



# Medicare Compliance and Fraud, Waste and Abuse (FWA) Training

# Overview & Objectives



- **What:** Compliance & Fraud Waste & Abuse (FWA) program requirements
  - Things you need to be aware of and implement into your practices.
- **Why:** Compliance programs help raise awareness and provide mechanisms to detect, prevent, correct non-compliance & FWA
  - You **must** report non compliance and suspected or known FWA activities to your compliance officer.
- **How:** Training and education
  - You must demonstrate training through completion of this training or an equivalent training
  - You must be able to ensure that training was completed for each of your staff and that you have a process for new hires.

# Overview & Objectives (continued)

- **Training must comply with 42 C.F.R. Parts 422.503(b)(4)(vi)(C) or 423.504(b)(4)(vi)(C) and include at a minimum the following:**
  - Laws and regulations related to MA and Part D FWA (i.e. False Claims Act, Anti-Kickback statute, HIPAA, etc.).
  - Obligations of FDRs to have appropriate policies and procedures to address FWA.
  - A process for reporting to the Part C or D Sponsor suspected FWA.
  - Protections for Sponsor employees and employees of FDRs who report suspected FWA.
  - Types of FWA that can occur in the settings in which employees work.

# Overview & Objectives (continued)

- **Methods of Training:**
  - Effective training methods include: interactive sessions led by expert facilitators, web-based tools, such as CMS' MED Learn site, Intranet sites, live or videotaped presentations, written materials, or any combination of these techniques, or any other methods, that are effective for the specific organization.
  - Effective training and education often includes engaging employees in substantive discussion to reinforce the organization's commitment to compliance with applicable laws, regulations, standards, and principles.
  - Training should be designed to ensure that employees understand what is expected of them regarding compliance.

# Overview & Objectives (continued)

- **Measuring Effectiveness of Training and Education:**
  - May include the use of tests or quizzes during training sessions, monitoring of compliance, use of FWA reporting logs to determine the effectiveness of the training/education and to demonstrate enhanced employee understanding of compliance and FWA issues. CMS noted that the number and quality of FWA reports will increase if employees receive effective training.
  - Feedback from employees to the Compliance Officer in the form of:
    - Evaluation forms, employee focus groups, one-to-one meetings between the compliance staff and small groups of employees and/or periodic attendance at departmental meetings.

# Overview & Objectives (continued)

- **Measuring Effectiveness of Training and Education (continued):**
  - Improved effectiveness by maintaining a dialogue between the Compliance Officer and all employees including management regarding compliance. Relevant inquiries include what employees think is helpful about the program, where they could use assistance and additional training and what suggestions they have for improving the program.
  - A continuing problem in a particular operational area, despite the training provided, can be indicative of ineffective training (among other factors). ***Please note that CMS did not elaborate on the other factors.***
  - Evaluation of the training is required to determine the effectiveness of the training. The evaluation must identify deficiencies and implement remedial actions to correct any deficiencies.



# Overview & Objectives (continued)

- **Who:** All First tier, Downstream and Related entities (FDR's) , including providers and delegated entities. This includes all staff, governing body members, CEO, Senior Administrators, and Managers down to the ultimate provider of care.
  - Medicare Providers who have met the FWA certification requirements through enrollment or accreditation are deemed for FWA training based on their Medicare participation, but not deemed for Compliance Training.
- **When:** Complete this training by annually by December 31<sup>st</sup> of each year.

# Overview & Objectives (continued)

- **FWA Provisions Under the Patient Protection and Affordable Care Act H. R. 3590**
- **Public Law 111 - 148 - Patient Protection and Affordable Care Act 2010**
  - Provides CMS authority to impose certain enhanced oversight and screening measures (i.e., licensure checks, background checks, and site visits) on providers and suppliers enrolling in Medicare, Medicaid, and CHIP. §1559
  - Introduces new Civil Monetary Penalties (CMPs) for certain types of infractions, including falsifying information on provider enrollment applications and delaying investigations and audits by the OIG. Title VI. §§6111, 6408
  - Enhances CMS authority to impose penalties on MA plans for violating the terms of their contract. § 6408 and § 2717 (a)(1)(2)(D)



# Overview & Objectives (continued)

- §6504 Requirement to report expanded set of data elements under MMIS to detect fraud and abuse.
- § 6604 Applicability of State law to combat fraud and abuse
- § 10606 Health care fraud enforcement.
  - (a) FRAUD SENTENCING GUIDELINES.— enhanced offense levels for conviction of a Federal health care offense relating to a Government health care program.
    - 2 levels – for loss not less than \$1,000,000 and < \$7,000,000
    - 3 levels – for loss not less than \$7,000,000 and < \$20,000,000
    - 4 levels – for loss not less than \$20,000,000
  - **Creates a strict liability standard “With respect to violations of this section, a *person* need not have actual knowledge of this section or specific intent to commit a violation of this section.”**

# Key Terms and Acronyms



## **Original Medicare**

- Medicare Part A - Hospital Insurance, which pays for inpatient care, skilled nursing facility care, hospice, and home health care.
- Medicare Part B - Medical Insurance: pays for doctor's services, and outpatient care such as lab tests, medical equipment, supplies, some preventive care and some prescription drugs.

## **Medicare Advantage Organizations (MAO)**

- Medicare Part C – is also know as Medicare Managed care, where coverage is through an MAO for coverage that would otherwise be through original Medicare under Part A and Part B.

## **Medicare Prescription Drug Sponsors**

Medicare Part D is Medicare Prescription Drug coverage which helps pay for prescription drugs, certain vaccines and certain medical supplies (e.g. needles and syringes for insulin).

