

CMS Mandated Training for First Tier, Downstream and Related Entities

Corporate Compliance and Ethics

January 1, 2009



**BlueCross BlueShield
of Florida**

An Independent Licensee of the
Blue Cross and Blue Shield Association

Throughout our history, Blue Cross and Blue Shield of Florida (BCBSF) has maintained a solid commitment to conduct our business with the highest degree of ethics and in compliance with all laws. Our company values clearly state our business decisions are based upon the highest ethical standards, including honesty, fairness and integrity.

The Compass ProgramSM (BCBSFs compliance and ethics program) is designed to educate our board members, employees and contingent workforce about federal and state laws and regulations, as well as ethical rules which apply to BCBSFs business, raise awareness of questionable conduct, monitor compliance and provide effective lines of communication for reporting suspected violations.

BCBSF relies on written policies and procedures to comply with business standards and federal and state laws. The company also has effective lines of communication, and a dedicated compliance officer and compliance committee to monitor suspected violations, and when appropriate, oversee corrective actions to prevent future violations.

BCBSF contracts with the Centers for Medicare & Medicaid Services (CMS) to offer health and prescription drug coverage to eligible enrollees. Collectively, BCBSF is referred to as a “Medicare Advantage (MA) Organization and Part D Plan Sponsor.”

BCBSF must follow applicable laws, regulations and guidance that govern the MA and Part D Plan Sponsors. CMS also requires these entities to attest that they are in compliance with legal and regulatory requirements.

As an entity that contracts with BCBSF to provide health, prescription and/or administrative services on behalf of our Medicare Advantage and/or Part D beneficiaries, your organization must meet new education and training requirements related to fraud, waste and abuse (FWA). The following slides provide learning objectives, revised regulations, definitions, education requirements, documentation requirements, relevant laws, examples of potential FWA, reporting and prevention mechanisms, attestation, training log and resources.

At the conclusion of this presentation, an authorized representative from your organization will need to complete the attached attestation and return it to BCBSF via email, fax or surface mail to the address provided.

Learning Objectives

At the conclusion of this presentation,

You will gain a better understanding of:

- New education and training regulations that govern Medicare Advantage and/or Part D Plans Sponsors.
- Definitions used to help entities detect and prevent fraud, waste, and abuse.
- Education and documentation needed to comply with the new federal government requirements.
- Relevant laws and examples of potential fraud, waste and abuse.
- Reporting and preventing potential fraud, waste and abuse.
- Attestation and training information.
- Resources.

Revised Regulations

On December 5, 2007, the Centers for Medicare & Medicaid Services (CMS) issued final rules in the Federal Register for 42 CFR Parts 422 and 423 of the Medicare Advantage Program and Prescription Drug Benefit Program, respectively.

BCBSF must:

- Maintain appropriate oversight and attest it will implement a compliance plan that includes effective training and education between the compliance officer, organization employees, contractors, agents and directors.
- Establish training and communication requirements for their first tier, downstream and related entities with which BCBSF has a contractual relationship.
- Obtain training logs and copies of attestations from their first tier, downstream and related entities to comply with this requirement.

Source: Federal Register – Part V Department of Health and Human Services, 42 CFR 422 and 423 [CMS-4124-FC], Wednesday, December 5, 2007.

Important Definitions

What are first tier, downstream and related entities?

First Tier Entity

- Any party that enters into a written arrangement acceptable to CMS with a Sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under MA and/or Part D.

Downstream Entity

- Any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a 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, but are not limited to, mail order pharmacies, firms providing agent/broker services, agents, brokers, marketing firms, and call center firms.

Sources: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006). Federal Register, Part V Department of Health and Human Services Centers for Medicare & Medicaid Services 42 CFR 422 and 423, Wednesday, December 5, 2007.

What are first tier, downstream and related entities?

Related Entity

- Any entity that is related to the MA organization by common ownership or control and:
 1. Performs some of the MA organization's management functions under contract or delegation;
 2. Furnishes services to Medicare enrollees under an oral or written agreement; or
 3. Leases real property or sells materials to the MA organization at a cost of more than \$2,500 during a contract period.

Source: Medicare Managed Care Manual Chapter 11 – Medicare Advantage Application Procedures and Contract Requirements (Rev. 83, 04-25-2007).

Fraud

- Federal health care fraud generally involves a person or entity's intentional use of false statements or fraudulent schemes (such as kickbacks) to obtain payment for, or to cause another to obtain payment for items or services payable under a Federal health care program. Some examples of fraud:
 - Billing for services not furnished;
 - Soliciting, offering or receiving a kickback, bribe or rebate; or
 - Violations of the physician self-referral ("Stark") prohibition.

