

**APPLICATION OF HEALTH CARE FRAUD AND ABUSE LAWS
TO THE MARKETING OF PHARMACEUTICALS AND
MEDICAL DEVICES**

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**I. PHARMACEUTICAL COVERAGE AND PAYMENT UNDER
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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 (Medicare Administrative Contractors, or MACs) under regulations and policies issued by Centers for Medicare & Medicaid Services (CMS).
 - c. Reimbursement to hospitals for inpatients is provided as a single, prospectively determined payment amount for each patient based on the patient's diagnosis related group (DRG). The DRG payment covers all items and services provided by the hospital to the patient. The DRG is based on the primary diagnosis, additional diagnoses, and the procedures performed.

- d. Drugs administered to an inpatient and devices used for the inpatient are included in DRG payment, not separately reimbursed.
 - e. An additional payment is available for a drug or device that is a new technology if it represents a substantial improvement over existing technologies, and the costs of the technology are high in relation to the DRG.
4. Part B
- a. Voluntary program covering physician, hospital outpatient, ambulatory surgical, and other non-inpatient services.
 - b. Administered by MACs under regulations and policies issued by CMS.
 - c. Prescription drug coverage and payment
 - (1) Limited coverage of prescription drugs includes:
 - (a) Drugs administered incident to physicians' services (in office or hospital outpatient settings) that are not generally self-administered. Generally injectables, e.g., chemotherapy agents and pain management drugs for cancer patients, radiopharmaceuticals, and other diagnostic imaging agents.
 - (b) Drugs used with durable medical equipment (DME) (non-disposable medical equipment used in the home). E.g., respiratory drugs used with nebulizers and medications used with infusion pumps.
 - (c) Other drugs specifically identified in statute: antigens; pneumococcal, influenza, and hepatitis B vaccines; blood clotting factors for hemophilia patients; immunosuppressive therapy drugs for organ transplant patients; erythropoietin for dialysis patients; self-

administered oral cancer drugs, and anti-emetics used in chemotherapy

- (2) Payment for Part B drugs used in hospital outpatient setting:

Most Medicare-reimbursable drugs administered in the hospital outpatient setting are included (“packaged”) in a global prospective payment based on ambulatory patient classifications (APCs). The APC payment is intended to cover all overhead, supplies, drugs, and equipment used in the delivery of the patient’s procedures or care. However, certain costly drugs are paid for 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 2014, most Part B hospital outpatient drugs that are reimbursed under a separate APC are reimbursed at 106 percent of Average Sales Price (ASP) (see below), and drugs eligible for transitional pass-through payments are also reimbursed at 106 percent of ASP.

- (3) Payment for Part B drugs in the physician’s office setting:

- (a) For 2005 and subsequent years, reimbursement for single source drugs is 106 percent of the ASP. ASP, which is reported quarterly to CMS by drug manufacturers, is the weighted average of prices to all customers, excluding government sales and other 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

different versions of the same multiple source drug.

- (b) The Medicare Prescription Drug Improvement and Modernization Act of 2003 (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. As of January 2014, the CAP program has not yet been resumed.

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 health maintenance organizations (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 Section 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 managed care organizations experienced in administering pharmacy benefits based on formularies.
 - d. Drug reimbursement to pharmacies is negotiated between the PDP and pharmacies. Voluntary drug rebates are negotiated between the PDP and drug manufacturers. Most PDPs operate tiered drug formularies with drug copay determined by tier. Manufacturer rebates frequently determine formulary tier for brand drugs. The government is statutorily prohibited from interfering in price and rebate negotiations.
 - e. Coverage gap and Coverage Gap Discount Program for brand drugs
 - (1) The Part D benefit has a "coverage gap" (sometimes called the "donut hole") in which the PDP reimburses for only a small portion of a beneficiary's drug expenses. In 2014, the coverage gap begins when the PDP and the enrollee have spent \$2,850 on covered drugs, and ends when the enrollee has spent \$4,550 in out-of-pocket expenses. After a deductible is met, an enrollee pays a copayment or coinsurance determined by the PDP before he enters the coverage gap and a small copayment or coinsurance after he leaves the coverage gap. In 2014, within the coverage gap, the PDP pays a minimum of 28% of the pharmacy's price

for generic drugs. For brand (NDA) drugs, the PDP pays for only 2.5% of the pharmacy's price, and the patient is responsible for paying 47.5% of that price. The remainder (50%) of the pharmacy's price is subsidized by brand drug manufacturers through the Coverage Gap Discount Program, which was established pursuant to the Patient Protection and Affordable Care Act (ACA), and became effective in January 2011.

- (2) Under the Coverage Gap Discount Program, in order for a manufacturer's brand (NDA) outpatient drugs to be covered under Part D, the manufacturer must sign an agreement with Health and Human Services (HHS) agreeing to pay rebates to PDPs equal to 50% of the price that each Part D enrollee who is in the coverage gap pays to a pharmacy for the manufacturer's brand drugs. Manufacturers are invoiced quarterly by a CMS contractor and pay the rebates directly to PDPs.

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 minimum 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 Medicaid Assistance Percentage) 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 an optional service under the 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:

Generally, pharmacies are reimbursed using a formula based on published average wholesale price (AWP), minus a specified percentage, plus a dispensing fee; or wholesaler acquisition cost (WAC), plus a specified percentage, plus a dispensing fee. AWP and WAC are reported by certain pricing publications. With the encouragement of CMS, certain states (e.g., CO, IA, ID, LA) have adopted an alternative payment formula based on actual acquisition cost (AAC) determined by periodic pharmacy surveys.

(c) Multiple source drugs:

For multiple source drugs for which at least three products are A rated (i.e., rated as therapeutically equivalent) in the Food and Drug Administration's (FDA's) Orange Book, CMS publishes "federal upper limits" (FULs). Where a FUL has been established, state Medicaid reimbursement may not exceed, in the aggregate, the FUL, plus a dispensing fee. "Dispense as written" scripts are exempted from FUL.

Under an amendment enacted as part of the ACA, the FUL is at least 175% of the weighted average of the most recently reported AMPs for the therapeutically equivalent (i.e., A-rated) products. However, CMS has not yet implemented the ACA FUL methodology. In the meantime, CMS continues to calculate FULs using a methodology set forth in prior regulations, under which FUL equals 150% of the lowest price (WAC or AWP) listed in a drug pricing compendium.

- (3) Medicaid Drug Rebate Program: As a condition for coverage of their drugs under Medicaid and Medicare Part B, pharmaceutical manufacturers must pay quarterly rebates to each state on outpatient drugs dispensed in the state to Medicaid beneficiaries. Rebate for NDA drugs equals greater of 23.1% of average manufacturer price (AMP) or difference between AMP and single best price to non-federal customer. Rebate for ANDA drugs equals 13% of AMP.
- (4) Supplemental Medicaid Rebates: A number of states have required pharmaceutical manufacturers to pay supplemental Medicaid 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. MEDICAL DEVICE COVERAGE AND PAYMENT UNDER MEDICARE

A. Part A

Payment for devices provided to a hospital inpatient is included in the prospective payment based on the patient's DRG, and are not separately reimbursed. However, an additional payment is available to the hospital for a new medical technology where the payment is determined to be inadequate and certain other conditions are met.

B. Part B

1. Hospital outpatient reimbursement

- a. Payment for devices used in the care of a patient in a hospital outpatient department is included in the prospective Ambulatory Payment Classification (APC) payment, and is not made separately for the device.
- b. However, transitional pass-through payments may be available if the device represents a substantial improvement over existing technologies, the cost of the device is not insignificant in comparison to the applicable APC, and certain other requirements are met.

2. Devices furnished in the physician's office

Physicians are paid a fee schedule amount for each procedure, which is identified by a Current Procedural Technology (CPT) code. The fee schedule amount includes a work component reflecting the time and intensity of the physician's services, a practice expense component reflecting the costs of overhead, equipment, and supplies, and a malpractice component. Devices provided to a patient in the physician's office are included in the fee-schedule payment, and are not paid separately.

3. Durable medical equipment (DME)

Certain devices regulated by FDA are treated as DME under Medicare. DME is equipment that is appropriate for use in the home, can withstand repeated use, is used for a medical purpose (rather than for patient comfort), and is not useful in the absence of illness or injury. Medicare payment for DME is based on a fee schedule. For certain categories of DME in certain metropolitan areas, CMS has implemented a competitive bidding process whereby suppliers who win bids are awarded contracts to provide the DME items at the bid price.

III. THE FEDERAL HEALTH CARE PROGRAM ANTI-KICKBACK LAW
(42 U.S.C. § 1320a-7b(b))

A. Prohibited Conduct

1. Knowing and willful

Prior to the enactment of the ACA, federal circuit courts had different interpretations of the intent standard under the anti-kickback law. The ACA resolved those differences by an amendment to the anti-kickback law specifying that a person need not have actual knowledge of the anti-kickback law or specific intent to commit a violation. ACA § 6402(f)(1).

2. 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 directly, in whole or in part” by the federal government, except the Federal Employee Health Benefit Program.

b. Includes, among other programs, Medicare, Medicaid, the Children’s Health Insurance Program, the Department of Veterans Affairs health network, TriCare, the Indian Health

Service, and the Maternal and Child Health Services Block Grant Program.

- c. Qualified Health Plans offered on health exchanges established pursuant to the ACA are not considered Federal health care programs by the Department of Health and Human Services. See Letter from Secretary Sebelius to Representative Jim McDermott (Oct. 30, 2013).
6. Statute also prohibits the knowing and willful solicitation or receipt of remuneration “in return for” the activities in Section 4(a) and (b), above.

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 three times the amount of illegal remuneration.
 - b. 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 five years where criminal conviction; permissive exclusion where administrative finding of kickback violation. 42 U.S.C. § 1320a-7(a), (b)(7).
 - b. Exclusion can apply to “indirect” suppliers, such as drug and device manufacturers, that do not submit claims to federal programs. 63 Fed. Reg. 46,676 (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) The Office of Inspector General (OIG) will waive exclusion if necessary to protect patient health – e.g., if a drug is necessary/unique.

c. Procedure

- (1) OIG proposes exclusion
- (2) Hearing before administrative law judge (ALJ)
- (3) Appeal to HHS Departmental Appeals Board
- (4) Judicial review

4. Penalties under the Federal False Claims Act

The ACA amended the anti-kickback law to provide that a claim submitted to a federal health care program that includes items or services resulting from an anti-kickback law violation constitutes a false claim for purposes of the Federal False Claims Act (FCA). ACA § 6402(f)(1). See Section VI.B.2 for a discussion of the penalties under the FCA.

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 co-insurance 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 for enrollees 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 cost-sharing amount after making reasonable efforts to collect it.
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. A manufacturer discount provided to a Part D beneficiary under the Coverage Gap Discount Program (see Section I.A.6.e above).

9. Remuneration protected under safe harbor regulations issued by the OIG.

D. Judicial Interpretations

1. The “One-Purpose” rule

- a. United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985).

Physician who performed cardiac monitoring paid “consulting fees” to referring physicians for initial consultations and interpretation of cardiac monitors. 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.

- b. United States v. Bay State Ambulance and Hosp. Rental Serv., Inc., 874 F.2d 20 (1st Cir. 1989).

Ambulance company paid consulting fees to hospital official, who recommended that hospital give ambulance contract to the company. Court confirmed one-purpose rule, holding that even opportunity to earn reasonable payment for services can be an inducement to refer.

- c. See also United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Kats, 871 F.2d 105 (9th Cir. 1989).

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.

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 OIG to establish safe harbor regulations describing activities protected from prosecution.
2. Original OIG safe harbor regulations promulgated July 29, 1991 (56 Fed. Reg. 35,952) interpreted four statutory exemptions and described seven additional regulatory safe harbors. Several of these regulations were significantly revised on November 19, 1999 (64 Fed. Reg. 63,518). Additional safe harbors have since been promulgated. See 61 Fed. Reg. 2122 (Jan. 25, 1996); 64 Fed. Reg. at 63,504, 63,518 (Nov. 19, 1999); 66 Fed. Reg. 62,979 (Dec. 4, 2001); 71 Fed. Reg. 45,109 (Aug. 8, 2006); 72 Fed. Reg. 56,632 (Oct. 4, 2007).
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, at 12 (Jan. 22, 1998).
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., OIG, 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 35,979 (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; and
 - (4) Effect on fair competition in the health care marketplace.

See, e.g., 56 Fed. Reg. at 35,956.

6. “Sham” transactions

- a. In 1994, 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. 37,202, 37,208 (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 63,530.

F. Summary of Pertinent Safe Harbors

- 1. This section summarizes six safe harbors of most interest to drug and device 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 63,527.
 - (2) However, in United States 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.
 - 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 group purchasing organization (GPO)) is charged based on arm’s-length transaction.

