



**REGAL MEDICAL GROUP**

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

# CMS Requirements

The Centers for Medicare and Medicaid Services (CMS) requires annual fraud, waste, and abuse training for organizations providing health, prescription drug, or administrative services to Medicare Advantage (MA) or Prescription Drug Plan (PDP) enrollees on behalf of a health plan.

Medicare Advantage and Part D Sponsors must provide FWA training to first tier entities and first tier entities must ensure that the FWA training is distributed to their downstream entities (and such distribution must be documented).

CMS requires that Medicare Advantage and Part D Sponsors have a compliance plan that guards against potential fraud, waste, and abuse. 42C.F.R. §422.503 (b)(4)(vi) and 42 C.F. R. § 423.504 (b)(4)(vi)

# Overview & Objectives

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- **What:** New federal requirements you must know.
- **Why:** Detect, prevent, and correct fraud, waste, and abuse; raise awareness about the issue.
- **How:** Medicare Advantage Organizations and Part D Plan Sponsors must implement an effective compliance plan including measures to detect, prevent, and correct fraud, waste, and abuse.
- **Who:** First tier, downstream, related and delegated entities.
- **When:** Complete this training now and annually by December 31<sup>st</sup> of each year.

# Key Terms and Acronyms

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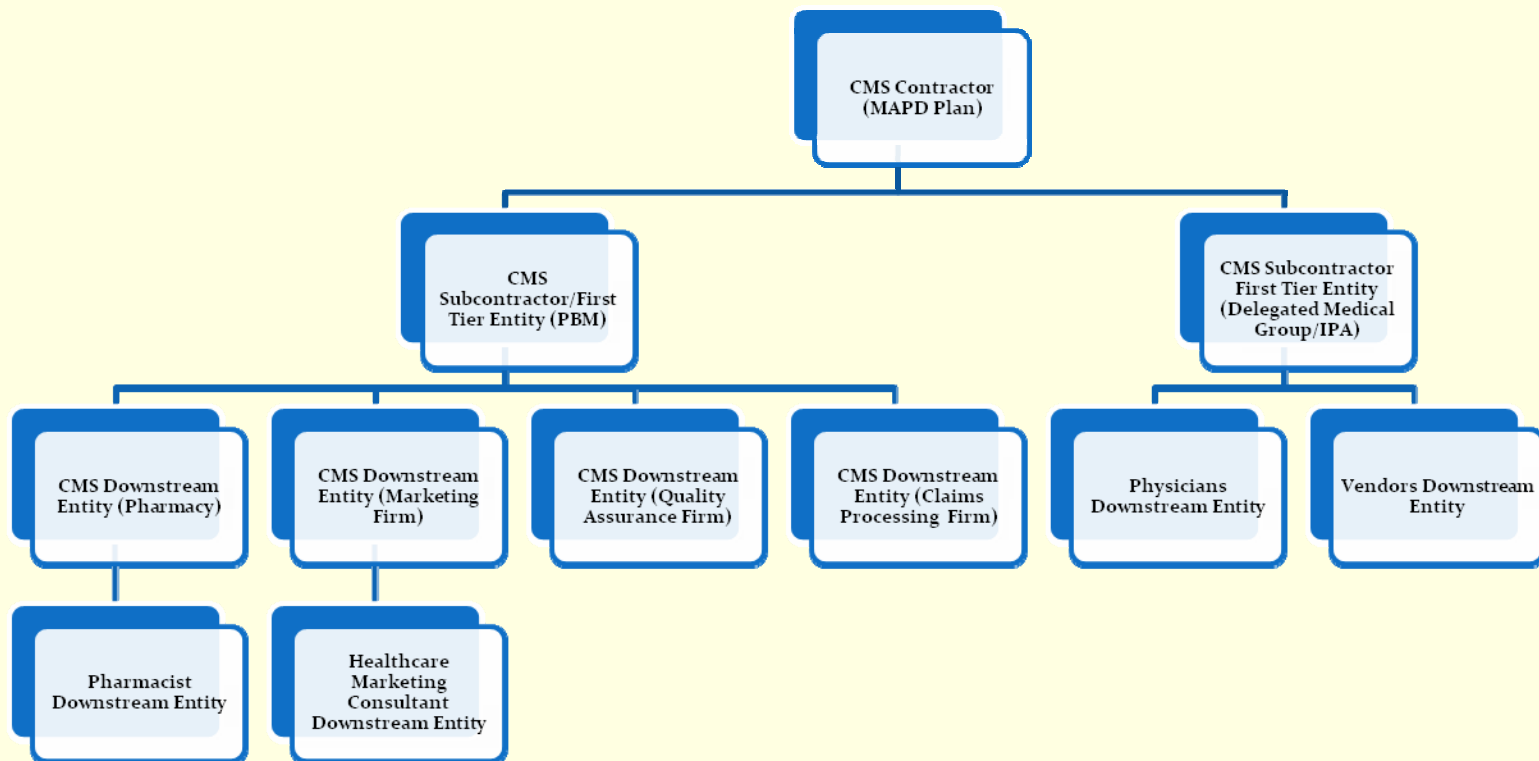
## ■ Medicare

