. State Antikickback Laws

1. Over 30 states have government assistance antikickback laws. Most are modeled after the federal antikickback law, but over half do not
have an exemption for discounts. Certain of these have a lower intent standard than the federal antikickback law. See, e.g., People v. Duz-Mor Diagnostic Lab., Inc., 80 Cal Rptr. 2d 419, 429-31 (Cal. Ct. App. 1998) (holding that California’s antikickback law, Welfare and Institutions Code § 14107.2, does not require the specific intent to violate the law that was held to be required by the federal law in Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)).

2. Certain states (FL, MA, MI, MN, OH, RI, TX, WA) have antikickback laws that apply to items and services reimbursed by public and private payors, or regardless of payor.

   a. A marketing arrangement from which Medicare and Medicaid beneficiaries are excluded in order to avoid penalty under the federal antikickback law could remain subject to state all-payor laws.

3. It is the position of the OIG that federal safe harbors do not preempt state antikickback law. 56 Fed. Reg. 35,952, 35, 957 (July 29, 1991). Courts decisions on the issue are inconsistent. Compare Florida v. Harden, 938 So. 2d 480 (Fla. 2006) (Florida Supreme Court holds that state antikickback law is preempted by federal antikickback law) with In Re Pharmaceutical Industry Average Wholesale Price Litigation, 478 F. Supp. 2d 164 (D. Mass. 2007) (construing California law on a motion to dismiss, the federal district court holds that the California antikickback law is not preempted by the federal antikickback law, but reserves the right to revisit the issue on a fuller record).

4. Certain states (e.g., Massachusetts) have been particularly active enforcers against pharmaceutical manufacturers.

F. Gift Disclosure Laws

1. State laws

   a. Vermont law requires pharmaceutical companies to disclose annually to the Vermont Attorney General the value, recipient, nature and purpose of gifts or 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. Companies are not required to disclose free samples of prescription drugs intended to be distributed to patients, compensation and reimbursement of expenses in connection with clinical trials, unrestricted grants for continuing medical education programs, and scholarships for medical students, residents or fellows to attend conferences of national, regional, or specialty medical associations, if the attendee is selected by the association. 33 Vt. Stat. Ann. § 2005.

b. **Minnesota** law prohibits pharmaceutical companies from giving any gifts to a practitioner in Minnesota exceeding, in the aggregate, $50.00 per year, except for (1) free samples of prescription drugs intended to be distributed to patients, (2) payments to sponsors of medical conferences and other educational programs, (3) reasonable honoraria and expenses of practitioners serving on the faculty of a professional or educational conference or meeting, compensation for professional or consulting services in connection with research projects, (5) publications and other educational materials, and (6) salaries or other benefits paid to employees. Minnesota also requires annual disclosure of expenditures in categories 2, 3, and 4 that exceed $100 in aggregate per practitioner per year. Minn. Stat. Ann. §§ 151.461; 151.47(1)(f).

c. **Maine** law requires pharmaceutical companies to disclose the value, nature, purpose and recipient of gifts or payments of more than $25.00 to physicians and other health care providers in Maine. Reporting must also include information relating to all expenses associated with advertising, marketing and direct promotion of prescription drugs through various media as they pertain to residents of Maine, with the exception of expenses associated with advertising purchased on a regional or national market level that may include Maine. Companies are not required to report expenses relating to samples provided free of any charge directly to consumers; expenses of $25 or less; reasonable compensation and reimbursement for bona fide clinical trial for a new
treatment; and reimbursement and scholarships for expenses for attending any type of “significant” education. 22 M.R.S.A. § 2698-A; Department of Health and Human Services, 10-144, Ch. 275, § 2.

d.  **Washington, DC and West Virginia** have laws similar to that of Maine. See D.C. Code § 48-833 and 17 D.C.M.R. Ch. 83; W. Va. Code § 5A-3C-13 and C.S.R. Title 206.

e.  **Massachusetts** enacted a law on Aug. 10, 2008 requiring pharmaceutical and medical device companies to report annually to the state Department of Public Health any payment or gift of more than $50 made to a healthcare professional. These gifts will be reported on the state's Web site. On December 10, 2008, the Massachusetts Department of Public Health issued a proposed regulation to implement the law. Mass. Gen. Laws Ch. 111N, § 6; Proposed 105 C.M.R. § 970.009 (Dec. 10, 2008).

2.  Federal gift disclosure proposals

a.  In January 2009, Senators Herb Kohl (D-WI) and Charles Grassley (R-IA) introduced legislation entitled the “Physician Payments Sunshine Act of 2009” that would require drug, biologic, medical device, and other medical supply manufacturers to whom payments are made under federal programs to disclose to the Secretary of Health and Human Services, on a quarterly basis (and in annual summaries), the amount of money they give to physicians through payments, gifts, honoraria, travel, and other means.

b.  On November 12, 2008, Senate Finance Committee Chairman Max Baucus (MO) released a broad outline of a health care reform plan entitled Call to Action, Health Care Reform 2009. Among other things, the plan would mandate disclosure of “gifts and other transfers of value made by drug and device companies to physicians and other health care professionals.”
G. State Compliance Program Requirements

1. In September, 2004, California enacted a law requiring pharmaceutical companies to implement a compliance program meeting the elements set forth in the OIG Compliance Program Guidance. See Cal. Health & Welfare Code § 119400 et seq. The law requires the compliance program to adopt policies to implement the PhRMA Code (see Section III.H) and establish specific dollar limits on gifts and other expenditures to physicians. Companies must post their compliance program on their websites and certify annually that they are in compliance with their programs.

2. In Nevada, the Board of Pharmacy in January 2008 adopted the PhRMA Code by reference, including any subsequent revisions in the PhRMA Code that the Board does not disapprove. Any drug manufacturer or wholesaler who employs a person to sell or market a drug in Nevada must annually submit to the Board either a statement that it uses the PhRMA Code as its marketing code of conduct, or, if it uses a modified version of the Code or does not use the Code, a copy of its marketing code of conduct. If a wholesaler or manufacturer does not use the PhRMA Code unaltered, it may be required to make changes in its marketing code of conduct if the Board finds it deficient. Nev. Rev. Stat § 639.570; Nev. Board of Pharmacy Rule R-122-07 (eff. Jan. 30, 2008)

3. Massachusetts enacted a law in August 2008 that, in addition to requiring gift disclosure (see F.1.e, above) mandates that the Department of Public Health issue a unified compliance Code that covers both pharmaceutical and medical device manufacturers. Mass. Gen. Laws Ch. 111N. The Department issued a proposed Code on December 10, 2008. The code includes some provisions that are applicable only to pharmaceutical manufacturers, and other provisions applicable only to device manufacturers. The Code tracks the PhRMA Code to some extent, while also including specific prohibitions and permissions that the Massachusetts statute requires. 105 C.M.R. § 970.000 et seq. Drug and device companies marketing products in Massachusetts must adopt and comply with the Code by July 1, 2009.
H. State Consumer Protection Laws

1. Most states have “little FTC laws” generally prohibiting unfair or deceptive acts or practices.

2. Under these laws, several states have brought enforcement actions against drug companies. Cases have been brought regarding companies offering undisclosed payments to pharmacists in return for recommending prescription switches. See Section IV.E.3, below.

3. Many states also have brought enforcement actions under these laws against PBMs, alleging that the PBMs engaged in deceptive practices related to rebates and other payments received from pharmaceutical manufacturers for prescription switches. These are discussed in Section IV.F, below.

4. Individuals also have invoked these state laws against pharmacies that distribute mailings to their patients for pharmaceutical manufacturers without revealing that they receive financial incentives from the drug manufacturer. In Kelly v. CVS Pharmacy, Inc., 2007 WL 2781163 (Mass. Super. 2007), the court held that it is an unfair act or practice for a pharmacy to use customer information that it obtained for the sole purpose of filling prescriptions for its own financial gain without the consent of the pharmacy customer. Under the contested arrangement, CVS sent letters to certain of its customers who had been prescribed certain medications that suggested that the customer could benefit from taking a cholesterol drug. The letter was on CVS stationary and sent by CVS/pharmacy staff. The letter contained a statement that Merck provided funding for the mailing, but did not disclose that CVS made a $1 profit on each letter it sent. The court held that disclosure of the pharmacy’s profit is so critical to the customer’s evaluation of the underlying information that it was fundamentally unfair of CVS not to provide it.

I. State Laws Regulating Professional Conduct Of Physicians and Pharmacists

1. Many states impose license revocation or other disciplinary action on physicians and/or pharmacists for fee splitting or receiving remuneration in return for “referring” a patient to any person, which
could be construed to include prescribing or supplying products of a particular drug company. See e.g., Fla. Stat. Ann. § 458.331(1)(i).


3. Though these statutes impose penalties only on the practitioner, drug companies should avoid marketing practices that could result in physicians or pharmacists breaching their ethical standards.

J. PhRMA Code

1. In July 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA) issued a revised version of the PhRMA Code on Interactions with Health care Professionals (the “PhRMA Code”), with which the member companies of PhRMA have voluntarily undertaken to comply. In July 2008, PhRMA issued a revised version of the Code, which took effect on January 1, 2009. Among other things, the revised Code provides that:

a. Items that do not have educational value such as pens, clipboards, and mugs may not be given to physicians even if the items only have nominal value. Companies may occasionally offer items designed primarily for the education of physicians or patients, such as anatomical models for exam rooms, brochures, or a medical text book, if the item is worth no more than $100.

b. Field sales representatives and their immediate managers may provide modest meals, on an occasional basis, in the physician’s office or hospital setting as part of an informational presentation to, or discussion with, the doctor.

