

**Update:**

# CMS Requirements for a Part D Program to Control Fraud, Waste and Abuse

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## Learning Objectives

1. Distinguish between fraud, waste and abuse.
2. Describe rules and regulations that pharmacies must comply with pertaining to the Part D Fraud, Waste and Abuse (FWA) program.
3. Identify the requirements recommended for inclusion in a pharmacy compliance program.
4. Describe the investigation process and punitive actions that can be taken by Medicare if pharmacies fail to comply.

## Introduction

The Centers for Medicare and Medicaid Services (CMS) estimates that 10 percent of paid Medicare claims could fall into the category of fraud, waste or abuse.<sup>1</sup> That could be a huge number, considering how many beneficiaries are actually using Medicare services on a day-to-day basis. In an attempt to combat this, regulations included in the Medicare Modernization Act (MMA) of 2003 included provisions to control fraud, waste and abuse (FWA) in the prescription drug program. As a result of these regulations, all contractors conducting business related to the prescription drug program must have FWA programs in place. Entities and professionals such as health plans, doctors, pharmacy benefit managers, pharmacies, pharmacists and technicians are included in the requirements to detect, correct and prevent FWA. More information on exact details of the requirements set

in place by CMS can be found in Chapter Nine of the *Medicare Prescription Drug Benefit Manual*.<sup>1</sup>

It is important to remember that the Medicare Part D program guidelines for FWA training are only a basic outline of criteria to direct FWA program development. Medicare does not provide a standardized FWA program for pharmacy professionals or any other provider.<sup>2</sup> Contractors conducting business with Medicare through the prescription drug program must, therefore, tailor individualized programs in order to comply with all Medicare rules and regulations. If guidelines are not in writing and complied with, it can be very easy for auditors to recover monies associated with prescription payments for Part D claims and potentially restrict pharmacies from participating in governmentally funded prescription programs in the future. For this reason alone, compliance training for the FWA program is extremely important.<sup>1</sup>

## Fraud, Waste and Abuse

The terms "fraud" and "abuse" can often be used interchangeably. However, as CMS defines abuse, it is typically not intentional, while fraud is considered to be committed intentionally. It is common for an investigation to begin with suspected abuse and later be determined to be fraud. This is why keeping a FWA program up-to-date and within standards is important for complying with the Medicare Part D requirements.<sup>2</sup>

## Fraud

Fraud is defined in Title 18, United States Code (U.S.C.) §1347, as "knowingly and willfully executing or attempting to execute a scheme or artifice to defraud any healthcare benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any healthcare benefit program."<sup>2</sup> CMS considers fraud to be when an "individual intentionally deceives or misrepresents the truth, knowing that it could result in some unauthorized benefit to himself or herself or some other individual."<sup>1</sup> Violators may include anyone in the position to file a Medicare claim.

An example of what fraud is not is when a pharmacy bills for a 90-



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day supply, fills only 30 days, but later revises the claim to the 30-day supply. Because the FWA program applies to health plans, doctors, pharmacy benefit managers, pharmacies, pharmacists and technicians, others can be involved in fraud as well. An example of fraud could include a person using someone else's insurance card to receive Part D benefits. Another example is if a doctor wrote a prescription for a larger quantity of medication than appropriate to assist the patient in decreasing their copayment. More examples of fraud can be found in Table 1.<sup>1</sup>

Another important factor to consider with the MMA and with the FWA compliance program is that technicians are, by law, not allowed to counsel patients about their medications. Doing so can be considered fraud because the patients are not receiving the service that they expect they will receive from a pharmacist.<sup>1</sup>

**Table 1 Examples of Fraud<sup>2</sup>**

|   |
|---|
| Adjusting claim forms/documentation to receive higher payment |
| Invalid diagnosis codes or dates                              |
| Incorrect billing resulting in duplicate paid claims          |
| Falsely billing for claims/services never provided            |
| Improperly billing noncovered items as covered items          |

**Waste and Abuse**

Waste can be defined as “to use, consume, spend or expend thoughtlessly or carelessly.”<sup>3</sup> As waste pertains to Medicare, it is often considered from the beneficiary's point of view. One example of waste is dispensing an older prescription for a patient when the doctor has changed the patient's medication therapy. Another example of waste is when drugs are provided that are not medically necessary.