- Part D coverage be through an MAO that adds Part D benefits, which is called a Medicare Advantage Prescription Drug Plan (MAPD), OR
- Part D coverage may be through a Prescription Drug Plan Sponsor (PDP)

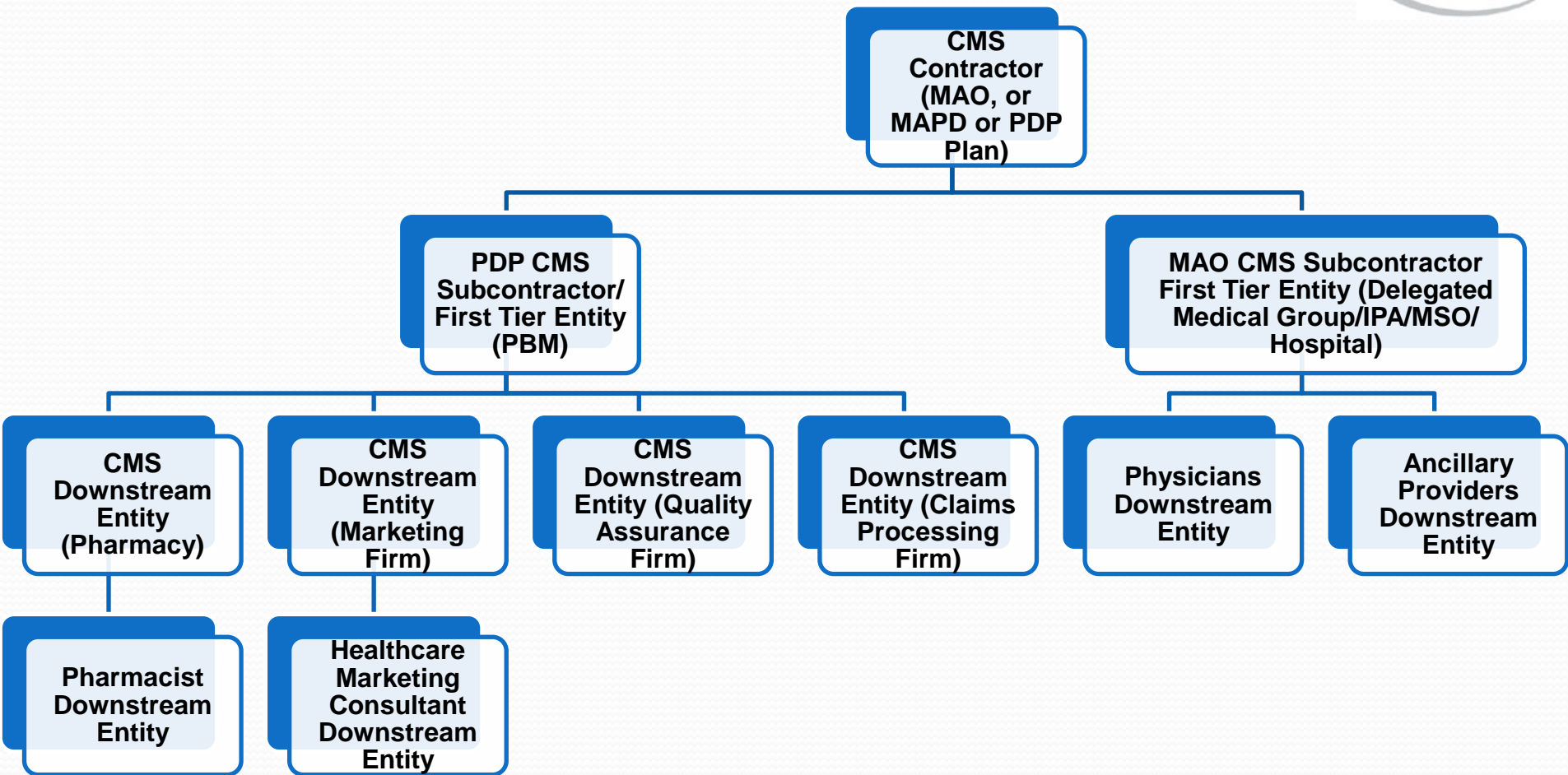
# Key Terms and Acronyms



**First Tier, Downstream and Related Entities (FDR's)** are entities contracted or subcontracted with an MAO or PDP Sponsor as defined below:

- **First Tier Entity:** A party contracted with an MAO or PDP Plan to provide administrative or health care services for MAO or PDP Plan members. Examples include: IPA's, Medical Groups, Management Services Organizations (MSO) Pharmacy Benefit Managers (PBM), hospitals, health clinics, directly contracted physicians, ancillary providers, brokers, field marketing organizations, agents, enrollment or claims processing entities.
- **Downstream Entity:** A party contracted with a First Tier Entity to provide administrative or health care services on behalf of the MAO or PDP Plan. Examples include subcontractors of an IPA /MSO/ hospital subcontractors such as physicians, claims processing firms, ancillary providers, PBM subcontractors such as pharmacies, subcontractors with of General Agencies or Field Marketing Organizations.
- **Related Entity:** A party connected MAO or PDP Plan by common ownership or control and performs some of the MAO or PDP management functions under contract or delegation.

# First Tier and Downstream Example



# Compliance

- CMS updated its Federal Regulations to clarify compliance program requirements which originally became effective on January 1, 2011. The new regulations provide guidance to prevent, detect and correct Medicare Parts C & D noncompliance and FWA.
  - Refer to C.F.R. and 42 C.F.R. §422.503(b)(4)(vi)(C) 42 C.F.R. § 423.504(b)(4)(vi)(C) for details on required training and education for General Compliance and FWA.
  - Additional regulatory guidance is in the CMS Part D Manual, under Chapter 9
  - [http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/PDBManual\\_Chapter9\\_FWA.pdf](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/PDBManual_Chapter9_FWA.pdf) (***please note that the 2012 final guidance has not been posted to CMS as of 7/16/12***)
  - This course was developed by ICE volunteers to provide a standard training & education program that combines general compliance and FWA training. Alternate training programs from MAO or PDP Plans, IPA's, Medical Groups, Hospitals, PBM's and other entities may be used to meet the overall compliance and FWA training requirements if they address both general compliance requirements and fraud, waste and abuse requirements.

# **CMS expects the Compliance Program to address compliance with all applicable laws, including but not limited to:**

- Title XVIII of the Social Security Act.
- Medicare regulations governing Parts C and D found at 42 C.F.R. §§ 422 and 423 respectively.
- Federal and State False Claims Acts (31 U.S.C. §§ 3729-3733).
- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)).
- The Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a(a)(5)).
- Physician Self-Referral (“Stark”) Statute (42 U.S.C. § 1395nn).
- Health Insurance Portability and Accountability Act.
- Fraud Enforcement and Recovery Act of 2009.
- Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the Federal government.
- Other applicable criminal statutes.
- Applicable provisions of the Federal Food, Drug, and Cosmetic Act.
- All sub-regulatory guidance produced by CMS such as manuals, training materials, HPMS memos, and guides;
- Contractual commitments.