- Part A - Hospital Insurance: pays for inpatient care, skilled nursing facility care, hospice, and home health care.
- 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.
- Part C - Medicare Advantage Plans (MA): combines Part A and Part B health benefits through managed care organizations. Some plans include Part D (MAPD plans).
- Part D – Prescription Drug Insurance: helps pay for prescription drugs, certain vaccines and certain medical supplies (e.g. needles and syringes for insulin). This coverage is available as a Prescription Drug Plan (PDP).

# Key Terms and Acronyms

- **First Tier Entity:** A party that enters into a written agreement with a MA Organization or Part D Plan Sponsor to provide administrative services or health care services for a Medicare eligible individual under the MA or Part D programs. Examples include IPA's, Medical Groups Pharmacy Benefit Manager (PBM), contracted hospitals, clinics, and allied providers.
- **Downstream Entity:** A party that enters into a written arrangement, with persons or entities involved in the MA or Part D benefit, below the level of the arrangement between a MA Organization or Part D Plan Sponsor and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. Examples include pharmacies, marketing firms, quality assurance companies, claims processing firms, and billing agencies.
- **Related Entity:** An entity that is related to the MA Organization or Part D Plan Sponsor by common ownership or control and performs some of the MA Organization or Part D Plan Sponsor's management functions under contract or delegation; furnishes services to Medicare enrollees under an oral or written agreement; or leases real property or sells materials to the MA Organization or Part D Plan Sponsor at a cost of more than \$2,500 during a contract.

# First Tier and Downstream Example



## How Does CMS Combat Fraud?

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- Close coordination with contractors, providers, and law enforcement agencies.
- Developing Medicare Program compliance requirements that protect stakeholders.
- Early detection through Medical Review and data analysis.
- Effective education of physicians, providers, suppliers, and beneficiaries.

# Best Practices for Preventing FWA

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- Develop a compliance program.
- Monitor claims for accuracy—ensure coding reflects services provided.
- Monitor medical records—ensure documentation supports services rendered.
- Perform regular internal audits.

## Best Practices for Preventing FWA

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- Establish effective lines of communication with colleagues and staff members.
- Ask about potential compliance issues in exit interviews.
- Take action if you identify a problem.
- Remember that you are ultimately responsible for claims bearing your name, regardless of whether you submitted the claim.

# CMS Requirements

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Federal law requires MA and Part D Sponsors to have a Compliance Plan\*.

An MA or Part D Sponsor must:

- Create a Compliance Plan that incorporates measures to detect, prevent, and correct fraud, waste, and abuse.
- Create a Compliance Plan that must consist of training, education, and effective lines of communication.
- Apply such training, education, and communication requirements to all entities which provides benefits or services under MA or PDP programs.
- Produce proof from first-tier, downstream and related entities to show compliance with these requirements.

