

Anti-Kick and the False Claim Statutes in the Healthcare Setting and Manufacturer Industry

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THIS PRESENTATION IS BASED ON THE PERSONAL OBSERVATIONS AND OPINION OF RENEE MALLETT.

OVERVIEW

- Background: Anti-Kickback Statute (AKS)
- Basic Prohibition
- Safe Harbors and Exceptions
- Analytical Framework for Evaluating AKS Issues
- Case Law and Settlements
- Corporate Compliance Program

Resources

BACKGROUND

WHY THE LAWS?

The Anti-Kickback, Stark and False Claims Acts are is intended to ensure that medical / healthcare providers' judgments are not compromised by improper financial incentives / inducements and are instead based on the best interests of their patients.

BACKGROUND



The Medicare Anti-Kickback Statute ("AKS") was created to fight concerns that financial arrangements between healthcare providers would motivate healthcare decisions resulting in higher health costs and lower quality of care.



AKS enforcement is **intent based**…



Kickback, bribes, incentives, payments, rewards, grease money, pay offs, inducements, palm greasing.

BACKGROUND

Unlike basic healthcare fraud laws, which focus on activities normally identified as fraudulent (e.g., false statements), Anti-kickback Statute (AKS) dissect common business arrangements between healthcare providers to determine whether one healthcare provider or manufacturer is paying the other healthcare provider (directly or indirectly) in exchange for patient referrals or other types of business.

In some AKS cases, the analysis pivots on whether the payment is blemished because "one purpose" of the payment is in exchange for referrals or buying of products … even if the arrangement is otherwise "99 percent pure".

AKS (enacted in 1972) is a criminal statute. Penalties for violations of the AKS include:

Criminal Fines of up to $25,000 per violation
Prison sentences of up to 5 years per violation
Civil fines of up to $25,000 per violation plus 3x the amount of the claims paid
False Claims Act Liability
Possible exclusion from Medicare and Medicaid

Main sources of guidance for AKS are regulatory comments, advisory opinions and cases (the statute is found at 42 U.S.C. § 1320a-7b)

The Office of Inspector General ("OIG") of the US Department of Health & Human Services ("HHS") chiefly enforces the AKS

BACKGROUND OF ANTI-KICKBACK STATUTE (AKS)

FALSE CLAIMS ACT

The Anti-Kickback Statute prohibits the knowing and willful payment of any remuneration to induce the referral of services, devices, products or drugs that are paid for by a federal healthcare program, such as Medicare, Medicaid or TRICARE.



Claims submitted to these programs in violation of the Anti-Kickback Statute give rise to liability under the False Claims Act.

FALSE CLAIMS ACT

- 31 U.S.C. §§ 3729-3733
- (a)(1)(A) false claims
- (a)(1)(B) false records material to false claims
- (a)(1)(C) conspiracy
- (a)(1)(G) reverse false claims
  - Origins in the Civil War – "Lincoln's Law"
- Substantial amendments:
  - 1943
  - 1986
  - 2009 – Fraud Enforcement Recovery Act (FERA)
  - 2010 – Patient Protection and Affordable Care Act (PPACA)