# Distribution of Compliance Policies and Procedures and Standards of Conduct

- CMS expects Sponsors and FDRs to distribute compliance policies and procedures and Standards of Conduct to all employees at the following times:
- Within 90 days of the time of hire of Sponsor and FDR employees (or initial contracting in the case of FDR organizations);
- Annually thereafter; and, whenever policies and procedures/Standards of Conduct are revised or updated.
- In addition, compliance policies and procedures and Standards of Conduct should be easily accessible to all employees of the Sponsor and of FDRs. This may include posting the policies, procedures and Standards on the employee intranet, on a Sponsor website for FDRs, in easily accessible department binders, etc.

# Distribution of Compliance Policies and Procedures and Standards of Conduct (continued)



- Because distribution of compliance policies and procedures and Standards of Conduct is essential to effectiveness, CMS expects Sponsors **to ensure** that its employees and employees of FDRs, as a condition of employment, read and agree to comply with all written compliance policies and procedures and Standards of Conduct **within 90 days of the date of hire and annually thereafter.**
- The Sponsor must be able to demonstrate to CMS that all employees and employees of FDRs have done so. **This may be accomplished by employee statements or certifications or otherwise.** CMS strongly recommends that the Sponsor coordinate tracking efforts to ensure that employees and FDR employees meet these requirements.
- The Sponsor's contracts with FDRs should include provisions that the FDR will implement and distribute to all FDR employees and board members either the Sponsor's Standards of Conduct and compliance policies and procedures, or comparable policies and procedures and Standards of Conduct of their own.



# Training Requirements



Compliance and FWA Training is required for all new hires within 90 days, and all employees, CEO, Governing body members, senior administrators and managers annually, and whenever policies/procedures are revised or updated thereafter.

- This is not intended to replace training on HIPAA Privacy, Security and breach reporting  
*(Acceptable to use ICE training or alternate equivalent training or to customize this based on your audience)*

## **Require Annual Compliance and FWA Training**

- Health Plan Staff that work with MA or Part D programs
- Pharmacy Benefit Managers (PBMs)
- Pharmacies and pharmacists
- Subcontractors such as claims processing firms
- Dentists
- IPA's / Medical Groups
- Optometrists

## **Require Annual Compliance Training but may be deemed as Medicare Providers for FWA**

- Hospitals
- SNFs
- Physicians (PCP's and Specialists)
- Ancillary providers (DME, Radiology, Lab etc.)
- Home Health Providers

# Effective Mechanisms To Ensure Fulfillment Of Compliance Training Requirements

- Sponsors must establish effective mechanisms to ensure that FDRs fulfill the compliance training requirements (e.g. incorporate the requirement into contracts with FDRs, collect attestations from FDRs, coupled with monitoring and auditing of a sample of FDRs to validate training requirements were fulfilled, etc.).
- Review and update, if necessary, the general compliance training at least annually, and whenever changes in regulations, policy or guidance require revision of the training materials. The governing body should review and approve the compliance training materials as part of its oversight responsibilities.
- Training should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of potential noncompliance or FWA.

# Effective Mechanisms To Ensure Fulfillment Of Compliance Training Requirements (continued)

- A review of the disciplinary guidelines for non-compliant or fraudulent behavior. The guidelines will communicate how such behavior can result in mandatory retraining and may result in disciplinary action, including possible termination when such behavior is serious or repeated or when knowledge of a possible violation is not reported.
- Attendance and participation in formal training programs as a condition of continued employment and a criterion to be included in employee evaluations.
- A review of policies related to contracting with the government, such as the laws addressing fraud and abuse or gifts and gratuities for Government employees.
- A review of potential conflicts of interest and the Sponsor's disclosure system.
- An overview of HIPAA, the CMS Data Use Agreement, and the importance of maintaining the confidentiality of Personal Health Information.
- An overview of the monitoring and auditing work plan of the organization.



# Specialized Compliance Training Requirement

- **42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)**
- Training and education of employees, managers, directors and FDRs in Medicare program compliance includes specialized training on issues posing compliance risks based on the individual's job function (e.g., pharmacist, statistician, customer service, etc.). Specialized training is necessary upon initial hire or appointment to the job function, when requirements change, when an employee works in an area previously found to be non-compliant with program requirements or implicated in past misconduct, and at least annually thereafter as a condition of employment
- Sponsors must require that FDRs administer specialized compliance training, or where there are sufficient organizational similarities, the Sponsor may choose to make its own specialized training programs available to these entities.

# Specialized Compliance Training Requirement (continued)

- Examples of specialized training for Sponsor employees, directors and FDRs include, but are not limited to training for those involved in:
  - Marketing the prescription drug benefit to Medicare beneficiaries;
  - Managing or administering the exceptions and appeals process;
  - Calculating TrOOP;
  - Making negotiated prices available to beneficiaries;
  - Submitting the payment bid to CMS;
  - Payment reconciliation;
  - Submitting Part C and D data to CMS;
  - Negotiating rebate agreements with Pharmaceutical Manufacturers, wholesalers, and other suppliers of Part D drugs;

# Specialized Compliance Training Requirement (continued)

- **(Examples Continued)**
- Negotiating pharmacy network agreements;
- Administering the Compliance Program and operations, i.e., the Medicare Compliance Officer and his/her staff;
- Conducting administrative activities necessary for the operation of the Part C and D benefits;
- Managing employer group plans; and
- Security and authentication instructions involved in Health Information Technology.
- Specialized compliance training must be reviewed and revised as needed but at least annually, especially as risk areas change and evolve over time. Sponsors must retain adequate records of their specialized training of employees, including attendance logs, materials distributed at training sessions and results of testing.



# Seven Key Compliance Plan Elements



## 1. Written Standards of Conduct:

- Develop & distribute written Standards of Conduct
  - Adopting the MAO / PDP plan standards or adopting company standards of your own that meet the requirements
  - Plan standards can be referred to on the MAO or PDP website / portal.
- Policies & Procedures to promote your commitment to compliance & address prevention, detection, and correction of potential fraud, waste, and abuse.

