

COMPLIANCE & FRAUD, WASTE & ABUSE AWARENESS TRAINING

First Tier, Downstream, and Related Entities

Overview

- The Centers for Medicare and Medicaid Services (CMS) spends over \$756 billion a year providing medical and pharmacy benefits to individuals.
- Medica has a relationship with CMS to provide medical and pharmacy benefits to individuals.
- Medica provides these medical and pharmacy benefits as a contracted Medicare Advantage Organization and a Part D plan sponsor.
- Medica, as a Medicare Advantage (MA) and Part D Plan Sponsor, must implement an effective compliance program to prevent, detect, and correct:
 - fraud, waste, and abuse (FWA)
 - noncompliance with Centers for Medicare and Medicaid (CMS) program requirements.
- Regulations require that Medica's compliance program include seven core elements.
- Written policies and procedures
- Designation of a Compliance Officer and Committee
- Training and education
- Effective lines of communication
- Well-publicized disciplinary standards
- Routine monitoring and identification of risks
- System for prompt response to issues

Purpose of these training materials:

- New CMS regulations require Medica to establish, implement, and provide effective training and education to any entity that it contracts with to provide administrative or health care services for Medicare eligible individuals under a Medicare Advantage or Part D program.
- The CMS regulations define these contracted entities as first tier, downstream, and related entities.

Definition of Contracted Entities

First Tier Entity

Any party that enters into a written arrangement, acceptable to CMS, with a MA or Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA or Part D programs.

Downstream Entity

Any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA or Part D benefit, below the level of the arrangement between a MA 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

Related Entity

An entity that is related to the Plan Sponsor by common ownership or control and performs some of the 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 Plan Sponsor at a cost of more than \$2,500 during a contract period.

- This training must be completed by 12/31/2010 and annually thereafter. Your organization must maintain records of this training. Records must include:
 - A) **Materials used for training,**
 - B) **Dates training was provided,**
 - C) **Methods training was provided,**
 - D) **Training logs identifying trained employees**
- Medica, CMS, or agents of CMS may request such records to verify that training occurred.
- If you or your organization has contracted with other entities (downstream entities) to provide health or administrative services to Medicare beneficiaries covered by Medica, you must provide this training material or training material that complies with CMS regulations to your subcontractor or downstream entity. You must ensure records of training are maintained by the subcontractor and any other entity that it may have contracted with to provide health or administrative services.

What does an Effective Compliance Program Look Like?

Compliance programs are framed on the seven elements of an effective program. Medica implements the seven elements through collaboration with the Corporate Compliance department and the business unit compliance leads throughout the organization. If Medica delegates any of its compliance activities to an entity that provide administrative or health services to Medicare members, effective oversight of those delegated activities must occur.

Element 1 of an Effective Compliance Program

Written Standards of Conduct and Policies & Procedures that:

- Describe an organization's commitment to comply with all Federal and State standards
- Provide guidance to employees and others on dealing with potential compliance issues
- Describe expectations as embodied in the standards of conduct

You should know that:

- ✓ *Medica's Standards of Conduct booklet and corporate policies can be found on the Medica intranet. Medica is in the process of making some of these materials available on Medica.com.*
- ✓ *Each Standard within the Medica Standards of Conduct booklet has a Related Resources section that lists the policies that support that standard.*

Element 2 of an Effective Compliance Program

Designation of a Compliance Officer and Committee that is:

- Accountable to senior management
- Employed by the organization
- Periodically reports to the governing body
- Responsible for oversight of the compliance program

You should know that:

- ✓ *Medica is committed to complying with CMS regulations and preventing detecting and correcting FWA.*
- ✓ *The Vice President of Compliance and Privacy reports compliance activity to the Board of Director's Audit Committee every quarter.*

Element 3 of an Effective Compliance Program

Training and Education that:

- Is provided to employees including, the chief executive and managers; governing body; and entities Medica partners with to provide administrative or health services to Medicare members.

- Must occur at least annually and as part of orientation of new employees; governing body members; and entities that Medica partners with to provide administrative or health services to Medicare members.