- (1) Definition excludes
 - (a) Cash or cash equivalents, except that 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. 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 63,528. See OIG, 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. Other discounts to a beneficiary besides routine waivers are permissible if they otherwise comply with the safe harbor. 59 Fed. Reg. 37,202, 37,206 (July 21, 1994) (preamble to proposed clarification).
 - (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 anti-kickback law.
 - (a) In Klaczak v. Consol. Med. Transp., 458 F.Supp. 2d 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 anti-kickback 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.
 - (b) In United States ex rel. Jamison v. McKesson Corp., 900 F. Supp. 2d 683 (N.D. Miss. 2012), the court concluded that an alleged discount arrangement was not "remuneration" under the anti-kickback law, where the government could not prove that the seller offered services below cost or below fair market value. Relying on a Black's Dictionary definition of "fair market value" as a price agreed upon on the open market in an arm's-length transaction, the court found that there was no evidence that the arrangement was not competitive or not an arm's-length transaction that would reveal the fair market value of the services.
- e. Definition of rebate: a 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 GPOs implicated anti-kickback statute because they were made prior to any purchase and not attributable to identifiable purchases of items or services.
 - (b) Proposed change to definition of “rebate” in safe harbor: rebate must be paid after sale. See 65 Fed. Reg. 63,035, 63,041 (Oct. 20, 2000). Proposal was not finalized. See 67 Fed. Reg. 11,928, 11,930 (Mar. 18, 2002).
 - (c) In October 2009, IVAX pharmaceuticals paid \$14 million to settle allegations that it allegedly paid nursing home pharmacy services company Omnicare \$8 million, including a \$2.5 million prebate, in exchange for Omnicare’s commitment to purchase \$50 million of drugs from IVAX.
- (2) Government has also objected to rebates paid for sales that occurred prior to the rebate agreement. See Settlement Agreement between United States and St. Jude Medical (June 2010) (FCA settlement for \$3,898,300; St. Jude allegedly provided back-end rebates on products purchased in quarters previous to rebate agreement).

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 the 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. It is sufficient to state actual price net of discount. 59 Fed. Reg. at 37,206.
 - 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; and
 - d) Refrain from impeding buyer’s ability to meet its obligations.
- iv) Seller not liable for reporting omissions of buyer. 64 Fed. Reg. at 63,527.
- v) Even if an arrangement does not meet all the conditions of the safe harbor, accurate reporting by seller 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 anti-kickback law. See United States 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. at 63,527.

(b) *Seller's and offeror's requirements*

- i) Same as for cost-reporting buyers (see 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 manufacturers and entities who provide services but are also purchasers/prescribers/formulary managers.
- c. 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 interval.
- (5) Terms of agreement may not be changed within one year. 56 Fed. Reg. at 35,973.
- (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.
 - (a) Safe harbor does not define “fair market value.” However, in other contexts, OIG has stated that fair market value “must reflect an arms length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them.” OIG, Special Fraud Alert on Arrangements for the Provision of Clinical Laboratory Services, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994); see also OIG, Advisory Opinion No. 10-16, at 6 n. 3 (Sept. 3, 2010); Letter from D. McCarty Thornton, Associate General Counsel, OIG, to T.J. Sullivan, IRS, re: acquisition of physician practices (Dec. 22, 1992) available at <http://oig.hhs.gov/Fraud/docs/safeharborregulations/acquisition122292.htm>.
- (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 63,552.

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 neither wholly owned by the GPO nor wholly owned by a corporate parent that also wholly owns the GPO.
 - b. Requirements
 - (1) GPO must have written agreement with each member either
 - (a) Providing that the maximum fee paid by vendors to the GPO will be three percent of price of vendor's goods; or
 - (b) If fee will exceed three percent, 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.
 - c. OIG Compliance Program Guidance advised structuring agreements with Pharmacy Benefit Managers (PBMs) to meet the GPO safe harbor. 68 Fed. Reg. 23,731, 23,736 (May 5, 2003).
 - d. Administrative fees passed through to GPO members: when a GPO passes through a portion of its administrative fees to its members, those members are required to treat such distributions as discounts or rebates. OIG, Advisory Opinion No. 13-09 (July 16, 2013); see also CMS Provider Reimbursement Manual, Part 1, Pub. No. 15-1, ch. 8, § 805.

5. Employees (42 C.F.R. § 1001.952(i))
 - a. Protects remuneration paid by employer to bona fide employee for the furnishing of a federally reimbursable item or service.
 - 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., OIG, Advisory Opinion No. 98-1 (Mar. 25, 1998) (percentage compensation paid by device company to non-employee marketing personnel was deemed potentially abusive).
 - d. Payments to an employee may not be protected under the safe harbor where the employment relationship is deemed to be a sham. One federal circuit court held that a violation of the anti-kickback occurred, despite the employee exemption, where some part of the payment to an employee was intended to induce referrals rather than as compensation under a bona fide employment relationship. United States v. Borrasi, 639 F.3d 774, 782 (7th Cir. 2011). See also United States v. Luis, No. 12-CV-23588, 2013 WL 4757838 (S.D. Fla. June 21, 2013) (payments to employees were not protected by the employee safe harbor because employees were paid for recruiting patients, not for furnishing or providing covered items or services).
6. Remuneration under risk-sharing arrangements (42 C.F.R. § 1001.952(t), (u))
 - a. Statutory exemption added by Health Insurance Portability and Accountability Act of 1996 (HIPAA). Statute required HHS to develop implementing rule by negotiated rulemaking process.

- 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. 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 MCO 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 and devices), but also items and services that are “reasonably related” to them, including patient education, social services, and utilization review.
- (a) Disease management not specified in rule itself, but identified as “reasonably related” in preamble. 64 Fed. Reg. 63,504, 63,509 (Nov. 19, 1999).
 - (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 63,509.
 - (c) “Items and services” do 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; and
 - (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.
- d. 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) Health insurer contracts with an Accountable Care Organization (ACO) paid on a capitated 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. Capitation methodology is the only one that appears practicable for drug or device manufacturers.
 - (b) *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.
 - (c) Utility of numeric standard probably limited to MCO arrangements with physicians and possibly pharmacists; has questionable applicability to drug and device manufacturers and other suppliers.
- (5) Agreement must meet requirements described above for agreements covered by 42 C.F.R. § 1001.952(t) (eligible MCO safe harbor). 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 arm’s-length transaction.
 - (d) Require a quality assurance program that protects against underutilization and specifies patient goals.
- (6) “Items and services” (see above).
- (7) No “swapping” (see above).
- (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.

- e. Utility for drug and device manufacturers
 - (1) 42 C.F.R. § 1001.952(t) could protect
 - (a) Agreements to supply drugs or devices and related patient education, and disease management services to beneficiaries of an “eligible MCO.”
 - (b) Drug 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 or dispensing on-formulary).
 - (2) 42 C.F.R. § 1001.952(u) could be useful for drug companies who offer drugs or devices, patient education, and/or disease management services to health plans (or their subcontractors) on a SFR basis.

7. Other safe harbors

- a. Joint venture returns and other 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 services¹
 - r. Goods, items, services, donations, and loans provided to Federally Qualified Health Centers
8. As mandated by HIPAA, 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

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), (y)(1); 71 Fed. Reg. 45110, 45128 (Aug. 8, 2006) (preamble).

ones. 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 Anti-Kickback Law

1. Compliance Program Guidance

- a. In May 2003, OIG issued a Compliance Program Guidance for Pharmaceutical Manufacturers (CPG). 68 Fed. Reg. 23,731 (May 5, 2003). The CPG sets forth elements of an effective compliance program and describes specific risk areas for manufacturers.
- 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;
 - (5) Compliance audits and monitoring;
 - (6) Policies for disciplinary action for non-compliance; and
 - (7) Policies for investigating non-compliance.
- c. Specific risk areas:

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 AWP, WAC, Best Price, and AMP.
- (2) Kickbacks and other illegal remuneration, including:
 - (a) Discounts and other terms of sale: 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 arm's-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 anti-kickback 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 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 health care 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 anti-kickback statute. Moreover, “marketing the spread” is viewed as evidence of intent to violate the anti-kickback 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. Although the draft CPG suggested that “discounts and rebates based on movement of market share” raise anti-kickback concerns (67 Fed. Reg. 62,057, 62,062 (Oct. 3, 2002)), this was deleted from the final CPG.

(e) Consulting and advisory payments.

(f) Entertainment, grants, gifts, continuing medical education (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).

(3) Drug Samples: 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.

d. In a footnote, OIG states that the CPG may also have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices.

2. OIG Advisory Opinions

a. Under the mandate of HIPAA, OIG has established procedures for requests for advisory opinions on, among other

things, whether particular arrangements involve prohibited remuneration under the anti-kickback law, or satisfy the conditions of a safe harbor. 42 C.F.R. Part 1008.

- 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. However, delays are frequent in practice.
- 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 and device 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 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, and 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, and 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 65,049 (Dec. 10, 1997).
4. Settlement agreements and indictments are window on government’s view of abusive arrangements.

IV. OTHER ANTI-KICKBACK AND RELATED LAWS

A. Federal False Claims Act

See separate discussion in Section VI.

B. Civil Monetary Penalty for Remuneration to Medicare or Medicaid Beneficiary (42 U.S.C. § 1320a-7a(a)(5), (i)(6))

1. Added to SSA 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 less than fair market value.”
5. Selected exceptions²
 - a. Exception for incentives given to individuals to promote the delivery of preventive care.
 - (1) OIG example: t-shirts, exercise videos, and 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. Id.
 - (4) Exception applies only to CMP provision and not to anti-kickback law. 63 Fed. Reg. at 14,395.
 - 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.
 - c. Exception for remuneration of nominal value: less than \$10 per item or \$50 annually. Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55,855, 55,856 (Aug. 30, 2002) (“Special Advisory Bulletin”).

² Complete regulatory and policy exceptions are at 42 C.F.R. §§ 1001.101 and 1003.102(b)(13) and Special Advisory Bulletin, 67 Fed. Reg. 55,855 (Aug. 30, 2002).

6. OIG has determined that drug manufacturers are not “providers, practitioners, or suppliers” for the purpose of the CMP, 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.

C. Anti-Kickback Act of 1986 (41 U.S.C. § 51 et seq.)

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. United States v. Warning, No. 93-CV-4541, 1994 WL 396432 (E.D. Pa. July 26, 1994).
 - a. Similar remuneration under Medicaid held unactionable, since Medicaid is grant, not contractual, program. United States v. Kensington Hosp., 760 F. Supp. 1120 (E.D. Pa. 1991).
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 V.G.3.c and d.

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 patients, and thus a prescription could constitute a referral in that situation. 66 Fed. Reg. 856, 872, 920 (Jan. 4, 2001).

E. State Anti-Kickback Laws

- 1. Over 30 states have government assistance anti-kickback laws. Most are modeled after the federal anti-kickback law, but over half do not have an exemption for discounts.
- 2. Certain states (FL, MA, MI, MN, OH, RI, TX, WA) have anti-kickback 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 anti-kickback law could remain subject to state all-payor laws.

- b. It is the position of OIG that federal safe harbors do not preempt state anti-kickback 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 anti-kickback law is preempted by federal anti-kickback 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 held that the California anti-kickback law is not preempted by the federal anti-kickback law, but reserves the right to revisit the issue on a fuller record).

F. Federal Payment Transparency Reporting Law ("Physician Payment Sunshine Act")

1. Congress passed the "Physician Payments Sunshine Act" as part of ACA in March 2010. ACA § 6002. CMS issued an implementing final rule in February 2013. 78 Fed. Reg. 9458 (Feb. 8, 2013).
2. *Reporting of payments and other transfers of value:* The law mandates that each "applicable manufacturer" of a covered drug, device, biological, or medical supply that is operating in the U.S. or its territories or possessions is required annually to electronically report information on payments or other transfers of value made during the prior year to (1) physicians and (2) teaching hospitals.
3. CMS' implementing regulation requires applicable manufacturers to collect information on covered payments beginning on August 1, 2013. Payments made between August 1 and December 31, 2013 must be reported by March 31, 2014, and reports will be due annually thereafter for payments made during the previous calendar year.
4. Under the CMS regulation, a "covered drug, device, biological, or medical supply" is a prescription drug, or a medical device or supply, that requires FDA premarket clearance or approval, where the drug or device is eligible for payment under Medicare, Medicaid, or a State Children's Health Insurance Program (SCHIP). An

applicable manufacturer with one covered product must report all payments to physicians and teaching hospitals, even if none of its other products are covered.