## 2. Designation of a Compliance Officer and Compliance Committee:

- A Compliance Officer is appointed to oversee a Compliance Committee accountable to Senior Management / the Board
  - The Compliance Officer is charged with the responsibility and authority of operating and monitoring the compliance program.

## 3. Effective Compliance Training:

- Development and implementation of regular, effective education, and training -- for employees, contractors, providers, managers, senior administrators and the Governing Board.

## 4. Effective Lines of Communication:

- Between the compliance officer and employees, managers, directors members of the compliance committee, and first tier, downstream and related entities.

# Seven Key Compliance Plan Elements



## 5. Internal Monitoring and Auditing:

- Measuring and evaluating risks
  - Using risk evaluation techniques, self reporting, & audits to monitor compliance,
  - Oversight activity, reporting and audits designed to test and confirm compliance, ensure that necessary corrective action is taken, identify risks associated with Parts C & D benefits
  - Oversight to identify other compliance risks to assist in the reduction of identified problem areas.
  - The monitoring & audit work plan must be reflective of the size, type of organization, risks and resources to assess performance in and at a minimum to areas identified as being at risk.

## 6. Disciplinary Mechanisms:

- Policies to consistently enforce standards
  - Policies for dealing with compliance issues, and with individuals, or entities that are excluded from participating in Medicare or Government programs.
  - Employees & FDRs must be informed that violation of standards will result in appropriate disciplinary action up to and including termination of employment.
  - Sponsors must be able to demonstrate that disciplinary standards are enforced in a timely, consistent, effective, and appropriate manner.

## 7. Procedures for responding to Detected Offenses / Corrective Action:

- Policies to respond to detected offenses
  - This includes initiating prompt and **effective** corrective action resulting in sustained compliance and prevention of similar issues.

(Refer to the Appendix for additional resources)



# Reasons to Implement a Compliance Plan

1. Adopting a Compliance Program concretely demonstrates the organization has a strong commitment to honesty and responsible corporate integrity
2. Compliance programs reinforce employees innate sense of right and wrong
3. An effective compliance program helps an organization fulfill its legal duty to the government
4. Compliance programs are cost effective:
  - expenditures are insignificant in comparison to the disruption and expense of defending against a fraud investigation
5. A compliance program provides a more accurate view of employee and contractor behavior relating to fraud and abuse
6. A compliance program provides guidance and procedures to promptly correct misconduct
7. An effective compliance program may mitigate False Claims Act liability or other sanctions imposed by the government by preventing non-compliance, fraud, waste and abuse.

# Fraud, Waste & Abuse Defined

- **Fraud:** Fraud is the intentional misrepresentation of data for financial gain.
- Fraud occurs when an individual knows or should know that something is false and makes a knowing deception that could result in some unauthorized benefit to themselves or another person.<sup>1</sup>
- **Waste:** Waste is overutilization: the extravagant, careless or needless expenditure of healthcare benefits or services that results from deficient practices or decisions.<sup>1</sup>
- **Abuse:** Abuse involves payment for items or services where there was no intent to deceive or misrepresent but the outcome of poor insufficient methods results in unnecessary costs to the Medicare program.<sup>2</sup>

Source:

1. CMS Glossary; CMS Medicare Learning Network (MLN)
2. Medicare Physician Guide: A Resource for Residents, Practicing Physicians, & Other Health Care Professionals, Tenth Edition (October 2008)

# Quick Reference Chart



Examples of Fraud <sup>1</sup>	Examples of Abuse <sup>2</sup>	Examples of Waste
<ul style="list-style-type: none"> <li>• Billing for services not furnished</li> <li>• Billing for services at a higher rate than is actually justified</li> <li>• Soliciting, offering or receiving a kickback, bribe or rebate</li> <li>• Deliberately misrepresenting services, resulting in unnecessary cost, improper payments or overpayment</li> <li>• Violations of the physician self-referral (“Stark”) prohibition</li> </ul> <p>Source:</p> <p>1. Medicare Physician Guide: A Resource for Residents, Practicing Physicians, &amp; Other Health Care Professionals, 10<sup>th</sup> Edition (10/08)</p>	<ul style="list-style-type: none"> <li>• Charging in excess for services or supplies</li> <li>• Providing medically unnecessary services</li> <li>• Providing services that do not meet professionally recognized standards</li> <li>• Billing Medicare based on a higher fee schedule than is used for patients not on Medicare</li> </ul> <p>Source:</p> <p>2. CMS Medicare Fraud and Abuse Web-based Training (April 2007)</p>	<ul style="list-style-type: none"> <li>• Over-utilization of services</li> <li>• Misuse of resources</li> </ul>

# Best Practices For Preventing FWA



- Develop an effective compliance program tailored to your organization
- Perform regular internal audits & monitoring against regulatory standards
  - Review for outliers / deviations form the norm
  - Confirm UM decisions, coding and claims are timely/accurate.
  - Confirm prompt refunds of overpayments (within 60 days)
- Ensure effective training & education is occurring, minimally for:
  - New hires within 90 days and annually for all Staff
  - Confirm Training occurs on HIPAA Privacy and breach reporting
  - Provide Training updates and Policy Updates when regulations change
  - Provide refresher Training on policies as part of any Corrective Action Plan
- Establish effective lines of communication with colleagues and staff members.
  - Ensure ALL staff are aware on how to report potential/actual FWA or compliance concerns
  - Take action! If you identify an FWA issue – you must report it.
  - Ask about potential compliance issues in exit interviews when staff leave.
- Remember: The Provider, Hospital, IPA and the MAO or PDP plan are each ultimately responsible for all claims and encounters that are submitted for payment with your name on the claim

# Penalties and Consequences of FWA

(Refer to detailed information on various regulations in the Appendix)