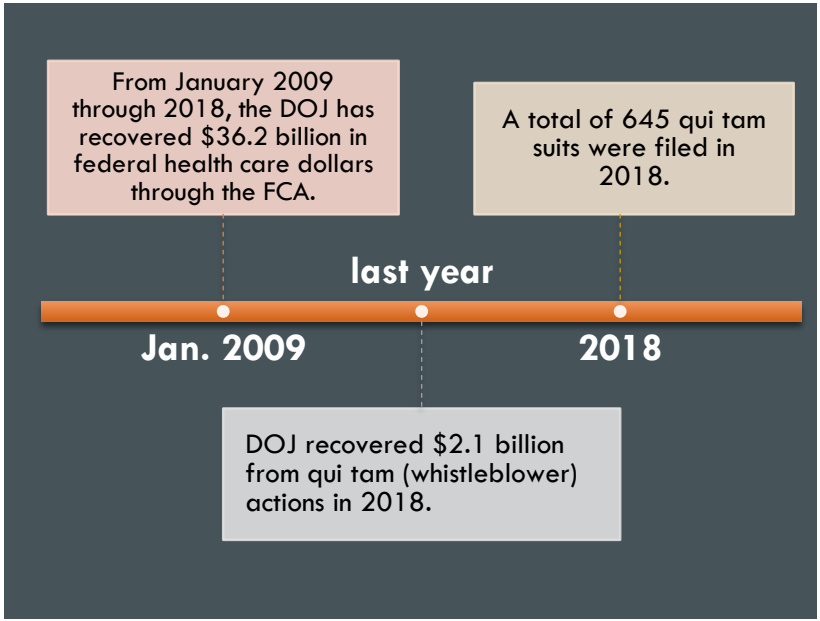
FALSE CLAIMS ACT

(A) knowingly presents, or causes to be presented, a **false or fraudulent** claim for payment or approval

(B) knowingly makes, uses, or causes to be made or used, a **false** record or statement material to a **false or fraudulent** claim

(G) knowingly makes, uses, or causes to be made or used, a **false** record or statement material to an obligation to pay or transmit money or property to the Government

HEALTHCARE FRAUD ENFORCEMENT



QUI TAM SUITS



Private individuals (relators) file *qui tam* complaints under seal alleging FCA violations



Increase in corporate relators



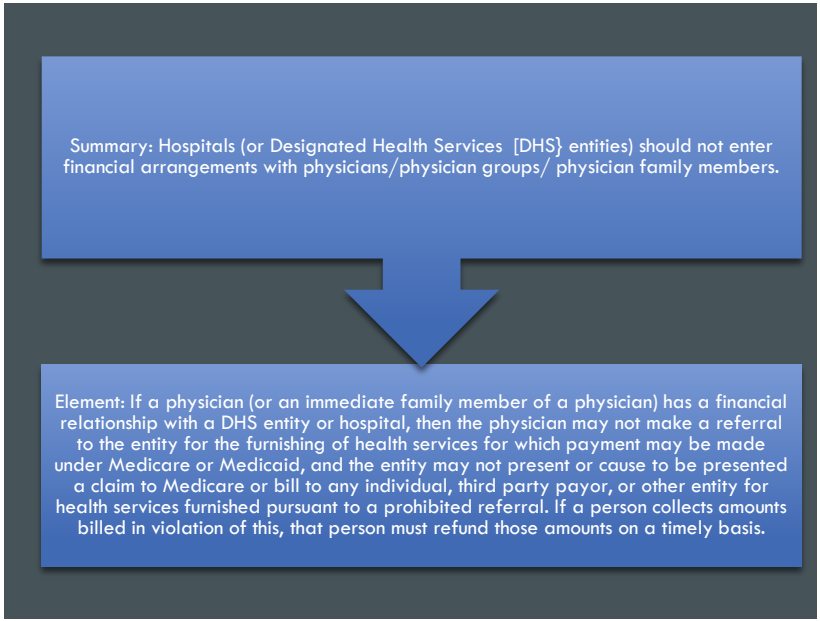
Sophisticated counsel taking FCA cases

BACKGROUND OF STARK

- Rep. Stark (1991) introduced the law to address perceived in adequacies in AKS (Stark was originally only applicable to physician-owned clinical labs).
- Stark is a civil, reimbursement law, and strict liability.
- Penalties include:
  - Non-payment or repayment ("payoff") of amounts payable or paid for services provided as a result of corrupted referral
  - Civil Fines of $23,683 per claim
  - False Claims Act Liability
  - Possible exclusion from Medicare and Medicaid
- Primary guidance for Stark are regulatory text, advisory opinions and cases (42 U.S.C. §1395nn)
- The Centers for Medicare and Medicaid Services ("CMS") enforces Stark.

