Fraud, Abuse, & Waste, Oh My!

Developing an Effective Compliance Program

Program speaker

The speaker for this program is Arlene Luu, RN, BSN, JD, CPHRM, Senior Patient Safety & Risk Consultant, MedPro Group (Arlene.Luu@medpro.com)

Arlene provides comprehensive risk management services to policyholders in MedPro Group's Western Division. She has more than 20 years of experience as a registered nurse and has worked as a defense attorney representing doctors, nursing homes, nurses, and other healthcare providers in medical malpractice cases.

Arlene's experience in risk management and patient safety includes working in the hospital setting and providing risk consulting services to physicians in all specialties, dental providers, medical groups, and healthcare facilities. She has presented and published information on various patient safety topics, and she has provided risk management guidance and support related to healthcare law, quality improvement, and risk exposure.

Arlene earned her bachelor of science degree in nursing from San Diego State University, a certificate in public health nursing for the state of California, and her juris doctorate degree from California Western School of Law. She is a licensed attorney in California and a certified professional in healthcare risk management (CPHRM).

Designation of continuing education credit

Medical Protective is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Medical Protective designates this enduring activity for a maximum of 1.0 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Academy of General Dentistry™
PACE
Program Approval for Continuing Education

The Medical Protective Company is designated as an Approved PACE Program Provider by the Academy of General Dentistry. The formal continuing dental education programs of this program provider are accepted by AGD for Fellowship/Mastership and membership maintenance credit. Approval does not imply acceptance by a state or provincial board of dentistry or AGD endorsement. The current term of approval extends from October 1, 2015, to September 30, 2018. Provider ID 218784.

The Medical Protective Company designates this continuing education activity as meeting the criteria for up to 1 hour of continuing education credit. Doctors should claim only those hours actually spent in the activity.

Disclosure

Medical Protective receives no commercial support from pharmaceutical companies, biomedical device manufacturers, or any commercial interest.

It is the policy of Medical Protective to require that all parties in a position to influence the content of this activity disclose the existence of any relevant financial relationship with any commercial interest.

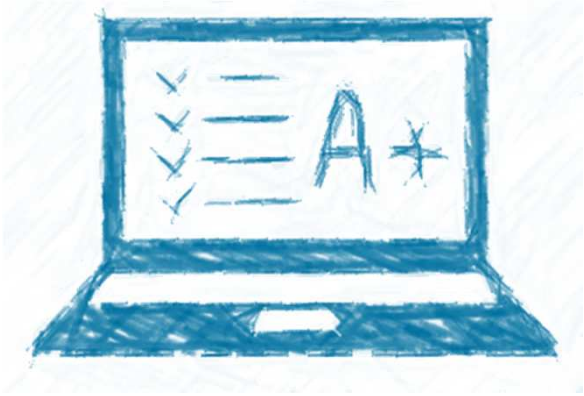
When there are relevant financial relationships, the individual(s) will be listed by name, along with the name of the commercial interest with which the person has a relationship and the nature of the relationship.

Today's faculty, as well as CE planners, content developers, reviewers, editors, and Patient Safety & Risk Solutions staff at Medical Protective have reported that they have no relevant financial relationships with any commercial interests.

Objectives

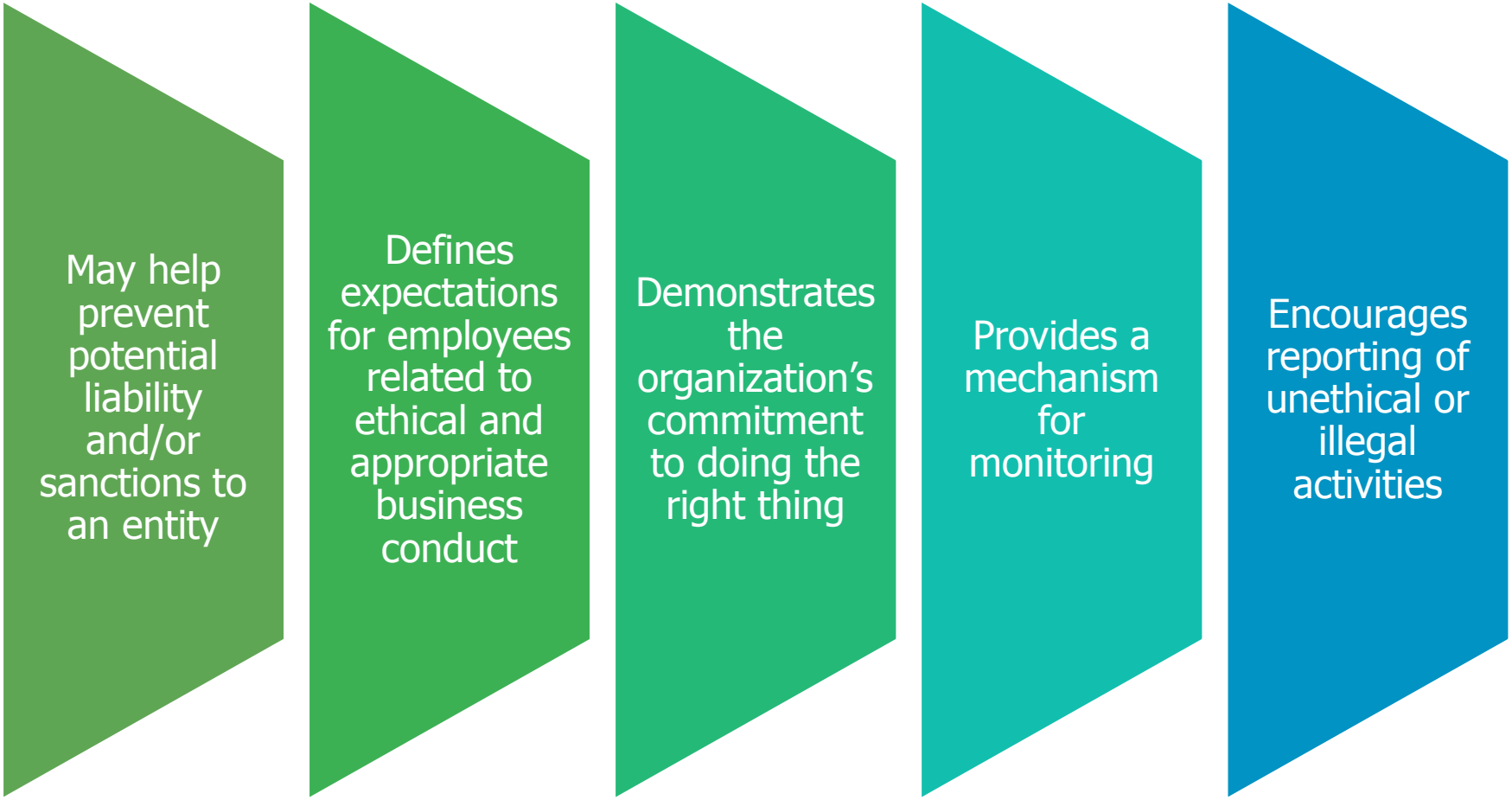
At the conclusion of this program, you should be able to:

- Demonstrate understanding of the laws pertaining to fraud, abuse, and waste
- Understand the seven fundamental elements of an effective compliance program as defined by the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG)
- Describe the key roles and responsibilities of a compliance officer and a compliance committee in a healthcare organization
- Identify resources to assist in developing a compliance program for a healthcare practice setting



What is a compliance program?