You should know that:

- ✓ *Medica requires first tier, downstream, and related entities to take general compliance and FWA Awareness training as part of becoming a new partner with Medica and annually thereafter.*

Element 4 of an Effective Compliance Program

Effective Lines of Communication must exist:

- Between the compliance officer, compliance committee, employees, managers and governing body
- That maintain confidentiality and allow anonymity if desired (e.g. telephone hotlines or mail drops)
- That are available to entities that Medica partners with to provide administrative or health services to Medicare members

You should know that:

- ✓ *You are encouraged to discuss any suspected compliance issue with appropriate individuals within your organization.*
- ✓ *Any suspected noncompliance or fraud, waste and abuse should be reported to your Medica business contact.*
- ✓ *If you prefer to remain unknown call Medica's Integrity Line: 1-866-595-8495*
- ✓ *No business partner will suffer any penalty or retribution for reporting in good faith any suspected misconduct or noncompliance.*

Element 5 of an Effective Compliance Program

Well-Publicized Disciplinary Standards that:

- Articulate expectations for reporting compliance issues and assist in their resolution;
- Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined; and
- Encourage good faith participation in the compliance program

You should know that:

- ✓ *Medica has a progressive discipline policy to address employee misconduct. The policy is available on Medica's intranet.*
- ✓ *Medica may alter or terminate business relationships as a result of a violation of Medica's Standards of Conduct.*
- ✓ *No business partner will suffer any penalty or retribution for reporting in good faith any suspected misconduct or noncompliance.*

Element 6 of an Effective Compliance Program

Routine Monitoring and Identification of Risks by:

- Conducting internal monitoring and auditing
- Obtaining external audits when appropriate
- Auditing and monitoring entities that Medica partners with to provide administrative or health services to Medicare members
- Evaluation of overall effectiveness of the compliance program

You should know that:

- ✓ *Proactive monitoring of business practices by management is vital to identifying potential compliance issues.*
- ✓ *Medica has an Internal Audit department that assesses the adequacy and effectiveness of Medica's financial controls.*
- ✓ *Corporate Compliance also has an audit function that assesses Medica's compliance with State and Federal laws.*

Element 7 of an Effective Compliance Program

System for Prompt Response to Issues that:

- Acknowledges issues as they are raised
- Requires appropriate investigation of potential compliance problems
- Corrects such problems promptly and thoroughly to reduce the potential for recurrence
- Includes procedures to voluntarily self report potential fraud or misconduct to CMS or its designee

You should know that:

- ✓ *Medica is required by law to respond timely to incidents of noncompliance. Examples include:*
 - Privacy incidents
 - Inquiries from regulators
- ✓ *You are encouraged to inquire about any compliance issues you may have reported.*
- ✓ *Call corporate compliance to discuss any questions you might have.*
- ✓ *No business partner will suffer any penalty or retribution for reporting in good faith any suspected misconduct or noncompliance.*

Oversight of compliance activities

Compliance Oversight

- Regulations state that Medica is ultimately responsible for oversight of any compliance activities delegated to entities that Medica partners with to provide administrative or health services to Medicare members.

You should know that:

- ✓ *As an entity contracted with Medica, you are responsible for maintaining a relationship that supports compliance with CMS regulations. The effectiveness of the compliance program is impacted by how you manage your business relationship with Medica.*

Examples of how Medica may establish oversight include:

- Requiring attestations to evidence compliance with specific activities
- Requesting copies of training logs
- Cooperation with auditing and monitoring activities

Purpose of a Compliance Program

The purpose of a compliance program is to prevent, detect, and correct:

- Noncompliance with CMS' program requirements; and
- Instances of Fraud, Waste, and Abuse

Examples of noncompliance with CMS' program requirements include:

- Not cooperating with CMS auditors
- Untimely submission of data to CMS
- Violating member privacy

The following section is designed to train you on what types of fraud, waste, and abuse you may encounter

What are Fraud Waste and Abuse?

Fraud:

- An intentional act of deception, misrepresentation or concealment in order to gain something of value. Examples include:
 - Billing for services that were never rendered
 - Billing for services at a higher rate than is justified
 - Deliberately misrepresenting services, resulting in unnecessary costs to the Medicare program, improper payments to providers or overpayments

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

Laws Created in Response to FWA

The False Claims Act:

- Prohibits any person from knowingly presenting or causing a fraudulent claim for payment.
- Protects individuals who report noncompliance or FWA.

The Anti-Kickback Statute:

- Makes it a crime to knowingly and willfully offer, pay, solicit, or receive, directly or indirectly, anything of value to induce or reward referrals of items or services reimbursable by a Federal health care program.

Self-Referral Prohibition Statute (Stark Law):

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

Who commits fraud, waste, and abuse?