5. An “applicable manufacturer” is defined as an entity engaged in the production of a covered product, but also includes another company under common ownership with the entity that assists it with production, promotion, sale, or distribution of a covered product.
6. Certain payments are exempt from reporting, including, among others: transfers of \$10 or less unless the aggregate annual transfers to a recipient exceed \$100 (both dollar amounts to be indexed); samples intended for patients; patient educational materials; a short-term (i.e., less than 90 days) loan of a device for evaluation; items or services provided under a warranty; discounts and rebates; and returns on publicly traded securities or mutual funds.
7. Reportable information includes the name and other information about the recipient; the amount, the form (e.g., cash, stock, in kind item) and nature (e.g., consulting fee, food, royalty, travel, research grant) of the payment; the name of any product involved; and other information specified by regulation.
8. Reported information will be posted by CMS on the internet in searchable format. However, public disclosure of payments made under a product development agreement or clinical trial will be delayed until product approval or four years after the payment is made, whichever is earlier. Manufacturers will have an opportunity to review their information before it is posted on the CMS web site.
9. The Act establishes civil penalties for non-compliance with reporting requirements.
10. *Ownership or investment interest reporting:* In addition, the manufacturers described above, as well as GPOs operating in the U.S. or its territories or possessions, will be required annually to electronically report information regarding any ownership or investment interest (other than publicly traded

securities) held by a physician or his/her immediate family member in the manufacturer or GPO during the preceding year. The information reported must include the amount invested by each physician, the value and terms of the ownership or investment interest, and any payments from the manufacturer or GPO to such physician. The information will be posted on the CMS web site in searchable form.

11. The Act preempts state laws that require reporting of the types of information covered in the Act, but does not preempt state requirements to report information of a type not required to be reported under the Sunshine Act or exempted under the Sunshine Act; requirements applicable to reporting entities and recipients other than those covered by the Act; or requirements to report information to a federal, state, or local government for public health purposes.
12. *Sample reporting:* The ACA contained a requirement for prescription drug manufacturers and authorized distributors of record, by April 1, 2012 and each subsequent year, to report to FDA the identity and quantity of samples requested by and distributed to each requesting practitioner, for drugs covered under Medicare or Medicaid. ACA § 6004. As of January 2014, FDA has delayed the implementation of this requirement until further notice. See FDA, Affordable Care Act (ACA § 6004), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm292040.htm> (last updated Mar. 15, 2013).

G. State Gift Prohibitions and Transparency Reporting Laws

1. Vermont (18 Vt. Stat. Ann. §§ 4631a, 4632; Vermont Attorney General's Office, "Guide to Vermont's Prescribed Products Gift Ban and Disclosure Law for 2013 Disclosures.")
 - a. Vermont law prohibits manufacturers of prescription drug, device, and biological products from providing certain types of gifts or payments to physicians and other health care providers, and requires annual disclosure to the state of the value, nature, purpose, and recipient of most other kinds of gifts or payments, regardless of amount.

- b. Manufacturers are permitted to provide certain gifts or payments but must disclose them. These include, but are not limited to: (1) samples of a prescribed product or reasonable quantities of an over-the-counter drug, nonprescription medical device, or item of nonprescription durable medical equipment provided to a health care provider for free distribution to patients; (2) free prescription drugs or OTC drugs, medical devices, biological products, medical equipment or supplies, or financial donations to a free clinic; (3) fellowship salary support through grants under certain conditions; (4) articles and educational items; (5) loan of medical device for a trial period of up to 120 days; and (6) other reasonable fees, payments, subsidies, or other benefits provided at fair market value.
 - c. Manufacturers may provide certain other gifts or payments without disclosure including, including but not limited to: (1) free or discounted prescription drugs to, or on behalf of, an individual through a patient assistance program; (2) coffee, snacks, or refreshments at a booth or seminar; (3) rebates and discounts; (4) royalties and licensing fees; (5) payment of reasonable expenses of an individual interviewing for employment at a manufacturer or for health care services on behalf of an employee of the manufacturer; and (6) distribution of product through a qualifying clinical trial or research project.
2. Minnesota (Minn. Stat. Ann. § 151.461).
- a. Minnesota law prohibits prescription drug manufacturers or wholesalers from offering or providing any gifts to a licensed health care practitioner in Minnesota exceeding an aggregate value of \$50 per year. Exemptions from this prohibition include: (1) free samples of prescription drugs intended to be distributed to patients; (2) support provided to scientific or educational programs; (3) payments to faculty of scientific or educational programs; (4) compensation for services in connection with genuine research; (5) publications and other

educational materials; and (6) salaries or other benefits paid to employees.

- b. Minnesota also requires prescription drug manufacturers to annually disclose expenditures in categories (3) and (4) above, made to licensed health care practitioners that exceed an aggregate amount of \$100. However, payments made to “physicians” as defined under the federal Physician Payments Sunshine Act do not need to be reported to the state. Furthermore, Minnesota has not required any reporting for 2012 or 2013, but has notified manufacturers that it will likely require reporting of payments to non-physician practitioners beginning in the 2014 calendar year. Minn. House Bill H.F. 1233, 88th Legislature, Art. 10 §§ 4, 6; “Gifts to Practitioners Prohibited – Frequently Asked Questions,” <http://www.phcybrd.state.mn.us/forms/giftsfaq.pdf> (last updated Jan. 20, 2010); Memorandum from Cody Wiberg, Executive Director, Minnesota Board of Pharmacy (June 24, 2013).
3. Washington, D.C. (D.C. Code § 48-833; D.C. Mun. Regs. tit. 22B, ch. 18.)

Washington D.C. law requires that prescription drug manufacturers or labelers disclose the value, nature, purpose, and recipient of gifts or payments of more than \$25 per day to physicians and other health care professionals licensed to practice in the District of Columbia. Companies are not required to report expenses relating to: (1) free samples intended for patients; (2) expenses of less than or equal to \$25 per day; (3) reasonable compensation for bona fide clinical trial; (4) support for physicians-in-training to attend scientific/educational meetings; (5) expenses associated with advertising and promotion for a regional or national market if the portion pertaining to D.C. cannot be reasonably determined; and (6) in certain instances, payments to health care professionals for participation in market research.

4. West Virginia (W. Va. Code § 16-29H-8; W.Va. Code R. § 210-1-1 et seq.)

West Virginia law requires prescription drug manufacturers to disclose payments of more than \$100 per year made to a prescriber as well as the total costs of advertising to consumers, prescribers, pharmacies, and patient advocacy groups in the state. Certain exemptions to these disclosure requirements apply.

5. Massachusetts (Mass. Gen. Laws ch. 111N; 105 Mass. Code Regs. 970.000 et seq.)
 - a. *Prohibitions:* Massachusetts law prohibits prescription pharmaceutical and medical device manufacturers from providing or paying for meals for health care practitioners that are: (1) part of an entertainment or recreational event; (2) offered without an informational presentation from the company; or (3) provided to the health care practitioner's spouse or guest.

In addition, prescription pharmaceutical and medical device manufacturers may not provide the following related to a CME event, third-party scientific or educational conference, or professional meeting ("covered event"): (1) financial support for the costs of travel, lodging, or other personal expenses of non-faculty health care practitioners (HCPs) attending a covered event; (2) compensation to a HCP for time spent at a covered event; (3) direct payment to a HCP for meals at a covered event, though an event organizer may apply funding from a company to provide meals to all participants; (4) payment for CME that does not meet the ACCME's Standards for Commercial Support or equivalent standards; or (5) advice on content or faculty of a CME event.

Furthermore, prescription pharmaceutical and medical device manufacturers are prohibited from providing:
(1) entertainment or recreational items of any value;
(2) payments of any kind or in kind items, except as

compensation for bona fide services; (3) complimentary items; (4) grants, scholarships, consulting contracts, or similar support in exchange for prescribing or using prescription drugs, biologics, or medical devices or committing to do the same; or (5) any other payment or remuneration prohibited by state or federal fraud and abuse laws. Certain exemptions from the prohibitions described above may apply.

- b. *Reporting:* For those gifts or payments that are permitted, pharmaceutical and medical device manufacturers are required to annually report any payment, subsidy, or economic benefit of \$50 or more made to a HCP, to the extent that such information was not also reported to a federal agency. Payments for, or the provision of, permitted food items must be reported on a quarterly basis. (As of the date of this memorandum, this reporting requirement has not yet been implemented.) All incidents of non-compliance must also be reported.
- c. *Marketing Code of Conduct:* Pharmaceutical and medical device manufacturers must also adopt a marketing code of conduct in compliance with state regulations. In addition, pharmaceutical and medical device manufacturers must adopt and submit to the state a description of their compliance training program, annually certify that they are in compliance with the regulations, and adopt and submit policies and procedures for investigating, taking corrective action regarding, and reporting non-compliance.

H. State Compliance Program Requirements

1. California (Cal. Health & Safety Code §§ 119400, 119402)

California law requires a pharmaceutical company to implement a comprehensive compliance program that is consistent with the OIG CPG for Drug Manufacturers, including policies for compliance with the PhRMA Code. A “pharmaceutical company” is defined as a manufacturer, repackager, packager, labeler, relabeler, or distributor of “dangerous drugs,” which is in turn defined to include prescription drugs and devices. Pharmaceutical companies must also establish specific dollar limits on gifts and other expenditures to

California medical or health physicians. Companies must post their compliance programs on their web sites and annually declare that they are in compliance with their programs. There is no requirement to submit compliance programs or declarations to the state.

2. Nevada (Nev. Rev. Stat § 639.570; Nev. Admin. Code §§ 639.616-.619, 639.69573-.69577)

Nevada has adopted the PhRMA and AdvaMed Codes into law by reference. Any manufacturer or wholesaler of prescription or OTC drugs or of prescription devices who employs a person to sell or market a product in Nevada must annually submit either a statement that it uses the PhRMA Code or AdvaMed Code (as appropriate) 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 or AdvaMed Code unaltered, it may be required to make changes in its marketing code of conduct to the extent it may be deficient.

3. Massachusetts

See discussion of Massachusetts compliance requirements in Section G.5, above.

4. Connecticut (Conn. Gen. Stat. §§ 21a-70d, 21a-70e)

Connecticut requires manufacturers, repackagers, relabelers, and distributors of prescription drugs, biologics, or medical devices to adopt and implement a code that is consistent with and contains at a minimum the requirements pursuant to the PhRMA Code or AdvaMed Code. The Connecticut law also requires these manufacturers to adopt a comprehensive compliance program in accordance with the OIG CPG for Drug Manufacturers.

I. State Consumer Protection Laws

1. Most states have “little FTC laws” generally prohibiting unfair or deceptive acts or practices.
2. Under these laws, numerous states have brought enforcement actions against drug and device companies challenging a variety of activities, including the following:

- a. *Switch payments:* Cases have been brought regarding companies offering undisclosed payments to pharmacists in return for recommending prescription switches. Several 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 V.F.2.e below.
- b. *Manufacturer-subsidized pharmacy communications:* In Kelley v. CVS Pharmacy, Inc., 23 Mass. L. Rptr. 87 (Mass. Sup. Ct. 2007), the court held that it is an unfair act or practice for a pharmacy to use customer information for its own financial gain without the consent of the pharmacy customer. CVS sent letters on its own letterhead to certain of its customers who had been prescribed certain medications suggesting that the customer could benefit from taking a cholesterol drug. 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.
- c. *Off-label promotion:* In October 2008, Pfizer settled consumer protection act claims in a multi-state settlement for approximately \$60 million to 32 states, related to alleged off-label promotion of Bextra for uses that FDA had expressly rejected. The settlement included a Consent Judgment requiring Pfizer to submit all direct-to-consumer (DTC) advertisements to FDA; comply with any FDA comment prior to running the advertisement; refrain from deceptive and misleading advertising and promotion of any Pfizer drug; and ensure that subjects in Pfizer-sponsored clinical trials receive adequate informed consent.

- d. *False promotion:* In July 2009, Merck & Co. Inc., Schering-Plough Corporation, and a joint venture of the two companies paid \$5.4 million and entered into an Assurance of Voluntary Compliance (AVC) and Stipulated General Judgment with 36 states to resolve the states' investigation into the companies' alleged delay in reporting adverse study results of cholesterol drug Vytorin. The study indicated that Vytorin was no more effective in reducing formation of plaque in carotid arteries than a generic drug. The companies promoted Vytorin in DTC advertisements during the time period between the date of study completion and publication of the results.
- e. *Non-disclosed conflicts of interest:* In May 2009, device manufacturer Synthes Inc. agreed to pay \$236,000 to settle allegations, pursuant to the New Jersey Consumer Fraud Act, that it failed to disclose financial conflict of interests, in the form of stock, of clinical investigators conducting studies of the device maker's products. Under the settlement, Synthes was obligated to collect, maintain, and disclose to New Jersey accurate data relating to the financial interests of all clinical investigators involved in all ongoing and future clinical trials for the company's medical devices.