# What is a Compliance Plan?

## Seven Key Elements

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An effective Compliance Plan includes seven core elements:

1. **Written Standards of Conduct:** development and distribution of written Standards of Conduct and Policies & Procedures that promote the MA Organization or Part D Plan Sponsor's commitment to compliance and that address specific areas of potential fraud, waste, and abuse.
2. **Designation of a Compliance Officer:** designation of an individual and a committee 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, such as this training.
4. **Internal Monitoring and Auditing:** use of risk evaluation techniques and audits to monitor compliance and assist in the reduction of identified problem areas.
5. **Disciplinary Mechanisms:** policies to consistently enforce standards and addresses dealing with individuals or entities that are excluded from participating in CMS programs.

# What is a Compliance Plan?

## Seven Key Elements

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6. **Effective Lines of Communication:** between the compliance officer and the organization's employees, managers, and directors and members of the compliance committee, as well as first tier, downstream and related entities.
  - Includes a system to receive, record, and respond to compliance questions, or reports of potential or actual non-compliance, while maintaining confidentiality.
  - First tier, downstream and related entities must report compliance concerns and suspected or actual misconduct involving the MA or Part D programs to the MA Organization or Part D Plan Sponsor.
  
7. **Procedures for responding to Detected Offenses and Corrective Action:** policies to respond to and initiate corrective action to prevent similar offenses including a timely, responsible inquiry.

# Fraud Waste & Abuse Defined

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**Fraud:** an intentional act of deception, misrepresentation, or concealment in order to gain something of value.

**Waste:** over-utilization of services (not caused by criminally negligent actions) and the misuse of resources.

**Abuse:** excessive or improper use of services or actions that are inconsistent with acceptable business or medical practice. Refers to incidents that, although not fraudulent, may directly or indirectly cause financial loss.

**Examples include:**

- Charging in excess for services or supplies.
- Providing medically unnecessary services.
- Billing for items or services that should not be paid for by Medicare.
- Billing for services that were never rendered.
- Billing for services at a higher rate than is actually justified.
- Misrepresenting services resulting in unnecessary cost to the Medicare program, improper payments to providers, or overpayments.

# FWA Training Requirement

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FWA training is required for all Part C and D first tier, downstream, related and delegated entities, including Medicare Advantage providers who administer the Part D drug benefit or provide health care services to Medicare Advantage enrollees.

- Pharmacy Benefit Managers (PBMs)
- Pharmacies and pharmacists
- Subcontractors such as claims processing firms
- Dentists
- Network Providers
  - Hospitals
  - Primary care providers
  - Ancillary providers
  - Specialists
  - IPA's
  - Medical Groups

# Stakeholders and Risks for FWA

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- Stakeholders include:
  - MA Organizations and Part D Sponsors
  - Providers
  - Pharmacies
  - Pharmacy Benefit Managers
  - Beneficiaries
  
- Schemes:
  - Vary in degree of severity
  - Are not necessarily unique to a single stakeholder
  - May involve multiple types of fraud, waste, or abuse

## ~~Examples of 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.

## **Examples of Risks**

### **MA Organizations and Part D Sponsors**

- Failing to provide medically necessary services.
- Marketing schemes such as offering beneficiaries a cash payment as an inducement to enroll in Part D.
- Selecting or denying beneficiaries based on their illness profile or other discriminating factors.
- Making inappropriate formulary decisions in which costs take priority over criteria such as clinical efficacy and appropriateness.

## Examples of Risks

### Providers Prescription Drug FWA

- Participating in illegal remuneration schemes, such as selling prescriptions.
- Switching a patient prescription rather than others based on illegal inducements rather than clinical needs.
- 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 of a prescriber's Drug Enforcement Agency (DEA) number, prescription pad, or e-prescribing log-in information.
- Falsifying information in order to justify coverage.