Repayment / Restitution is just the start

- **False Claims Act : \$5,500 up to \$11,000 per claim plus up to triple the amount of the claim in damages**
  - Criminal and/or civil prosecution & Imprisonment
  - Suspension/loss of provider license / Medicare Provider number
  - Exclusion from the Medicare program / Government Contracts
- **AntiKickback**
  - MAO / PDP enrollment freeze and sanctions under CMS authority up to \$25,000 per beneficiary impacted ant-kickback violation
  - Providers: up to five years in prison and fines of up to \$25,000
    - If a patient suffers bodily injury as a result of any kickback scheme, such as unnecessary procedures, the prison sentence may be 20+ years
    - Administrative civil penalties up to \$50,000 and exclusion from the federal healthcare programs participation

# Penalties and Consequences of FWA



(continued)

(Refer to detailed information on various regulations in the Appendix)

- **HIPAA Privacy and Security Breaches**
  - Payment for credit monitoring and restoration services
  - Various State and Federal Monetary penalties
- **Health Information Technology for Economic and Clinical Health (HITECH) Act Penalties**
  - Penalties up to \$1.5 Million for all violations of an identical provision

*(Note: the Patient Protection and Affordable Care Act (PPACA) may provide for increased penalties and restitution amounts)*

# Provisions of False Claims Act

- The False Claims Act, in part, prohibits any person from:
  - Knowingly presenting, or causing to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval
  - Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government
  - Conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid
  - A violator may be liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.
- Source: 31 U.S.C. § 3729



# Physician Self-Referral Prohibition Statute (Stark Law)

- The Physician Self-Referral Prohibition Statute, commonly referred to as the “Stark Law,” prohibits:
  - A physician from referring Medicare patients for certain designated health services to an entity with which the physician or a member of the physician’s immediate family has a financial relationship -unless an exception applies.
  - An entity from presenting or causing to be presented a bill or claim to anyone for a designated health service furnished as a result of a prohibited referral.
- Source: 42 U.S.C. §1395nn



# Health Insurance Portability and Accountability Act (HIPAA)

- Among other things, HIPAA, was enacted to improve the efficiency and effectiveness of health information systems through the establishment of standards and requirements for the electronic transmission of certain health information.
  - Regulations include standards for certain electronic transactions, minimum security requirements, and minimum privacy protections for individually identifiable health information covered entities (i.e., protected health information).
- HIPAA includes a provision that established the Medicare Integrity Program (MIP)
  - The goal of the MIP is to pay it right -pay the right amount, to the right provider or supplier, for the right service, to the right beneficiary.
  - The CMS staff, Fiscal Intermediaries, and carriers work within a wide range of Medicare programs to improve payment accuracy.
    - These programs include cost report auditing, the Medicare Secondary Payment (MSP) provisions, Medical Review (MR), and anti-fraud activities to improve payment accuracy.
- Source: Prescription Drug Benefit Manual, Chapter 9 –Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006) section 80.3
- CMS Medicare Fraud and Abuse Web-based Training (April 2007)

# Types of FWA

- MAO or PDP Fraud
- Member Fraud
- Provider Fraud
- Pharmacy Fraud
- Each carries a set of implications that we need to be aware of as part of our daily activities to help prevent FWA

# MAO / PDP PLAN - FWA



## **Failure to Provide Medically Necessary Services**

- Fails to provide medically necessary items or services that the organization is required to provide (under law or under the contract) to a Part C or Part D plan enrollee, and that failure adversely affects (or is likely to affect) the enrollee.

## **Inappropriate Enrollment/Disenrollment**

- Improperly reporting enrollment and disenrollment data to CMS to inflate prospective payments. For example, Sponsor fails to effect timely disenrollment of beneficiary from CMS systems upon beneficiary's request.

## **Marketing Schemes**

- Offering beneficiaries a cash payment as an encouragement to enroll in a Plan.
  - Gifts that are above the CMS allowed \$15 exemption, gifts convertible to cash, or "meals" (anything beyond the light snacks that guidance allows)

## **Unsolicited door-to-door marketing.**

- Use of unlicensed agents, where required by state law.
- Enrollment of individual in a Medicare Plan without knowledge or consent.
- Stating that a marketing agent/broker works for or is contracted with the Social Security Administration or CMS

## **Formulary or Coverage Decisions**

- Making inappropriate formulary decisions or coverage decisions based on inducements
- Delaying access to necessary covered drugs

# Beneficiary (Member) FWA



The following are examples of fraud by Medicare beneficiaries (members):

## Identity Theft

- Using a different member's I.D. card to obtain prescriptions, services, equipment, supplies, doctor visits, and/or hospital stays.
  - Individuals who "loan" their I.D. card could mean they get the wrong blood type in their medical record or other significant risks to care.

## Doctor Shopping

- Visiting several different doctors to obtain multiple prescriptions for painkillers or other drugs. Might point to an underlying scheme (stockpiling or black market resale).

## Improper Coordination of Benefits

- Beneficiary fails to disclose multiple coverage policies, or leverages various coverage policies to "game" the system

## Prescription Fraud

- Resale of Drugs or Black Market
  - Falsely reporting loss or theft of drugs or feigns illness to obtain drugs for resale on the black market.
- Falsifying or modifying a prescription

# Provider FWA



Kickbacks: Soliciting, offering, or receiving a kickback, bribe, or rebate

- For example, paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment.

Inducements: Such as copay waivers or free services to retain patients

- Caution required when dispensing free medications from pharmacy companies. Should have consistent policies reviewed by legal.

False Claims: Billing for services not rendered or supplies not provided

- For example, billing for appointments the patient failed to keep.
- Billing for a “gang visit” in which a physician visits a nursing home billing for 20 nursing home visits without furnishing any specific service to individual patients.

Double billing

- Such as billing both Medicare and the beneficiary, or billing both Medicare and another insurer.

Date of Service: Misrepresenting the date services were rendered

Identity: Misrepresenting the identity of the individual who received the services.

# Provider FWA



Rendering Provider: Misrepresenting who rendered the service

- Such as billing for an office visit when the only services were an injection by a medical assistant.

False Coding or Services: Billing for a covered item or service when the actual item or service provided was a non-covered item or service.

Unnecessary Care: Providing unnecessary procedures or prescribing unnecessary drugs.