J. 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).
2. Certain states specifically prohibit the receipt of remuneration in return for prescribing or promoting the sale of drugs or devices. See, e.g., La. Rev. Stat. Ann. § 37:1285(A)(19).

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.

K. PhRMA Code

1. In July 2002, PhRMA issued a revised version of 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.
2. As discussed above, 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.
3. California, Connecticut, and Nevada require pharmaceutical manufacturers to adopt compliance programs consistent with the PhRMA Code.
4. Among other things, the PhRMA Code provides that:
 - a. *Branded gifts*: 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. *Meals*: 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. 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 HCPs at a restaurant to ensure that the program complies with FDA requirements).

- c. *Prohibition on entertainment:* Entertainment and recreational events (such as golf or sporting events) aimed at HCPs may not be provided by pharmaceutical companies.
- d. *Consulting agreements:* Consulting agreements are appropriate and compensation and expense reimbursement may be provided to a HCP, provided that the HCP is rendering legitimate services for the pharmaceutical company.
- e. *Training:* Drug companies must ensure that their sales representatives receive adequate training about the laws, regulations, and industry codes of practice that govern interactions with HCPs.
- f. *Disclosure to formularies:* Drug companies that have retained a HCP who is a member of a committee that develops formularies or clinical practice guidelines must require the HCP to disclose those services to the committee for at least two years after the termination of the arrangement.
- g. *Prescriber data:* Companies should take steps to ensure the responsible use of prescriber data. Companies should respect the wishes of any HCP who does not want his prescriber data disclosed to sales representatives.
- h. *Certification:* Company CEOs and Compliance Officers should certify each year that they have processes in place to comply with the PhRMA Code.

L. AdvaMed Code

1. The Advanced Medical Technology Association (AdvaMed) has issued a “Code on Ethics on Interactions with Healthcare Professionals.” Initially issued in 2005, the AdvaMed Code was revised on December 18, 2008. The revised Code went into effect on July 1, 2009. Like the PhRMA Code, the AdvaMed Code is a voluntary code with which AdvaMed members have undertaken to comply.

2. Connecticut and Nevada require device manufacturers to adopt compliance programs consistent with the AdvaMed Code.
3. Among other things, the revised AdvaMed Code provides that:
 - a. *Branded gifts:* Branded items that do not have educational value or benefit patients such as pens, clipboards, and mugs may not be given to physicians, even if the items only have nominal value. A company may occasionally offer items that serve a genuine educational function for HCPs or that benefit patients. Any item should have a value of \$100 or less, except for medical textbooks or anatomical models used for educational purposes. Items for the benefit of patients include starter kits and educational brochures, but do not include scrubs or office supplies.
 - b. *Prohibition against entertainment:* Entertainment and recreational events (such as theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips) for HCPs may not be provided by medical device companies.
 - c. *Modest meals associated with HCP business interactions:* A medical device company may provide modest meals as an occasional business courtesy in connection with business interactions with HCPs that involve the presentation of scientific, educational, or business information. The meal should be incidental to the bona fide presentation of scientific, educational, or business information and be presented in a manner conducive to the presentation of the information. A business presentation does not include development of good will or business relationships. The company may only provide meals for health care professionals who actually attend the meals. The meal should not be part of entertainment or a recreational event. Company should offer meals at a location conducive to bona fide scientific, educational, or business discussions, including HCP's site or off-site if the HCP's site is inappropriate or impractical.

- d. *Conference meals and refreshments:* The company may provide funding to a conference sponsor to support the provision of meals and refreshments to conference attendees. The company may provide meals and refreshments directly if provided to all HCP attendees and in a manner consistent with the standards of the sponsor of the conference and the body accrediting the educational activity (meals can be provided to only some of the attendees if the meals meet the requirements of meals associated with bona fide business interactions described above). Meals and refreshments must be modest in value and subordinate in time and focus to the purpose of the conference and must be clearly separate from the CME portion of the conference.
- e. *Evaluation and demonstration products:* Companies may provide single or multiple use products at no charge to allow HCPs to evaluate the product if certain criteria are met.
- f. *Provision of coverage, reimbursement, and health economics information:* Companies may provide accurate, objective, timely, and complete coverage, reimbursement, and health economic information regarding their devices. Moreover, device companies may collaborate with HCPs, patients, and organizations that represent their interests to achieve government and commercial payor coverage decisions, guidelines, and policies, as well as adequate reimbursement levels that allow patients to access medical technologies. The Code provides a list of examples of permissible activities related to coverage, reimbursement, and health economics issues. The Code cautions that companies cannot provide reimbursement support as an unlawful inducement.
- g. *Consulting arrangements with health care professionals:* Companies may pay consultants fair market value compensation for performing bona fide consulting services, provided the services are intended to fulfill a legitimate business need and do not constitute an unlawful inducement.

- h. *Compliance program:* The Code “strongly encourages” companies to adopt the Code and to implement an effective compliance program that incorporates the following seven elements:
 - (1) Written policies and procedures
 - (2) Compliance officer and committee
 - (3) Effective training and education
 - (4) Effective lines of communication including a mechanism for anonymous reporting
 - (5) Internal monitoring and auditing
 - (6) Enforcement through well-publicized disciplinary guidelines
 - (7) Prompt response to problems and corrective action
- i. *Certification Program:* The Code “strongly encourages” companies who adopt the Code to certify annually that they have adopted the Code and implemented an effective compliance program. The CEO and chief compliance officer, or individuals with equivalent responsibilities, must sign the certification.

M. Health Care Fraud (18 U.S.C. § 1347)

- 1. Prohibited Acts
 - a. Knowingly and willfully
 - b. executing, or attempting to execute a scheme or artifice
 - (1) to defraud any health care benefit program; or
 - (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or 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. “Health care benefit programs” include both public and private medical benefit plans. 18 U.S.C. § 24(b).
3. Penalties
 - a. Imprisonment for not more than 10 years (20 years if serious bodily injury results; up to life imprisonment if death results).
 - b. Fines
4. Paying kickback, by itself, is insufficient to establish health care fraud
 - a. A 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 to comply with Medicare requirements, constituted a knowing misrepresentation, and therefore health care fraud, where the individual continued to pay kickbacks after signing the form. United States v. Medina, 485 F.3d 1291, 1297-98 (11th Cir. 2007). See also United States v. Luis, No. 12-cv-23588, 2013 WL 4757838 (S.D. Fla. June 21, 2013).

V. PROBLEM AREAS FOR DRUG AND DEVICE MARKETING UNDER THE ANTI-KICKBACK LAWS

A. Free Goods, Services, and Other Benefits

1. 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 anti-kickback laws if they could influence the recipient’s prescribing or utilization decisions. Programs that link the receipt of a free good, service, or benefit to prescribing or utilization volume are at particular risk.

2. 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 35,952, 35,978 (July 29, 1991).
 - 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 in which OIG cautioned about the provision of free office equipment, health care supplies, and services provided to HCPs.
 - d. Free product support services: The OIG’s CPG for Pharmaceutical Manufacturers cautions that value-added services potentially implicate the anti-kickback statute. According to the OIG, limited reimbursement support services and other services that are tailored to the purchased products and have no independent value may not implicate the anti-kickback law, unless they are combined with another program that confers a benefit on a referring provider. 68 Fed. Reg. at 23,735.
 - e. Value added services related to products may be eligible for protection under the eligible managed care organization safe harbor.
 - f. Examples of advisory opinions – problematic free goods or services

(1) Advisory Opinion No. 06-16 (Oct. 3, 2006)

DME manufacturer proposed to provide advertisement assistance and reimbursement consulting services to certain of its DME supplier customers. The manufacturer either would directly develop and pay for the DME supplier's advertising of the 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. 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 No. 02-14 (Sept. 30, 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 CMP provision 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 anti-kickback statute if the intent to induce referrals of items or services reimbursable by federal health care programs was present.

(3) Advisory Opinion No. 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.

g. Examples of advisory opinions – permissible free goods or services

(1) Advisory Opinion No. 12-19 (Nov. 30, 2012)

Closed-door pharmacy supplying community homes for the disabled offered customers free use of web-based software, which could be used to electronically order medications from the pharmacy and to generate state-required forms related to the ordering and use of medications supplied by the pharmacy. Pharmacy also supplied free paper copies of such forms. Citing longstanding policy distinguishing between free items and services that are integrally related to the underlying items or services and those that are not, OIG found the arrangement not to be abusive, primarily because the free software and forms could only be used as part of the underlying pharmacy services and had no independent value. However, OIG disapproved of a related pharmacy proposal to offer customers free licenses to software that could be used for patient and practice management.

(2) Advisory Opinion No. 11-07 (June 1, 2011)

Pediatric vaccine manufacturer proposed to offer cost-free vaccine reminder program to health insurers and health care entities, under which their patients who had already received the vaccine would receive postcard and telephonic reminders that an additional dose was due. The reminders did not specify a specific vaccine or course of vaccination, and did disclose the manufacturer's sponsorship. Though finding that the reminder would financially benefit the participating insurers and providers by defraying expenses they might otherwise incur, and perhaps could increase

office visits, OIG determined not to impose sanctions because the reminders were transparent as to funding, did not recommend any particular vaccine or course of treatment, would not cause overutilization, and would enhance the immunization rate of children.

(3) Advisory Opinion No. 08-05 (Feb. 15, 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 would not implicate either the anti-kickback law or the beneficiary inducement statute. 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.

(4) Advisory Opinion No. 08-02 (Jan. 29, 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 Internal

Revenue Code (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.

(5) Advisory Opinion No. 07-16 (Dec. 5, 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.

3. Examples of enforcement actions

a. Free goods and samples

- (1) In December 2012, Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC, agreed to pay \$109 million to settle qui tam FCA allegations that the company gave physicians kickbacks in the form of free units of Hyalgan, a viscosupplement knee injection, to induce the physicians to purchase and prescribe the product. The government alleged that Sanofi arranged with physicians to give them a negotiated number of free units in return for a specified number of units purchased, in order to effectively lower the price of Hyalgan, with the expectation that the physicians would bill for the free units. The company also

allegedly submitted false ASP reports for Hyalgan that failed to account for the free units contingent on Hyalgan purchases. In addition to the corporate settlement, a district sales manager for Sanofi was excluded from federal health care programs for five years for his role in this activity.

- (2) In December 2012, International Nephrology Network (INN) agreed to pay \$15 million to settle civil FCA allegations that, among other things, INN conspired with Amgen, Inc., manufacturer of Aranesp, to offer kickbacks to prescribers of Aranesp. Amgen allegedly included free drug in the form of unnecessary overfill in Aranesp vials, and Amgen and INN, which distributed Aranesp, allegedly encouraged providers to administer the free overfill to patients and bill Medicare and other government programs for the free overfill. INN also allegedly provided meals, travel, grants, retreats, free consulting services, speaker fees, and other remuneration to providers to influence them to select Aranesp.
- (3) In July 2009, Endoscopic Technologies Inc. (Estech) agreed to pay \$1.4 million to settle FCA allegations. Estech allegedly provided free products such as generators used to power its disposable equipment as well as disposable equipment used to perform surgical ablations such as scopes, trays, and bovie cords in exchange for a commitment to lock in a certain market share for the company's products. Estech also allegedly provided free marketing assistance and referral services to cardiothoracic surgeons to induce them to perform procedures using the company's products.
- (4) In September 2001, TAP Pharmaceutical Products Inc. entered into a plea agreement and \$875 million settlement with the federal government concerning

alleged violations of the anti-kickback law, the FCA, and the PDMA. 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. The company also allegedly provided free office equipment, VCRs, and other items to physicians. Several physicians and at least one sales representative pleaded guilty to charges of conspiring with TAP to defraud Medicare.

In June 2003, AstraZeneca PLC pleaded guilty and paid \$355 million to settle claims similar to those in TAP.

b. Free travel and gifts

- (1) In January 2013, Victory Pharma entered into a plea agreement and \$11.4 million settlement of allegations under the FCA and anti-kickback statute. Victory Pharma was charged with providing kickbacks to practitioners in the form of tickets to professional and collegiate sporting events; tickets to concerts and plays; spa outings; golf and ski outings; dinners at expensive restaurants; and numerous other events to induce physicians to prescribe the company's drugs.
- (2) In October 2011, Dfine, Inc. agreed to pay \$2.39 million to settle allegations that it violated the FCA. Among other activities, Dfine allegedly provided kickbacks in the form of travel expenses, lavish dinners, entertainment, and promotional speaker fees to physicians to induce them to use Dfine devices to treat spinal fractures.
- (3) In December 2010, Elan Corporation, PLC and Elan Pharmaceuticals, Inc. entered into a plea agreement and a \$203 million settlement concerning misdemeanor misbranding under the Federal Food, Drug, and Cosmetic Act (FDC Act) and alleged

violations of the FCA. Among other things, the company allegedly provided kickbacks in the form of expenses paid trips to sham advisory board meetings in resort locales.