## Examples of Risks Providers

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- Failing to provide medically necessary services.
- Offering beneficiaries a cash payment as an inducement to enroll in Part D.
- Selecting or denying beneficiaries based on their illness profile or other discriminating factors.
- Making inappropriate formulary decisions in which costs take priority over criteria such as clinical efficacy and appropriateness.
- Altering claim forms, electronic claim records, medical documentation, etc.
- Limiting access to needed services—for example, by not referring a patient to an appropriate provider.

## Examples of Risks Providers

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- 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).
- Billing for services not rendered or supplies not provided would include billing for appointments the patient failed to keep. Another example is 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 Medicare and another insurer.
- Misrepresenting the date services were rendered or the identity of the individual who received the services.
- Misrepresenting who rendered the service, or billing for a covered service rather than the non-covered service that was rendered.

## **Examples of Risks**

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### **Pharmacists**

Pharmacists may engage in inappropriate billing practices such as:

- Billing for a brand name when generics are dispensed, billing for non-covered prescriptions as covered items, or
- Billing for prescriptions that are never picked up. They may also split a prescription inappropriately—for example, by splitting a 30-day prescription into 4 7-day prescriptions. This incurs additional costs in the form of copayments and dispensing fees.
- Engaging in unlawful remuneration, such as remuneration for steering a beneficiary toward a certain plan or drug, or for formulary placement.
- Making inappropriate formulary decisions.
- Failing to offer negotiated prices.

## Examples of Risks

### Pharmacists

- Prescription drug shorting is when the pharmacist provides less than the prescribed quantity and intentionally does not inform the patient but bills for the fully-prescribed amount.
- Bait and switch pricing occurs 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
- 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 is when a pharmacy either pushes a beneficiary through the coverage gap, so the beneficiary can reach catastrophic coverage before they are eligible, or keeps a beneficiary in the coverage gap so that catastrophic coverage never occurs.

## Examples of Risks

### Medicare Beneficiaries

Misrepresenting personal information by:

- Sharing a beneficiary ID card
- Falsifying identity, eligibility, or medical condition in order to illegally receive the drug benefit
- Attempting to use the enrollee identity card to obtain prescriptions when the enrollee is no longer covered under the drug benefit.
- Looping (i.e., arranging for a continuation of services under another beneficiary's ID)

Forging and altering prescriptions.

Doctor shopping is when a beneficiary consults a number of doctors for the purpose of obtaining multiple prescriptions for narcotic painkillers or other drugs.

Doctor shopping might be indicative of an underlying scheme, such as stockpiling or resale on the black market.

## Examples of Risks

### Pharmaceutical Wholesalers

- 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.

## Examples of Risks Pharmaceutical Manufacturers

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- Lack of integrity of data to establish payment and/or determine reimbursement:
  - Inappropriate documentation of pricing information: Manufacturers must maintain accurate and complete documentation of their pricing information.
  
- Kickbacks, inducements, and other illegal remuneration:
  - Inappropriate marketing and/or promotion of products (sales, marketing, discounting, etc.) reimbursable by federal health care programs.
  - Inducements offered if the purchased products are reimbursable by any of the federal health care programs. Examples of potentially improper inducements include inappropriate discounts, inappropriate product support services, inappropriate educational grants, inappropriate research funding, or other inappropriate remuneration.

# Examples of Risks

## Pharmaceutical Manufacturers

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- **Formulary and formulary support activities**
  - Examples of potential fraud and abuse include inappropriate relationships with formulary committee members, payments to PBMs, and formulary placement payments in order to have manufacturer's products included on a Plan's formulary.
- **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.
- **Illegal promotion of off-label drug usage** through marketing, financial incentives, or other promotion campaigns.
- **Illegal usage of free samples:** Providing free samples to physicians knowing and expecting those physicians to bill the federal health care programs for the samples.

## Relevant Laws

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**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.