A corporate compliance program is an "effective program to prevent and detect violations of law." — United States Sentencing Commission



Source: United States Sentencing Commission. (2015, November). *Guidelines manual.* Retrieved from http://www.ussc.gov/guidelines-manual/2015/2015-ussc-guidelines-manual

Why have a compliance program?

Compliance programs are a requirement under the Patient Protection and Affordable Care Act (ACA).

Source: Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010).

U.S. Government Accountability Office

The U.S. Government Accountability Office's (GAO's) 2015 *High-Risk Series: An Update* designates Medicare as a high-risk program because of its size and complexity, which makes it vulnerable to fraud, waste, and abuse.

In 2014, Medicare financed healthcare for 51 million individuals at a cost of about $603 billion.

The Centers for Medicare & Medicaid Services (CMS) estimates that improper payments totaled close to $60 billion in 2014.

GAO suggests progress has been made — some as a result of the ACA; however, more is needed to address the issues and ensure Medicare is sustainable.

Source: U.S. Government Accountability Office. (2015, February). *High-risk series: An update* (GAO-15-290). Retrieved from http://www.gao.gov/products/GAO-15-290

HHS-OIG

- **Mission:** Protect the integrity of HHS by preventing waste, fraud, and abuse in federally funded healthcare programs — i.e., Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).
- HHS-OIG offers voluntary compliance program tools and resources to help healthcare providers and suppliers avoid fraudulent conduct and prevent the submission of false and erroneous claims.
- In 2000, HHS-OIG published *Compliance Program Guidance for Individual and Small Group Physician Practices.*

Source: U.S. Department of Health and Human Services, Office of Inspector General. (n.d.). About us. Retrieved from http://oig.hhs.gov/about-oig/about-us/

HHS-OIG and the ACA

The HHS-OIG believes that significant reductions in fraud and abuse liability can be accomplished through the use of compliance programs.

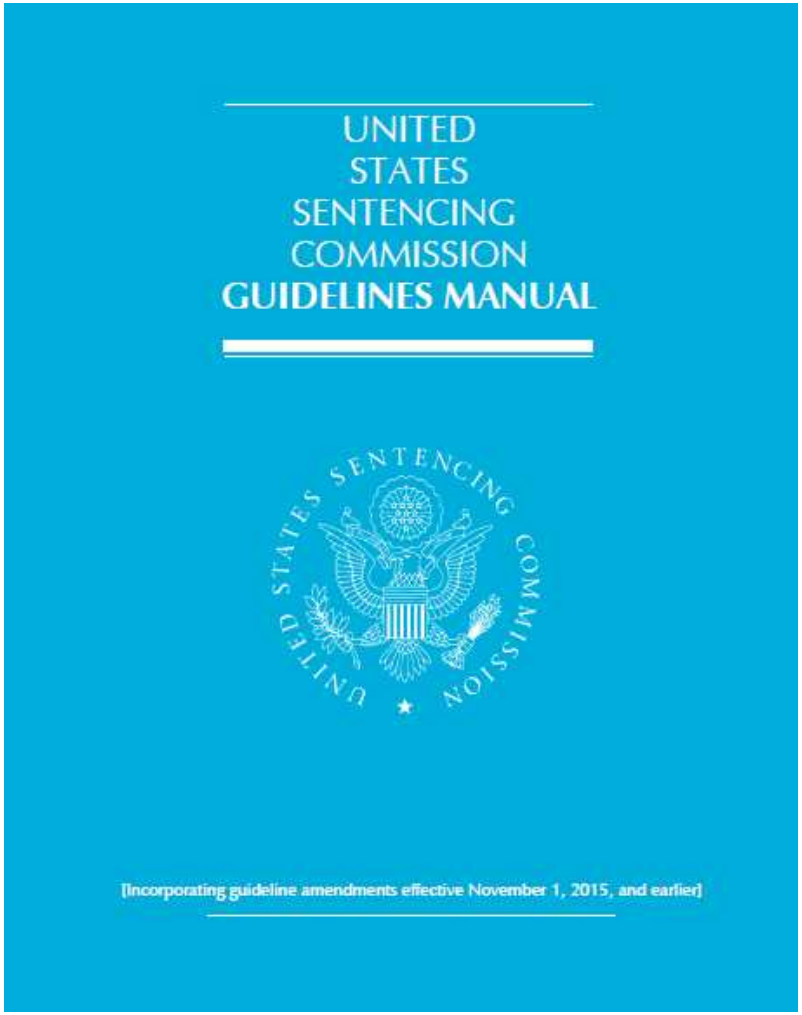
An effective program can minimize the consequences resulting from a violation of the law.

Section 6401 of the ACA authorizes the Secretary of HHS, in consultation with HHS-OIG, to establish core elements of a compliance program.

HHS-OIG advises using the seven elements in Chapter 8 of the *2010 U.S. Federal Sentencing Guidelines Manual* as core compliance program elements.

What are the *Federal Sentencing Guidelines?*

The United States Sentencing Commission (USSC) *Guidelines Manual* sets forth rules for a uniform sentencing policy for individuals and organizations convicted of felonies and serious (Class A) misdemeanors in the U.S. federal courts system.