Abuse

- In general, program abuse, which may be intentional or unintentional, directly or indirectly results in unnecessary or increased costs to the Medicare Program. Some examples of abuse:
 - Charging in excess for services or supplies;
 - Providing medically unnecessary services; or
 - Providing services that do not meet professionally recognized standards.

Source: Medicare Physician Guide: A Resource for Residents, Practicing Physicians, and Other Health Care Professionals – Ninth Edition: July 2007; and CMS Medicare Fraud and Abuse – Web-based Training (April 2007).

Waste

- Use or expend carelessly, extravagantly, or to no purpose.

Medicare Drug Integrity Contractor (MEDIC)

- An organization that the CMS has contracted with to perform specific program integrity functions for Part D under the Medicare Integrity Program. The MEDIC is CMS' designee to manage CMS' audit, oversight, and anti-fraud and abuse efforts in the Part D benefit.

Pharmacy Benefit Manager (PBM)

- An entity that provides pharmacy benefit management services, including contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies.

Sources: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006); and The Oxford Pocket Dictionary (Pub. 2008).

Education Requirements

According to federal regulations, BCBSF is ultimately responsible for oversight and monitoring of education and training of first tier, downstream and related entities.

How can you as one of these entities comply with the FWA education and training requirements?

Three Options:

1. Provide your own training in accordance with CFR 422.504(b)(4)(vi)(c) or 423.504(b)(4)(vi)(c) *“Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.”* Please see the Resource slide for websites that have FWA information.
2. Take training from another MA and/or Part D Plan Sponsor, or other organization.
3. Complete training provided by BCBSF.

Your organization must maintain internal training logs, and submit the required attestation within the designated timeframe to BCBSF.

BCBSF Fraud, Waste and Abuse Training

- Documentation Requirements
- Relevant Laws
- Examples of Potential FWA
- Reporting and Preventing FWA

Documentation Requirements

Your organization is required to complete the attestation on slide **[32]** which must be signed by an authorized representative. Upon request, your organization may be required to submit copies of training logs demonstrating that your employees received fraud, waste and abuse training.

If your organization has contracted with **other entities** to provide health and/or administrative services on behalf of BCBSF Medicare Advantage and/or Part D beneficiaries you will need to obtain attestations from those entities that they have completed FWA training. In addition, those entities will also need to provide your organization with copies of their training logs.

Relevant Laws

The False Claims Act prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. When submitting claims data to CMS for payment, BCBSF and our subcontractors must certify that claims data is true and accurate to the best of their knowledge and belief.

The False Claims Act is enforced against any individual/entity that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government.

Note: Intent to defraud is not necessary to prove that the government was in fact defrauded, so long as it is established that the person acted “with intent to defraud.”

Source: 42 U.S.C. 1320a-7b. Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006); and <http://www.lectlaw.com>.

Section 1128B9b) of the Social Security Act (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward business payable (or reimbursable) under the Medicare or other Federal health care programs.

For example, recent kickback cases have involved unlawful referral payments in form of free office space, free equipment, free drugs or supplies, inflated or sham consulting contracts, and travel and entertainment to physicians by hospitals, pharmaceutical companies and laboratories.

In addition to applicable criminal sanctions, an individual or entity may be excluded from participation in the Medicare and other Federal health care programs and subject to civil monetary penalties. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

Source: 42 U.S.C. 1320a-7b. Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006); and Testimony of Lewis Morris, Chief Counsel to the Inspector General U.S. Department of Health and Human Services (April 6, 2006).

Examples of Potential FWA

MA and/or Part D Plan Sponsor

Unlawful Marketing Schemes:

- Offering beneficiaries a cash payment as an inducement to enroll in Part D.
- Unsolicited door-to-door marketing.
- Enrollment of beneficiaries without their knowledge or consent.
- Stating that a marketing agent/broker works for or is contracted with the Social Security Administration or CMS.
- Misrepresents the product being marketed as an approved Part D Plan when it actually is a Medigap policy or non-Medicare drug plan.
- Requires beneficiaries to pay up front premiums.

Source: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006).

Pharmacy Benefit Manager (PBM)

Unlawful Remuneration:

- PBM receives unlawful remuneration in order to steer a beneficiary toward a certain plan or drug, or for formulary placement. Includes unlawful remuneration from vendors beyond switching fees.

Failure to Offer Negotiated Prices:

- Occurs when a PBM does not offer a beneficiary the negotiated price of a Part D drug.

Source: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006).

Retail Pharmacy

Bait and Switch Pricing:

- 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.