CMS defines abuse as “practice that either directly or indirectly results in unnecessary costs to the Medicare program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary.”<sup>1</sup> Examples of waste and abuse can be found in Table 2.

**Table 2 Examples of Waste and Abuse<sup>2</sup>**

|  |
|--|
| Sending claims to Medicare when the patient has primary insurance coverage |
| Breaking the assignment agreement  |
| Setting a higher fee schedule for services for Medicare patients           |
| Providing excessive services that are not medically necessary              |
| Providing services that are not professionally recognized standards        |

**Anti-Kickback Statute and the Physician Referral “Stark” Statute**

The Anti-Kickback Statute, as CMS defines it, “prohibits offering, soliciting, paying, or receiving remuneration for referrals for services that are paid in whole or in part by Medicare.”<sup>1</sup> An example of a violation of this statute would be if the pharmacist owned her own pharmacy and encouraged her patients to go with a particular Part D

plan because she gets better reimbursement from them.<sup>2</sup>

The Physician Self-Referral “Stark” Statute, as defined by CMS, “prohibits a physician from making a referral for certain designated health services to an entity in which the physician (or a member of his or her family) has an ownership/investment interest or with which he or she has a compensation arrangement, unless an exception applies.”<sup>1</sup> Exceptions to this statute include laboratory, physical therapy, radiology, durable medical, home health and radiation therapy services. In other words, if a physician referred his patient to his wife's pharmacy, this would be considered a violation of the Physician Self-Referral Statute.<sup>2</sup> Additional details on this can be found in the Code of Federal Regulations accessible at [www.gpoaccess.gov/cfr/index.html](http://www.gpoaccess.gov/cfr/index.html).

**False Claims Act**

The False Claims Act ties in with all of the other rules and regulations stated already. The act reads “it's a crime for any person or organization to knowingly make a false record or file a false claim regarding any federal health program.”<sup>4</sup> This includes any state or federal healthcare program, including Medicare and Medicaid. It is important to note the wording of this act, because if you are not participating in a false claim but know that it is occurring, you can be prosecuted as well just because you know about it. This act can actually be enforced by anyone, meaning if you know about a false claim and choose to prosecute the party, you can do so and you will receive a portion of the monetary settlement that the government receives. These settlements come from penalties to the party involved in the false claims. The guilty party can be charged up to three times the amount of the claims submitted and have fines on top of that of \$5,000–10,000 for each claim falsely submitted.<sup>4</sup>

**Office of Inspector General (OIG) Exclusions**

Providers conducting business with Part D must also be aware of regulations pertaining to OIG exclusions. The OIG outlines the exclusions that are regulated by CMS. Included on the OIG exclusion list are individuals or entities found guilty of fraudulent activity and excluded from participation in all governmentally funded program reimbursement. This list can be found on the OIG website ([www.oig.hhs.gov](http://www.oig.hhs.gov)) and should be checked by employers before hiring a new employee to ensure the pharmacy is compliant with CMS regulations. It should be understood that there is no payment made by any federal healthcare program for any items or services furnished, ordered or prescribed by an excluded individual or entity.<sup>5</sup> If it is found that someone in the pharmacy has been excluded by the OIG, the pharmacy could be audited and penalized as though they have been filing false claims.