3 The Advanced Medical Technology Association (AdvaMed), an association of medical device manufacturers, has issued a similar “Code on Ethics on Interactions with Healthcare Professionals.” Initially issued in 2005, the AdvaMed Code was revised on December 18, 2008. The revised Code will take effect on July 1, 2009.
Sales representatives or their immediate managers may not provide a meal at a restaurant or other location outside of the hospital or office setting. A sales representative can attend a speaker program with health care professionals at a restaurant to ensure that the program complies with FDA requirements.

c. Entertainment and recreational events (such as golf or sporting events) aimed at health care professionals may not be provided by pharmaceutical companies.

d. Consulting agreements are appropriate and compensation and expense reimbursement may be provided to a health care professional, provided that the health care professional is rendering legitimate services for the pharmaceutical company.

e. Drug companies must ensure that their sales representatives receive adequate training about the laws regulations and industry codes of practice that govern interactions with health care professionals.

f. Drug companies that have retained a health care professional who is a member of a committee that develops formularies or clinical practice guidelines must require the health care professional to disclose those services to the committee for at least two years after the termination of the arrangement.

g. Companies should take steps to ensure the responsible use of prescriber data. Companies should respect the wishes of any healthcare professional who does not want his prescriber data disclosed to sales representatives.

h. Company CEOs and Compliance Officers should certify each year that they have processes in place to comply with the code.

2. As discussed in section II.G.1, above, the OIG stated in its CPG for pharmaceutical manufacturers that the PhRMA Code is the minimum acceptable level of conduct for pharmaceutical manufacturers, although it did not consider activities that complied with the PhRMA Code to be safe harbored.
K. Healthcare Fraud (13 U.S.C. § 1347)

1. Prohibited Acts
   a. Willfully and knowingly
   b. executing, or attempting to execute a scheme or artifice to
      i. defraud any health care benefit program or
      ii. obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money as property owned by, or under the custody or control of, any health care benefit program
   c. in connection with the delivery of or payment for health care benefits, items, or services

2. Penalties
   a. imprisonment of not more than 10 years
   b. fines

4. Paying kickback, by itself, insufficient to establish healthcare fraud
   a. One federal appeals court has held that paying kickbacks alone is insufficient to establish health care fraud “without someone making a knowing false or fraudulent misrepresentation to Medicare.” The court found that an individual’s signing of Medicare provider applications, including a form promising not to pay kickbacks, when the individual planned to continue to pay kickbacks would qualify as healthcare fraud. U.S. v. Medina, 485 F.3d 1291, 1297-28 (11th Cir. 2007).
IV. PROBLEM AREAS FOR DRUG MARKETING UNDER THE ANTIKICKBACK LAWS

A. Free Goods and Services

1. OIG guidance

   a. Preamble to discount safe harbor discusses practice of giving away free computers. OIG draws distinction between a computer that has no value other than as part of a service being offered (e.g., to print out laboratory tests), and a personal computer that can be used for a variety of purposes. The latter “may well constitute an illegal inducement.” 56 Fed. Reg. at 35978.

   b. 1994 “Special Fraud Alert on Prescription Drug Marketing Schemes” targets prizes, gifts, other benefits based on recipient’s prescribing practices.

   c. OIG “Free Goods” letters: series of informal letters from OIG to providers in 1997 addressed arrangements involving free goods and services.

   d. Advisory opinions – problematic free goods or services

      (1) Advisory Opinion 06-16 (Oct. 10, 2006)

      DME manufacturer proposed to provide advertisement assistance and reimbursement consulting services to certain of its DME suppliers. The manufacturer either would directly develop and pay for the DME supplier’s advertising of the DME manufacturer’s product or it would reimburse the DME supplier, either in cash or goods, for the advertising. The DME manufacturer also proposed to offer free reimbursement consulting services to DME suppliers, including general claims submission and coding information and training for the DME supplier’s staff on reimbursement. The OIG found the proposal to clearly implicate the anti-kickback statute because valuable services would be provided to the selected
DME suppliers, sparing them costs they would otherwise incur to promote and operate their businesses.

(2) Advisory Opinion 02-14 (Oct. 7, 2002)

Infusion therapy company proposed to give free personal safety equipment (helmets, knee pads, medical information alert bracelets and the like) and electronic pagers for use only in case of an emergency. OIG stated that the donation of free equipment and pagers would implicate the beneficiary inducement civil monetary penalty provision (see Section III.B) to the extent it exceeds $10 per item, with an aggregate annual benefit of $50. Moreover, the program would involve remuneration that would violate the antikickback statute if the intent to induce referrals of items or services reimbursable by federal health care programs was present.

(3) Advisory Opinion 98-16 (Nov. 3, 1998)

Mail order pharmacy proposed to place licensed pharmacist in transplant center and pay the pharmacist’s wages and benefits. OIG found arrangement to be potentially abusive, since pharmacy’s payment of employee’s wages would shift costs from the center to the pharmacy, and the center had potential to steer patients to the pharmacy.

(4) Advisory Opinion 97-6 (Oct. 8, 1997)

Hospital restocks ambulances that bring patients to hospital with drugs and supplies cost free. OIG said where remuneration relates directly to delivery of patients, provision of free goods would be “highly suspect.”
e. Advisory opinions – permissible free goods or services

(1) Advisory Opinion 08-05 (Feb. 22, 2008)

Pharmaceutical manufacturer proposed to install electronic kiosks in the waiting rooms of various primary care physicians. The electronic kiosks would administer an interactive questionnaire about four disease states for which the manufacturer produces treatments. OIG found that the proposed kiosks would not constitute prohibited remuneration to either the physicians or the patients and thus do not implicate either the anti-kickback act or the CMP. The kiosks would not offer patients incentives such as coupons or offers of free products. The physicians would not receive space rental, utilities fees or other compensation for hosting the kiosks. OIG differentiated the kiosks from multi-functional computers or fax machines which it has previously found to be objectionable remuneration.

(2) Advisory Opinion 08-02 (Feb. 5, 2008)

To encourage doctors to complete online surveys, a company that has pharmaceutical manufacturers as clients proposed to contribute a pre-determined cash amount to a public charity designated by the physician in exchange for each survey the physician completed. OIG determined that it would not impose sanctions against the proposed arrangement. OIG noted that the program contains various safeguards to ensure that the program does not provide disguised kickbacks. For instance, all donations would go directly to the charities, and the doctors would not receive a tax deduction or any other monetary benefit. Only charities that are public, 501(c)(3), and meet the public support test under section 509(a) of the IRC are eligible for the program. The charity would have unfettered freedom to use the funds. Also, the physician would certify that he or she does not have a financial interest in the chosen charity.
(3) Advisory Opinion 07-16 (Dec. 12, 2007)

Home health care provider for postoperative total knee and hip joint replacement patients proposed to send patients, who had already been referred to the home health agency, an educational video in the days prior to surgery. OIG found that the proposal would not implicate the CMP and that it would not impose sanctions under the anti-kickback statute. OIG concluded that the distribution of free videos was unlikely to influence patients to choose the agency to provide postoperative items and services payable by Medicare or Medicaid. The video did not provide medical advice tailored to the specific individual, but instead provided general suggestions and recommended that the patient consult a physician.

(4) Advisory Opinion 00-10 (Dec. 26, 2000).

Drug company’s reimbursement assistance program found not to violate the antikickback law. OIG said free drug program for uninsured patients could violate antikickback law, but OIG would not impose sanctions since participants in the program are predominantly low-income, usage of the program is infrequent, and there are inherent controls against overutilization of the drug.

2. Enforcement actions

a. Wyeth Ayerst settled with Massachusetts Attorney General (May 1989) and later with the OIG (July 1993) to resolve kickback-related claims arising from Patient Profile program. Wyeth offered physicians medical texts and credits toward free airline tickets to educational meetings in return for completing profile questionnaire for new Inderal LA patients. Wyeth denied wrongdoing.
b. Rugby Group settled in May 1994 with Massachusetts AG in case involving free vacations offered to pharmacists purchasing specified volume of Rugby products.

c. SmithKline Beecham paid $325 million in February 1997 to settle charges against SmithKline Laboratories. Suit primarily involved false claims allegations, but government also alleged that SmithKline offered free computers, fax machines, refrigerators, and payment of rent to physicians who referred patients for laboratory tests. SmithKline denied wrongdoing.

d. In September 2001, TAP Pharmaceutical Products, Inc. entered into a plea agreement and settlement with the federal government concerning alleged violations of the antikickback law, the federal False Claims Act, and the Prescription Drug Marketing Act of 1987 (PDMA). TAP pleaded guilty to one count of conspiring with physicians to violate the PDMA, agreed to pay $875 million in criminal fines and civil penalties, and entered into a Corporate Integrity Agreement (“CIA”) with the OIG.

According to charging documents, the company’s sales representatives provided large quantities of free samples of Lupron, a prostate cancer agent, to urologists to induce the use of Lupron, expecting the doctors to bill Medicare for the samples. Company also alleged to have provided free office equipment, VCRs, and other items to physicians. TAP also settled allegations that it caused false claims to be submitted to Medicare by inflating the average wholesale price reported to pricing services for Lupron, thereby increasing government reimbursement to customers for the drug. See discussion of False Claims Act in Section V.E., below. Several physicians and at least one sales representative, pleaded guilty to charges of conspiring with TAP to defraud Medicare.