- (4) In July 2006, Medtronic, Inc. agreed to pay \$40 million to settle allegations that it violated the FCA. Medtronic allegedly provided kickbacks, including lavish trips to desirable locations, to physicians that used Medtronic spinal implant products.
- (5) In May 2006, Lincare Holdings Inc., a durable medical equipment supplier, agreed to pay \$10 million and entered into a Corporate Integrity Agreement (CIA) to settle an OIG civil monetary penalty proceeding, in which OIG alleged that the company violated the anti-kickback statute and Stark Law. Lincare allegedly provided 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.
- (6) In October 2005, Serono, S.A., and its U.S. subsidiaries, pleaded guilty and entered into a \$704 million settlement agreement concerning charges of marketing adulterated devices under the FDC Act, violations of the anti-kickback statute, and allegations of FCA violations. Among other claims, Serono sales and marketing personnel allegedly promoted Serostim, a drug for AIDS wasting, by offering physicians who increased their prescribing of Serostim a free trip to Cannes, France for a medical conference.

4. Patient Assistance Programs

- a. On November 7, 2005, the OIG issued a Special Advisory Bulletin providing guidance on the application of the fraud and abuse laws to patient assistance programs (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, OIG expressed its concern that manufacturer PAPs that provide cost-sharing assistance (e.g., copayment assistance programs) could violate the federal health care program anti-kickback statute by providing something of value to Federal health care program beneficiaries who use the manufacturer's products.

- b. 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. 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. 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 No. 06-14 (Sept. 21, 2006); Advisory Opinion No. 06-19 (Oct. 26, 2006); Advisory Opinion No. 07-04 (Mar. 30, 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. OIG has also issued several advisory opinions that have declined to impose sanctions on PAPs sponsored by independent charitable organizations that are consistent with the Special Advisory Bulletin. These opinions involve both drugs and devices. See, e.g., Advisory Opinion No. 11-05 (May 13, 2011) (copay assistance to for genetic testing for cancer diagnosis); Advisory Opinion No. 10-19 (Sept. 17, 2010) (in kind donations of DME intended for financially needy individuals); Advisory Opinion No. 10-06 (May 20, 2010) (drug copay assistance); Advisory Opinion No. 07-06 (July 23, 2007) (same); Advisory Opinion No. 07-18 (Dec. 19, 2007) (same); Advisory Opinion No. 06-04 (Apr. 20, 2006) (same); Advisory Opinion No. 06-10 (Sept. 14, 2006) (same).

5. Drug Coupons

a. Drug manufacturers distribute patient coupons and cards, through HCPs, print media, and web sites, that offer dollars off of a patient's drug copayment or cash price. Most often, the coupons are redeemed by the patient at the pharmacy when filling a prescription for the drug, and the pharmacy is reimbursed by the manufacturer for the coupon/card benefit amount.

b. *OIG opposition:* In its Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (Nov. 7, 2005), OIG stated that manufacturer cost-sharing subsidies for Part D drugs would be "squarely prohibited by the [anti-kickback] statute, because the manufacturer would be giving something of value (i.e., the subsidy) to beneficiaries to use

its product.” See also Advisory Opinion 02-13 (Sept. 27, 2002) and Advisory Opinion No. 03-3 (Feb. 3, 2003) (same; Part B drugs).

- c. In light of OIG’s view, most manufacturer drug co-pay coupons typically exclude Federal health care program beneficiaries from eligibility. In its Workplan for FY 2013, OIG announced its intention to conduct investigations of manufacturer co-pay subsidy programs, in order to identify safeguards that drug companies have in place to ensure that Medicare Part D beneficiaries do not use coupons to obtain drugs. OIG reiterated that coupons under federal health care programs implicate the anti-kickback law. HHS OIG Work Plan for FY 2013, at 45.
- d. *Coupons and qualified health plans:* In a letter to Representative Jim McDermott dated October 30, 2013, Secretary of HHS Kathleen Sebelius wrote that HHS does not consider qualified health plans (QHPs) and other programs established under the ACA to be “Federal health care programs” for purposes of the federal anti-kickback statute. This means that coupons for drugs covered by Medicare or Medicaid are not actionable under that law. However, in a November 4, 2013 memorandum, CMS stated that it has “significant concerns” with commercial entities subsidizing cost sharing obligations under QHPs, and “discourages this practice and encourages issuers to reject such third party payments.”
- e. Several states with all-payor anti-kickback laws have taken a more favorable view, enacting exemptions from their anti-kickback laws for prescription drug discounts offered to consumers through coupons and similar programs. See Mass. Gen. Laws ch. 175H, § 3(b); Mich. Comp. Laws § 752.1004a; Minn. Stat. § 62J.23, Subdiv. 2(b); R.I. Gen. Laws § 5-48.1-3(c)(6).
- f. Various union health plans have filed lawsuits alleging that brand-name drug manufacturers violated the Racketeer Influenced and Corrupt Organizations Act (RICO) and committed commercial bribery when they provided co-pay

subsidy coupons to privately-insured consumers for branded prescription drugs. The complaints allege that, by routinely reducing co-pays through their coupon programs, the defendants in these lawsuits undermined the cost-sharing arrangements set up by the health plans with their members, and caused the plans to (1) pay higher reimbursements for the subsidized drug than the true cost of the drug; and (2) pay for more brand-name drugs, at higher prices, instead of lower-cost generics. These cases are in various stages of litigation, and have not yet been settled nor adjudicated definitively. See, e.g., Memorandum and Order, Am. Fed'n of State, Cnty. & Mun. Emps. Dist. Council 37 Health & Sec. Plan v. Bristol-Meyers Squibb Co., No. 12-cv-2238, (S.D.N.Y. June 3, 2013) (opinion granting in part defendants' motion to dismiss); Order on Motion to Dismiss, Plumbers & Pipefitters Local 572 Health & Welfare Fund v. Merck & Co. Inc., No. 12-cv-1379 (D.N.J. Apr. 29, 2013) (opinion granting defendant's motion to dismiss without prejudice); Order on Motion to Dismiss, Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Novartis Pharms. Corp., 12-cv-1403 (D.N.J. June 24, 2013).

- g. Drug and device manufacturers offering consumer coupons should ensure that beneficiaries of federal and state government health care programs are excluded from eligibility, and that the procedures for implementing these exclusions are effective.

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 protects combination discounts when the goods and services are reimbursed by the same Federal health care program using the “same methodology.” 42 C.F.R. § 1001.952(h)(5)(ii).
 - a. In a proposed change to discount safe harbor, OIG would have specified that “same methodology” means same DRG, prospective payment, or per diem, but does not include fee schedules. 65 Fed. Reg. 63,035, 63,041 (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. 11,928, 11,930 (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.”
- 5. OIG has especially objected to combination discounts that “shift” the discount away from Medicare or Medicaid. See 64 Fed. Reg. at 63,530.
 - 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 No. 99-2 (Feb. 26, 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 No. 02-10 (July 30, 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, OIG concluded that the discount safe harbor 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 anti-kickback 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 No. 01-8 (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 No. 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. In June 2003, Abbott Laboratories Ross Products Division pleaded guilty and entered into a \$382.4 million settlement concerning allegations that it violated the FCA and charges that it obstructed a criminal investigation of a health care offense. 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 representatives 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."
- b. In January 2000, Fresenius Medical Care AG pleaded guilty and entered into a \$486 million settlement concerning allegations that it violated the FCA and charges that company subsidiaries violated the anti-kickback statute and/or conspired to defraud the government. 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). Several company officials also were indicted. See United States v. Shaw, 106 F. Supp. 2d 103 (D. Mass. 2000).

- c. United States 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 anti-kickback law, but physician was acquitted because Medicare carriers had previously approved of the discounts.

8. “Swapping”

- a. OIG uses the term “swapping” to describe a type of bundled discount where a seller offers a discount on items or services that are not covered by Medicare or Medicaid to induce the customer to refer business that is covered by these federal programs.
- b. For example, in Advisory Opinion No. 99-13 (Nov. 30, 1999), a pathologist provider offered discounts to referring physicians on their non-Federal health care program patients, with the expectation that the physicians would refer their Federal health care program beneficiaries for pathology services. OIG found that the arrangement posed a significant risk of improper “swapping”.
- c. In Advisory Opinion No. 12-09 (July 23, 2012), OIG cautioned that one of the primary indicia of improper swapping was the offer of a discount on non-federal business

that is below cost or otherwise commercially unreasonable. Such discounts give rise to an inference that the provider may be swapping the below-cost rates for non-discounted, federally-reimbursed business. See also Advisory Opinion No. 11-11 (July 28, 2011) (same).

d. Enforcement

- (1) In May 2011, Quest Diagnostics, Inc. and its subsidiaries agreed to pay \$241 million to settle allegations that it violated the California FCA. The companies allegedly provided capitated and fee-for-service discounts on laboratory tests for non-Medi-Cal patients to induce purchasers to refer Medi-Cal patients to laboratory. See also Laboratory Corporation of America (LabCorp) August 2011 settlement resolving almost identical allegations.
- (2) In October 2013, Omnicare announced a \$120 million settlement of a qui tam FCA case alleging that Omnicare engaged in “swapping.” The Department of Justice declined to intervene in the case. Omnicare allegedly paid nursing homes kickbacks in the form of discounted prescription drugs for Medicare Part A patients, to induce the nursing homes to obtain drugs from Omnicare for their Medicare Part D patients. Payment for Part A drugs is included in a fixed prospective payment, while Part D drugs are reimbursed separately.

C. Consulting or Service Fees

1. Pharmaceutical and device companies provide remuneration to individuals or entities who are customers or potential customers to obtain a variety of services. For example, fees are paid to physicians for serving as consultants or advisors on scientific or marketing matters, for serving as speakers on behalf of the company, or for serving as investigators in clinical or other investigations.

2. Consulting fee arrangements have been targeted by the government where they are tied to prescribing practices or utilization of the company's products, 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.

3. Enforcement actions involving consulting fees
 - a. In December 2013, Abbott Laboratories paid \$5.475 million to settle FCA allegations that the company paid kickbacks to physicians to induce them to arrange for the hospitals with which they were affiliated to purchase Abbott's carotid, biliary, and peripheral vascular products. The alleged kickbacks took the form of payments for teaching assignments, product training assignments, speaking engagements, and other physician education consulting engagements.
 - b. In October 2011, Pfizer, Inc. agreed to pay \$14.5 million to settle allegations that it violated the FCA. Among other allegations, Pfizer allegedly provided kickbacks in the form of preceptorships, consulting opportunities, speaking opportunities, and journal clubs.
 - c. In February 2008, Merck & Co. Inc. agreed to pay \$650 million to settle FCA allegations that, among other things, the company provided kickbacks in the form of preceptorships, speaker fees, and consultant and advisory board fees to induce physicians to prescribe its drugs.
 - d. In September 2007, four orthopedic implant manufacturers -- Zimmer Inc., Depuy Orthopedics, Inc., Biomet Inc., and Smith and Nephew, Inc. -- pleaded guilty, entered into 18-month deferred prosecution agreements, entered into a civil settlement and entered into a five-year CIA concerning allegations that they violated the FCA, and charges that they violated the anti-kickback statute. Each of the four companies 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. 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 physicians' 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.

- e. In July 2007, Bristol-Myers Squibb agreed to pay over \$515 million to settle allegations that it violated the FCA. From 2000-2003, the Company allegedly provided 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.
- f. In July 2006, Medtronic, a medical device manufacturer, agreed to pay \$40 million and entered into a CIA to settle allegations that it violated the FCA by paying kickbacks to physicians who used Medtronic spinal implant products, including allegedly sham consulting agreements and sham royalty agreements.
- g. On July 30, 2004, Schering-Plough Corp. pleaded guilty and agreed to pay \$435 million in civil and criminal fines concerning allegations that the company violated the FCA and charges that subsidiary Schering Sales Corporation violated 18 U.S.C. § 1001 prohibiting false statements. Schering-Plough Corporation allegedly paid illegal remuneration to its managed care customers in exchange for retaining Claritin on the customer's formulary, in violation of the anti-kickback statute and the FCA. 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. Schering Sales Corporation was excluded from participating in federal health care programs for five years.