- This includes appropriate review that patients meet the Certification of Medical Necessity requirements

Altering Medical Records: Erroneous or false or late entries in the medical record

- Late entry in the record, such as an addendum must be entered sequentially in the record according to coding rules

Delay in Care: Delay in authorizing or providing access to medically necessary care

- Physician office errors in non timely submission of auth requests can result in delay in care.
- Regulations measure the 72 hours for expedited and the 14 days for standard pre service requests based on the date and time the patient makes the request

Patient Dumping: Encouraging disenrollment for high cost patients to costs and defer care to original Medicare when in a capitated model.



# Provider Prescription Drug FWA



Over Prescribing: Over-prescription of false prescription of narcotics

Selling Prescriptions: Participating in illegal remuneration schemes, such as selling prescriptions.

Inducements: Prescribing medications based on illegal inducements, rather than the clinical needs of the patient.

- Such as pharmacy manufacturer incentives, trips, or discounted services

Not Medically Necessary: Writing prescriptions for drugs that are not medically necessary, often in mass quantities, and often for individuals that are not patients of a provider.

Theft – Identity Fraud: Theft of a prescriber’s Drug Enforcement Agency (DEA) number, prescription pad, or e-prescribing log-in information.

Falsifying Justification: Falsifying information in order to justify coverage, such as ruling out lower cost generics –especially

Dilution or Illegal Importation: Diluted substances or substituted provider administered drugs that may be either less than effective or contraindicated or illegal importation of drugs used or sold as covered drugs.

# Pharmacists FWA



## False Billing:

- Billing for prescriptions that are never picked up
- Billing for a brand name when generics are dispensed,
- Billing for non-covered prescriptions as covered items

## Splitting prescriptions

- For example, by splitting a 30-day prescription into 4 7-day prescriptions to get additional copayments and dispensing fees.

## Steering & Kickbacks:

- Engaging in unlawful remuneration, such as remuneration for steering a beneficiary toward a certain plan or drug, or for formulary placement.

## Overcharging:

- Failing to offer negotiated prices.
- Collecting higher copays than specified

## Short Fills

- Prescription drug shorting
  - Providing less than the prescribed quantity and bills for the fully-prescribed amount.



# Pharmacists FWA



## Bait and switch pricing

- When a beneficiary is led to believe that a drug will cost one price, but at the point of sale, the beneficiary is charged a higher amount.

## Forging and altering prescriptions

- Modification to scripts or dosage
- Modifications to allowable refills

## Expired Drugs or Tainted Drugs:

- Dispensing drugs that are expired or have not been stored or handled in accordance with manufacturer and FDA requirements.

## Manipulating the True Out-of-Pocket cost

- When a pharmacy falsely pushes a beneficiary through the coverage gap, into catastrophic coverage before they are eligible, or keeps a beneficiary in the coverage gap so that catastrophic coverage never occurs.

# Pharmaceutical Wholesaler FWA



## Counterfeit Drugs:

- Counterfeit and adulterated drugs through black and grey market purchases
  - This includes but is not limited to fake, diluted, expired, and illegally imported drugs.

## Diverters

- Brokers who illegally gain control of discounted medicines intended for places such as nursing homes, hospices and AIDS clinics. Diverters take the discounted drugs, mark up the prices, and rapidly move them to small wholesalers. In some cases, the pharmaceuticals may be marked up six times before being sold to the consumer.

## Inappropriate documentation of pricing information

- Submitting false or inaccurate pricing or rebate information to or that may be used by any Federal health care program.

# Pharmaceutical Manufacturer FWA



## Kickbacks, inducements, and other illegal remuneration:

- Inappropriate marketing and/or promotion of products
- Inducements offered if the purchased products are reimbursable by any of the federal health care programs such as discounts, inappropriate product support services, educational grants, research funding, etc.

Records Management: Lack of integrity of data to establish payment and/or determine reimbursement, such as missing or inappropriate documentation of pricing information

## Formulary and formulary support activities

- Inappropriate relationships with P & T committee members,
- Payments to PBMs for formulary placement

## Inappropriate relationships with physicians

- “Switching” arrangements, when manufacturers offer physicians cash payments or other benefits each time a patient’s prescription is changed to the manufacturer’s product from a competing product.
- Incentives offered to physicians to prescribe medically unnecessary drugs.
- Consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research funding.
- Improper entertainment or incentives offered by sales agents.

Off Label Use: Illegal promotion of off-label drug usage

Billing for Free Samples: Illegal usage of free samples to physicians knowing and expecting those physicians to bill the federal health care programs for the samples.

# Required Reporting

Violations of the code of conduct, ethics or any fraud, waste or abuse must be reported. Not reporting fraud or suspected fraud can make you a party to a case by allowing the fraud to continue.

- Your organization must have internal mechanisms for reporting compliance & FWA concerns (your compliance office or compliance hotline)
- Your report may be anonymous
- You may also report concerns to the respective Medicare Advantage Organization or Part D Plan sponsor
- 1-800-MEDICARE.
- Fraud or suspected fraud may also be reported anonymously as outlined by any health plans on their web portals or your internal reporting mechanisms, or the MEDICS.

Everyone has the right and responsibility to report possible fraud, waste, or abuse.

**Remember:** You may report anonymously and retaliation is prohibited when you report a concern in good faith.

# Include Policies, Procedures and Training on Whistleblower Protections

***Whistleblower:*** An employee, former employee, or member of an organization who reports misconduct to people or entities that have the power to take corrective action. Also known as a civil Qui Tam action. This in some cases leads to criminal prosecution under the either the False Claims Act or the Anti-Kickback Rule as well.

A provision in the False Claims Act allows individuals to:

- Report fraud anonymously
- Sue an organization on behalf of the government and collect a portion of any settlement that results

Employers cannot threaten or retaliate against whistleblowers.

# Remember to Protect Confidentiality

Carefully handle all data than can identify the member -

- This includes any of the elements noted below:
  - Social Security , Medicare ID (HICN) or **Health Plan Member I.D. number**
  - Member Name, Address, Phone, Date of Birth
  - Medical Record Number / Patient Account Number
- Review your internal HIPAA training
- Review your internal policies and practices for reporting of any security and privacy breach to your respective HIPAA security or privacy officer
- Reporting ***MUST*** be done immediately if you become aware of or suspect a breach may have occurred.