BASIC PROHIBITIONS

STARK PROHIBITIONS



STARK BASIC PROHIBITION – SIX FACTORS NEEDED FOR A STARK VIOLATION

- A physician who
- Makes a referral
- For a designated health service
- Payable by Medicare (or Medicaid)
- To an entity
- With which the physician (or an immediate family member) has a financial relationship
- – All of these terms have statutory and/or regulatory definitions

STARK RESOURCES

- Statute – 42 USC 1395nn
- Regulations – 42 CFR 411.350 to 411.389
  - – Phase 1 Regulations – 66 FR 856 (January 4, 2001)
  - – Phase 2 Regulations – 69 FR 16054 (March 26, 2004)
  - – Phase 3 Regulations – 72 FR 51012 (September 5, 2007)
  - – Phase 3.5 Regulations – 73 FR 48434 (August 19, 2008)
  - – Amendments – 80 FR 70886 (November 16, 2015)

AKS BASIC PROHIBITION

- Basic Prohibition (Part 1)
  - Summary: Do not solicit or accept payments in exchange for past or future referrals of federal healthcare program beneficiaries. A manufacturer or distributor cannot knowingly and willfully offer, pay, solicit to induce the recommendation, referral, purchase or use of any item or services reimbursed under a Federal or Government Healthcare Program.
  - Elements: The AKS prohibits ***a person*** from ***knowingly and willfully soliciting or receiving*** any ***remuneration (anything of value)***, directly or indirectly, overtly or covertly, in cash or in kind, ***in return for referring or recommending an individual*** to ***another person*** to receive ***items or services*** or to purchase, lease, order, or arrange for any ***good, facility, item or service*** payable under a ***Federal health care program***.

The court held that if at least part of a hospital's remuneration to a physician "was 'intended to induce' him to refer patients" to the hospital, "the statute was violated, even if the payments were also intended to compensate for professional services." United States v. Borassi, No. 09-4088 (7th Cir. May 4, 2011) (quoting United States v. Greber, 760 F.2d 68, 72 (3d Cir. 1985)).

AKS – THE "ONE PURPOSE" TEST

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- The AKS prohibits offering/providing remuneration if "one purpose" of the remuneration is to:
  - reward **past** referrals, or
  - to induce **current or future** referrals.
- When structuring/analyzing referral source arrangements, it is important to remember that the Government takes the position that any proof of bad intent can taint a deal that's otherwise fully legally compliant. This is the case even if the "proof" takes the form of an e-mail or a note that can be read in multiple ways. When faced with an e-mail or note like that, it's helpful to speak directly with the sender and seek (and document) clarification of the intent to comply with the AKS.

AKS BASIC PROHIBITION – 5 FACTORS NEEDED FOR AN AKS VIOLATION

1. A financial arrangement between a ***health care provider, manufacturer, distributor, supplier, or vendor*** and a ***referral source;***
2. The ***referral or recommendation*** by the referral source of a third-party (including a patient) to receive goods or services from the health care provider, supplier, or vendor (or, potentially, the intent to refer);
3. The payment for such goods or services by ***Medicare, Medicaid, or any other governmental health care program(Federal Employees Health Benefit Plan, Tricare, Children's Health Insurance Program, Veterans Administration, Indian Health Service, Black Lung Insurance Program, Railroad Medicare, Social Security Minor Survivor Health Benefits, etc.);***
4. A ***financial relationship*** of any type between the health care provider, supplier, or vendor and the referral source; and
5. ***ONE intent*** that the financial relationship serve as a reward or inducement for the referral source to refer or recommend third-parties to the health care provider, supplier, or vendor to receive goods or services payable under Medicare, Medicaid, or any other governmental health care program.

Note: None of these ***terms*** have a fixed statutory or regulatory definition. Instead, these ***terms*** are defined by advisory opinions and court decisions.

BASIC PROHIBITIONS - SUMMARY

- Referrals from everyone (all persons / businesses can be referral sources)
- Any items or services
- Intent must be proven (knowing and willful)
- Applies to all Federal Health Care programs

AKS SAFE HARBORS

- Congress mandated the Office of Inspector General ("OIG") to promulgate Safe Harbors to help eliminate provider/supplier confusion about the applicability of AKS
- OIG uncomfortable with this responsibility given the fact that each Safe Harbor effectively deprives the U.S. Department of Justice of the authority to prosecute potentially abusive business arrangements
- As a result, the OIG only provided Safe Harbor protection to arrangements which it felt posed little to no opportunity for abuse of Federal health care programs

AKS SAFE HARBORS



The Safe Harbors promulgated by the OIG generally include numerous standards (each of which, in the OIG's view, represents a safeguard against possible abuse of Federal health care programs).



As a result, the Safe Harbors tend to be very narrow, thereby preventing many common business arrangements from fitting within a Safe Harbor.