4. Drug and device 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 to the conditions of the personal services safe harbor, particularly those relating to fair market value compensation. 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 under the anti-kickback law where they were linked to prescribing practices; provided for research with questionable scientific value; and/or were excessive for the research performed. Educational grants have also been challenged where offered for purposes that did not relate to education, or offered to induce or reward product purchases or prescribing.
2. OIG guidance
 - a. "Special Fraud Alert on Prescription Drug Marketing Schemes" objected to grants for research of questionable scientific value.
 - b. The CPG for Pharmaceutical Manufacturers advised that research funding must be fair market value for legitimate, reasonable, and necessary services. OIG cautioned against research grants linked directly or indirectly to the purchase of product, or the misuse of research grants to induce purchases without triggering Medicaid best price obligations.

OIG also cautioned that research and educational grants should not be conditioned on the purchase of product, even if the research or educational purpose is legitimate. OIG

recommended that a manufacturer's educational and research grant-making processes be insulated from sales and marketing functions. 68 Fed. Reg. at 23,735-36.

3. Examples of enforcement actions involving grants
 - a. In May 2012, Abbott Laboratories pleaded guilty and agreed to pay a total of \$1.5 billion in criminal and civil fines in connection with allegations that the company violated the FCA and charges of misdemeanor misbranding under the FDC Act. Among other activities, the company allegedly paid physicians to conduct studies as a reward for prescribing the drug.
 - b. In June 2011, Novo Nordisk, Inc. agreed to pay \$25 million to settle allegations that it violated the FCA by, among other things, providing physicians unrestricted educational grants to induce prescribing of the company's drug.
 - c. In April 2011, Serono Laboratories Inc., EMD Serono Inc., Merck Serono S.A, and Ares Trading S.A. agreed to pay \$44.3 million to settle allegations that the companies violated the FCA. Among other activities, the companies allegedly provided kickbacks in the form of grants to write prescriptions of the multiple sclerosis drug Rebif.
 - d. In December 2010, Kos Pharmaceuticals pled guilty and agreed to pay over \$40 million total in civil and criminal fines in connection with allegations that violated the FCA and conspired to violate the federal anti-kickback statute. Among other alleged activities, the company allegedly provided kickbacks in the form of grants to induce physicians to prescribe or recommend Niaspan and Advicor.
 - e. In February 2008, Merck & Co., Inc. agreed to pay \$650 million to settle claims that it violated the FCA. Among other activities, the company allegedly offered educational grants, grants for computers, and fees for sham "clinical experience" studies and focus groups, to induce doctors to prescribe its drugs.

- f. In April 2007, Cell Therapeutics, Inc. agreed to pay \$10.5 million to settle allegations that it violated the FCA by, among other things, offering grants for sham clinical studies that required little work on the part of the physicians to induce physicians to prescribe its orphan drug, Trisenox.

E. “Seeding Studies,” Registries, and Other Post-Marketing Studies

- 1. The government has used the term “seeding studies” to refer to post-marketing studies or registries involving payments to investigators where the study or registry is conducted primarily for marketing reasons rather than to generate useful scientific data.
- 2. In the CPG for Pharmaceutical Manufacturers, OIG cautioned that “[p]ost-marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug.” 68 Fed. Reg. at 23,735.
- 3. Examples of enforcement actions involving post-marketing studies and registries
 - a. In July 2013, Amgen paid over \$15 million to settle a qui tam FCA lawsuit alleging that the company paid unlawful kickbacks to physicians in the form of payments for data. Under a postmarketing program called “Deep Dive,” Amgen allegedly paid physicians who prescribed the company’s chemotherapy drug a fee to fill out a brief Internet questionnaire.
 - b. In December 2011, Medtronic, Inc. agreed to pay \$23.5 million to settle allegations that it violated the FCA. Among other activities, Medtronic allegedly used two post-market studies and two device registries as a means to pay participating physicians illegal kickbacks to induce them to implant Medtronic pacemakers and defibrillators. The studies and registries required a new or previous implant of a Medtronic device in each patient. Medtronic paid participating physicians a fee ranging from approximately \$1,000 to \$2,000 per patient.

- c. In October 2011, DFine, Inc. agreed to pay \$2.39 million to settle allegations that it violated the FCA. The company allegedly used customer surveys known as User Preference Evaluations (UPE) to pay participating physicians illegal kickbacks to induce them to use the company's vertebral augmentation devices for Medicare beneficiaries. The UPE survey allegedly required use of a new DFine device in each patient. DFine paid physicians \$250- \$500 per patient to participate in the survey.
- d. In January 2011, St. Jude Medical agreed to pay \$16 million to settle allegations that it violated the FCA. The Company allegedly used three post-market studies and a registry to increase device sales by paying certain physicians to select St. Jude pacemakers and implantable cardioverter defibrillators. The company allegedly paid each participating physician up to \$2,000 per patient to participate.
- e. In December 2009, Guidant Corp. agreed to pay \$22 million to settle allegations that it violated the FCA. The company allegedly designed and used four post-marketing studies to increase sales of certain of the company's devices by paying physicians to select Guidant cardiac rhythm management (CRM) devices to implant in their patients rather than devices manufactured by Guidant's competitors. Each of the studies required participating physicians to implant multiple Guidant CRM devices (three-to-five devices depending on the study) and, in each study, Guidant paid each participating physician a fee (\$1,000 to \$1,500 depending on the study).
- f. In May 2008, Biovail Pharmaceuticals, Inc. 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 studies, companies should have policies 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.

F. Payments to Pharmacists

Drug companies provide compensation to pharmacies for providing patient counseling on the use of a particular drug, providing educational or promotional materials to patients, distributing refill reminders, 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 anti-kickback law or state consumer protection laws.

1. 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.

2. Enforcement

- a. In October 2013, Johnson and Johnson (J&J) paid over \$2.2 billion to settle criminal liability under the FDC Act and civil claims under the FCA involving off-label promotion and alleged kickbacks to physicians and nursing home pharmacy chains. With regard to the pharmacy chain claims, the FCA complaint alleged that J&J paid market share rebates, data-purchase fees, grants, and educational funding to nursing home pharmacy chain Omnicare, in return for Omnicare implementing “active intervention programs” designed to influence nursing home residents’ physicians to prescribe J&J drugs.
- b. In April 2013, Amgen Inc. agreed to pay \$24.9 million to resolve allegations that it violated the FCA. The company allegedly provided kickbacks to several long-term care pharmacy chains, in the form of performance-based market share or volume rebates. In return, the nursing home pharmacy chain allegedly implemented therapeutic interchange programs designed to switch nursing home patients to Aranesp.
- c. In May 2012, Abbott Laboratories pleaded guilty and agreed to pay \$1.5 billion in criminal and civil fines to settle allegations that the company violated the FDC Act by engaging in off-label promotion, and violated the FCA by, among other things, providing rebates to long term care pharmacy providers based on increases in the use of diabetes drug Depakote in the nursing homes serviced by the pharmacy providers.
- d. In Kelley v. CVS Pharmacy, Inc., 23 Mass. L. Rptr. 87 (Mass. Sup. Ct. 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.

- e. In separate multi-state actions in 1993-94, three drug companies were charged with violations of state consumer protection laws for having allegedly paid pharmacists on a per-patient basis for providing counseling on particular drugs and for completing questionnaires on new patients. The states alleged that the purpose of the payments was to induce pharmacists to call physicians to obtain prescription "switches" to the company's 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 re American Cyanamid Co., Sept. 8, 1993 (\$50,000); Assurance of Discontinuance/Assurance of Voluntary Compliance, In re Miles, Inc., March 28, 1994 (\$605,000); Assurance of Discontinuance/Assurance of Voluntary Compliance, In re Upjohn Company, July 29, 1994 (\$675,000).
3. 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.

G. Payments to PBMs

1. Pharmaceutical manufacturers often provide compensation and/or rebates to PBMs for formulary access, a particular formulary position, achieving specified market share percentages, or for other marketing activities.
2. OIG has stated that these compensation arrangements may implicate the anti-kickback statute, and OIG is particularly critical of fee-per-switch arrangements. 68 Fed. Reg. at 23,736, 23,738. However, the

CPG for Drug Manufacturers suggests that rebates to PBMs may fit within the safe harbor for payments to GPOs, 42 C.F.R. § 1001.952(j). See 68 Fed. Reg. at 23,736. 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.

3. Examples of enforcement actions
 - a. 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.
 - b. In April 2007, Pfizer subsidiary Pharmacia & Upjohn Company, Inc. pled guilty to a violation of the anti-kickback 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.
 - c. In September 2005, PBM AdvancePCS settled FCA 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. As part of the

settlement, AdvancePCS agreed to more transparency in its rebate contracts, and to provide more detailed information to its member plans.

- d. In 2004 and 2006, PBM Medco Health Solutions settled claims under the Federal Anti-Kickback Act and state consumer protection laws, in which the government alleged that 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. Medco paid \$137.5 million to settle the federal claims and \$29.2 million to settle the state claims.

VI. FALSE CLAIMS LIABILITY FOR DRUG AND DEVICE MARKETING ACTIVITIES

A. Potential Liability of Pharmaceutical and Device Companies

1. Although pharmaceutical and device manufacturers generally do not submit claims to Medicare, Medicaid, or other programs, they are potentially subject to liability under false claims laws for:
 - a. Antikickback law violations;
 - b. Providing inappropriate advice on coding and reimbursement;
 - c. Manipulation of AWP or ASP (drugs);
 - d. Underpayment of Medicaid Rebates (drugs); and
 - e. FDC Act violations

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

1. Prohibits, among other things:
 - a. Knowingly presenting or causing to be presented a false or fraudulent claim for payment.
 - b. Knowingly using or causing to be used a false record or statement material to a false or fraudulent claim.
 - c. Knowingly using or causing to be used a false record or statement material to an obligation to pay money to the government.
 - d. Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the government.
2. Civil penalty of \$5,500 to \$11,000 per claim plus three times damages (two times damages if self-report within 30 days after knowledge of violation).
3. “Knowing” defined as
 - a. actual knowledge;
 - b. acting in deliberate ignorance of the truth or falsity of the information; or
 - c. acting with reckless disregard of the truth or falsity of the information.
 - d. No specific intent to defraud government required.
4. Causing the submission of false or fraudulent claims may violate the FCA even if the entity actually submitting the claim is “innocent” -- i.e., does not know that the claim being submitted is false. See e.g., United States ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 343 (D. Mass. 2011) (defendant alleged to have caused practitioners to submit false claims through off-label promotion).

5. Qui Tam provision (31 U.S.C. § 3730)

- a. Though 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 intervene and take over prosecution, relator receives 15-25% of any award or settlement, depending on his/her contribution to the prosecution of the suit. If government declines to intervene, relator receives 25-30% of award or settlement. Percentages may be reduced by court if relator planned and initiated the violative conduct.
- c. Relators are frequently current or former employees of the defendant.

C. Kickbacks as Basis for FCA Liability

1. Pre-ACA law

- a. Prior to the enactment of the ACA, with some exceptions, courts generally permitted the government and qui tam relators to proceed under the FCA with claims based on anti-kickback law violations, relying on either an express or an implied certification theory. See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12, 17-18 (D. Mass 2007) (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”).
- b. The government and relators routinely alleged that antikickback law violations were also violations of the FCA.

Many of the settlements described in Section V involved FCA allegations founded on kickback violations.

2. ACA amendment to the anti-kickback law
 - a. Effective March 23, 2010, the ACA amended the anti-kickback law to provide that a claim submitted to a Federal health care program that includes items or services resulting from an anti-kickback law violation constitutes a false claim for purposes of the FCA. ACA § 6402(f)(1); 42 U.S.C. § 1320a-7b(g).
 - b. This permits private individuals (e.g., current or former employees) to bring antikickback allegations under the FCA's qui tam provisions, even though there is no private right of action under the antikickback law itself.

D. Liability for Providing Reimbursement Advice

1. Some drug and device companies provide advice to customers or potential customers on reimbursement coding to use for a product, for a procedure in which the product is used, or for a test used to determine the need for the product.
2. Drug and device companies and health care consultants have been prosecuted for allegedly giving improper coding advice to providers, thereby causing false claims to be submitted.
 - a. In February 2010, Atricure, Inc. agreed to pay \$3.79 million to settle allegations that it violated the FCA. The relator alleged that the company advised hospitals to upcode its surgical ablation device for atrial fibrillation.
 - b. In July 2009, Endoscopic Technologies Inc. (Estech) paid \$1.4 million to settle allegations that it violated the FCA. Among other things, the relator alleged that the company advised hospitals that they could maximize revenue by upcoding use of the device in a minimally invasive, closed chest procedure to a procedure code for open-heart surgery to

obtain an excess reimbursement of approximately \$20,000 per procedure.