# Health Plan Hotline Information

- Refer to the ICE website under approved documents, Contracting and Compliance Team, Fraud, Waste and Abuse Training Tools at:  
<http://www.iceforhealth.org/library.asp?sf=&scid=2047#scid2047>
- (Should you wish to customize this slide, include the Health Plan Hotline information on this slide for the MAO's and PDP Plans with which you contract)



# Entities / Individuals Excluded from Medicare or Government Programs



- Compliance Programs must carefully monitor payments go to proper entities. This includes payments to employees, providers, contractors and subcontractors
- Medicare Advantage Organizations, Part D Sponsors and contracted entities are required to check the OIG and General Services Administration (GSA) exclusion lists for **all new employees** and at least once a year for all employees including the governing board, senior administration and managers thereafter to validate that employees and other entities that assist in the administration or delivery of services to Medicare beneficiaries are not included on such lists.
  - OIG List of Excluded Individuals/Entities (LEIE):  
<http://exclusions.oig.hhs.gov/search.html>
  - General Services Administration (GSA) database of excluded individuals/entities: <http://epls.arnet.gov/>
- Under the HITECH Act, if payments are made to an excluded / sanctioned provider, overpayment recovery must occur within 60 days of your being aware of the overpayment to mitigate potential False Claims Act (FCA) liability.
  - You need an effective program to sweep your claims files monthly for Part C & D for retro exclusions to trigger prompt recovery.



Thank you for participating and expanding compliance program effectiveness by ensuring you and your organization adopt the learning's into your individual compliance programs and business practices.



## Appendix

The attached materials include were designed to assist with your Compliance Program Development

# Compliance Program Summary Expectations

- ❑ Conduct business activities and interactions ethically and with integrity.
- ❑ Conduct business activities in full compliance with all applicable statutory and regulatory prohibitions against fraud, waste, and abuse.
- ❑ Report potential and actual FWA issues, activity
- ❑ Establish policies and procedures to prevent, detect, and require reporting of potential fraud, waste, or abuse.

# Compliance Program Tips



Ensure policies, procedures, training and monitoring are in place to prevent FWA including:

1. Charging for services or supplies beyond those received?
  2. Providing medically unnecessary services?
  3. Billing for items or services that should not be paid for by Medicare?
  4. Billing for a prescription that was left but never picked up?
  5. Billing for services at a higher rate than is actually justified?
  6. Misrepresenting services resulting in unnecessary cost to the Medicare program, improper payments to providers, or overpayments, such as including codes that are not reflected in a medial record or claim.
- **Eliminate Risks to Individuals**
  - Unnecessary procedures may cause injury or death.
  - Falsely billed procedures create an erroneous record of the patient's medical history.
  - Diluted or substituted drugs may render treatment ineffective or expose the patient to harmful side effects or drug interactions.
  - Prescription narcotics on the black market contribute to drug abuse and addiction

# Relevant Laws

**The Anti-Kickback Statute** makes it a criminal offense to knowingly and willfully solicit, receive, offer or pay remuneration (including any kickback, bribe or rebate) in return for:

- Referrals for the furnishing or arranging of any items or service reimbursable by a Federal health care program
- Purchasing, leasing, ordering or arranging for the purchasing or leasing of an item or service reimbursable by a Federal health care program
- **Remuneration** is defined as the transfer of anything of value, directly or indirectly, overtly or covertly in cash or in kind. When this happens, both parties are held in criminal liability of the impermissible “kickback” transaction.

**The False Claims Act, or FCA** was enacted in 1863 to fight procurement fraud in the Civil War. The FCA has historically prohibited knowingly presenting or *causing to be presented* to the federal government a false or fraudulent claim for payment or approval.



# Relevant Laws



## **Self-Referral Prohibition Statute (Stark Law) 42 C.F.R. §411.350 through §411.389**

- Prohibits A physician from referring Medicare patients for certain designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship - unless an exception applies.
- An entity from presenting or causing to be presented a bill or claim to anyone for a designated health service furnished as a result of a prohibited referral.

## **The Beneficiary Inducement Statute 42 U.S.C. §1320 a-7a(a)(5)**

- Prohibits certain inducements to Medicare beneficiaries, i.e. waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

# Relevant Laws



## **Health Insurance Portability and Accountability Act (HIPAA) 42 C.F.R. §164.501**

- Transaction standards
- Minimum security requirements
- Minimum privacy protections for protected health information
- National Provider Identifier numbers (NPIs).
- **American Recovery and Reinvestment Act of 2009 (HITECH Act) 42 C.F.R. Parts 412, 413, 422 and 495; 45 C.F.R. Subtitle A Subchapter D**
- Expands government authority to Act related to HIPAA issues:
  - Accountability for Business Associates
  - Higher penalties to deter illegal activities by individuals:
    - Higher penalties mean violations are “not” just considered the “cost of doing business”

## **Excluded Entities and Individuals:**

- First tier, downstream and related entities may not employ or contract with entities or individuals who are excluded from doing business with the federal government.

## Relevant Laws (continued)

- **The Patient Protection And Affordable Care Act of 2010 (PPACA) or the Affordable Care Act aka ObamaCare.**
- **Penalty \$50,000 per false statement** for knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or fails to grant timely access. §6408. (a) et seq.
- **Penalty \$ 15,000 per each day** for failure to act. §6408. (a) et seq.

# Case Studies – HIPAA implications

UCLA Case involving data security challenges and creation of access controls on the chain of information.

- 68 Workers improperly accessed records
- 1 employee reviewed Farrah Fawcett's records on 104 days!
- Indictment by Federal Grand Jury
  - Up to 10 years prison time for selling information
  - Update July 8, 2011: UCLA Health System agreed to pay \$865,500 as part of a settlement with federal regulators for employees reviewing the medical records of Britney Spears, Farrah Fawcett and then-California First Lady Maria Shriver.

## Expansion of Privacy Rule

- Octomom - Bellflower Hospital fined \$437,500 for loss of records
  - 15 Fired, 8 Disciplined
- Violators to pay higher penalties under new regulations

# Case Studies HIPAA Implications (Laptops & electronic PHI – encryption mitigates risk (continued))



North Dakota – Humana required to pay \$50,000 to offset costs of investigation of PHI disclosure

February 28, 2006 - Oregon – Providence Health System employee had backup tape stolen from his car with information on 365,000 patients.