**Requirements of a Compliance Program**

As previously stated, Medicare estimates that 10 percent of all claims paid are attributable to fraud, waste or abuse. This is a huge economic burden on the Medicare program as healthcare costs continue to rise. Due to these concerns, Medicare has made a

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priority of recuperating costs associated with FWA. Medicare suggests that each contractor conducting business with Part D, including pharmacies, either develop a program based on Chapter Nine or integrate the ideas of Chapter Nine into an existing compliance program. Whichever of the two choices the pharmacy chooses, there are seven elements that are required for the FWA program. These elements can be found in Table 3. Anything done beyond these seven requirements are merely suggestions to guarantee that the program implemented is completely compliant.<sup>1</sup>

**Table 3 Seven Required Elements to a Medicare Compliance Program<sup>1</sup>**

|  |
|--|
| 1. Implementing written policies, procedures and standards of conduct      |
| 2. Designating a compliance officer and compliance committee               |
| 3. Conducting effective training and education                             |
| 4. Developing effective lines of communication                             |
| 5. Enforcing standards through well-publicized disciplinary guidelines     |
| 6. Conducting internal monitoring and auditing                             |
| 7. Responding promptly to offenses and developing a corrective action plan |

To elaborate specifically on element number two, a compliance officer (CO) and a compliance committee must be in place to ensure that all parties are in compliance with the FWA program. Neither the CO nor the committee may be subcontracted.<sup>1</sup>

Medicare recommends that the CO be a full-time employee other than the corporate compliance officer that most pharmacies already have in place. This is only a recommendation, not a requirement. This would allow the Medicare CO to focus on the FWA program. The CO is responsible for developing, operating and monitoring the program. Other duties that are typically involved include, but are not limited to:

- creating/coordinating training for employees within the pharmacy.
- increasing awareness of how to report fraud without retaliation.
- working closely with the compliance committee, being receptive of new ideas.
- presenting quarterly reports to the owner, president and/or chief executive officer of the pharmacy.
- coordinating internal investigations and implementing corrective action.<sup>1</sup>

The compliance committee is directly overseen by the CO. The committee should be representative of senior management,

**Table 4 Components of a Policies and Procedures Manual<sup>1</sup>**

|   |
|---|
| • The commitment to comply with all portions of the FWA program                                     |
| • Procedures for identifying fraud, waste or abuse (Including over/underpayment)                    |
| • Processes to manage an inquiry and deal with CMS audits in a reasonable time period               |
| • Processes to refer an inquiry to CMS (Must be within 60 days of discovery)                        |
| • Process allowing an employee to make an inquiry without retaliation from the company or coworkers |
| • Procedures for how to comply with the 10-year record retention rules                              |

pharmacists and technicians to ensure that a wide variety of staff is involved in making the decisions. Legal staff, personal auditors and statistical analysts could also be included. The committees' duties include, but are not limited to:

- conducting quarterly meetings, or more frequently as needed.
- guaranteeing training and education is being completed by all staff.
- overseeing policies and procedures to ensure that they are up to date.
- ensuring that procedures are being followed on a daily basis.
- coordinating new ways to prevent problems in the program.<sup>1</sup>

The CO and the committee must work together to create a written document the pharmacy will use to follow the Medicare FWA requirements. This written document should include a code of conduct and policies and procedures. The code of conduct defines ethical behavior for the pharmacy and employees. It also should include the pharmacy's commitment to abide by the requirements set by CMS; how employees can report instances that may be suspected as fraud, waste or abuse; the expectations of how all employees at the pharmacy will comply; and what will happen to employees if they do not comply.<sup>1</sup> This code of conduct should be assessed periodically by the CO and the compliance committee to determine if changes need to be made.<sup>2</sup>

The policies and procedures manual must be written to ensure that the activities done on a daily basis are compliant with the program. A list of parts that should be included in the policies and procedures manual can be found in Table 4. These are just a few of the requirements of the manual. A full list can be found in Chapter Nine. The policies and procedures manual should also be reviewed often to ensure that it stays up-to-date with the requirements of CMS. It is recommended to have this done at the quarterly CO and committee meetings.<sup>1</sup>