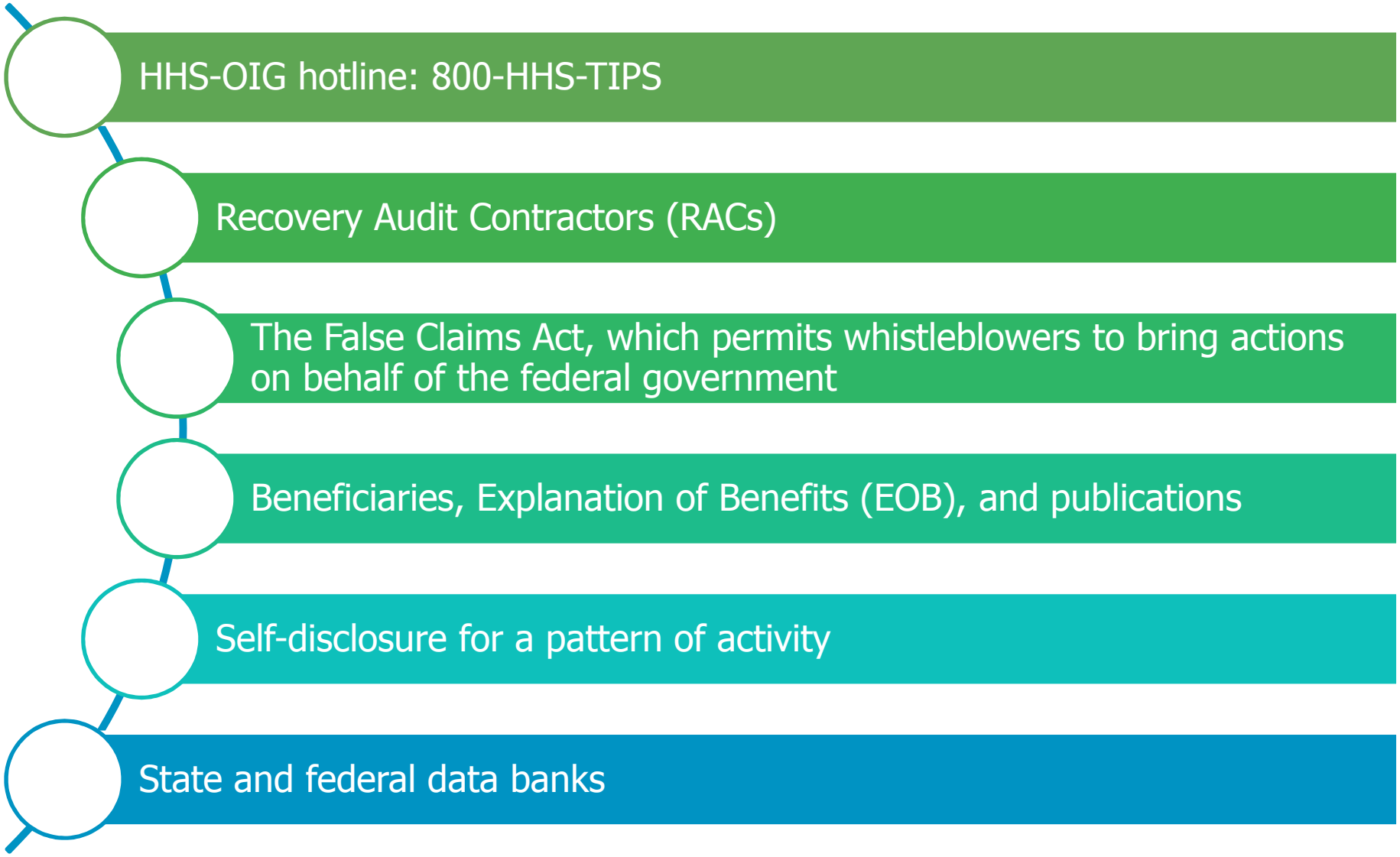
Source: USSC, *Guidelines manual,* http://www.ussc.gov/guidelines-manual/2015/2015-ussc-guidelines-manual

Creating an ethical culture

- The overall goal of an effective compliance program is to create an ethical corporate culture.
- An ethical corporate culture reduces the chance that fraud and abuse will occur.
- If fraud and abuse does occur, an effective compliance program reduces the chance that it will go undetected.

The Fraud and Abuse Laws

How fraud and abuse are uncovered



The fraud and abuse laws

Physician Self-Referral Law (42 U.S.C. § 1395nn)

Anti-Kickback Statute (42 U.S.C. § 1320a–7b(b))

False Claims Act (31 U.S.C. §§ 3729–3733)

Civil Monetary Penalties Law (42 U.S.C. § 1320a–7a)

Exclusion Authorities (42 U.S.C. §§ 1320a–7, 1320c–5)

Criminal Health Care Fraud Statute (18 U.S.C. §§ 1347, 1349)

Anti-Kickback Statute

Prohibits the *knowing* and *willful* payment of anything of value to induce or reward referrals for federal healthcare program business.

Physicians cannot offer any type of compensation to Medicare and Medicaid beneficiaries to influence their choice of healthcare provider.

Physicians often are targeted as a potential source of referral to other providers, pharmaceutical companies, and medical supply companies.

Some payments and business practices are protected as part of safe harbor provisions.

Fraud and abuse headlines

Department of Justice

U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE — Thursday, October 22, 2015

Springfield Doctor Indicted in Anti-Kickback Case

BOSTON – A Springfield gynecologist was arrested today in connection with allegedly accepting free meals and speaker fees from a pharmaceutical company in return for prescribing its osteoporosis drugs, allowing pharmaceutical sales representatives to access patient records and lying to federal investigators.

Rita Luthra, M.D., 64, of Longmeadow, was indicted on one count of violating the Anti-Kickback Statute, one count of wrongful disclosure of individually identifiable health information and one count of obstructing a criminal health care investigation by lying to federal agents and directing an employee to do the same. The indictment also seeks $23,500 in criminal forfeiture.

According to court documents, from October 2010 through November 2011, Warner Chilcott, a pharmaceutical company based in Rockaway, N.J., allegedly paid Luthra $23,500 to prescribe its osteoporosis drugs, Actonel® and Atelvia®. On 31 occasions, a Warner Chilcott sales representative allegedly brought food to Luthra's medical office for her and her staff, and paid Luthra $750 to talk with her for 25-30 minutes while she ate. On another occasion, Warner Chilcott paid to cater a barbeque that Luthra hosted at her home for her friends. Warner Chilcott also paid Luthra $250 for speaker training, despite the fact that she never spoke to any other physicians. It is alleged that Luthra's prescriptions of Warner Chilcott's osteoporosis drugs increased during the time that she was paid by the company, and precipitously declined once she stopped being paid. Luthra also allowed a Warner Chilcott sales representative to access protected health information in her patients' medical files. She further provided false information to federal agents when interviewed about her relationship with Warner Chilcott, and allegedly directed one of her employees to also lie.

Anti-Kickback, HIPAA, obstruction violations

Allegations	Pharmaceutical company paid the physician $23,500 to prescribe its osteoporosis medications.
	Pharmaceutical sales representative brought food to the physician's office 31 times.
	Sales representative paid the physician $750 for ~30-minute conversation.
	Company paid to cater a barbeque at the physician's home.
	Company paid the physician $250 for speaker training, even though she never spoke to any other physicians.
	The physician wrote more prescriptions for the osteoporosis medications during the time she was paid by the pharmaceutical company; prescriptions precipitously declined once she stopped receiving payment.