REGULATORY SAFE HARBORS

- A business arrangement does not need to fit within a Safe Harbor to avoid violating the AKS (given that a party's motive or intent is an element of an AKS violation)
- A business arrangement which does not fit within a Safe Harbor only violates AKS if all five (5) factors needed for a violation of AKS are present
- From the OIG's perspective, it is simply a matter of prosecutorial discretion whether such business arrangements are prosecuted.

Investment Interest	Space Rentals	Equipment Rentals
Personal Services and Management Contracts	Sales of Medical Practices	Referral Services
Warranties	Discounts or Rebates	Employees
Group Purchasing Organizations	Waiver of Beneficiary Coinsurance and Deductible Amounts	Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
Price Reductions Offered to Health Plans	Practitioner Recruitment	Obstetrical Malpractice Insurance Subsidies
Cooperative Hospital Services Organization	Referral Arrangements for Specialty Services	Price Reduction for Eligible Managed Care Organizations
Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations	Ambulance Replenishing	Donations to Federally-Qualified Health Centers
Electronic Prescribing Items and Services	Electronic Health Records, Items and Services	

AKS SAFE HARBOR LIST

ANALYTICAL FRAMEWORK

ANALYTICAL FRAMEWORK



Step 1

Draw the Financial Arrangement and Referral Streams



Step 2

Review the Factors of the Basic Prohibition. Note AKS may already be violated if the parties have the requisite intent.



Step 3

If Basic Prohibitions apply, determine:

Is there a Safe Harbor?

Restructure the Financial Arrangement to fit within a Safe Harbor

Seek an Advisory Opinion

Abandon the Financial Arrangement

CASES AND SETTLEMENTS

TEVA - $54MM SETTLEMENT – SPEAKER PROGRAM - 2020

Two former sales representatives became the whistleblowers.

Teva sales reps retained physician speakers that were high volume prescribers and then monitored their prescription utilization.

Nominations for speakers came from the company's sales and marketing departments, as opposed to medical or clinical affairs.

Healthcare providers' attending three or more events related to the same drug within six months.

Healthcare providers "rotating" by attending sequential Teva programs as the speaker at one and audience member at the other.

Educational programs were held in restaurants, expensive meals and alcohol were served;

The audience was frequently made up of either Teva representatives, speakers themselves, repeat attendees, or physicians' family members"; and

Teva's materials were not modified to take into account the given audience, the materials were too simplistic to benefit practicing health care professionals and contained outdated information.

AVANIR KICKBACK CONSPIRACY - $103MM SETTLEMENT - 2019

- **2 Physicians & 2 Sales Reps Indicted**
- **Transfers of Value:**
  - Speaking engagements
  - Firearms training
  - Meals and coffee
  - Fax machine and accessories
  - Prior Authorization assistance (accessing PHI without patients' permission)



Politics & Government

Ohio Settles With Avanir Pharmaceuticals On Kickback Allegations

Several states and the federal government settled with Avanir over accusations the company engaged in a kickback conspiracy.

By Chris Mosby, Patch Staff
Sep 30, 2019 2:25 pm ET

Like 41 Share Reply

October 2011 through December 2016

Nuedexta, a drug approved for a rare condition characterized by uncontrollable laughing and crying, known as pseudobulbar affect, or PBA.

- **Speakers Bureau**
  - Little to no educational content
  - False and fictitious sign in sheets submitted by Reps
  - Drug promoted for off-label uses
  - Dr. R received $331,550 in Honoria
- **To increase prescription volume, Physicians:**
  - Falsely diagnosed patients
  - Falsified symptoms and diagnoses
  - Submitted fictitious prior authorizations