Training and education is one of the seven elements required by CMS for the FWA program.<sup>1</sup> The earlier version of Chapter Nine included language indicating recommended amounts of compliance training required for providers: general compliance training (two hours) and specialized compliance training (four hours). This has since been removed and no specific time requirements are in place; however, training must be completed and documented at the time of contracting, upon hiring and annually thereafter. If the pharmacy has not already implemented the FWA Compliance program, it is important that they do so immediately. If a pharmacy has already implemented this program, it is important that they continue to adhere to the program. It is also important to provide annual training sessions for existing employees and training sessions for new employees to ensure that the pharmacy is up-to-date with the compliance training

requirements. This training must be documented and kept on record for 10 years. CMS personnel and other contractors doing business with Part D (health plans and pharmacy benefit managers) can contact a pharmacy at any time and ask for documentation to verify that everyone in the pharmacy has completed compliance training.<sup>1</sup> This training can include, but is not limited to, any of the following: CE programs, staff meetings, educational programming or requiring reading of certain literature.<sup>2</sup>



## CMS Monitoring of the FWA Program

The investigation process can include multiple parts. The most common parts are the Medical Review (MR) and the Probe Review (PR).<sup>2</sup> Both of these play a specific role in discovering and investigating fraud and abuse.

The MR works by identifying billing errors with coverage and coding proactively and then pursuing those problems.<sup>2</sup> Pharmacies that submit claims they believe to be correct, but that may have potential problems, are subject to three possible corrective actions: education of fully correct billing procedures, prepayment review and post payment review. Submission of actual paper records rarely occurs with MR, but if it does occur, it is most likely related to further investigations leading to a PR.

A PR consists of CMS requesting 20 to 40 claims from one pharmacy to check for a possible trend in billing errors. The claims are then assessed and if errors are found, overpayment is collected and determinations for the next step are made. If overpayment is found, automatic repayment to CMS is expected. If this payment is not made, it can be subject to interest at a rate that is determined by law.<sup>2</sup>

There is one main entity, the Medicare Drug Integrity Contractor (MEDIC), involved in the investigation process through CMS.<sup>1</sup> However, pharmacies can benefit by doing continual audits internally with Special Investigation Units (SIUs).<sup>2</sup> SIUs and MEDICs are integral to the success of the FWA program. SIUs are employed or contracted by the pharmacy or health plan to do continual audits and preliminary investigations into the possible fraudulent activity before referring it to a MEDIC. If a pharmacy self-reports a fraudulent activity or possible abuse and is working to correct the activity, the severity of action will be minimized. Primary investigations are not a requirement for pharmacies to conduct, nor are they even a high priority recommendation; however, it can help to ensure that the compliance program is functioning as it was intended to function.<sup>2</sup>

MEDICs have three main purposes: preventing, detecting and auditing for FWA. These responsibilities can be detailed further and include:

- evaluating data to discover fraud and abuse currently occurring.
- examining possible fraud in regards to enrollment, eligibility determination or distribution.
- investigating fraud complaints and making referrals to law enforcement when necessary.<sup>6</sup>

When MEDICs arrive for an audit, they have the right to request any and all information that pertains to the claim(s) in question. This information must be given to them within 30 days of the request, unless otherwise indicated by the MEDIC when the original request is made. MEDICs may find that their investigation discovers an accidental error instead of fraudulent activity. If this is the case, the MEDIC would return the information to CMS and not pursue legal ramifications.<sup>1</sup>

Once the investigation process has begun, there are a few different options for what can happen, depending on the severity of the fraudulent activity. The first of these options is as simple as claim denials or revocations. Also, if new fraudulent activity arises and it is being investigated, CMS can actually suspend reimbursement to the pharmacy for as long as 180 days. This cannot be appealed, but the pharmacy can submit a written rebuttal. If the pharmacy is confident they

did not take part in fraudulent activity, they may continue to submit claims to the Medicare Part D plan. These claims will be processed; however, the pharmacy will not be paid any reimbursement until the fraudulent activity has been thoroughly investigated and the pharmacy is cleared of any accusations.<sup>2</sup> If the pharmacy is not cleared of the suspected charges, Civil Monetary Penalties (CMPs) can be imposed on the pharmacy with penalties being up to \$10,000 per violation. In addition, the pharmacist(s), technician(s) and pharmacy involved in the fraudulent activity can be excluded from the Medicare program for a minimum of five years.<sup>1</sup>