On July 14, 2004, a federal jury in Boston acquitted eight TAP defendants of conspiracy to pay kickbacks to prescribers, conspiracy to defraud Medicaid, and conspiracy to violate the Prescription Drug Marketing Act.
e. In June 2003, Astra Zeneca PLC pleaded guilty to charges similar to TAP, with regard to Zoladex, Astra Zeneca’s prostate cancer drug. Astra Zeneca paid $355 million and entered into a CIA similar to TAP’s.

f. In June 2003, Ross Products, a division of Abbott Laboratories, pleaded guilty to providing free goods and up-front payments to customers and providing misleading documentation about the cost of the free goods. Abbott paid $622 million and entered into a corporate integrity agreement.

g. In October 2005, Serono, S.A., and its U.S. subsidiaries, pleaded guilty to two charges of conspiracy relating to the promotion and marketing of Serostim, a drug for AIDS wasting. Serono agreed to pay $704 million to settle the criminal charges and civil False Claims Act allegations, and entered into a CIA. Serono sales and marketing personnel promoted Serostim by offering physicians that increased their prescribing of Serostim a free trip to Cannes, France for a medical conference.

h. In May 2006, Lincare Inc., a durable medical equipment supplier, paid $10 million and entered into a corporate integrity agreement to settle OIG allegations that Lincare paid illegal kickbacks, including providing sporting and entertainment tickets, gift certificates, rounds of golf, golf equipment, fishing trips, meals, advertising expenses, office equipment, and medical equipment.

i. In July 2006, Medtronic, one of the largest medical device manufacturers, settled allegations that it had paid kickbacks, including lavish trips to desirable locations, to physicians that used Medtronic spinal implant products. Medtronic agreed to pay $40 million and enter into a corporate integrity agreement.

j. In 2007, Advance Neuromodulation Systems, Inc. paid $2.95 million and entered into a CIA to settle allegations that the company provided physicians with sports tickets, trips for doctors and their families, dinners, and additional gifts. See Section IV.D., below, for discussion of sham study.
k. In September 2007, Bristol-Myers Squibb (BMS) agreed to pay over $515 million and entered into a CIA to settle several *qui tam* lawsuits brought pursuant to the False Claims Act. The government alleged that from approximately 1994-2001, BMS’ wholly owned subsidiary Apothecon knowingly and willfully paid kickbacks to retail pharmacy and wholesale customers in the form of free goods, stocking allowances, price protection payments, trade show payments, rebates, and market share payments. Paying the physicians and others illegal remuneration to induce referrals, according to the government, knowingly caused submission of false claims to the federal health care programs. See also Section IV.C. (discussion of allegations relating to consulting fees); Section V.G. (off-label promotion); Section V.E. (AWP manipulation).

l. In February 2008, Merck & Co. paid xx to settle civil allegations under FCA, federal antikickback laws, state false claims laws, and the Medicaid Rebate statute. Merck allegedly provided kickbacks in the form of free gifts to induce doctors to prescribe its drugs. See also Section V.F. (discussion of allegations concerning underpayment of Medicaid Rebates) and Section IV.D. (kickbacks in the form of grants).

m. See also *U.S. v. Hughes*, 823 F. Supp. 593 (N.D. Ind. 1993) (pacemaker salesmen offered purchasers tickets for entertainment events, gifts, medical equipment, cash payments, registration fees for medical seminars, dinners, female escorts and prostitutes); *U.S. v. Bay State Ambulance*, 874 F.2d at 26 (free cars).

3. Programs in which free goods or benefits (other than safe harbored discounts) are offered to practitioners, institutions, formulary managers, or pharmacies are problematic under the antikickback laws if they could influence the recipient’s prescribing or utilization decisions. Programs that link the receipt of a free good or benefit to prescribing or utilization volume are at particular risk.
4. Value-added services

a. The CPG for pharmaceutical manufacturers cautions that value-added items and services potentially implicate the antikickback statute because they can induce or reward referrals, and can distort the cost of the products with which they are associated. Value-added items and services that are targeted to a potential referral source and that eliminate an expense the customer would otherwise have borne are likely to be problematic, according to the OIG. Ordinary reimbursement assistance hotlines are not problematic, but, for example, offering free practice management consulting services could violate the statute. 68 Fed. Reg. at 23,735.

b. Programs involving value-added services provided cost-free (e.g., assistance with computer software, management consulting, reimbursement consulting, educational services) should be analyzed carefully. Offer should not be dependent on the volume of utilization of the company’s products.

(1) Drug-related value-added services provided to a Medicare/Medicaid risk-contractor (or its subcontractor), or to a health plan (or its subcontractor) under a risk-sharing agreement, may be protected under the risk-sharing exemption. See Section II.F.6, above.

5. Patient Assistance Programs

a. Patient assistance programs (PAPs) through which indigent patients receive discounted or free drugs have long been thought to be low-risk programs. However, with the introduction of Medicare Part D in 2006, many of those who qualified for PAPs now qualify for Medicare coverage of their outpatient drugs. On November 7, 2005, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services issued a Special Advisory Bulletin providing guidance on the application of the fraud and abuse laws to PAPs that offer assistance in obtaining outpatient
prescription drugs to financially needy Medicare beneficiaries who enroll in the Medicare Part D drug benefit. OIG Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (Nov. 7, 2005). While recognizing that PAPs historically provided needy patients with access to free or discounted drugs, the OIG expressed its concern that manufacturer PAPs that provide cost-sharing assistance (e.g., copayment assistance programs) could violate the federal healthcare program antikickback statute by providing something of value to federal healthcare beneficiaries that use the manufacturer’s products.

b. The OIG advised that manufacturer-sponsored programs that provide copayment assistance are inherently problematic, and urged manufacturers to transition patients to less abusive arrangements, such as independent charitable foundations that provide copayment assistance to financially needy patients, regardless of what product the patient was prescribed. Alternatively, manufacturers may sponsor programs that provide drugs for a patient outside of the Part D program, provided that no claims are submitted to Medicare, the cost of the drugs does not count towards the patient’s true out of pocket expenses (TrOOP), and the program covers the patient for the entire Part D year, not just that part of the year that the patient lacks adequate coverage (e.g., during the “donut hole” period).

c. The OIG has issued several advisory opinions in the wake of the Special Advisory Bulletin that have declined to impose sanctions on patient assistance programs sponsored by drug manufacturers that adhere to the Special Advisory Bulletin.

(1) For example, Advisory Opinion 06-03 (April 18, 2006) addressed the provision of free drugs to Medicare Part D patients outside of the Part D plan. The OIG stated that although the program could constitute illegal remuneration, it would not impose penalties, because the PAP provided free drugs to financially needy patients, and did not seek reimbursement from Medicare, nor did such drugs count toward the
patient’s TrOOP costs. In short, the PAP complied with the Special Advisory Bulletin.

(2) See also Advisory Opinion 06-14 (Sept. 26, 2006); Advisory Opinion 06-19 (Nov. 2, 2006); Advisory Opinion 07-04 (April 6, 2007) (similar opinions on patient assistance programs sponsored by drug manufacturers that did not seek reimbursement from Medicare, did not count toward the patient’s TrOOP costs, and awarded assistance to patients based on objective measures of financial need).

d. The OIG has also issued several advisory opinions that have declined to impose sanctions on patient assistance programs sponsored by independent charitable organizations that are consistent with the Special Advisory Bulletin.

(1) For example, Advisory Opinion 06-04 (April 27, 2006) addressed a non-profit independent foundation that provided copayment assistance to needy patients. Because the program was not dependent on which drugs the patient received, the OIG indicated that it would not impose sanctions on the foundation. See also Advisory Opinion 06-10 (Sept. 21, 2006); Advisory Opinion 07-06 (July 30, 2007); Advisory Opinion 07-18 (Jan. 3, 2007).

B. Combination or “Bundled” Discounts

1. Providing one good at a discount or cost-free in return for purchasing another good.

2. Examples

a. Discount on drug X earned by purchasing specified volume of drug Y.

b. Discount on product line earned by achieving specified market share for drug X.
c. Discount on device in return for agreement to purchase drug used with it, or free drug offered in return for purchasing device.

3. Discount safe harbor revised in November 1999 to protect combination discounts when the goods and services are reimbursed by the same Federal health care program using the same methodology. 64 Fed. Reg. 63518.

   a. In a proposed change to discount safe harbor, OIG would have specified that fee schedules are not considered same methodology. 65 Fed. Reg. 63035, 63041 (Oct. 20, 2000). Under proposed rule, combination discount involving two or more different drugs would not be eligible for safe harbor, since drugs are reimbursed under fee schedule-type methodology. However, this proposal was not finalized. See 67 Fed. Reg. 11928, 11930 (Mar. 18, 2002).

4. Combination discounts offered to a Medicare/Medicaid risk contractor (or its subcontractor) could be safe harbored under the risk-sharing exemption regardless of reimbursement methodology. This is because the exemption applies to entities providing “items or services, or a combination thereof.” See Section II.F.6, above.