PACIFIC HOSPITAL AND DR DANIEL CAPEN - 2019

- Dr Capen, 70, spinal surgeon, sentenced to 2 ½ years in Federal Prison.
- The kickback scheme centered on Pacific Hospital in Long Beach, which specialized in surgeries, especially spinal and orthopedic procedures. Pacific Hospital's owner, Michael D. Drobot, conspired with doctors, chiropractors and marketers to pay kickbacks in return for the referral of thousands of patients to Pacific Hospital for spinal surgeries and other medical services paid for primarily through the California workers' compensation system.
- Capen received kickbacks for referring surgeries to Pacific Hospital and also for using medical hardware from a Pacific Hospital-affiliated entity during the spinal surgeries he performed. He also received kickbacks for referring medical services such as urine and drug testing to Pacific Hospital-affiliated entities.
- In total, between 1998 and 2013, Capen accounted for approximately $142 million of Pacific Hospital's claims to insurers, on which the hospital was paid approximately $56 million. Capen admitted to receiving at least $5 million in kickbacks during the course of his crimes.
- Drobot is serving a five-year prison sentence for conspiracy and paying illegal kickbacks and has admitted that he orchestrated a wide-ranging fraudulent kickback scheme where paid more than $50 million in bribes to doctors to steer hundreds of millions of dollars in spinal surgeries to his hospital. Drobot ultimately profited millions of dollars from the scheme. Drobot currently faces additional federal criminal charges for allegedly violating a court forfeiture order by illegally selling his luxury cars.

DAVID LANE BRYNS, FORMER CEO OF PUTMAN COUNTY MEMORIAL HOSPITAL, UNIONVILLE, MISSOURI - 2019

- The former CEO of a Missouri hospital pleaded guilty today for his role in a pass-through billing scheme in which the hospital was used to submit fraudulent claims for toxicology and blood testing, resulting in multiple insurance companies and the Missouri Medicaid program paying over $100 million in claims.
- According to admissions made as part of his guilty plea, in 2016, Byrns and another individual took control of Putnam, a rural hospital in Missouri, through a management agreement with the hospital's board, and Byrns was installed as the hospital's CEO.
- Byrns and others, including a laboratory owner, then arranged for urine drug tests (UDTs) and blood tests to be performed on a massive scale at diagnostic testing laboratories outside Missouri, on behalf of individuals who were not Putnam patients and who otherwise had no connection to Putnam.
- To obtain samples for testing, Byrns and his co-conspirators entered into arrangements with marketers, who solicited samples from substance abuse treatment centers, sober living homes, physicians' offices and other sources throughout the United States, in exchange for a portion of the insurance reimbursements. Many of the tests conducted were medically unnecessary.

OLYMPUS SETTLEMENT - $646MM (2016)

Olympus gave doctors and hospitals kickbacks, including loans of endoscopes, valued at "$20k or more," "in order to win business and induce purchases of Olympus products." Other examples of improper conduct:

- Donation of tens of thousands in equipment to "neutralize" competitor efforts;
- $400k in endoscopes to doctors believed to have role in hospital purchasing;
- Donation to hospital system for new hospital because "we need access for potential sell of $300k";
- Program for no-charge loans for months and sometimes more than a year "for the express purpose of inducing customers to purchase that equipment."
- When leases ended, allow customers to keep old equipment and skip several months of payment in order to induce new lease.

GLAXO SMITH KLINE LLC - $3B (2012)

GlaxoSmithKline LLC (GSK) has agreed to plead guilty and pay $3 billion to resolve its criminal and civil liability for off-label promotion of several drugs, failure to report safety data, and false price reporting practices.



GSK was criminally charged with promoting several drugs, including Paxil®, Wellbutrin®, Advair®, Lamictal® and Zofran®, for uses not approved by the U.S. Food and Drug Administration - a practice known as off-label promotion.



GSK was also charged with offering kickbacks to doctors including lavish vacations, concert tickets and paid speaking engagements.

CHRIST HOSPITAL - $108 MM - 2010

Christ Hospital resolves kickback saga with federal government

October 29, 2010

The Christ Hospital entered into an agreement that will give the federal government's inspector general the right to monitor the hospital for five years.

The agreement "closes the door" on a decade-long kickback case in which Christ Hospital was alleged to have compensated cardiologists for referring patients to the hospital, according to the statement. In May, Christ Hospital and its former parent, the Health Alliance of Greater Cincinnati, paid a total of $108 million to settle the suit.

Earlier, Christ Hospital had refused to sign a corporate integrity agreement with the government, calling such a deal "costly, burdensome and unnecessary. That refusal led to the government's threat to exclude the hospital from federal Medicare and Medicaid payments.

ABBOTT LABORATORIES - $622MM (2003)

FBI health-care sting uses mob case treatment

August 24, 2003|By Bruce Japsen, Chicago Tribune staff reporter.