Anti-Kickback, HIPAA, obstruction violations

Other Allegations	Physician allowed sales representative to access protected health information in patients' medical files.
	Physician provided false information to federal agents when interviewed about her relationship with the pharmaceutical company and also directed an employee to lie.
Charges	Violating Anti-Kickback Statute (up to 5 years in prison, 3 years of supervised release, and $25,000 fine).
	Disclosure of individually identifiable health information (1 year in prison and/or a fine of $50,000).
	Obstructing a criminal healthcare investigation (up to 5 years in prison, 3 years of supervised release, and a fine of $250,000).

Physician Self-Referral (Stark) Law

- Prohibits physician referrals for certain designated health services to entities with which the physician or an immediate family member has a financial relationship.
- Financial relationships can include investment interest, ownership, or compensation arrangements.
- Improper referrals can lead to overutilization, increased costs, corruption of medical decision-making, patient steering, and unfair competition.

Designated healthcare services

- Clinical laboratory services
- Physical therapy, occupational therapy, and outpatient speech therapy services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment (DME) and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Source: U.S. Department of Health and Human Services, Office of Inspector General. (n.d.). *A roadmap for new physicians: Avoiding Medicare and Medicaid fraud and abuse.* Retrieved from http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf

Fraud and abuse headlines

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Friday, October 16, 2015

United States Resolves $237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians

The Department of Justice announced today that it has resolved a $237 million judgment against Tuomey Healthcare System for illegally billing the Medicare program for services referred by physicians with whom the hospital had improper financial relationships. Under the terms of the settlement agreement, the United States will receive $72.4 million and Tuomey, based in Sumter, South Carolina, will be sold to Palmetto Health, a multi-hospital healthcare system based in Columbia, South Carolina.

"Secret sweetheart deals between hospitals and physicians, like the ones in this case, undermine patient confidence and drive up healthcare costs for everybody, including the Medicare program and its beneficiaries," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "This case demonstrates the United States' commitment to ensuring that doctors who refer Medicare beneficiaries to hospitals for procedures, tests and other health services do so only because they believe the service is in the patient's best interest, and not because the physician stands to gain financially from the referral. The Department of Justice is determined to prevent the kind of abuses uncovered in this case, and we are willing to take such cases to trial to protect the integrity of the Medicare program."

The judgment against Tuomey related to violations of the Stark Law, a statute that prohibits hospitals from billing Medicare for certain services (including inpatient and outpatient hospital care) that have been referred by physicians with whom the hospital has an improper financial relationship. The Stark Law includes exceptions for many common hospital-physician arrangements, but generally requires that any payments that a hospital makes to a referring physician be at fair market value for the physician's actual services, and not take into account the volume or value of the physician's referrals to the hospital.

The government argued in this case that Tuomey, fearing that it could lose lucrative outpatient procedure referrals to a new freestanding surgery center, entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey and, in exchange, paid them compensation that far exceeded fair market value and included part of the money Tuomey received from Medicare for the referred procedures. The government argued that Tuomey ignored and suppressed warnings from one of its attorneys that the physician contracts were "risky" and raised "red flags."

Stark Law, False Claims Act, and Whistleblower Provision

Allegations	Payments to referring physicians must be at fair market value (FMV) for actual services; they cannot take into account the volume or value of referrals to the hospital.
	Fearing the loss of lucrative outpatient procedure referrals to a new freestanding surgery center, the hospital entered into contracts with 19 specialists that required the physicians to refer their outpatient procedures to the hospital in exchange for compensation that far exceeded FMV value and included money paid by Medicare.
	Warnings from a hospital attorney that the physician contracts were risky and raised red flags were ignored and suppressed.

Stark Law, False Claims Act, and Whistleblower Provision

More Details

The case arose from lawsuit filed by an orthopaedic surgeon in October 2005; surgeon was offered, but refused to sign, one of the illegal contracts.

Orthopaedic surgeon will receive $18.1 million under the settlement.

"This case demonstrates the United States' commitment to ensuring that doctors who refer Medicare beneficiaries to hospitals for procedures, tests and other health services do so only because they believe the service is in the patient's best interest, and not because the physician stands to gain financially from the referral." (Department of Justice news release, October 16, 2015)

False Claims Act

Prohibits the submission of claims for payment to Medicare or Medicaid that the healthcare provider *knows or should have known* to be false or fraudulent.

Penalties for filing false claims may be up to three times the actual loss plus $11,000 per claim filed.

Penalties also can include criminal charges and imprisonment.

The whistleblower provision allows individuals to file a lawsuit on behalf of the United States and receive some of the money recovered.

Qui tam lawsuits

- The False Claims Act contains a "qui tam" provision that allows individuals who have knowledge that an organization is defrauding the government to "blow the whistle" on illegal activity.
- The federal government has 60 days to investigate and decide whether they want to intervene in the case.
- Whistleblowers are entitled to between 15% and 25% of the total recovery.

- If the government does not intervene, the whistleblower can recover up to 30% of the total award.

Fraud and abuse headlines

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Tuesday, September 15, 2015

Florida Hospital District Agrees to Pay United States $69.5 Million to Settle False Claims Act Allegations

North Broward Hospital District, a special taxing district of the state of Florida that operates hospitals and other health care facilities in the Broward County, Florida, area, has agreed to pay the United States $69.5 million to settle allegations that it violated the False Claims Act by engaging in improper financial relationships with referring physicians, the Justice Department announced today.

"The Department of Justice has long-standing concerns about improper financial relationships between health care providers and their referral sources, because those relationships can alter a physician's judgment about the patient's true health care needs and drive up health care costs for everybody," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "In addition to yielding a recovery for taxpayers, this settlement should deter similar conduct in the future and help make health care more affordable."

"Our citizens deserve medical treatment uncorrupted by excessive salaries paid to physicians as a reward for the referral of business rather than the provision of the highest quality healthcare," said U.S. Attorney Wifredo A. Ferrer of the Southern District of Florida. "This office will be steadfast in continuing to devote all necessary resources to ensure that anyone rendering medical care does so for the sole benefit of the patient and in compliance with the law."

"Improper financial rewards given to physicians in exchange for patient referrals corrupts medical decision making and inflates health care costs," said Special Agent in Charge Shimon R. Richmond of the U.S. Department of Health and Human Services-Office of Inspector General (HHS-OIG). "Our agency will continue to root out such behavior from our health care system."

The settlement announced today resolved allegations that the hospital district provided compensation to nine employed physicians that exceeded the fair market value of their services. The United States contended that these agreements violated the Stark Statute and the False Claims Act. The Stark Statute restricts the financial relationships that hospitals may have with doctors who refer patients to them.

False Claims and Whistleblower Provision

Allegations	Individuals who owned a critical access hospital and a management company claimed to be serving the hospital in various management and directorship positions; however, they did little of the work for which the hospital paid them.
	Any work they did was duplicative of work performed by hospital and management company staff.
	The owners improperly claimed the expenses of personal luxury automobiles on the hospital's cost reports.
	The management company wrongfully charged the hospital for work that one of the owners did at his other businesses.