5. OIG has especially objected to combination discounts that “shift” the discount away from Medicare or Medicaid. See 64 Fed. Reg. at 63530.

   a. This occurs when a discount is provided on a good that is not separately reimbursed or is reimbursed based on fixed prospective payment, in return for an agreement to purchase an undiscounted item that is separately reimbursed.

   b. Government pays full price for undiscounted item and does not get benefit of discount on item that is not separately reimbursed.

   c. See, e.g., Advisory Opinion 99-2 (Feb. 25, 1999) (discounts on prospectively reimbursed Part A ambulance services could
induce referral of non-discounted, fee-for-service Part B services).

6. OIG Guidance

a. Advisory Opinion 02-10 (Aug. 7, 2002) involved two types of discounts for the purchase of dialysis equipment and supplies. The first was a uniform discount on all dialysis equipment and supplies, based on the aggregate annual purchases of all such equipment and supplies. The second was based on the total annual purchases of certain designated items, or all items, if the purchaser bought a minimum quantity of one or more specified items. As an initial matter, the OIG concluded that the discount safe harbor under the federal health care program antikickback law did not apply to either of these proposals, because the safe harbor does not protect bundled discounts unless the items are reimbursed by a federal health care program under the same payment methodology, and Medicare uses three different payment methodologies for dialysis services and equipment, depending on where dialysis occurs. OIG stated that the first discount program would not result in sanctions, but the second program did raise concerns under the antikickback statute, because the bundled discount could lead to cost-shifting among reimbursement systems, distort the true cost of items, and lead to overutilization.

b. Advisory Opinion 01-08 (July 3, 2001). Involved offer to skilled nursing facilities of non-powered therapeutic mattresses, other support surfaces, a sufficient number of powered mattresses to address residents' wound care needs and skin and wound care products in exchange for a fixed discounted price per bed. OIG permitted this program because (1) it applied to all patients regardless of the payor; (2) participating facilities are reimbursed at an all-inclusive rate, so there was no financial incentive to buy unneeded products or services; (3) only the surgical wound supplies were potentially reimbursable
separately, and this represented a very small percentage of the price; and (4) this program was the only financial arrangement between the company and the facilities, so there was no risk of "swapping" of low prices for the opportunity to provide other unrelated items or services to participating facilities.

c. Advisory Opinion 99-3 (Mar. 16, 1999). Involved offer to skilled nursing facilities of free non-powered mattress with rental of powered mattress. OIG approved because (1) company invoices apportioned the total discount between the two items in proportion to their fair market values; and (2) the mattresses would be reimbursed primarily under a prospective payment system.

7. Enforcement

a. Settlement between U.S. and Abbott Laboratories Ross Products Division (June 2003)

Ross allegedly provided enteral nutrition infusion pumps at no charge in exchange for a customer’s agreement to buy a predetermined amount of related pump sets. Sales reps allegedly advised customers that they could bill Medicare separately for both the pump and the pump sets. Government alleged, among other things, that the structure of the bundled transaction “made it difficult for Medicare to discern the true and reasonable charges associated with the equipment.” Abbott denied the allegations and settled for $382.4 million. See Settlement Agreement between U.S. and Abbott Laboratories, June 2003. See also Information, U.S. v. CG Nutritionals, Criminal No. 03-30144(GPM) (S.D. Ill. 2003) (related criminal action against Abbott subsidiary).

b. Criminal plea and civil settlement between DOJ and Fresenius Medical Care (Jan. – Feb. 2000).
(1) Government alleged that, among other things, company offered discounts and rebates on medical supplies sold to renal dialysis centers in return for the referral of blood tests for dialysis patients to the company’s clinical laboratory subsidiary. Medicare reimbursement for the medical supplies was included in a fixed capitated rate, but the non-discounted tests were reimbursed on a fee-for-service basis. Government alleged discounts and rebates on supplies (which did not benefit Medicare) were kickbacks paid to secure referrals of lab tests (which were paid separately by Medicare).


c. U.S. v. Levin, 973 F.2d 463 (6th Cir. 1992)

Manufacturers of intraocular lenses (IOLs) offered ophthalmologist free surgical supplies with each IOL. IOLs reimbursed separately by Medicare at $400, but supplies (worth $100) not separately reimbursed. Government prosecuted under antikickback law, but physician was acquitted because Medicare carriers had previously approved of the discounts.

C. Consulting or Service Fees

1. Pharmaceutical companies provide remuneration to entities that are customers or potential customers to obtain a variety of services.

2. Examples

   a. Fees to physicians for consultations on scientific or marketing matters.

   b. Compensation to HMOs to conduct outcomes studies or provide drug utilization data.
c. Compensation to MCOs to develop disease-oriented educational materials.

3. Consulting fee arrangements have been targeted by the government where they are tied to prescribing practices or utilization of the company’s drugs, where fees are in excess of fair market value for services rendered, and/or where there is no documentation of services rendered or audit rights.

4. Enforcement actions involving consulting fees


   b. Settlement agreement and sentencing documents in the TAP Pharmaceuticals case allege that TAP paid physicians to attend consultant meetings at up-scale resorts but that no consulting services were actually provided. See, e.g., Sentencing Memorandum, U.S. v. TAP Pharmaceutical Products, Inc., No. 01-CR-10354-WGY (Dec. 4, 2001) at 52-55.

   c. On July 30, 2004, Schering-Plough Corporation settled claims that the company paid illegal remuneration to its managed care customers in exchange for retaining Claritin on the customer’s formulary, in violation of the federal health care program antikickback statute and The Federal False Claims Act. The government alleged that a data fee to the managed care customer was both a disguised discount and
remuneration intended to induce the managed care organization to retain Claritin on formulary. The data fee was for a report that contained the same information as quarterly reports previously sent to Schering-Plough. As part of the settlement, Schering Sales Corporation, a subsidiary of Schering-Plough Corporation, pleaded guilty and agreed to pay a $52.5 million criminal fine. Schering Sales Corporation was excluded from participating in federal health care programs for five years.

d. In May 2006, Lincare Inc., a durable medical equipment supplier, paid $10 million and entered into a corporate integrity agreement to settle allegations that Lincare paid illegal kickbacks, including payments for “Medical Director Agreements” and other allegedly sham consulting agreements.

e. In July 2006, Medtronic, a medical device manufacturer, entered into a settlement agreement to settle allegations that it had paid kickbacks to physicians using Medtronic spinal implant products, including allegedly sham consulting agreements and sham royalty agreements. See also Section IV.A.2.i. In September 2007, then-Senate Finance Committee Ranking Member Charles Grassley (R-IA) sent Medtronic a letter that asked the device company to respond to claims that the firm’s “practices of providing physicians with inordinately high consulting fees, free travel, and other perks distort decision-making among doctors and obscure the best interest of patients.”

f. In April, 2007, Cell Therapeutics paid $10.5 million to settle allegations that it violated the False Claims Act by providing kickbacks in the form of sham consulting agreements, consulting dinners with high-class dinners and honoraria, and all-expense paid meetings held at resort locations where all the company paid for all expenses, to induce doctors to prescribe its orphan drug Trisonex. For instance, Cell Therapeutics allegedly paid doctors $500 to $1000 to attend three hour dinners or conferences to listen to presentations on the off-label use of the drug. Cell Therapeutics allegedly held a dinner at the Ritz Carlton in Philadelphia and paid each
attendee $500, See Section V.G. for discussion of FCA allegations concerning off-label promotion.

g. In July 2007, Bristol-Myers Squibb paid over $515 million to settle allegations, among others, that from 2000-2003, it paid kickbacks to physicians and to some physician assistants and nurse practitioners in the form of consulting fees and expenses to participate in consulting and advisory board meetings. See also Section IV.A.2.j (allegations regarding free goods); Section V.G. (off-label promotion); Section V.E. (AWP) and Section V.F. (Medicaid Rebate underreporting).

h. In September 2007, four orthopedic implant manufacturers -- Zimmer Inc., Depuy Orthopedics, Inc., Biomet Inc., and Smith and Nephew, Inc. -- pled guilty to violations of the antikickback law; entered into 18-month deferred prosecution agreements and settled allegations of FCA violations. Each company paid a substantial sum as part of the settlement: Zimmer paid $169.5 million; Depuy paid $84.7 million; Smith and Nephew paid $28.9 million and Biomet paid $26.9 million. Each company also entered into a 5-year Corporate Integrity Agreement (CIA). The four companies allegedly provided kickbacks in the form of consulting agreements where the physicians performed negligible work or no work at all in exchange for the doctors’ promise to only use the paying company’s products. A fifth company, Stryker Orthopedics, Inc., voluntarily cooperated with the government and thus avoided a deferred prosecution agreement, instead entering into a Non-Prosecution Agreement which required Stryker to implement the same reforms as the other companies.

i. In February 2008, Merck and Co. Inc. settled allegations, among others, that it paid kickbacks in the form of preceptorships, speaker fees, consultant and advisory board fees to prescribe its drugs. See Section IV.D. (discussion of grant allegations).
5. Drug companies that contract to obtain services of physicians, MCOs, PBMs, and other entities that have the potential to prescribe or influence the utilization of the company’s products should ensure that agreements conform as closely as possible with the conditions of the personal services safe harbor, particularly those relating to compensation. See Section II.F.3, above. In addition, consultants should be required to maintain documentation of time/resources expended and services performed, subject to company audit.

D. Grants

1. Research grants to physicians and their institutions have been targeted where they were linked to prescribing practices; provided for research with questionable scientific value; and/or were excessive for the research performed.