The FCA was recently amended through the American Recovery and Reinvestment Act of 2009 (ARRA) to expand the scope of liability and give the government enhanced investigative powers. FCA liability now extends to subcontractors working on government funded projects as well as those who submit claims for reimbursement to government agents and state agencies. This may indicate FCA liability for claims submitted to MAO and Medicaid HMOs.

The **Anti-Kickback Statute** makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.

Remuneration includes anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

**The Beneficiary Inducement Statute** 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

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## **Self-Referral Prohibition Statute (Stark Law):**

- Prohibits physicians from referring Medicare patients to an entity with which the physician or physician's immediate family member has a financial relationship—unless an exception applies.

## **Red Flag Rule (Identity Theft Protection):**

- Requires “creditors” to implement programs to identify, detect, and respond to patterns, practices, or specific activities that could indicate identity theft.

## **Health Insurance Portability and Accountability Act (HIPAA):**

- Transaction standards
- Minimum security requirements
- Minimum privacy protections for protected health information
- National Provider Identifier numbers (NPIs).

## **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.

## **Administrative Sanctions**

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- Denial or revocation of Medicare provider number application.
- Suspension of provider payments.
- Addition to the OIG List of Excluded Individuals/Entities (LEIE).
- License suspension or revocation.

## Civil Monetary Penalties (CMPs), Litigation and Settlements

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- The Social Security Act authorizes the imposition of CMPs when Medicare determines that an individual or entity has violated Medicare rules and regulations.
  - Typically, penalties involve assessments of significant damages such as CMPs up to \$25,000 for each Medicare Advantage enrollee adversely affected.
- The United States Attorney's Office may file a civil suit or decide that the interest of the Medicare Program is best served by settling a case out of court.
  - The civil suit or settlement may include a Corporate Integrity Agreement (CIA)
    - A CIA requires the individual or entity to accomplish specific goals (e.g., educational plan, corrective action plan, reorganization) and be subject to periodic audits by the federal government.

## Possible Civil and Criminal Penalties

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- False Claims Act
  - For each false claim: \$5,500 - \$11,000
  - If the government proves it suffered a loss, the provider is liable for three times the loss
  
- Up to five years in prison and fines of up to \$25,000 for violations of the Anti-kickback Statute
  
- If a patient suffers bodily injury as a result of the scheme, the prison sentence may be 20+ years

# Remediation

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- Education
- Administrative sanctions
- Civil litigation and settlements
- Criminal prosecution
  - Automatic debarment
  - Prison time

## Exclusion Lists

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- 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 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/>

## Reporting Potential Fraud, Waste, and Abuse

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

### **Report issues or concerns to:**

- Your organization's compliance office or compliance hotline and/or,
- The compliance officer or compliance hotline of the applicable Medicare Advantage Organization or Part D MA Organization or Part D Plan Sponsor(s) with whom you participate; compliance hotline numbers are available on each organization's web site and/or,
- 1-800-MEDICARE.

### **Remember:**

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

# Whistleblower Protections

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***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.

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.

## Fraud, Waste, and Abuse Resources

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

- Department of Health and Human Services Office of Inspector General:
  - <http://oig.hhs.gov/fraud/hotline/>
- Centers for Medicare and Medicaid Services (CMS):
  - <http://www.cms.hhs.gov/FraudAbuseforProfs/>
- CMS Information about the Physician Self Referral Law:
  - [www.cms.hhs.gov/PhysicianSelfReferral](http://www.cms.hhs.gov/PhysicianSelfReferral)
- CMS' Prescription Drug Benefit Manual
  - [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual\\_Chapter9\\_FWA.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf)
- Medicare Learning Network (MLN) Fraud & Abuse Job Aid
  - [http://www.cms.hhs.gov/MLNProducts/downloads/081606\\_Medicare\\_Fraud\\_and\\_Abuse\\_brochure.pdf](http://www.cms.hhs.gov/MLNProducts/downloads/081606_Medicare_Fraud_and_Abuse_brochure.pdf)

# Compliance Contacts

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Thank you for participating in this  
Compliance Training about CMS  
Fraud Waste and Abuse.