Dental fraud and abuse headlines

08-12-2015

Colorado Dentist Agrees to Voluntary Exclusion

- On August 12, 2015, Dr. Robert E. Hackley, Jr., DDS, agreed to be excluded from participation in all Federal health care programs for a period of three years. OIG conducted an investigation of Dr. Hackley for dental care he provided to patients at Small Smiles Dentistry for Children in Colorado Springs, Colorado. OIG's investigation revealed that Dr. Hackley furnished dental services to patients of a quality which failed to meet professionally recognized standards of care, including: performing medically unnecessary dental procedures, failing to treat existing dental conditions, and performing dental procedures that were below professionally recognized standards of care. Senior Counsels Geoffrey Hymans and Tamara Forys represented OIG.

06-30-2015

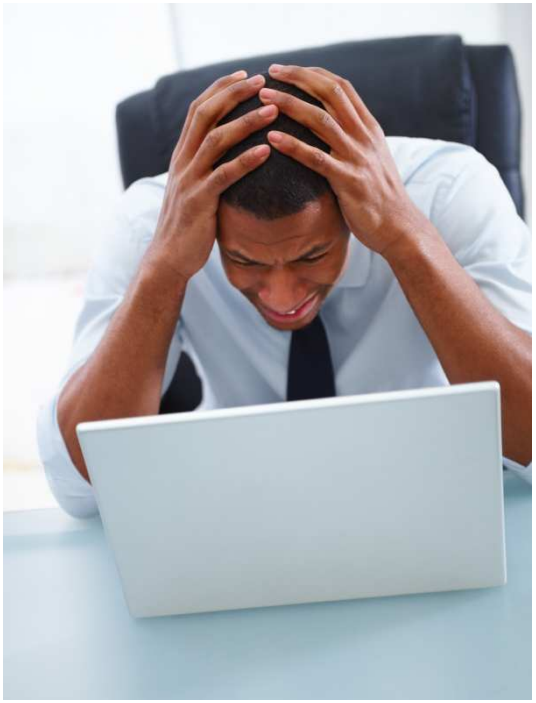
Dental Practice Settles Case Involving Excluded Individual

- On June 30, 2015, Adam Diasti, D.D.S., P.C. (Diasti), a dental services provider, entered into a $22,319.26 settlement agreement with OIG. The settlement agreement with OIG resolves allegations that Diasti employed an individual who was excluded from participating in any Federal health care programs. OIG's investigation revealed that in two Diasti-affiliated California dental offices, the excluded registered dental assistant provided items and services to patients that were billed to Federal health care programs. Senior Counsel Keshia Thompson represented OIG with the assistance of Paralegal Specialist Jennifer McKoy and Program Support Assistant Tynishia Gardner.

Source: Department of Health and Human Services, Office of Inspector General. (n.d.). Civil monetary penalties and affirmative exclusions. Retrieved from http://oig.hhs.gov/fraud/enforcement/cmp/

Exclusion Statute and Civil Monetary Penalties Law

- **Exclusion Statute:** HHS-OIG must exclude individuals or entities from participation in all federal healthcare programs when certain offenses are committed.
  - Examples of exclusionary offenses include Medicare fraud; patient abuse or neglect; felony convictions for other healthcare-related fraud, theft, or other financial misconduct; and unlawful manufacture, distribution, prescription, or dispensing of controlled substances).
  - HHS-OIG has discretionary exclusion authority on certain offenses (e.g., misdemeanor convictions and provision of unnecessary or substandard services).
- **Civil Monetary Penalties Law:** HHS-OIG can seek civil monetary penalties ranging from $10,000 to $50,000 and/or exclusion for a myriad of offenses, such as violating the fraud and abuse laws and EMTALA violations.



Red flag activities

- Billing for medically unnecessary services
- False records or statements
- Improper certifications for home health or DME
- Payment for providing anything of value to induce beneficiaries
- Retention of overpayments
- Suspicious physician incentive plans
- Upcoding

Corporate integrity agreements

- Corporate integrity agreements (CIAs) are contracts between providers and HHS-OIG as part of a settlement.
- Providers agree to obligations in exchange for the HHS-OIG not seeking exclusion from federal healthcare programs.
- CIAs usually last 5 years and include requirements to:
    - Hire a compliance officer/appoint a compliance committee
    - Develop written standards and policies
    - Implement a comprehensive employee training program
    - Retain an independent review organization for annual reviews
    - Establish a confidential disclosure program
    - Restrict employment of ineligible persons
    - Report overpayments, reportable events, and investigations
    - Provide implementation and annual report