- c. In May 2008, Medtronic Spine, formerly Kyphon Inc., agreed to pay \$75 million to settle allegations that it violated the FCA. 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.
 - d. In June 2003, Abbott Laboratories Ross Products Division 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.
3. Advising customers on coding of products or related procedures or diagnostic tests could be risky where coverage or the appropriate coding is ambiguous. If coding advice is provided, it should be conservative and the customer should be clearly notified that it has responsibility for determining the appropriate reimbursement coding.
 4. The mere provision of limited, product-specific reimbursement assistance does not violate the anti-kickback law. In an advisory opinion, 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 anti-kickback law. OIG, Advisory Opinion No. 00-10 (Dec. 15, 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 did not have any substantial value independent of the product. See also Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003). But see Advisory Opinion No. 06-16 (Oct. 3, 2006) (proposed reimbursement consulting services not free-standing or limited in nature and would potentially provide substantial independent value to DME supplier).

E. Inflation of AWP/ASP

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

2. *Federal FCA cases:* The Department of Justice and qui tam relators have brought lawsuits under the FCA challenging drug company practices involving inflating reported AWP while reducing or maintaining net prices to purchasers. In these cases, the government or qui tam relators allege 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. The government and relators have alleged that these practices caused false claims to be presented to Medicare and/or Medicaid. A number of drug companies, including the following, have settled cases involving these allegations, often combined with other allegations:
 - Bayer Corporation, September 2000 -- \$14 million
 - TAP Pharmaceutical Products, Inc., September 2001 -- \$875 million
 - Astra Zeneca, June 2003 -- \$355 million
 - GlaxoSmithKline, September 2005 -- \$150 million
 - Bristol-Myers Squibb, September 2007 -- \$515 million
 - Aventis Pharmaceuticals, September 2007 -- \$190 million.
 - Dey L.P., December 2010 -- \$208 million
 - Abbott Laboratories, Inc., B. Braun Medical Inc. and Roxane Laboratories Inc., December 2011 -- \$421 million collectively

3. *State cases:* Several states have filed lawsuits against numerous pharmaceutical manufacturers alleging 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 AWP or WACs.

- a. See, e.g., Complaint, Massachusetts v. Mylan Labs, Inc., No. 03-cv-11865 (D. Mass. Sept. 25, 2003). In this case, 10 defendants settled with the state before trial for \$20.3 million. Warrick Pharmaceuticals went to trial and ultimately settled on appeal for \$24 million.
- b. In a series of separate lawsuits brought by Texas alleging that manufacturers inflated wholesaler prices they reported to the state, 14 drug manufacturers have settled since 2003 for a total of \$342.1 million.
- c. Lawsuits brought by Wisconsin against a number of drug manufacturers alleging inflation of AWP are ongoing. In June 2012, the Wisconsin Supreme Court ruled in favor of the state on certified questions in connection with a \$9 million verdict against Pharmacia.
- d. In 2010, Louisiana sued over 100 drug manufacturers alleging inflation of AWP. Over a three year period ending in November 2013, all of the companies settled for a combined amount of \$238 million.
- e. Drug manufacturers have prevailed in certain state cases
 - (1) In July 2012, the Alabama Supreme Court reversed a jury verdict against Sandoz, ruling that the state had knowledge that Sandoz's published prices were not net prices.
 - (2) In 2009 the Alabama Supreme Court reached a similar decision on an appeal by brand manufacturers.
 - (3) In October 2012, the Kentucky Court of Appeals reversed jury verdicts against Sandoz (\$16 million) and AstraZeneca (\$114.7 million), finding that the state had failed to establish causation for any damages.

4. Private individuals and employer plans have also brought cases against numerous drug companies alleging that AWP inflation and marketing of the spread caused private 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, No. 01-cv-12257 (D. Mass., June 12, 2003). In September 2009, U.S. Court of Appeals for the 1st Circuit affirmed district court rulings awarding \$13 million in damages against AstraZeneca. Eighteen other drug manufacturers settled in March 2008 for a total of \$125 million.
5. Inflation of ASP
 - a. In December 2012, Sanofi-Aventis U.S. Inc. and Sanofi-Aventis U.S. LLC, agreed to pay \$109 million to settle qui tam FCA allegations that the company gave physicians free units of Hyalgan, a viscosupplement knee injection, in return for purchases of a specified number of units. In addition to allegations that the free units violated the antikickback law, the government alleged that Sanofi submitted false ASPs by failing to account for the free units, which resulted in an inflated Medicare payment rate for Hyalgan.

F. Underpayment of Medicaid Rebates

1. Pharmaceutical manufacturers must pay quarterly rebates to each state on outpatient drugs dispensed in the state to Medicaid beneficiaries. Rebate for NDA drugs equals greater of 23.1% of AMP or difference between AMP and single best price to non-federal customer. Rebate for non-innovator (ANDA) drugs equals 13% of AMP. 42 U.S.C. § 1396r-8. Pharmaceutical manufacturers report AMP and best price to CMS.
2. 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. OIG also noted the importance of calculating AMP and best price accurately. Id.

3. A number of drug manufacturers have been targeted in FCA cases for allegedly decreasing their Medicaid rebates by reporting inflated best prices or reduced AMPs, or by incorrectly reporting their drugs as non-innovator drugs; rather than innovator drugs. Following are examples of such cases.
 - a. In July 2012, GlaxoSmithKline (GSK) paid \$3 billion to settle criminal liability under the FDC Act and civil claims under the FCA involving off-label promotion, alleged kickbacks, and alleged price reporting violations. With regard to the latter, GSK allegedly gave nominal pricing to certain customers on condition that the customer purchase other products, but failed to take the low prices into account as bundled discounts in Medicaid Rebate best price, thereby reducing its Medicaid rebates.
 - b. In February 2012, Dava Pharmaceuticals paid \$11 million to settle FCA claims that the company incorrectly designated certain of its innovator drugs as non-innovator drugs in order to pay the lower Medicaid rebate applicable to those drugs, and also miscalculated AMP, resulting in reduced Medicaid rebates.
 - c. In October 2009, Mylan Pharmaceuticals, UDL Laboratories, AstraZeneca Pharmaceuticals, and Ortho-McNeil Pharmaceutical settled allegations that they underpaid Medicaid rebates by incorrectly classifying several “innovator” authorized generic drugs as “non innovator” drugs subject to lower rebates. UDL and Mylan paid a combined amount of \$118 million; AstraZeneca agreed to pay \$2.6 million. Ortho-McNeil agreed to pay \$3.4 million.
 - d. In May 2009, Aventis Pharmaceuticals Inc. agreed to pay \$65 million to settle FCA allegations that it sold private labeled Azmacort, Nasacort, and Nasacort AQ to Kaiser Permanente Medical Care Program and its affiliate Group Health Cooperative and failed to include the sale in best price, thereby reducing its Medicaid rebates.

- e. In November 2005, King Pharmaceuticals Inc. paid \$124 million to settle FCA allegations that King's procedures, methodologies, and training for price reporting were severely deficient, causing false AMP and best price reports and non-federal average manufacturer price (non-FAMP) reports. Those false reports allegedly resulted in underpayment of Medicaid Rebates and overcharges to Department of Veterans Affairs (VA) facilities and 340B covered entities.
- f. In October 2002, Pfizer Corporation settled allegations that it allegedly misreported the Lipitor Medicaid rebate best price by concealing cash discounts to key managed care customers in exchange for favorable status on the managed care organization's formulary. Pfizer settled those allegations for \$49 million.

G. False Certification of Compliance in Corporate Integrity Agreement (CIA) as Basis for FCA Liability

- 1. In September 2007, the Department of Justice (DOJ) brought an FCA action for over \$30 million in damages and penalties against Christi R. Sulzbach, the Associate General Counsel and corporate integrity program director at Tenet Healthcare Corporation. DOJ alleged that Ms. Sulzbach violated the FCA when she submitted false declarations of compliance with health care laws in a CIA imposed on Tenet's predecessor, National Medical Enterprises, despite knowing about Stark Law violations committed by a Tenet hospital. This allegedly caused the government to pay \$18 million in Medicare reimbursements which it otherwise would not have paid. The case was ultimately dismissed as barred by the statute of limitations. United States v. Sulzbach, No. 07-cv-61329, 2010 WL 1531492 (S.D. Fla. Apr. 16, 2010).
- 2. Under recent CIAs, numerous specified corporate officers and employees are required to annually certify that their applicable business units comply with the CIA and with Federal health care program requirements and/or FDA requirements. See, e.g., CIAs between HHS OIG and Johnson & Johnson (Oct. 2013); Par Pharmaceutical, Inc. (Mar. 2013); GlaxoSmithKline (July 2012);

Abbott Laboratories (May 2012). Although the Sulzbach case was dismissed, it demonstrates the government's willingness to sue responsible officers and management personnel for false CIA certifications where the company is not compliant.

H. 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 basic theory in these cases is that, by promoting off label uses, the company caused claims for reimbursement to be submitted to Medicare and/or Medicaid, and the claims were false because the off-label uses were not medically accepted indications covered under state Medicaid programs. In many cases, communications made in the course of the defendant's off-label promotion are also alleged to be false or misleading. In most, but not all, of these cases, the FCA claims are accompanied by criminal charges under the FDC Act. Some examples of these cases are described below.
 - a. On November 4, 2013, Johnson & Johnson (J&J) and its subsidiary, Janssen Pharmaceuticals, paid over \$2.2 billion to resolve criminal and civil liability regarding the company's promotion of Risperdal, Invega, and Natrecor. J&J pleaded guilty to misbranding under the FDC Act for off-label promotion of Risperdal, and also settled FCA claims that the company had promoted Risperdal, Invega, and Natrecor for off-label indications, paid kickbacks to physicians to induce them to prescribe Risperdal, and paid kickbacks to nursing home pharmacy chain Omnicare to induce the switching of patients to Risperdal from competing drugs.

According to the Criminal Information, although Risperdal was approved only for the treatment of schizophrenia and FDA denied Janssen's application to expand the indication to include the treatment of psychosis in Alzheimer's patients, Janssen established an Elder Care sales force to promote Risperdal to prescribers and nursing home staff for the treatment of a variety of psychological symptoms of dementia. The government's complaint in the FCA action

additionally alleged that Janssen was aware that Risperdal posed serious health risks for the elderly, but downplayed these risks by withholding publication of adverse studies and conducting post-hoc reanalyses of adverse studies to slant the conclusions in a more favorable light. Janssen also allegedly promoted Risperdal for treating various symptoms of childhood disorders, which was an off-label indication until 2006.

- b. In July 2012, GlaxoSmithKline agreed to pay \$3 billion to resolve criminal FDC Act misbranding and civil FCA allegations focusing on off-label promotion of Paxil, Wellbutrin, Avandia, and other products. GSK pleaded guilty to promoting Paxil, which was not indicated for pediatric use, for treating depression in pediatric populations. Among other things, GSK helped prepare and publish a journal article that misrepresented that Paxil demonstrated effectiveness in a trial of the drug for depression in pediatric patients, when, in fact, no such efficacy was demonstrated. GSK also withheld adverse data from two other studies. GSK also promoted Wellbutrin, which was indicated for major depressive disorder, for weight loss, sexual dysfunction, and other off-label uses by paying physicians to attend meetings and sham advisory boards and sponsoring purportedly independent CME events. In addition, GSK failed to report certain post-marketing safety data to FDA regarding Avandia. The civil FCA complaint also alleged off-label promotion of additional GSK drugs, as well as the payment of kickbacks to prescribers and the reporting of an inflated best price to the Medicaid Drug Rebate Program.
- c. In December 2010, Elan Corporation, PLC and Elan Pharmaceuticals, Inc., pleaded guilty and entered into a civil settlement to resolve allegations related to promotion of the epilepsy drug Zonegran for off-label uses. The company allegedly directed its sales force to promote for off-label uses. The company also allegedly hired advertising agencies to prepare standard promotional materials, and had the slides certified as CME, for use in presentations on off-label uses. The company allegedly detailed and provided samples to physicians who did not treat epilepsy. Elan paid \$203.5

million to settle criminal FDC Act liability and civil FCA liability. Eisai, Inc. paid \$11 million to settle similar claims relating to Zonegran.