2. OIG guidance

“Special Fraud Alert on Prescription Drug Marketing Schemes” targeted grants for research of questionable scientific value. See Section II.G.2, above.

3. Enforcement actions involving grants

a. Criminal prosecution against Genentech employees, Caremark, Inc., and David R. Brown, M.D. (see Section IV.C.4, above).

b. $450,000 civil settlement between U.S. and Hoffmann-LaRoche. Company was alleged to have provided grants for research that was of questionable scientific value or was never completed. Company denied wrongdoing. Settlement Agreement Between United States and Hoffmann-LaRoche, Sept. 2, 1994.

c. TAP Pharmaceuticals settlement (Sept. 2001). Company alleged to have offered unrestricted educational grants to MCO in order to obtain exclusive formulary placement for Lupron. See Sentencing Memorandum, U.S. v. TAP
d. Cell Therapeutics civil settlement (April 2007). Company alleged to have offered grants for sham clinical studies that required little work on the part of the physicians to induce physicians to prescribe its orphan drug, Trisenox. See Section V.G. (off-label promotion allegations); Section IV.D. (consulting agreements).

e. Advance Neuromodulation Systems, Inc. CMP settlement with OIG (2007). Company entered into a 3-year CIA with OIG and paid $2.95 million. Company alleged to have paid doctors $5,000 for every five new patients tested with an ANS product. Program allegedly did not provide any significant clinical value; $5,000 data collection fee was not fair market value; and ANS’ research department did not use the collected data. See Section IV.A. for discussion of free gift allegations.

f. Merck & Co., Inc. civil settlement (February 2008). Company alleged to have offered educational grants, grants for computers, sham “clinical experience” studies and focus groups, to induce doctors to prescribe its drugs. See Section IV.C. for discussion of consulting agreement allegations.

g. In June 2005 and January 2006, the Senate Finance Committee sent letters to numerous drug companies requesting information relating to educational grants for continuing medical education programs. Among other things, the letters sought information relating to the role of sales and marketing personnel in the grant approval process, and expressed concern that grants were steered to recipients that were known to promote the use of the companies’ products for unapproved uses. In September 2007, then-Senate Finance Committee ranking member Charles Grassley (R-IA) sent a letter to Medtronic that asked the device company to explain its process for providing funds to doctors to attend medical meetings and for other educational activities. See
Section IV.C. for discussion on request for information in regards to consulting fees.

f. Biovail Pharmaceuticals, Inc. settlement (May 16, 2008). Company pled guilty to conspiracy and kickback charges and paid a $22.2 million criminal fine arising from the company’s Proving Long Acting Through Experience (PLACE) program, a post-marketing “experience” study for its heart medication Cardizem L.A. (24 hour time-release diltiazem). The PLACE program paid thousands of physicians up to $1,000 each in return for starting a certain number of patients on Cardizem LA and completing questionnaires. These payments allegedly exceeded fair market value of the physician’s time. Moreover, Biovail’s sales force was heavily involved in recruiting investigators, and PLACE was not designed in a manner that would provide new or meaningful scientific data about the drug.

4. In structuring grant programs for basic research, Phase IV studies, or independent investigator IND studies, companies should have SOP providing that:

   a. Awards are based on review of scientific merits of research, including review of protocol.

   b. Marketing considerations and input of sales and marketing personnel in the award procedure are minimized.

   c. Research is monitored by requiring periodic and final reports, right to audit, and submission of manuscripts.

   d. Grant amount is appropriate for scope of research.

   e. Unused funds are refunded.

   f. Grants are paid out of research or other non-marketing budget.
E. Payments to Pharmacists

1. Companies provide compensation to pharmacies for providing patient counseling on the use of a particular drug, providing educational or promotional materials to patients, performing registry administration functions, and other services. Since pharmacists make dispensing decisions under generic substitution laws, and can also influence a physician’s prescribing decision, such compensation may implicate the antikickback law or state consumer protection laws.

2. OIG guidance

“Special Fraud Alert on Prescription Drug Marketing Schemes” targets (1) payments to a provider for recommending a change in prescription from one product to another; and (2) remuneration to pharmacists in exchange for performing marketing tasks, including sales-oriented educational or counseling contacts, or physician and/or patient outreach.

3. Enforcement

a. In separate multi-state actions in 1993-94, three drug companies were charged with violations of state consumer protection laws. Actions were spearheaded by Attorney General of Minnesota.

b. The companies were alleged to have paid pharmacists on a per-patient basis for providing counseling on particular drugs and for completing questionnaires on new patients. In each case, the government alleged that the purpose of the payments was to induce pharmacists to call physicians to obtain prescription “switches” to the company’s product. In one of the cases, the company allegedly paid pharmacies for each switch from a company product coming off-patent to the company’s new patented product. The states alleged that the payments, and the failure to disclose them to consumers and
physicians, were deceptive trade practices. All three companies denied any wrongdoing and settled. See Assurance of Discontinuance/Assurance of Voluntary Compliance, In the Matter of American Cyanamid Co., Sept. 8, 1993 ($50,000); Assurance of Discontinuance/Assurance of Voluntary Compliance, In the Matter of Miles, Inc., March 28, 1994 ($605,000); Assurance of Discontinuance/Assurance of Voluntary Compliance, In the Matter of the Upjohn Company, July 29, 1994 ($675,000).

d. A fourth drug company and its PBM affiliate also settled a multistate action involving formulary compliance telephone calls made by PBM employees to physicians without disclosure that the PBM was owned by the drug company. Under the settlement, the PBM was permitted to continue the compliance call program with proper disclosure of the program to physicians and patients. See Agreement, In the Matter of Merck & Co., Inc. and Medco Containment Services, Inc., Oct. 1995 ($1,955,000).

e. In Kelly v. CVS Pharmacy, Inc., 2007 WL 2781163 (Mass. Super. 2007), the court held that a pharmacy violated the Massachusetts consumer protection law when it was paid by a drug company to send letters to its customers concerning the company’s drug, but did not disclose in the letter that the pharmacy was making a profit on each letter sent. See Section III.H, above.

4. In light of state and federal scrutiny, direct remuneration to pharmacists should comply to the extent possible with the safe harbor for discounts or personal services agreements, or the exemption for risk-sharing arrangements. Disclosure to patients and/or physicians may also be warranted.

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4 FDA also issued a Warning Letter to one of these companies based on concerns about potential safety problems caused by a change in prescription, and unsubstantiated claims made to encourage such a change. See Warning Letter to The Upjohn Company from Cheryl Fossum Graham, M.D., Nov. 25, 1992.
F. Payments to PBMs

1. Pharmaceutical manufacturers often provide compensation and/or rebates to pharmacy benefits managers (PBMs) for formulary access, a particular formulary position, therapeutic interchange communications to physicians and patients, achieving specified prescribing market share percentages, or for other marketing activities. OIG has stated that these compensation arrangements may implicate the antikickback statute.

2. In June 2003, the Department of Justice and three states intervened in two qui tam False Claims Act actions against a PBM. Among other things, the PBM allegedly required its employees to call physicians to obtain prescription switches to formulary drugs so that the PBM could obtain lucrative, undisclosed market share rebates from the manufacturers of the formulary drugs. The switching program is alleged to have endangered patients and increased costs to government programs while increasing revenue to the PBM. Second Amended Qui Tam Complaint, U.S. ex. Rel. Hunt and Gauger et al. v. Merck & Co., Inc. et al., No. 99-CV-2332 (E.D. Pa. Mar. 18, 2003). See also West Virginia ex rel. McGraw v. Medco Health Solutions, Inc., Civil Action No. 02-C-2944, (W. Va. Cir. Ct., Nov. 11, 2002) (similar claims).

   a. In 2004, Medco settled claims for injunctive relief in the qui tam suit, including allegations relating to therapeutic interchanges. Medco also agreed to pay $29.2 million to settle an investigation by 20 states alleging unfair trade practices under state law ($20 million to the states in damages, $6.6 million to the states in fees and costs, and $2.5 million to a consumer fund for restitution to patients).

   b. The Settlement Agreement provided that Medco may contact physicians to obtain written or verbal consent from the physician for a switch. Medco is required to notify patients of the switch and of a process by which they can decline the switch. Medco is not required to obtain written consent from the patient before switching the patient’s medication.

   c. In September 2004, the District Court ruled that the False Claims Act allegations, including allegations based on the

d. In October 2006, Medco paid $137.5 million to settle the remaining allegations, and entered into a CIA.

3. In September 2005, AdvancePCS – now a wholly-owned subsidiary of Caremark Rx, Inc. – settled civil False Claims Act and Public Contract Anti-Kickback Act allegations that it received kickbacks from pharmaceutical manufacturers in return for favorable formulary treatment of the manufacturers’ products. AdvancePCS agreed to pay $137.5 million and entered into a corporate integrity agreement with the OIG. The alleged kickbacks took the form of excessive administrative fees, service agreements, flat fee lump sum and flat fee percentage rebate contracts for heavily utilized drugs. AdvancePCS was also alleged to have caused pharmaceutical manufacturers to misstate their best price as part of the Medicaid Drug Rebate Program through its solicitation of the lump sum payments. As part of the settlement, AdvancePCS agreed to more transparency in its rebate contracts, and to provide more detailed information to its member plans.

3. In April 2007, Pfizer subsidiary Pharmacia & Upjohn Company, Inc. pled guilty to a violation of the antikickback law and paid a criminal fine of $19.68 million. The company awarded a distribution contract to a certain PBM, whose bid was $12.3 million higher than competing bids, in order to induce the PBM to improve the formulary position of the company’s drugs.