SWANSEA, Ill. — Federal agents are using mob-busting tactics to root out fraud in the health-care industry.

The FBI used an innocuous, white one-story warehouse tucked between a shipping company and a sewage treatment plant in this small town to snare some of the world's largest medical product-makers engaging in illegal marketing practices.

Inside the bogus business, which sits about 15 miles southeast of St. Louis and was named Southern Medical Distributors, sales representatives from companies that included Abbott Laboratories were caught on audio and videotape in a large conference room showing undercover agents how to allegedly cheat government health insurance programs, according to government records.

The marketing practices of Abbott's Ross Products Division included:

- Providing free enteral feeding pumps to nursing homes and DME suppliers in exchange for those buyers agreeing to purchase a specific number of pump sets
- Claiming that nursing homes and DME suppliers could bill Medicare or Medicaid for the pumps, which had been supplied for free; and
- Providing monetary encouragement to DME suppliers and nursing homes to buy products from Ross.

CORPORATE COMPLIANCE PROGRAM



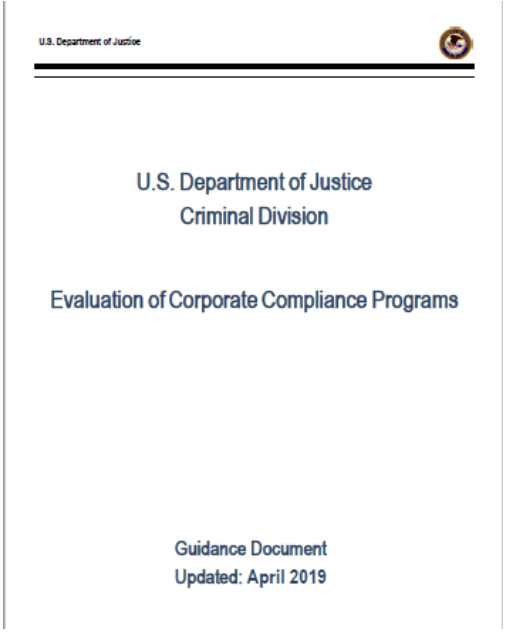
"EFFECTIVE COMPLIANCE PROGRAMS PLAY A CRITICAL ROLE IN PREVENTING MISCONDUCT, FACILITATING INVESTIGATIONS, AND INFORMING FAIR RESOLUTIONS," ASSISTANT ATTORNEY GENERAL BRIAN A. BENCZKOWSKI SAID. "TODAY'S GUIDANCE DOCUMENT IS PART OF OUR BROADER EFFORTS IN TRAINING, HIRING, AND ENFORCEMENT TO HELP PROMOTE CORPORATE BEHAVIORS THAT BENEFIT THE AMERICAN PUBLIC AND ENSURE THAT PROSECUTORS EVALUATE THE EFFECTIVENESS OF COMPLIANCE IN A RIGOROUS AND TRANSPARENT MANNER."

CRIMINAL DIVISION ANNOUNCES PUBLICATION OF GUIDANCE ON EVALUATING CORPORATE COMPLIANCE PROGRAMS

The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in investigating of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300.

These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one." JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000).

Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. See U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11).


U.S. Department of Justice

U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

Guidance Document
Updated: April 2019

FUNDAMENTAL QUESTIONS



1. “Is the corporation’s compliance program well designed?“



2. “Is the program being applied earnestly and in good faith?“ In other words, is the program being implemented effectively?



3. “Does the corporation’s compliance program work“ in practice?

RISK ASSESSMENT

- **Risk Management Process** – What methodology has the company used to identify, analyze, and address the particular risks it faces? What information or metrics has the company collected and used to help detect the type of misconduct in question? How have the information or metrics informed the company's compliance program?

- **Risk-Tailored Resource Allocation –** Does the company devote a disproportionate amount of time to policing low-risk areas instead of high-risk areas, such as questionable payments to third-party consultants, suspicious trading activity, or excessive discounts to resellers and distributors? Does the company give greater scrutiny, as warranted, to high-risk transactions (for instance, a large-dollar contract with a government agency in a high-risk country) than more modest and routine hospitality and entertainment?