- d. In September 2009, Pfizer Inc. and its subsidiary Pharmacia & Upjohn, Inc. agreed to pay \$2.3 billion and entered into a criminal plea agreement and civil settlement related to allegations that it engaged in off-label promotion of Bextra and other products and paid kickbacks to providers to induce them to prescribe the products. The Criminal Information and civil FCA complaint described a number of violative practices, including:
- Promoting Bextra for general acute pain and surgical pain, despite the fact that Bextra was approved only for osteoarthritis, rheumatoid arthritis, and primary dysmenorrhea, and FDA had declined to approve these additional indications because of a concern about cardiovascular thromboembolic events.
 - Paying over 5,000 physicians honoraria and expense-paid trips to the Bahamas, Virgin Islands, and other resorts to attend approximately 100 sham consultant meetings discussing unapproved uses and dosages of Bextra.
 - Making unsubstantiated claims that Bextra was superior to Vioxx, a competing anti-inflammatory drug.
 - Sending physicians Medical Inquiry Response letters discussing unapproved uses of Bextra, when the physicians had not requested such letters.
 - Providing Bextra samples to dentists, oral surgeons, and other surgeons who did not treat patients for any of Bextra's approved indications.
 - Preparing Bextra promotional slides and distributing them to physicians to present at purportedly independent CME events.
 - Hiring medical writers to draft articles on Bextra for unapproved uses, recruiting authors, and arranging publication, without disclosure of the company's role.
- e. In April 2010, AstraZeneca, L.P., and AstraZeneca Pharmaceuticals, L.P. (collectively, AZ) settled FCA allegations for \$520 million. The government claimed that

AZ engaged in off-label promotion of Seroquel, which was approved for the treatment of schizophrenia, bipolar disorder and bipolar depression. AZ allegedly targeted its promotion to physicians who do not treat schizophrenia or bipolar disorder, such as physicians who treat the elderly and pediatricians. The company allegedly influenced the content of purportedly independent CME programs, retained physicians to give talks on unapproved uses, and recruited physicians to serve as authors of off-label articles that were ghostwritten by medical writing companies retained by AZ. AZ also allegedly paid kickbacks to physicians in the form of speaker fees and honoraria and travel expenses to attend sham consultant meetings.

- f. 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 plead guilty to a misdemeanor violation of the FDC Act, and settled 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 had abandoned a plan to seek a dementia indication. Lilly also promoted Zyprexa to primary care physicians for the treatment of behavior symptoms for which the drug was not approved.
- g. In May 2004, Warner-Lambert Company LLC entered into a plea agreement and settlement for a total of \$430 million in criminal fines and civil penalties regarding allegations that Warner-Lambert's subsidiary, Parke-Davis, promoted its drug Neurontin for off-label uses, distributed an unapproved drug, and distributed a misbranded drug (by failing to provide adequate directions for the unapproved uses), in violation of the FDC Act. 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.

In a 2003 court decision in the Warner-Lambert case, the federal district court held that it was not necessary for the relator to demonstrate that Warner-Lambert lied to physicians, since "truthful off-label marketing ... and financial incentives like kickbacks would suffice" to establish a violation. United States v. Parke-Davis, No. 96-cv-11651, 2003 WL 22048255, at 2 (D. Mass. Aug. 22, 2003).

2. Some courts have rejected qui tam FCA claims based on off-label promotion.
 - a. United States ex rel. Hopper v. Solvay Pharmaceuticals, 590 F. Supp. 2d 1352, 1359 (M.D. Fla. 2008), aff'd 588 F.3d 1318 (2009), cert. denied, ___ U.S. ___, 130 S. Ct. 3465 (2010). This case held that the existence of false claims may not be inferred from the presence of off-label promotion, and 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. See also United States ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 345 (D. Mass. 2011) (off-label promotion of device alone is insufficient to establish FCA violation; fraudulent claims must be submitted).
 - b. 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.
3. Off-label promotion of devices
 - a. In December 2013, Genzyme Corp. paid \$22.28 million to settle FCA allegations that the company engaged in off-label promotion of Septrafilm, a bioresorbable device approved by FDA for reducing adhesions after open abdominal surgery. Genzyme allegedly instructed physicians how to prepare a

“slurry” by adding saline to Seprafilm and using the mixture in laparoscopic surgeries, for which Seprafilm is not approved. Borrowing the theory used against drug companies, the government and relators alleged that provider claims for Seprafilm used in this manner were false because Medicare does not pay for unapproved devices, and Genzyme caused these claims to be submitted by promoting use of the slurry.

- b. *Higher burden for devices*: One court has held that there is an added burden for relators alleging an FCA action based on off-label promotion of a device as opposed to a drug. For a device, plaintiff must show that the use being promoted was not only unapproved, but that it lacked safety and efficacy, and was therefore not medically necessary. United States ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 347-49 (Dist. Mass. 2011).
4. On December 3, 2012, the United States Court of Appeals for the Second Circuit vacated on First Amendment grounds the criminal conviction under the FDC Act of Alfred Caronia, a former sales representative for Orphan Medical, Inc. United States v. Caronia, 703 F.3d 149 (2d Cir. 2012). The sales representative was convicted for promoting the drug Xyrem for a use that had not been approved by FDA. The court found that, under the First Amendment, “the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.” Id.

After Caronia, defendants will be more likely to raise First Amendment defenses to off-label promotion allegations brought, not only under the FDC Act, but also under the FCA. See, e.g., Defendant’s Motion to Dismiss the Second Amended Complaint, United States ex rel. Cestra v. Cephalon, Inc., 10-cv-6457 (S.D.N.Y. 2013). However, the First Amendment does not protect false or misleading speech. In the FCA off-label promotion cases brought to date, the government and relators have generally alleged that the defendants misrepresented available data, made unsubstantiated comparative claims, understated safety concerns, or made other false or misleading statements in the course of their off-label promotion. In order to

use Caronia in support of their cases, defendants will have to show that their off-label promotion was truthful and non-misleading.

I. Other FDA Violations as Basis for FCA Liability

1. Failure to Submit Required PMA Supplement: Settlement in United States ex rel. Einer v. Orthologic Corp., Civ-S-96-2166 (E.D. Cal. Aug. 17, 1998)

- a. Qui tam FCA 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 devices 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. Failure to Report Adverse Events as Basis for FCA Liability

- a. In June 2003, Endo Vascular Technologies (EVT) (a subsidiary of Guidant Corporation) agreed to pay \$92.4 million to settle criminal FDC Act and civil FCA liability. 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.

- b. United States ex rel. Kazimiroff v. Dentsply Int'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 as required by the FDC Act and FDA regulations. Selling products that did not comply with the FDC Act was a violation of Dentsply's Federal Supply Schedule contract with the VA. Thus, submitting invoices for payment to the VA for non-compliant devices was alleged to constitute a false claim under the FCA.

- c. In a qui tam case brought against Takeda Pharmaceutical Co. Ltd., the relator alleged that all of the claims submitted for the defendant's drugs were false because Takeda had not properly submitted adverse event reports to FDA. The lower court held that relator had failed to allege her case with the requisite specificity under Fed. R. Civ. P. 9(b) because she did not sufficiently plead that the alleged misconduct resulted in the submission of false claims. United States ex rel. Ge v. Takeda Pharmaceutical Co. Ltd., 2012 WL 5398564 (D. Mass. 2012). Interestingly, on appeal, the government (which had not intervened) filed an amicus brief opposing FCA liability for failure to submit adverse event reports except in the rare case where such failures are so serious that FDA would have withdrawn approval for all indications had the events been reported. The government stated that simply alleging that a company failed to comply with adverse event reporting requirements is insufficient to state an FCA claim. On appeal, the First Circuit affirmed the dismissal on Rule 9(b) grounds, but did not rule on whether failure to submit adverse event reports could be actionable under the FCA. United States ex rel. Ge v. Takeda Pharmaceutical Co. Ltd., ___ F.3d ___, 2013 WL 6399780 (1st Cir. 2013).

3. Violation of cGMPs

- a. In October 2010, SB Pharmco Puerto Rico Inc., a subsidiary of GlaxoSmithKline, PLC pleaded guilty to felony interstate

shipment of adulterated drugs under the FDC Act and settled civil FCA allegations related to its now-closed Cidra, Puerto Rico manufacturing plant. The company paid \$750 million to resolve the criminal and civil liability. The Criminal Information stated that the company knowingly sold and distributed flawed tablets, contaminated products, and products which differed in purity and strength from their NDA-approved values. The FCA complaint alleged that, by selling adulterated drugs, GSK knowingly caused false and/or fraudulent claims to be submitted to, or caused purchases by, Medicaid and other federal health care programs.

4. Marketing defective devices

- a. In January 2011, Guidant Corp. (a subsidiary of Boston Scientific Corp.) paid \$296 million in criminal fines and pleaded guilty to violations of the FDC Act for marketing implantable cardioverter defibrillators that the company knew were defective, and for concealing information about the defects from the FDA. Following the criminal plea, the government intervened in a qui tam FCA case alleging that Guidant caused claims to be submitted to Medicare for the defective implants. Guidance settled the FCA claims in October 2013 for \$30 million.

5. Marketing unapproved drugs

- a. In September 2010, Forest Pharmaceuticals, Inc. paid \$313 million to resolve criminal FDC Act and civil FCA liability. The government claimed, among other things, that Forest marketed Levothroid (levothyroxin), which was then unapproved, disregarding an FDA mandate that manufacturers of unapproved levothyroxin products must phase down distribution of these products until FDA approval was obtained. The FCA complaint alleged that Forest failed to notify CMS that Levothroid was unlawfully marketed, thereby causing false claims to be submitted to Medicaid.
- b. In 2002, former CMS employee Constance Conrad filed a qui tam FCA complaint against a number of manufacturers who marketed unapproved prescription drugs and prescription

vitamins and minerals, alleging that, by obtaining NDC numbers for these products and reporting prices and drug information to the Medicaid Drug Rebate Program, the defendants falsely represented to CMS that the products were lawfully marketed prescription drugs entitled to coverage under Medicaid. Tenth Amended Complaint, United States ex rel. Conrad v. Abbott Laboratories, Inc., No. 02-cv-11738 (D. Mass. July 26, 2011). Several of the defendants settled. The government declined to intervene against the remaining defendants, and the case was dismissed on jurisdictional grounds in February 2013.

- c. In September 2013, the State of Louisiana sued over 50 drug manufacturers who allegedly market unapproved drugs under the state consumer protection law, the state medical assistance program integrity law, common law fraud, and other common law theories. Like the relator in the Conrad case, Louisiana alleges that the manufacturers “trick[ed] the system into believing that certain drugs have FDA approval” when they did not, resulting in Medicaid payment for uncovered drugs. The case is ongoing. Complaint, State of Louisiana v. Abbott Laboratories, Inc., No. 3:13-cv-00681 (M.D. La., Sept. 12, 2013).

IV. GENERAL GUIDELINES FOR EVALUATING MARKETING PROPOSALS

A. Determine whether anti-kickback statute applies

1. Is “remuneration” offered?
2. Is at least one purpose to induce the prescribing/purchase/lease of company’s product?
3. Will beneficiaries of federal health care programs or state government programs be affected?

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

B. Conform to an applicable 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 product instead of lower cost product?
- D. Assess the potential to bias treatment decisions or steer patients to a particular product or provider
- E. Discounts
 - 1. Comply with discount safe harbor to extent possible.
 - 2. Maintain adequate paper trail. Invoices, contracts, and 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 a cost-reimbursed item to unreimbursed or fixed-reimbursement item.
 - 4. Free goods and services may be problematic -- ensure legal review.
- F. Consulting or Service Arrangements
 - 1. Conform with safe harbor for personal services contracts to extent possible.
 - 2. Compensation should be demonstrably consistent with fair market value and not be related to prescribing/purchasing practices or potential.
 - 3. Services should not be duplicative and should demonstrably serve a genuine business purpose for the company.
 - 4. Consultant should be required to maintain adequate documentation of time/resources expended.

G. Grants

1. Requests should be evaluated based on scientific merit.
2. Grants should not be linked to prescribing history or potential.
3. Marketing and sales personnel should not have a role in the award process.
4. Ensure adequate monitoring of research activities.

H. Post-Marketing Studies

1. Study should have genuine research purpose, adequate design, written protocol.
2. Number of investigators/subjects should be appropriate for objectives of the study.
3. Investigators should be selected by clinical staff without involvement of marketing and sales personnel. Prescribing/purchasing history or potential should not be taken into account.
4. Written investigator agreement
5. Compensation should be fair market value for services performed beyond those paid by insurance, and should not take into account prescribing history or potential.
6. Post-marketing study may not
 - a. Be used as a vehicle for promoting off-label use or compensating physicians for prescribing
 - b. Solicit information of questionable value (e.g., physician satisfaction)
 - c. Be used to track physicians' prescribing practices
 - d. Provide compensation to participating physicians that is inordinate in relation to work performed

- I. Establish a Compliance Program
 1. Benefits
 - a. Enhances ethical business conduct among employees and reduces chances of anti-kickback 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. 8,987, 8,988 n.2 (Feb. 23, 1998) (preamble to compliance program guidance for hospitals).
 - c. Existence of effective compliance program may reduce sentence under Federal Sentencing Guidelines. See Federal Sentencing Guidelines § 8C2.5(f).
 2. Essential elements
 - a. Written Code of Ethics and marketing 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.
 3. Consult the CPG for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).