Prescription Drug Shorting:

- Pharmacist provides less than the prescribed quantity and intentionally does not inform the patient or make arrangements to provide the balance but bills for the fully-prescribed amount.

Prescription Forging or Altering:

- Where existing prescriptions are altered, by an individual without the prescriber's permission to increase quantity or number of refills.

Source: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006).

Provider*

Illegal Remuneration Schemes:

- Provider is offered, or paid, or solicits, or receives unlawful remuneration to induce or reward the prescriber to write prescriptions for drugs, products or services

Script Mills:

- Provider writes 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 provider.

Theft of Provider's DEA Number or Prescription Pad:

- Prescription pads and/or DEA numbers can be stolen from prescribers. This information could illegally be used to write prescriptions for controlled substances or other medications often sold on the black market.

* Refer to Exhibit A for additional examples of potential FWA committed by providers

Source: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006).

Pharmaceutical Manufacturer

Illegal Off-label Promotion:

- 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 sample.

Source: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006).

Beneficiary

Misrepresentation of Status:

- A Medicare beneficiary misrepresents personal information, such as identity, eligibility, or medical condition in order to illegally receive the drug benefit. Enrollees who are no longer covered under a drug benefit plan may still attempt to use their identity card to obtain prescriptions.

Identify Theft:

- Perpetrator uses another person's Medicare card to obtain prescriptions.

Resale of Drugs on Black Market:

- Beneficiary falsely reports loss or theft of drugs or feigns illness to obtain drugs for resale on the black market.

Doctor Shopping:

- Beneficiary or other individual consults a number of doctors for the purpose of inappropriately obtaining multiple prescriptions for narcotic painkillers or other drugs. Doctor shopping might be indicative of a underlying scheme, such as stockpiling or resale on the black market.

Source: Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse (Rev.2, 04-25-2006).

Reporting and Preventing FWA

Compliance with state and federal laws, and regulations has always been a priority of BCBSF. If your organization or another downstream entity that you contract with to provide health, prescription and/or administrative services on behalf of BCBSF Medicare Advantage and/or Part D beneficiaries identifies potential fraud, waste and abuse, please contact BCBSFs Special Investigation Unit (SIU).

Calling the toll free hotline at 1-800-678-8355 or sending an email to specinvestunit@bcbsfl.com are two easy ways to report potential FWA. Below are examples of information that will assist BCBSFs SIU with an investigation:

- Contact information (e.g., Name of individual making the allegation, address, telephone number).
- Type of item or service involved in the allegation.
- Place of service.
- Nature of the allegation(s).
- Timeframe of the allegation(s).

As situations warrant, BCBSFs SIU may make referrals to appropriate law enforcement and/or the MEDIC.

CMS follows four parallel strategies to prevent fraud and abuse:

- Preventing fraud through effective enrollment and through education of physicians, providers, suppliers and beneficiaries.
- Early detection through Medical Review (MR) and data analysis.
- Close coordination with partners, including contractors, the MEDIC and law enforcement agencies.
- Applying fair and firm enforcement policies.

Attestation, Training Log and Resources

Pursuant to the final rule issued in the Federal Register for 42 CFR Parts 422 and 423 of the Medicare Program on Wednesday, December 5, 2007, Medicare Advantage and Part D sponsor is ultimately responsible for compliance plan oversight, including monitoring training and education, and complying with all statutory and regulatory requirements.

Attestation

As a first tier, downstream or related entity _____ attests that it has conducted appropriate education and training to identify, correct and prevent potential fraud, waste and abuse, per the final rule issued in the Federal Register for 42 CFR Parts 422 and 423 of the Medicare Program on Wednesday, December 5, 2007. Please select the method of education and training that your organization chose to comply with the final rule requirement.

- Conducted our own education and training per CFR 422.504(b)(4)(vi)(c) or 423.504(b)(4)(vi)(c).
- Took training and education provided by a Medicare Advantage and/or Part D sponsor, or other organization.
- Took training and education provided by Blue Cross and Blue Shield of Florida.

Signature attests that your organization has completed appropriate education and training to identify, correct and prevent potential fraud, waste and abuse, and your organization will furnish upon request to Blue Cross and Blue Shield of Florida (BCBSF) training logs to validate that training was completed. In addition, your organization will obtain attestations from other entities that provide health, prescription and/or administrative services on behalf of BCBSF Medicare Advantage and/or Part D beneficiaries, and upon request obtain training logs to verify that fraud, waste and abuse training was completed by those entities.