The Medicare Incentive Reward Program (IRP) has been established to promote the reporting of fraud and abuse. Persons providing information that leads to recovery of \$100 or more will be given a reward from Medicare. However, the reward will not exceed 10 percent of the money recovered. A person can be reported for fraudulent billing and questions regarding fraudulent or abusive billing can be directed to 1-800-HHS-TIPS.<sup>2</sup> More information on this topic can be found in Chapter Three of the *Medicare Program Integrity Manual*.<sup>7</sup>

## Examples of Administrative Actions

These examples demonstrate to providers that fraudulent activity is a serious problem, and pharmacies, hospitals and durable medical equipment (DME) providers are truly being fined for fraudulent billing activities.

A pharmacist in New York was sentenced to 55 months in prison and received a CMP of \$1.325 million. The pharmacist was found guilty of fraudulently billing for refills that were not authorized by the doctor, billing for brand name drugs when generics were provided and billing for prescriptions that were never actually filled.<sup>5</sup>

A DME provider in Florida was found guilty of billing fraudulent claims from April to October of 2006. The majority of the fraudulent activity was related to billing claims without doctor authorization. The provider was sentenced to 30 months in jail and received a CMP of \$1.4 million.<sup>5</sup>

Another DME provider in Florida was found guilty of providing fraudulent prescriptions for non-commercially available aerosol medications. The provider was sentenced to 151 months in jail and received a CMP of \$3.4 million. Many other people were prosecuted as well for being involved in this, including doctors and patients, and all received monetary kickbacks while being involved. Due to this, they were all prosecuted accordingly.<sup>5</sup>

Another DME owner in Florida was found to have entered into an agreement with a pharmacy to receive monetary kickbacks for each patient referral. The owner was found guilty of violating the Anti-Kickback Statute, sentenced to 10 months in prison and received a CMP of \$11,000.<sup>5</sup>

## Summary

Medicare requirements pertaining to the FWA compliance program began on January 1, 2005, with the start of the Medicare Part D program. It was established by CMS to ensure that money is not lost through day-to-day claims. Pharmacists, pharmacies, technicians and other entities must follow the requirements of the program defined in Chapter Nine of the *CMS Prescription Drug Benefit Manual*. It is very important that the CO and the compliance committee be aware of

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## Continuing education

CMS requirements in order to keep the policy and procedures manual up-to-date, as well to ensure that employees are getting the appropriate training and education.

### References

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6. Burke, R., Powers, Pyles, Sutter, Fraud, Waste and Abuse Oversight in Medicare Part D Program, Pharmaceutical Commerce, in press 2006.
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**Table 5 Glossary**

| Term                               | Definition  |
|------------------------------------|---|
| Fraud                              | Individual intentionally deceives or misrepresents the truth, knowing that it could result in some unauthorized benefit to himself or herself or some other individual  |
| Waste                              | To use, consume, spend or expend thoughtlessly or carelessly  |
| Abuse                              | Practice that either directly or indirectly results in unnecessary costs to the Medicare program, improper payment, payment for services that fail to meet professional recognized standards of care or services that are medically necessary |
| Anti-Kickback Statute              | Prohibits offering, soliciting, paying or receiving remuneration for referrals for services that are paid in whole or in part by Medicare   |
| Physician Referral "Stark" Statute | Prohibits a physician from making a referral for certain designated health services to an entity in which the physician has ownership/investment interest or with which he or she has a compensation arrangement, unless an exception applies |
| False Claims Act                   | It is a crime for any person or organization to knowingly make a false record or file a false claim regarding any federal health program  |
| OIG Exclusions                     | A list of people excluded from billing any federal plan, compiled by the Office of Inspector General and CMS  |
| MEDIC                              | Medicare Drug Integrity Contractor, contracted by CMS to prevent, detect and audit for fraud, waste and abuse   |
| SIU                                | Special Investigation Units are contracted by the pharmacy or the health plan to do continual audits and preliminary investigations before referring on to MEDICs   |
| Medical Review                     | MEDICs or SIUs identify billing errors with coverage and coding proactively and then pursue those problems  |
| Probe Review                       | MEDICs or SIUs request 20 to 40 claims from a pharmacy to check for a possible trend in billing errors  |
| CMP                                | Civil Monetary Penalties are monetary punishments handed out by CMS to penalize pharmacies for fraud, waste and abuse   |
| IRP                                | Medicare Incentive Reward Program provides monetary rewards to individuals who report pharmacies/ pharmacists participating in fraudulent activity  |