4. In February 2008, PBM Caremark Rx. LLC entered into a consent decree that settled allegations that it had engaged in deceptive practices in violation of 28 States’ consumer protection statutes. Caremark agreed to pay the states a total amount of $41 million. Caremark allegedly encouraged physicians to switch patients to different brand-name prescriptions, and falsely said the switches would save the physicians’ patients or their health plans money. Caremark also allegedly did not disclose to client employer health plans financial incentives that Caremark would obtain as a result of the switches, such as rebates from the drug manufacturers. The consent decree included detailed restrictions on prescription
interchange activities and requirements for disclosure to physicians and patients.

5. In July 2008, PBM Express Scripts, Inc. (ESI) agreed to pay $27 million to settle litigation with the state of New York. New York alleged that Express Scripts breached its contract with the State to administer a drug benefit for state employees and also violated New York’s consumer protection law. New York alleged that ESI was obligated to pass on all of the rebates it received as a result of Empire Plan members’ use of the manufacturers’ drugs, and ESI improperly retained rebates for itself and disguised parts of rebates as administrative fees so it would not have to pass on those rebates. New York also claimed that ESI switched patients from cheaper drugs to more expensive drugs. As part of the Consent Order and Judgment, ESI must make specified disclosures to existing and prospective client plans.

7. OIG’s CPG for pharmaceutical manufacturers is particularly critical of fee-per-switch arrangements. However, the CPG suggests that market share rebates to PBMs may fit within the safe harbor for payments to group purchasing organizations (GPOs), 42 C.F.R. § 1001.952(j). See 68 Fed. Reg. at 23736. Compliance with the GPO safe harbor requires, among other things, that payment must be authorized in advance by the PBM’s customers, and must be disclosed in writing at least annually. This is a novel interpretation of the GPO safe harbor, since a PBM’s customers are not typically traditional purchasers; rather they reimburse for drugs.

V. FALSE CLAIMS LIABILITY FOR DRUG MARKETING ACTIVITIES

A. Potential Liability of Pharmaceutical Companies

1. Although pharmaceutical manufacturers generally do not submit claims to Medicare, Medicaid, or other programs, they are potentially subject to liability under false claims laws for:

   a. Kickback violations

   b. Providing advice on reimbursement coding
c. Manipulation of AWP

d. Underpayment of Medicaid Rebate

e. Federal Food, Drug, and Cosmetic Act violations

B. Federal False Claims Act (31 U.S.C. § 3729)

1. Prohibits

a. Knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment.

b. Knowingly using or causing to be used a false record or statement to get a false claim paid.

2. Civil penalty of $10,000 per claim plus 3 times damages (2 times damages if self-report within 30 days after knowledge of violation).

3. “Knowing” defined as

a. actual knowledge;

b. acting in deliberate ignorance; or

c. acting with reckless disregard.

d. No specific intent to defraud government required.


a. Though federal False Claims Act (FCA) cases are ordinarily prosecuted by the Department of Justice, a private individual (“relator”) may sue on behalf of himself and the government, except where the information on which the suit is based has been publicly disclosed and the individual is not an original source of the information.

b. Relator is required to notify government of suit. If government decides to take over prosecution, relator receives 15-25% of any award or settlement.
c. Relators are frequently current or former employees of the defendant.

C. Kickbacks as Basis for FCA action

1. With some exceptions, courts have generally permitted the government and qui tam relators to proceed under the FCA with claims based on antikickback law violations, relying on either an express or an implied certification theory.

2. Express certification theory


(1) Court held violation of antikickback law alone does not necessarily render claims false under FCA.

(2) Plaintiff must also prove that provider falsely certified in claim submission that it complied with antikickback law, and that Medicare payment was conditioned on claimant’s certification of compliance. Mere submission of claim is not an “implied” certification of compliance with antikickback law.


(1) Citing Thompson, Court found that relator stated a claim under the FCA by alleging that hospital, which received discounts and incentives from device company, certified compliance with antikickback law knowing certification to be false.

(2) Court also declined to dismiss relator’s claim that Zimmer paid kickbacks that it knew would result in submission by the hospital of false compliance certifications. Zimmer therefore could cause the false
certifications, even though Zimmer did not submit the certifications or review the hospital’s certifications.

3. Implied certification theory


   (1) Violations of antikickback statute are actionable under FCA, even if claims would have been paid absent the kickback and there was no loss to Medicare.

   (2) Plaintiff must show that defendants engaged in kickbacks with the purpose of inducing payment from government.

   (3) Unlike Fifth Circuit in Thompson, Court did not hold that provider must have expressly certified to compliance with the antikickback law in order for a FCA claim to be stated.


   (1) Violation of antikickback law states a claim under FCA if plaintiff can show that kickbacks “tainted” the Medicare claims. Court did not explain how “taint” could occur.


    Defendant submitting claim to Medicaid can be liable under FCA for anti-kickback violation even without
affirmative certification of compliance with the anti-kickback law: “[T]he FCA is violated when a Medicaid claim is presented to the state government in violation of the Anti-kickback statute, even if there is no express certification of compliance with the statute.” The court justified its finding on the grounds that courts should read FCA broadly to accomplish the statute’s remedial goal.

4. The government routinely alleges that antikickback allegations were also violations of the FCA. For example:

   a. Serono (2005): FCA case alleged that kickbacks given to physicians, including free testing devices and free trips to Cannes, France, caused the submission of false and/or fraudulent claims to federal programs for Serono’s AIDS wasting drug, Serostim. See Section IV(A)(2)(g).


5. FCA creates de facto private right of action under antikickback law

   a. Decisions in In re Pharmaceutical Industry Average Wholesale Price Litigation and Zimmer show that courts are willing to permit antikickback claims against drug and device companies to proceed under the FCA under express or implied certification theories. This permits private individuals (e.g., current or former employees) to bring antikickback allegations, even though there is no private right of action under the antikickback law itself.

D. Liability for Providing Reimbursement Advice

   1. Some drug companies provide advice to customers or potential customers on reimbursement coding to use for a drug, for a procedure in which the drug is used, or for a test used to determine the need for the drug.
2. Several drug and device companies and a health care consultant have been prosecuted for allegedly giving improper coding advice to providers, thereby causing false claims to be submitted.

3. In May 2008, Medtronic Spine, formerly Kyphon Inc., paid $75 million to settle a qui tam FCA case. Among other things, the government and the relator alleged that Kyphon engaged in a marketing scheme to persuade hospitals that they could maximize revenue for kyphoplasty procedures by admitting patients for one-night stays and billing under certain DRGs, rather than performing the procedures on an outpatient basis.

4. In April 2006, a physician who was a consultant and speaker for Jazz Pharmaceuticals was indicted on four counts relating to off-label promotion and fraud on a health benefit plan under 18 U.S.C. § 1347. The physician was alleged to have advised physicians to conceal evidence of non-reimbursable off-label uses in claims submitted for Xyrem, a Jazz Pharmaceutical product. The fraud charges were later dropped and the physician pled guilty in August 2008 to a misdemeanor violation of the FDC Act for off-label promotion. U.S. v. Gleason, Cr. No. 06-229 (E.D.N.Y. April 5, 2006).

5. One company settled FCA and related allegations that it provided enteral nutrition pumps free with an agreement to purchase related supplies, then advised customers that they could bill Medicare separately for the pumps and the supplies. See Settlement Agreement between U.S. and Abbott Laboratories Ross Products Division, June 2003.

6. In one qui tam case, the government alleged that a manufacturer of lymphedema pumps caused false claims to be submitted by advising its customers that the device qualified for a Medicare reimbursement code entitled to high payment, when it knew or should have known that the pump only met criteria for a code reimbursed at a much lower rate. The company maintained that the rules were ambiguous and that it provided a good faith interpretation to customers. The company paid $4.9 million to settle the suit. Settlement Agreement, U.S. ex rel. Wells v. Huntleigh Technology PLC, Civ. Action No. 95-95 (D.N.J. July 4, 1995). See also U.S. v. Beiersdorf-Jobst (N.D. Ohio 1996) (same).
7. In July 2004, Ernst & Young paid $1.5 million to settle allegations that it knowingly provided hospitals with incorrect coding advice relating to outpatient clinical laboratory tests, which were allegedly not medically necessary. U.S. v. Ernst & Young, Civ. Act. No. 04-0041 (E.D. Pa. July 19, 2004) (settlement agreement).

In an internal fraud alert and a special advisory bulletin, the OIG has criticized abusive practices by consultants, including recommending inappropriate codes to increase reimbursement, and offering to maximize a provider’s billings in return for a percentage of the resulting reimbursement revenue increase. OIG, Special Advisory Bulletin: Practices of Business Consultants (June 2001); OIG, Medicare Fraud Alert 97-01.

8. Although coding of drugs generally is straightforward, advising customers on reimbursement of procedures or diagnostic tests relating to a drug could be risky where coverage or the appropriate coding is ambiguous. If coding advice is provided, it should be conservative and customer should be clearly notified that it has responsibility for determining the appropriate reimbursement coding. Percentage compensation arrangements for reimbursement consulting should be avoided.