- **Updates and Revisions** – Is the risk assessment current and subject to periodic review? Have there been any updates to policies and procedures in light of lessons learned? Do these updates account for risks discovered through misconduct or other problems with the compliance program?

POLICIES AND PROCEDURES



Design – What is the company's process for designing and implementing new policies and procedures, and has that process changed over time? Who has been involved in the design of policies and procedures? Have business units been consulted prior to rolling them out?



Comprehensiveness – What efforts has the company made to monitor and implement policies and procedures that reflect and deal with the spectrum of risks it faces, including changes to the legal and regulatory landscape?



Accessibility – How has the company communicated its policies and procedures to all employees and relevant third parties? If the company has foreign subsidiaries, are there linguistic or other barriers to foreign employees' access?



Responsibility for Operational Integration – Who has been responsible for integrating policies and procedures? Have they been rolled out in a way that ensures employees' understanding of the policies? In what specific ways are compliance policies and procedures reinforced through the company's internal control systems?



Gatekeepers – What, if any, guidance and training has been provided to key gatekeepers in the control processes (e.g., those with approval authority or certification responsibilities)? Do they know what misconduct to look for? Do they know when and how to escalate concerns?

TRAINING AND COMMUNICATION

- **Risk-Based Training** – What training have employees in relevant control functions received? Has the company provided tailored training for high-risk and control employees, including training that addresses risks in the area where the misconduct occurred? Have supervisory employees received different or supplementary training? What analysis has the company undertaken to determine who should be trained and on what subjects?
- **Form/Content/Effectiveness of Training** – Has the training been offered in the form and language appropriate for the audience? Is the training provided online or in-person (or both), and what is the company's rationale for its choice? Has the training addressed lessons learned from prior compliance incidents? How has the company measured the effectiveness of the training? Have employees been tested on what they have learned? How has the company addressed employees who fail all or a portion of the testing?
- **Communications about Misconduct** – What has senior management done to let employees know the company's position concerning misconduct? What communications have there been generally when an employee is terminated or otherwise disciplined for failure to comply with the company's policies, procedures, and controls (e.g., anonymized descriptions of the type of misconduct that leads to discipline)?
- **Availability of Guidance** – What resources have been available to employees to provide guidance relating to compliance policies? How has the company assessed whether its employees know when to seek advice and whether they would be willing to do so?

CONFIDENTIAL REPORTING AND INVESTIGATION PROCESS

- **Effectiveness of the Reporting Mechanism** – Does the company have an anonymous reporting mechanism, and, if not, why not? How is the reporting mechanism publicized to the company's employees? Has it been used? How has the company assessed the seriousness of the allegations it received? Has the compliance function had full access to reporting and investigative information?
- **Properly Scoped Investigations by Qualified Personnel** – How does the company determine which complaints or red flags merit further investigation? How does the company ensure that investigations are properly scoped? What steps does the company take to ensure investigations are independent, objective, appropriately conducted, and properly documented? How does the company determine who should conduct an investigation, and who makes that determination?
- **Investigation Response** – Does the company apply timing metrics to ensure responsiveness? Does the company have a process for monitoring the outcome of investigations and ensuring accountability for the response to any findings or recommendations?
- **Resources and Tracking of Results** – Are the reporting and investigating mechanisms sufficiently funded? How has the company collected, tracked, analyzed, and used information from its reporting mechanisms? Does the company periodically analyze the reports or investigation findings for patterns of misconduct or other red flags for compliance weaknesses?

INCENTIVES AND DISCIPLINARY MEASURES



Human Resources Process – Who participates in making disciplinary decisions, including for the type of misconduct at issue? Is the same process followed for each instance of misconduct, and if not, why? Are the actual reasons for discipline communicated to employees? If not, why not? Are there legal or investigation-related reasons for restricting information, or have pre-textual reasons been provided to protect the company from whistleblowing or outside scrutiny?



Consistent Application – Have disciplinary actions and incentives been fairly and consistently applied across the organization? Are there similar instances of misconduct that were treated disparately, and if so, why?



Incentive System – Has the company considered the implications of its incentives and rewards on compliance? How does the company incentivize compliance and ethical behavior? Have there been specific examples of actions taken (e.g., promotions or awards denied) as a result of compliance and ethics considerations? Who determines the compensation, including bonuses, as well as discipline and promotion of compliance personnel?