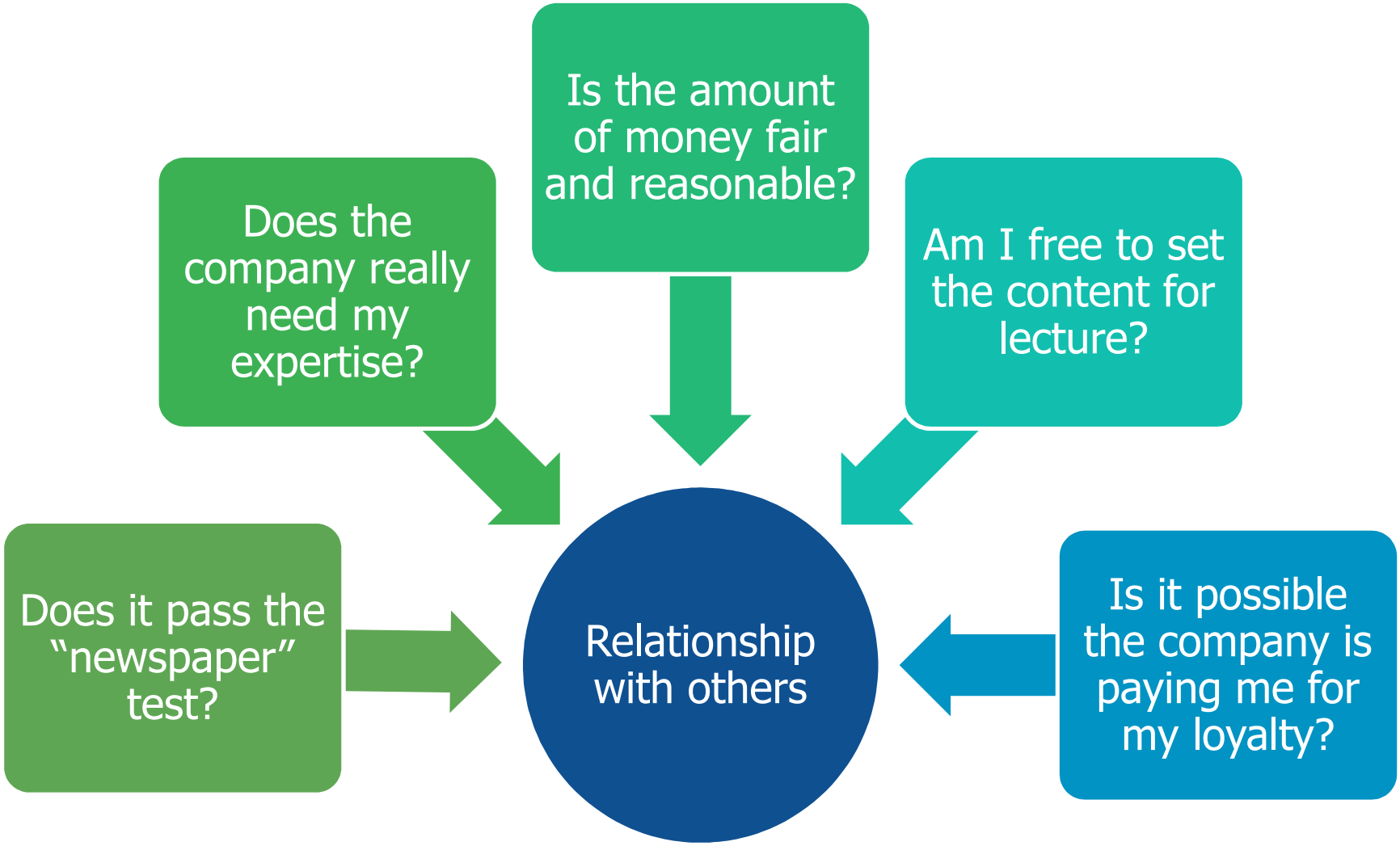
Sample CIA

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JOHN SUNGHOON WON, D.D.S., M.D.; JOHN S. WON, D.D.S., M.D., P.A. D/B/A PRESTON ORAL AND MAXILLOFACIAL SURGERY

I. PREAMBLE

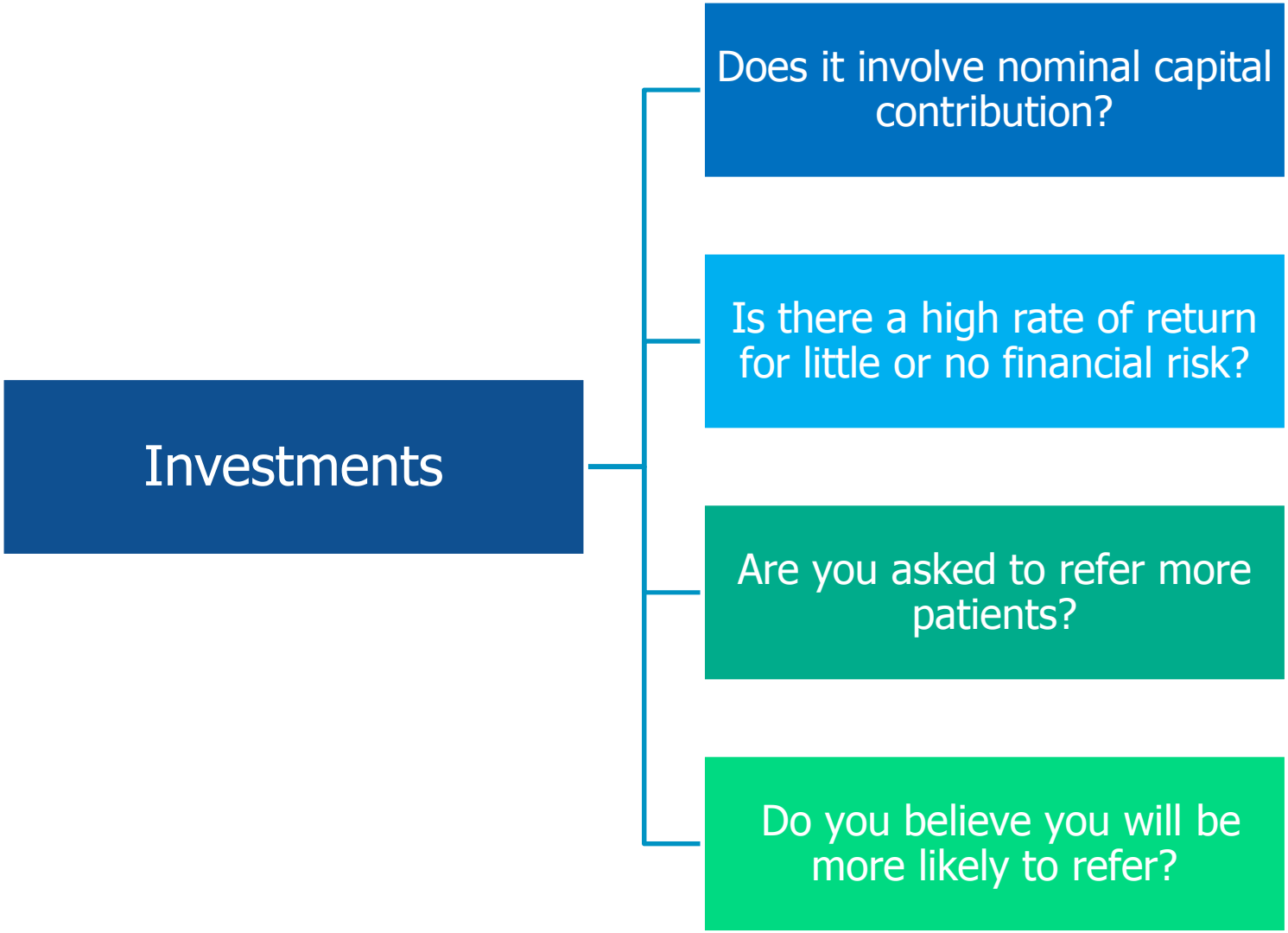
John Sunghoon Won, D.D.S., M.D.; and John S. Won, D.D.S., M.D., P.A. d/b/a Preston Oral and Maxillofacial Surgery (collectively, "Dr. Won") hereby enter into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this IA, Dr. Won is entering into a Settlement Agreement with the United States.

Relationships with others



Source: HHS-OIG, *A roadmap for new physicians,* http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf

Investments in business ventures



Source: HHS-OIG, *A roadmap for new physicians,* http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf

Billing red flags

- Are you billing for services you rendered?
- Are the services medically necessary?
- Are you billing for services of an excluded provider?
- Are you billing separately for services already included in the global fee?
- Are you billing for services performed by an improperly supervised or unqualified employee?