9. The mere provision of reimbursement assistance does not violate the antikickback law. In an advisory opinion, the OIG concluded that a reimbursement assistance program offered by a drug company for its injectable pediatric drug indicated for prophylaxis against a respiratory virus did not implicate the federal antikickback law. OIG Advisory Opinion 00-10 (Dec. 28, 2000). OIG explained that because reimbursement services are considered part of the product and the cost is included in the product’s price, the reimbursement assistance program does not have any substantial value independent of the product. But see Advisory Opinion 06-16 (Oct. 10, 2006) (proposed reimbursement consulting services not free-standing or limited in nature and would potentially provide substantial independent value to DME supplier) (Section IV.A., above).
E. Inflation of AWP

1. Drug reimbursement under Medicare Part B before 2005 was based on average wholesale price (AWP) reported to pricing compendia (e.g., Redbook, First DataBank). Drug reimbursement under Medicaid continues to be based on AWP or on wholesale acquisition cost (WAC) reported by manufacturers to pricing compendia (Redbook, First DataBank).

2. The Department of Justice has brought lawsuits challenging drug company practices related to reporting AWP to pricing compendia, and practices involving increasing reported AWP while reducing or maintaining prices to purchasers. Government is alleging that companies inflated reported AWP to increase the “spread” between Medicare/Medicaid reimbursement and actual cost to customers, and used this profit spread as a marketing tool. Government alleges that these practices caused false claims to be presented to Medicare/Medicaid.

3. A number of states have also filed lawsuits against multiple pharmaceutical manufacturers for violations based primarily on inflation of AWP or WAC and marketing of the “spread”. The complaints allege violations of state deceptive trade practices laws, false claims laws, state civil RICO laws, commercial bribery laws, and Medicaid fraud prohibitions. The states generally claim that the alleged conduct caused damages to Medicaid, private third-party payors, and state residents, all of whom paid too much as a result of the inflated AWPs or WACs. See, e.g., Complaint, Massachusetts v. Mylan Labs et al., 03-CV-11865 PBS (D. Mass. June 12, 2003).

4. Private individuals and employer plans have also brought cases against multiple drug companies alleging that AWP inflation and marketing of the spread caused plans to pay inflated reimbursement amounts and caused enrollees to pay inflated copayments. See, e.g., Amended Master Consolidated Class Action Complaint, In Re Pharmaceutical Industry Average Wholesale Price Litigation, Civil Action No. 01-CV-12257-PBS (Dist. Mass., June 12, 2003).

5. Most of these federal, state, and private suits have been consolidated in the U.S. District Court for the District of Massachusetts.
Defendant drug manufacturers’ motions to dismiss and motions for summary judgment have so far largely been denied.

6. Several drug manufacturers have settled these cases.

a. Bayer Corporation settled these allegations in September 2000 for $14 million and agreed to a five year corporate integrity agreement (“CIA”). The CIA provides that Bayer will report the average selling prices of its drugs in order to assist the government in setting reimbursement rates. Bayer denied any wrongdoing and asserted that its pricing practices were consistent with industry standards.

b. TAP Pharmaceutical Products, Inc. settled allegations that it violated the FCA based on inflation of AWP and marketing the spread in September 2001 for a combined total of $875 million in criminal fines and civil penalties. TAP also settled allegations that it provided kickbacks and caused false claims to be submitted by distributing large amounts of free samples expecting physicians to bill Medicare for them. (See Section IV.A.2, above.)


d. Bristol-Myers Squibb settled allegations in 2007 that it artificially inflated spreads between inflated prices and the actual acquisition costs of the AWP covered drugs. The government also claimed that BMS incorrectly calculated the Medicaid Rebate best price for the anti-depression drug, Serzone. (See Section V.F., above).

F. Underpayment of Medicaid Rebates

1. Pharmaceutical manufacturers must pay quarterly rebates to each state on outpatient drugs dispensed in state to Medicaid beneficiaries. Rebate for NDA drugs equals greater of 15.1% of average manufacturer price (AMP) or difference between AMP and single best price to non-federal customer. Rebate for ANDA drugs
equals 11% of AMP. 42 U.S.C. § 1396r-8. Pharmaceutical manufacturers report AMP and best price to CMS.

2. In September 2000, Bayer Corporation settled allegations that it failed to include price concessions in best price calculations and thereby underpaid Medicaid rebates to the states. Documents disclosed to a Congressional committee showed that Bayer employees offered purchasers unrestricted educational grants, free goods, or discounted short-dated goods in lieu of actual price discount in order to avoid setting a new best price. The government contended that these and similar price concessions should have been included in the best price calculations. Bayer settled these allegations for $14 million and entered into a five year CIA. See section V.E.4, above.

3. In April 2003, Bayer pleaded guilty and entered into a global settlement regarding additional allegations that it underpaid Medicaid rebates between 1995 to 2000. The company paid $257.2 million to settle the joint civil and criminal investigation. Bayer had entered into an agreement with Kaiser Permanente to repackage certain Bayer drugs under Kaiser’s private label, thereby evading best price reporting obligations, since Kaiser owned the private label NDC number. GlaxoSmithKline settled similar civil allegations and paid $88 million.

4. On July 30, 2004, Schering-Plough Corporation agreed to settle government allegations of FCA liability and to pay the United States, state Medicaid programs, and entities that purchase drugs under the 340B Program, $292,969,482 in civil penalties for losses suffered as a result of Schering-Plough inflating the best price for Claritin under the Medicaid Drug Rebate program. Schering-Plough allegedly failed to include a “data fee,” the time value of prepaid rebates, or discounted services that were part of “added value” arrangements with certain managed care organizations when it reported the best price for Claritin to the government, which resulted in the underpayment of rebates to state Medicaid programs. The government ignored the parties’ characterization of the payment as a data fee, and considered it a discount intended to induce the managed care organization to maintain Claritin on formulary.
5. In August 2006, Schering Sales Corporation, a subsidiary of Schering Plough Corporation, pleaded guilty to making false statements to HCFA (now CMS) regarding its best price for Claritin. Specifically, Schering provided free Claritin Reditabs to an HMO contingent on the HMO purchasing other units of Claritin Reditabs, so that the HMO would receive a blended price resulting from the free and purchased units that was lower than Schering’s reported best price. By reporting a false best price, Schering retained approximately $4,392,000 in Medicaid Rebates that would otherwise have been owed. Schering pleaded guilty to one count of conspiracy to make a false statement to the government in violation of 18 U.S.C. § 1001, and agreed to pay $435 million (including $180 in criminal fines) to settle these and other allegations relating to off-label promotion, discussed in Section V.G., below. Schering Sales Corporation, which is a shell corporation, was permanently excluded from participating in federal health care programs.

6. In July 2007, Bristol-Myers Squibb settled allegations that it knowingly failed to include in best price the low prices at which is sold private-label Serzone to a large commercial purchaser, and thereby underpaid Medicaid rebates. See also Section IV.A., above (free goods).

7. In February 2008, Merck & Co. Inc. settled civil allegations under the Medicaid Rebate statute, and other statutes. The government claimed that Merck misreported the Medicaid Rebate best price for Zocor, Vioxx, and Pepcid products by omitting nominal pricing to hospitals. See also Section IV.A., above (free goods).

8. The OIG’s CPG for pharmaceutical manufacturers states that “[w]here appropriate, manufacturers’ reported prices should accurately take into account “price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced price services, grants, or other price concessions or similar benefits offered to some or all purchasers.”” 68 Fed. Reg. at 23,733-34. The OIG also noted the importance of calculating AMP and best price accurately. Id.
G. Off-Label Promotion as Basis for FCA Liability

1. The government and qui tam relators have brought numerous FCA cases against drug companies based on allegations of off-label promotion. The theory in these cases is that, by promoting off label uses, the company caused claims for reimbursement to be submitted to Medicaid, and the claims were false where the off-label uses were not covered under state Medicaid programs. Some examples of these cases are described below.

   a. On May 13, 2004, Warner-Lambert Company LLC (“Warner-Lambert”) entered into a plea agreement and settlement for a total of $430 million in criminal fines and civil penalties with the United States Attorney for the District of Massachusetts regarding allegations that Warner-Lambert’s subsidiary, Parke-Davis, promoted its drug Neurontin for off-label uses, distributing an unapproved drug, and distribution of a misbranded drug (by failing to provide adequate directions for the unapproved uses), in violation of the FDC Act. The Criminal Information alleges that Warner-Lambert’s marketing strategy for Neurontin consisted of various avenues of off-label promotion including false statements made to physicians regarding the safety and efficacy of Neurontin for unapproved uses through sales representatives, Medical Liaisons, consultants’ meetings and advisory board meetings, and teleconferences. This was the first FCA settlement predicated on off-label promotion by a pharmaceutical company.

   b. In a 2003 court decision in the Warner-Lambert case, the district court held that it was not necessary for the relator to demonstrate that Warner-Lambert lied to physicians, since “truthful off-label marketing (ineligible for federal safe harbors) and financial incentives like kickbacks would suffice” to establish a violation. United States v. Parke-Davis, No. 96-11651, 2003 U.S. Dist. LEXIS 15754, at *3 (D. Mass. Aug. 22, 2003).
c. In October 2006, InterMune, Inc. pled guilty to misbranding under the Food, Drug, and Cosmetic Act, entered into a two-year deferred prosecution agreement, and settled FCA allegations concerning its off-label promotion of Actimmune (Interferon gamma-1b). InterMune also entered a 5-year Corporate Integrity Agreement. As part of the settlement, the company paid nearly $37 million.