## Continuing Education Self-Assessment Questions

1. Which of the following can be considered fraudulent activities?
  - a. Improperly billing items
  - b. Receiving duplicate payments
  - c. Listing incorrect diagnosis codes
  - d. All of the above
2. What is the main difference between fraud and abuse?
  - a. Fraud is intentional, while abuse is unintentional.
  - b. Fraud is unintentional, while abuse is intentional.
  - c. Fraud is directed at Medicare, while abuse is directed at any third party payor.
  - d. There is no difference between fraud and abuse.
3. If Dr. Thomas referred his patients to a particular pharmacy because he would receive a monetary reward from that pharmacy for the referral, which of the following is he violating?
  - a. Anti-Kickback Statute
  - b. Physician Self-Referral Statute ("Stark")
  - c. Both of the above
  - d. Neither of the above
4. Which of the following is false regarding the False Claims Act?
  - a. Fines can be imposed up to \$5,000-10,000 for each claim.
  - b. Charges can be given up to 10 times the amount of the claim.
  - c. It's a crime for any person or organization to knowingly make a false record.
  - d. If you know of someone committing a false claim, you can be prosecuted as well.
5. Which of the following is required by CMS to comply with the FWA program?
  - a. Documentation of training and education
  - b. Code of conduct
  - c. Policies and procedures manual
  - d. All of the above
6. Keeping the policies and procedures manual up-to-date for the pharmacy is the duty of which of the following?
  - a. Compliance officer
  - b. Compliance committee
  - c. Special investigation unit
  - d. Both a and b
7. When does training and education for the FWA program need to be completed?
  - a. Annually
  - b. At the time of hire
  - c. At the start of a new contract with a Medicare Part D sponsor
  - d. All of the above
8. Which of the following is intended to proactively identify billing errors with coverage and coding?
  - a. Probe Review
  - b. Medical Review
  - c. Drug Utilization Review
  - d. All of the above
9. What are the three main purposes of MEDICs?
  - a. Preventing, investigating and prosecuting
  - b. Investigating, auditing and prosecuting
  - c. Preventing, detecting and auditing
  - d. Detecting, auditing and prosecuting
10. Which of the following is not part of a Civil Monetary Penalty (CMP)?
  - a. \$10,000 per violation
  - b. Exclusion from all third party payors for a minimum of five years
  - c. Exclusion from the Medicare program for a minimum of five years
  - d. All of the above are parts of the CMP

### Update: CMS Requirements for a Part D Program to Control Fraud, Waste and Abuse

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PCE EVALUATION — Circle the appropriate rating number for items 1 through 4.

1. What is your evaluation of the article you read?  
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2. The author's coverage of the subject material was:  
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3. How useful will the content of this article be in your practice?  
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It took me \_\_\_\_\_ hour(s) and \_\_\_\_\_ minute(s) to read this article and complete the questions.

What other topics would you like to see presented in MPA's home study articles? \_\_\_\_\_

#### Answer Sheet Instructions

Please write the letter of the correct answer to each question in the space provided.

1. \_\_\_\_\_ 6. \_\_\_\_\_
2. \_\_\_\_\_ 7. \_\_\_\_\_
3. \_\_\_\_\_ 8. \_\_\_\_\_
4. \_\_\_\_\_ 9. \_\_\_\_\_
5. \_\_\_\_\_ 10. \_\_\_\_\_