Source: HHS-OIG, *A roadmap for new physicians,* http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf

The Seven Fundamental Elements of an Effective Compliance Program

HHS-OIG's seven fundamental elements

Source: Department of Health and Human Services, Office of Inspector General. (n.d.). Health care compliance program tips. Retrieved from http://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf

Ensuring program success

Gain support of board and executive staff

Provide ongoing staff education, particularly in the high-risk areas

Audit high-risk areas

Monitor for compliance

Ensure consistency in enforcement

Element 1: Implement policies, procedures, and standards of conduct

Compliance policies, procedures, and standards should:

- Identify model behavior for employees and explain how to report suspected instances of compliance problems or unethical conduct.
- Specify in detail the duties of the CO and CC (both of whom should be involved in developing the policies, procedures, and standards).
- Provide guidelines for periodic monitoring and review of policies, procedures, and standards.

Once developed, compliance policies, procedures, and standards should be reviewed with, and distributed to, all employees of the organization within 90 days of hire and at least annually.

Employees should acknowledge review and understanding of the policies.

Compliance materials should be readily available for review.

Compliance plan outline

I. **Code of Conduct**
   A. CEO message and mission and value statement
   B. Laws — e.g., conflicts of interest; HIPAA; fraud, waste, and abuse

II. **Administration of the Compliance Plan**
   A. Compliance officer and compliance committee duties

III. **Training and Education**

IV. **Communication**

V. **Auditing and Monitoring**
   A. Scope and methods

VI. **Disciplinary Action**

VII. **Responding to Detected Offenses and Corrective Action**
   A. Violations, investigations, and reporting

Element 2: Provide compliance program oversight

Compliance Officer

- The CO has primary responsibility for the structure and administration of the compliance program and reports directly to the CEO or senior management.
- The CO is informed about the outcomes of audits and monitoring; reports compliance enforcement activity to the board of directors; reviews and performs assessments of the program; and reports annually to the board of directors.

Compliance Committee

- The CC is a multidisciplinary committee that develops, reviews, and updates policies and procedures; develops and audits the work plan and risk assessment plan; attends operational staff meetings; monitors and audits compliance performance; enforces disciplinary standards; recommends policy, procedure, and process improvements; and enforces compliance program requirements at all levels of the organization.

Baseline risk assessment

- A baseline risk assessment is a formal review of the major fraud, waste, and abuse areas.
- The assessment should include areas of concern identified by CMS and others, as well as a classification of the risk levels.
- Areas identified as high-risk should be audited more frequently. Examples include coding and billing, work with excluded providers, false claims, gifts from vendors, and physician compensation.
- The risk assessment results should be an essential component in developing and addressing the monitoring and auditing work plans.

Element 3: Use due diligence in the delegation of authority

Perform background checks on all new management employees.

Perform periodic background checks on existing management employees.

"Use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program."

— United States Sentencing Commission

United States Sentencing Commission. (2010). 2010 Federal Sentencing Guidelines Manual (§8B2.1(b)(3)). Retrieved from http://www.ussc.gov/guidelines-manual/2010/2010-8b21

Element 4: Provide training and education

- Ensure adequate understanding of expectations under the code of conducts and standards in the compliance plan.
- Enforce mandatory training for all employees.
- Provide a comprehensive review of the compliance plan and code of conduct upon initial hire, and review the plan annually thereafter.
- Ensure that training is interactive and includes compliance scenarios that might potentially be encountered.
- The CO should regularly communicate compliance messages via other informal training methods.
- Document the provision of all compliance training.

Opening the lines of communication

Require employees to report issues in a timely manner.

Establish a formal process for managers to communicate compliance issues and corrective action results to staff.

Develop an anonymous reporting process to prevent fear of retaliation.

Ensure several methods for reporting compliance and ethical concerns.

Have the CO and CC evaluate the effectiveness of the reporting process.

- Employees should be familiar with what issues to report, who to report to, and the timeframe for reporting concerns.
- Employees should be encouraged to report, and feel comfortable reporting, issues to multiple individuals (e.g., any manager, the CO, and the CC).

Element 5: Conduct internal monitoring and auditing

- Monitor to ensure procedures are working as intended.
- Follow up on recommendations and corrective action plans to verify they are being implemented.
- Ensure monitoring occurs on a regular basis (weekly or monthly).
- Ensure the monitoring work plans cover frequency of monitoring, person(s) responsible, and issues of concern for the organization.

Element 5: Conduct internal monitoring and auditing

Audit annually to ensure compliance with statutory and CMS requirements.

- Internal staff or an external organization can conduct audits, and auditing may include a variety of methods.

Develop a written report of findings and recommendations.

Ensure auditing work plans include a start schedule, methods used, results, and corrective actions.

Element 6: Enforce standards through discipline

Apply consistent and timely discipline when an investigation confirms an offense.

Make sure employees are well of aware of disciplinary policies.

Clearly write disciplinary policies and describe expectations and consequences for noncompliance.

Make sure policies include sanctions for failure to:

- Comply with the code of conduct.
- Detect noncompliance when routine observation or due diligence should have provided notice.
- Report actual or suspected noncompliance.