FDA approved Actimmune for treatment of chronic granulomatous disease and severe, malignant osteoporosis. From 2000 to 2002, InterMune, Inc. conducted a Phase III clinical trial of the product for the treatment of IPF, a fatal lung disease for which no available treatment existed. The Phase III trial failed to establish statistically significant evidence of benefit for the primary endpoint of progression-free survival or any of the secondary endpoints. Despite these poor results, InterMune, Inc. issued a press release that depicted the study as a success. The company then distributed the misleading information to both pulmonologists and patients. It also encouraged its sales force to promote the drug for that unapproved indication.

In 2008, a grand jury indicted former InterMune CEO W. Scott Harkonen on wire fraud and felony FDC Act charges for his role in the creation and dissemination of the false and misleading information.

d. In April 2007, Pfizer subsidiary Pharmacia & Upjohn Company, LLC entered into a 36-month deferred prosecution for the off-label promotion of growth hormone Genotropin. FDA has approved Genotropin for the long-term treatment of children suffering from growth failure as a result of inadequate endogenous growth hormone levels, but Pharmacia & Upjohn LLC promoted the drug for “anti-aging” and cosmetic claims. The Pfizer subsidiary agreed to implement specific training programs to prevent future illegal off-label promotion, and paid a monetary penalty of $15 million for its off-label activities. See also Section IV.F., above (discussion of allegations relating to kickbacks to a PBM).
e. Also in April 2007, Cell Therapeutics settled civil allegations that it violated the False Claims Act when it promoted Trisenox (Arsenic Trioxide), which FDA approved for the orphan indication of acute promyelocytic leukemia (APL) for off-label treatment of various forms of cancer. The government alleged that the company’s actions caused physicians who prescribed the drug off-label to submit false claims for reimbursement to the Medicare Program from 2001 to 2005. See also Section IV.C., above (consulting services).

f. In July 2007, Bristol-Myers Squibb settled allegations that the company promoted its anti-psychotic drug Abilify in the pediatric population and to treat dementia-related psychosis, both of which were off-label uses, despite a black box warning against use in dementia-related psychosis. See also Section IV.A. (gifts) (See also Otsuka America Pharmaceutical, Inc. $4 million settlement concerning claims that it also promoted Abilify off-label in violation of the False Claims Act).

g. In January 2009, Eli Lilly entered into a $1.415 billion dollar settlement to resolve allegations of off-label promotion of Lilly’s antipsychotic drug, Zyprexa, which was approved for bipolar disorder and schizophrenia. Lilly pleaded guilty to a misdemeanor violation of the FDC Act, paying a criminal fine of $515 million and an additional $100 million forfeiture. The remaining $800 million resolved civil allegations under the FCA and related state claims. According to the Criminal Information, Lilly management trained sales representatives to promote Zyprexa to the long term care market to treat symptoms of dementia, an off-label use, when the data supporting Zyprexa’s use in dementia was mixed and Lilly, in fact, abandoned a plan to seek a dementia indication. Lilly also promoted Zyprexa to primary care physicians for the treatment of dementia symptoms.
7. Some courts recently have rejected qui tam FCA claims based on off-label promotion.

a. In 2008, a federal district court dismissed a qui tam amended complaint brought against Ortho Biotech Products (OBP) under the FCA. Among other things, the complaint alleged that Ortho promoted off-label dosing of anti-anemia drug Procrit in violation of the FDC Act and used sham drug trials to falsify eligibility for Medicare reimbursement for off-label uses of the drugs. The court dismissed the complaint on the grounds that the plaintiffs had not pled with the requisite particularity required by Federal Rules of Civil Procedure 9(b). U.S. ex rel. Duxbury v. Ortho Biotech Products, 551 F. Supp. 2d 100, 115 (D. Mass. 2008).

b. See also U.S. ex rel. Hopper and Hutto v. Solvay Pharmaceuticals, 8-04-CV-2356-T-23TGW (M.D. Fla. Aug. 1, 2008); U.S. ex rel. Kennedy v. Aventis Pharmaceuticals, 2008 U.S. Dist. LEXIS 100444 (Dec. 10, 2008). These cases also held that the relators had failed to comply with Fed. R. Civ. P. (9)(b) by failing to include specific allegations of actual false claims that were submitted to the government.

c. Where the government intervenes in a qui tam suit, dismissal on Rule 9(b) grounds is less likely, because the government has access to information about specific claims that were submitted to Medicare or Medicaid.

H. Other FDA Violation as Basis for FCA Liability


a. Qui tam case initially brought by former employee. Orthologic, a manufacturer and distributor of bone growth stimulators, sold the devices to Medicare beneficiaries and billed Medicare.
b. Orthologic began to market a modified device in March 1994. Orthologic received FDA Warning Letter in 1996 notifying company that the modified devices required a PMA supplement. Government alleged that Company continued selling device and billing Medicare for it, knowing that devices that require FDA approval but do not have it are not covered. Orthologic denied the allegations and settled for $1 million.

2. Endo Vascular Technologies (EVT) (a subsidiary of Guidant Corporation) entered into a plea agreement with the U.S. Department of Justice on June 12, 2003. In the plea agreement, Guidant acknowledged that it had attempted to conceal 6,228 adverse event reports associated with its Ancure stent graft for abdominal aortic aneurysms between 1999 and 2001. The devices were allegedly misbranded in that EVT failed to report, as required by law, information that the system may have caused or contributed to deaths or serious injuries. The Government further alleged that the system was misbranded because it did not bear adequate directions for use, and that the company submitted false claims to Medicare for the adulterated and misbranded devices. Guidant agreed to pay $92.4 million to settle the case. In addition to the settlement agreement, Guidant and EVT agreed to enter into a Corporate Integrity Agreement.

3. In a December 2000 settlement involving Lifescan, Inc., OIG alleged that the company violated FCA by marketing an adulterated and misbranded device for which federal and state programs were caused to pay. Lifescan settled for $60 million without admitting false claims liability and entered into Corporate Integrity Agreement.

4. U.S. ex rel. Kazimiroff v. Dentsply Internat’l. In March 2003, Dentsply International, Inc. paid $600,000 to settle civil false claims relating to sales of dental cement to the federal government. Dentsply had failed to submit required adverse event reports, and was therefore not in compliance with the Federal Food, Drug, and Cosmetic Acts (FDCA) and FDA regulations. Selling products that did not comply with the FDCA was a violation of Dentsply’s Federal Supply Schedule contract with the Department of
Veterans Affairs (VA). Thus, submitting invoices for payment to the VA for non-compliant devices was alleged to constitute a false claim under the FCA.

I. False Certification of Compliance with Corporate Integrity Agreement as Basis for FCA Liability

A corporate executive’s false certification of compliance with a Corporate Integrity Agreement can trigger FCA liability. On September 18, 2007, the Department of Justice brought an action to recover tens of millions of dollars under the FCA against Defendant Christi R. Sulzach, the associate general counsel and corporate integrity program director at Tenet Healthcare Corporation. DOJ alleged that she violated the FCA when she submitted false declarations of compliance with a corporate integrity agreement imposed on Tenet’s predecessor National Medical Enterprises, thus causing the government to pay $18 million in Medicare reimbursements which it otherwise would not have paid.

VI. GENERAL GUIDELINES FOR EVALUATING MARKETING PROPOSALS

A. Determine whether antikickback statute applies

1. Is “remuneration” offered?

2. Is at least one purpose to induce the prescribing/purchase of company’s product?

3. Will beneficiaries of federal health care programs or state government programs be affected?

   a. Even if not, will state all-payor laws apply?

B. Conform to safe harbor to extent possible

C. Assess financial impact on federal health care programs

1. Is there a potential to cause overutilization, or use of higher cost drug instead of lower cost drug?

D. Assess the potential to bias treatment decisions
E. Discounts

1. Comply with discount safe harbor to extent possible.

2. Maintain adequate paper trail. Invoices, contracts, reconciliation statements should permit accurate reporting to federal programs and notify customer of reporting obligations.

3. Bundled discounts are more problematic than product-by-product discounts, especially where discount is “shifted” away from cost-reimbursed item to unreimbursed or fixed-reimbursement item.

F. Free goods and services are problematic -- ensure legal review

G. Consulting or service arrangements

1. Conform with safe harbor for personal services contracts to extent possible.

2. Compensation should be consistent with fair market value and not be related to prescribing/purchasing practices or potential.

3. Consultant should be required to maintain adequate documentation of time/resources expended.

H. Grants

1. Requests should be evaluated based on scientific merit.

2. Grants should not be linked to prescribing history or potential.

3. Marketing considerations and input of sales and marketing personnel should be minimized in the award process.

4. Ensure adequate monitoring of research activities.

I. Establish a Compliance Program

1. Benefits
a. Enhances ethical business conduct among employees and reduces chances of antikickback violation.

b. If violation occurs, effective compliance program predating the violation is taken into account by OIG in determining extent to which enforcement is warranted. See, e.g., 63 Fed. Reg. 8987, 8988 n. 2 (Feb. 23, 1998) (preamble to compliance program guidance for hospitals).


2. Essential elements

a. Written Code of Ethics and fraud and abuse policies and procedures.

b. Initial and periodic training of sales, marketing and other personnel.

c. Oversight by high level management compliance officer.

d. Internal reporting system (e.g., hotline).

e. Procedure for internal investigations.

f. Monitoring of marketing programs.

g. Sanctions for violations of policy.