(Signature)

Name: _____

Title: _____

(Date)

Please return this completed attestation to:

Sample

Employee Name - Print	Employee Signature	Name of Training (E.g., BCBSF)	Date of Training	Manager's Initials

The following federal government websites are sources of information regarding fraud, waste and abuse education, detection, correction and prevention.

Department of Health and Human Services Office of Inspector General

<http://www.oig.hhs.gov/hotline.html>

Centers for Medicare & Medicaid Services

<http://www.cms.hhs.gov/MDFraudAbuseGenInfo/>

http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

Social Security Administration

<http://www.ssa.gov/oig/guidelin.htm>

Exhibit A

Examples of potential FWA by providers

General

- Billing for items or services not rendered or not provided as claimed;
- Submitting claims for equipment or supplies and services that are not reasonable and necessary;
- Double billing resulting in duplicate payment;
- Billing for non covered services as if covered;
- Knowing misuse of provider identification numbers, which results in improper billing;
- Unbundling (billing for each component of the service instead of billing or using all inclusive code);
- Failure to properly code using coding modifiers;
- Altering medical records;
- Improper telemarketing practices;
- Compensation programs that offer incentives for items or services ordered and revenue generated;
- Inappropriate use of place of service codes;
- Routine waivers of deductibles coinsurance;
- Clustering; and
- Upcoding the level of service provided.

Exhibit A

Examples of potential FWA by providers

Skilled Nursing Facility (“SNF”)

- SNFs improperly upcoding resident RUGs assignments to gain higher reimbursement;
- SNF improperly utilizing therapy services to inflate the severity of the RUG classification to obtain additional reimbursement; and
- DME or supplies offered by DME provider that are covered by the Medicare Part A benefit in the SNF’s payment.

Hospital

- Failure to follow the same day rule;
- Abuse of partial hospitalization payments;
- Same day discharges and readmissions;
- Improper billing for observation services;
- Improper reporting of pass through costs;
- Billing on an outpatient basis for “inpatient only” procedures;
- Submitting claims for medically unnecessary services by failing to follow the FI’s local policies; and
- Improper claims for cardiac rehabilitation services

Exhibit A

Examples of potential FWA by providers

Physicians and Others

- Chiropractor intentionally billing Medicare for physical therapy and chiropractic treatments that were never actually rendered for the purpose of fraudulently obtaining Medicare payments;
- A psychiatrist billing Medicare, Medicaid and TriCare, and private insurers for psychiatric services that were provided by his nurses rather than himself;
- Physician certifies on a claim form that he performed laser surgery on a Medicare beneficiary when he knew that the surgery was not actually performed on the patient;
- Physician instructs his employees to tell the OIG investigators that the physician personally performs all treatments when, in fact, medical technicians do the majority of the treatment and the physician is rarely present in the office;
- Physician, who is under investigation by the FBI and the plan, alters records in an attempt to cover up improprieties;
- Neurologist knowingly submits electronic claims to the Medicare carrier for tests that were not reasonable and necessary and intentionally upcoded office visits and electromyograms to Medicare;
- Podiatrist knowingly submits claims to the Medicare and Medicaid programs for non-routine surgical procedures when he actually performed routine, non covered services such as the cutting an trimming of toenails and the removal of corns and calluses; and
- Performing tests on a beneficiary to establish medical necessity.

Exhibit A

Examples of potential FWA by providers

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

- DME provider billed for items or services not provided to the beneficiary;
- Continued billing for rental items after they are no longer medically necessary;
- Resubmission of denied claims with different information in an attempt to be improperly reimbursed;
- Providing and/or billing for substantially excessive amounts of DME items or supplies;
- Upcoding a DME item by selecting a code that is not the most appropriate;
- Providing a wheelchair and billing for the individual parts (unbundling);
- Delivering or billing for certain items or supplies prior to receiving a physicians' order and/or appropriate certificate of necessity;
- Completing portions of the certificate of necessity that is reserved for completion by the treating physician only;
- Cover letters to encourage physicians to order medically unnecessary items or services;
- Improper use of the ZX modifier;
- Providing false information on the DMEPOS supplier enrollment form;
- Knowing misuse of a supplier number, which results in improper billing.

Exhibit A

Examples of potential FWA by providers

Home Health Providers

- Furnishing more visits than as medically necessary;
- Duplicate billing for the same service;
- Submission of claims for home health aide services to beneficiaries that did not require any skilled qualifying service;
- Provision of personal care services by aides in assisted living facilities when such is required by the assisted living's State licensure;
- Providing services at no charge to an assisted living center;

Ambulances

- Provision of free transportation to beneficiaries to influence their selection of a particular provider, practitioner or supplier

Hospice

- Hospice providing nursing services for non-hospice patients