Element 7: Respond promptly and undertake corrective action

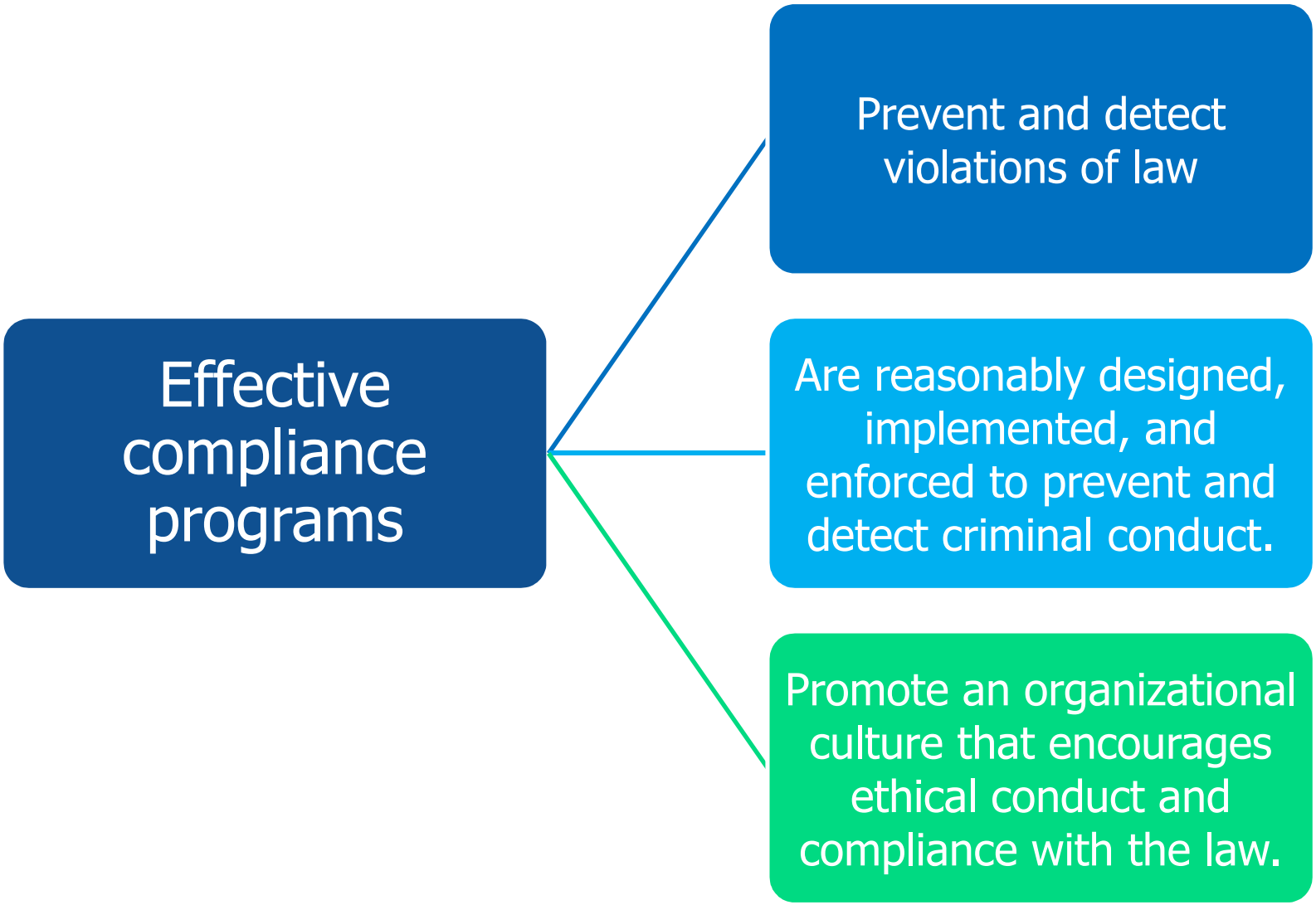
Use corrective actions when vulnerabilities, noncompliance, or potential violations are identified.

Identify offenses through a report or the results of a risk assessment, auditing, or monitoring.

Implement corrective action, such as:

- Education and training.
- Repayment of overpayments.
- Disciplinary action against responsible employees.

Summary



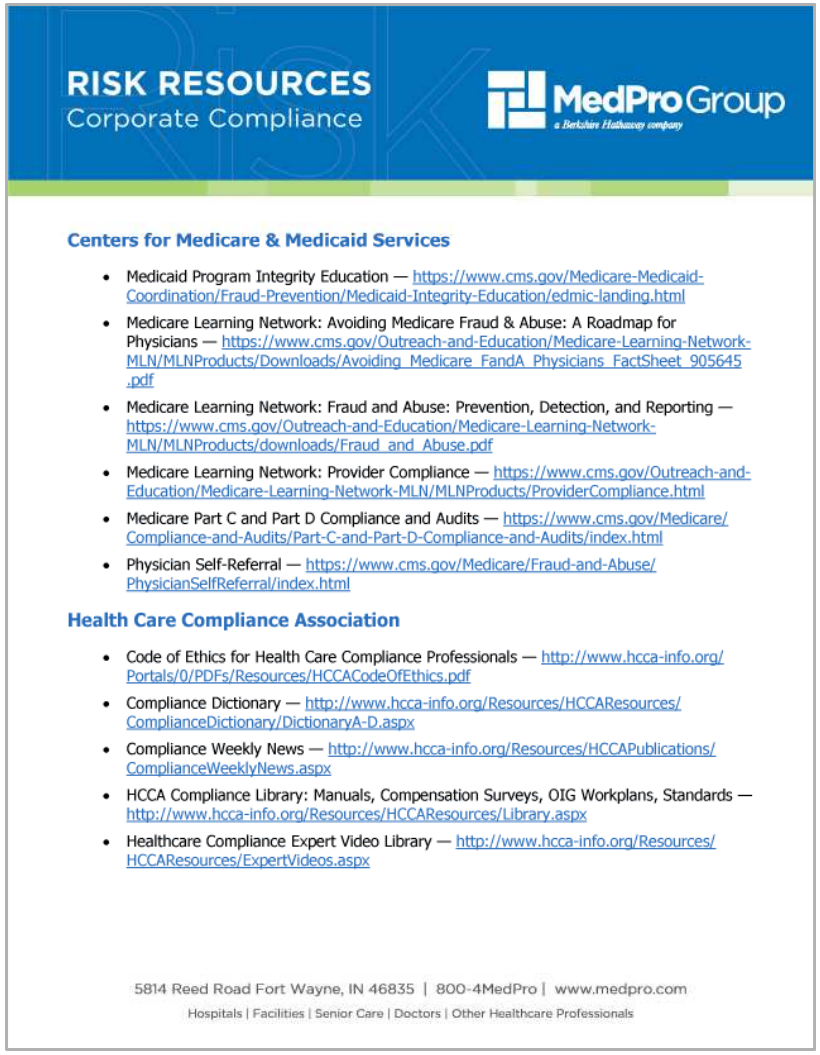
United States Sentencing Commission. (2015). Guidelines manual (chapter 8). Retrieved from http://www.ussc.gov/guidelines-manual/2015/2015-ussc-guidelines-manual

Resources

Resources

Check out PS&RS's corporate compliance resource list at: http://www.medpro.com/rm-resource-lists.

Don't forget to follow us on Twitter @MedProProtector for timely patient safety and risk information, great resources, and information about upcoming educational opportunities.



RISK RESOURCES
Corporate Compliance

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Centers for Medicare & Medicaid Services

- Medicaid Program Integrity Education — https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html
- Medicare Learning Network: Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians — https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_FandA_Physicians_FactSheet_905645.pdf
- Medicare Learning Network: Fraud and Abuse: Prevention, Detection, and Reporting — https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf
- Medicare Learning Network: Provider Compliance — https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html
- Medicare Part C and Part D Compliance and Audits — https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html
- Physician Self-Referral — https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html

Health Care Compliance Association

- Code of Ethics for Health Care Compliance Professionals — http://www.hcca-info.org/Portals/0/PDFs/Resources/HCCACodeOfEthics.pdf
- Compliance Dictionary — http://www.hcca-info.org/Resources/HCCAResources/ComplianceDictionary/DictionaryA-D.aspx
- Compliance Weekly News — http://www.hcca-info.org/Resources/HCCAPublications/ComplianceWeeklyNews.aspx
- HCCA Compliance Library: Manuals, Compensation Surveys, OIG Workplans, Standards — http://www.hcca-info.org/Resources/HCCAResources/Library.aspx
- Healthcare Compliance Expert Video Library — http://www.hcca-info.org/Resources/HCCAResources/ExpertVideos.aspx

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