Unfortunately, FWA may be present in all corners of the health care system. Here are some examples:

- Beneficiaries
- Employees of health plans
- Home health agencies
- Hospitals
- Laboratories
- Medical equipment suppliers
- Pharmacies
- Pharmaceutical manufacturers
- Pharmacy benefit managers
- Physicians, nurses, and other health care providers

Examples of FWA (Prescriber)

Illegal Payment Schemes:

- Prescriber is offered, paid, solicits or receives unlawful payment to induce or reward the prescriber to write prescription for drugs or products.

Script Mills:

- Prescribers write prescriptions for drugs that are not medically necessary, often in mass quantities, and often for patients that are not theirs. These scripts are usually written, but not always, for controlled drugs for sale on the black market, and might include improper payments to the prescriber.

Theft of Prescriber's Drug Enforcement Agency Number or Prescription Pad:

- Prescription pads and/or DEA numbers stolen from prescribers. This information could illegally be used to write prescriptions for controlled substances or other medications.

Examples of FWA (Wholesaler)

Counterfeit, Impure Drugs through Black Market:

- Black Market includes fake, diluted, expired, illegally imported drugs, etc.

Diverters:

- Individuals who illegally gain control of discounted medicines and mark up the prices and move them to small wholesalers.

Inappropriate Documentation of Pricing Information:

- Submitting false or inaccurate pricing or rebate information.

Examples of FWA (Beneficiary)

Identity Theft:

- Using a member's I.D. card that does not belong to that person to obtain prescriptions, services, equipment, supplies, doctor visits, and/or hospital stays.

Doctor Shopping:

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

Examples of FWA (Pharmaceutical Manufacturer)

Illegal Off-label Promotion:

- Promotion of off-label drug use.

Illegal Usage of Free Samples:

- Providing free samples to prescribers knowing and expecting prescriber to bill Medicare for the sample.

Kickbacks, Inducements, Other Illegal Payments:

- Inappropriate marketing or promotion of products reimbursable by federal health care programs or inappropriate discounts or educational grants

Examples of FWA (Plan Sponsor)

Payments for Excluded Drugs:

- Receiving payment for drugs not covered by the Plan sponsor's formulary

Marketing Schemes:

- Offering beneficiaries a cash payment as an encouragement to enroll in a Medicare Plan, Unsolicited door-to-door marketing, Use of unlicensed agents, Enrollment of individual in a Medicare Plan without such individual's knowledge or consent. stating that a marketing agent/broker works for or is contracted with the Social Security Administration or CMS

Examples of FWA (Pharmacy Benefit Manager)

Prescription Drug Switching:

- PBM receives a payment to switch a beneficiary from one drug to another or influence prescriber to switch patient to a different drug.

Prescription Drug Splitting or Shorting:

- PBM mail order pharmacy intentionally provides less than the prescribed quantity, does not inform the patient or make arrangements to provide the balance and bills for the fully-prescribed amount; Splits prescription to receive additional dispensing fees.

Examples of FWA (Billing)

Inappropriate Billing Practices

- Billing for services not provided
- Misrepresenting the service that was provided
- Billing for a higher level than the service actually delivered
- Billing for non-covered services or prescriptions as covered items

Reporting Suspected or Actual FWA

- Report all suspected or actual Fraud, Waste, and Abuse.
- Report all suspected or actual noncompliance with regulations
- No business partner will suffer any penalty or retribution for reporting in good faith any suspected misconduct or noncompliance

You should know that:

- ✓ *You are encouraged to speak to your manager, HR representative, or compliance lead about suspect noncompliance or FWA*
- ✓ *Medica's department for handling FWA is the Special Investigations Unit.*
 - 952-992-1736
 - 1-800-458-5512 (option 1, option 8, ext. 28478)
 - Or go to the Fraud and Abuse page on Medica.com
 - If you prefer to remain anonymous call the Medica Integrity Line 1-866-595-8495

Additional Resources

Laws, regulations and organizational policies can be complex and can sometimes be confusing. While Medica believes that employees and business partners try to do what is right, the right thing to do may not always be clear.

We are all responsible for compliance, and we are all responsible for ensuring that we follow the laws and regulations that govern our work.

- CMS' Prescription Drug Benefit Manual – Chapter 9;
<http://www.cms.gov/Manuals/IOM/list.asp>
- Code of Federal Regulations, 42 CFR 422.503 and 42 CFR 423.504;
<http://www.gpoaccess.gov/cfr/index.html>
- Office of the Inspector General; <http://oig.hhs.gov/fraud/hotline/>

**You have completed the training.
Congratulations!!**