- Ordered to pay for credit monitoring and credit restoration services and enhance HIPAA security program.

July 1, 2012 - The Alaska Department of Health and Human Services (“Alaska DHHS”), the state’s Medicaid agency, agreed to pay U.S. Health and Human Services \$1.7 million to settle alleged violations of the HIPAA Security Rule.

<http://www.healthtechlaw.com/2012/07/01/alaska-medicaid-pays-1-7-million-to-settle-hipaa-violations/>

# Case Studies HIPAA Implications (Laptops & electronic PHI – encryption mitigates risk



- 3/13/2012 Tennessee - Blue Cross Blue Shield of Tennessee (BCBST) reported that 57 unencrypted computer hard drives were stolen from a leased facility in Tennessee. The drives contained the protected health information (PHI) of over 1 million individuals, including member names, social security numbers, diagnosis codes, dates of birth, and health plan identification numbers.
  - (BCBST) agreed to pay the U.S. Department of Health and Human Services (HHS) \$1,500,000 to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) *The enforcement action is the first resulting from a breach report required by the Health Information Technology for Economic and Clinical Health (HITECH) Act Breach Notification Rule.*
  - BCBST failed to implement appropriate administrative safeguards to adequately protect information remaining at the leased facility by not performing the required security evaluation in response to operational changes. In addition, the investigation showed a failure to implement appropriate physical safeguards by not having adequate facility access controls; both of these safeguards are required by the HIPAA Security Rule.
  - <http://www.hhs.gov/news/press/2012pres/03/20120313a.html>



# Case Studies Health Care Fraud

- July 2, 2012 - GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data ~ Largest Health Care Fraud Settlement in U.S. History
- <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>
- July 2, 2012 - NextCare Inc., an urgent care chain, will pay \$10 million to settle allegations it improperly billed Medicare, the Medicaid programs of Colorado, Virginia, Texas, North Carolina, and Arizona, and other federal healthcare programs, the Department of Justice (DOJ).
- <http://www.justice.gov/opa/pr/2012/July/12-civ-843.html>

# Web Resources



Resource	Link
Centers for Medicare and Medicaid Services (CMS)	<a href="http://www.cms.gov">www.cms.gov</a>
Chapter 6 – Protecting the Medicare Trust Fund	<a href="http://www.cms.gov/MLNProducts/downloads/chapter6.pdf">http://www.cms.gov/MLNProducts/downloads/chapter6.pdf</a>
Fraud & Abuse General Information	<a href="http://www.cms.gov/FraudAbuseforProfs/">http://www.cms.gov/FraudAbuseforProfs/</a>
Federal Register citations 42 CFR 422.50342, 422.50442, CFR 423.50442 and 423.505	<a href="http://www.cms.gov/quarterlyproviderupdates/">http://www.cms.gov/quarterlyproviderupdates/</a>
Federal Bureau of Investigation	<a href="http://www.fbi.gov/">http://www.fbi.gov/</a>
Health Insurance Portability and Accountability Act (HIPAA)	<a href="http://www.cms.gov/HIPAAGenInfo/o1_Overview.asp">http://www.cms.gov/HIPAAGenInfo/o1_Overview.asp</a>
Medicare Fraud and Abuse Brochure	<a href="http://www.cms.gov/MLNProducts/downloads/Fraud_and_Abuse.pdf">http://www.cms.gov/MLNProducts/downloads/Fraud_and_Abuse.pdf</a>
Medicare Learning Network (MLN)	<a href="http://www.cms.gov/MLNGenInfo/">www.cms.gov/MLNGenInfo/</a>
Medicare Managed Care Manual	<a href="http://www.cms.gov/Manuals/IOM/">http://www.cms.gov/Manuals/IOM/</a>

# Web Resources



Resource	Link
HITECH ACT	<a href="http://www.hipaasurvivalguide.com/hitech-act-text.php">http://www.hipaasurvivalguide.com/hitech-act-text.php</a>
Office of Inspector General Department of Health and Human Services	<a href="http://oig.hhs.gov/">http://oig.hhs.gov/</a> (refer to OIG Guidance on Compliance Plans)
National Health Care Anti-Fraud Association	<a href="http://www.nhcaa.org">http://www.nhcaa.org</a>
Part D Prescription Drug Benefit Manual	<a href="http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage">http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage</a>
Physician Self Referral Law “Stark Law”	<a href="http://www.cms.gov/PhysicianSelfReferral">www.cms.gov/PhysicianSelfReferral</a>
Red Flag Rule	<a href="http://www.ftc.gov/bcp/edu/microsites/redflagrule/index.shtml">http://www.ftc.gov/bcp/edu/microsites/redflagrule/index.shtml</a>
Social Security Administration	<a href="http://oig.ssa.gov/what-abuse-fraud-and-waste">http://oig.ssa.gov/what-abuse-fraud-and-waste</a>
Social Security Laws	<a href="http://www.ssa.gov/OP_Home/ssact/comp-ssa.htm">www.ssa.gov/OP_Home/ssact/comp-ssa.htm</a>



# Web FWA Resources

Federal government web sites are sources of information regarding detection, correction, and prevention of fraud, waste, and abuse:

Resource	Link
Department of Health and Human Services Office of Inspector General:	<a href="http://oig.hhs.gov/fraud/hotline/">http://oig.hhs.gov/fraud/hotline/</a>
Centers for Medicare and Medicaid Services (CMS):	<a href="http://www.cms.hhs.gov/FraudAbuseforProfes/">http://www.cms.hhs.gov/FraudAbuseforProfes/</a>
CMS Information about the Physician Self Referral Law:	<a href="http://www.cms.hhs.gov/PhysicianSelfReferral">www.cms.hhs.gov/PhysicianSelfReferral</a>
CMS Prescription Drug Benefit Manual	<a href="http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf">http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf</a>
Medicare Learning Network (MLN) Fraud & Abuse Job Aid	<a href="https://www.cms.gov/Outreach-and-Education/Training/NationalMedicareTrainingProgram/Training-Library-Items/CMS1248271.html">https://www.cms.gov/Outreach-and-Education/Training/NationalMedicareTrainingProgram/Training-Library-Items/CMS1248271.html</a>