



Effective January 1, 2009 – The Centers for Medicare & Medicaid Services (CMS) has set forth guidance and requirements related to pharmacy participation in Medicare Part D. CMS requires Medicare plan sponsors and Medicare plan providers to have the following in place:

- Policies and procedures to identify and address fraud, waste and abuse (FW&A) in the delivery of prescription drugs through the Medicare benefit.
- A procedure to facilitate pharmacy associates' fraud, waste and abuse training and education.

In accordance with these CMS regulatory requirements, Prescription Drug Programs (PDPs) are requiring that participating pharmacies train associates in FW&A. The above CMS requirements of Medicare plan sponsors and Medicare plan providers are part of the compliance plan elements in the Medicare Prescription Drug Benefit regulations published on January 28, 2007 (70 Fed. Reg. 4194 (2005)). The regulations list the core elements of a compliance plan and the specific requirements addresses the following:

- Written Policies and Procedures and Standards of Conduct
- Compliance Officer and Compliance Committee
- Training and Education
- Effective Lines of Communication
- Enforcement of Standards through well publicized disciplinary guidelines
- Monitoring and Auditing
- Corrective Action Procedures
- Comprehensive Fraud and Abuse Plans – Procedures to voluntarily self-report potential fraud or misconduct

HISTORY

Four types of entities are permitted to contract with plan sponsors. They are: First-tier Entities; Downstream Entities, Related Entities, and Contractors.

A First-tier Entity is any party that enters into a written arrangement to provide administrative services or health care services for a Medicare-eligible individual. In most cases, this will be a pharmacy benefit manager (PBM).

A Downstream Entity is any party that enters into a written arrangement below the level of arrangements between first-tier entities and a plan sponsor. This might include the provider of health or administrative services. Consider a PBM contracting with pharmacies. The pharmacies would be downstream entities.

A Related Entity is an entity related to a plan sponsor by common ownership which performs some management functions under contract, or furnishes services to Medicare enrollees, or leases real property or sells materials to the plan sponsor. An example is where a plan sponsor is the parent company of its own in-house PBM.

Plan sponsor contracts with these entities require specified protections and CMS acceptability. The Part D Compliance Officer, working with the Compliance Committee, should develop processes and procedures to promote and ensure that any first-tier, downstream, or related entities are in compliance with all applicable laws, rules, and regulations.

STATE LAWS

Some state laws may be superseded (pre-empted) by Medicare Part D laws and regulations. Sponsors should check with CMS if questions arise.



PHARMACY FRAUD, WASTE AND ABUSE:

The following section describes examples of pharmacy fraud, waste and abuse. Examples of potential fraud, waste and abuse include but are not limited to:

- **Inappropriate billing practices:** Inappropriate billing practices at the pharmacy level occur when pharmacies engage in the following types of billing practices:
 - ◆ Incorrectly billing of secondary payers to receive increased reimbursement.
 - ◆ Billing for non-existent prescriptions
 - ◆ Billing multiple payers for the same prescriptions, except as required for coordination of benefit transactions.
 - ◆ Billing for brand when generics are dispensed.
 - ◆ Billing for non-covered prescriptions as covered items.
 - ◆ Billing for prescriptions that are never picked up (i.e., not reversing claims that are processed when prescriptions are filled but never picked up).
 - ◆ Billing based on “gang visits,” e.g., a pharmacist visits a nursing home and bills for numerous pharmaceutical prescriptions without furnishing any specific service to individual patients.
 - ◆ Inappropriate use of dispense as written (“DAW”) codes.
 - ◆ Prescription splitting to receive additional dispensing fees.
 - ◆ Drug diversion.
- **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.
- **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 forging or altering:** Where existing prescriptions are altered, by an individual without the prescriber’s permission to increase quantity or number of refills.
- **Dispensing expired or adulterated prescription drugs:** Pharmacies dispense drugs that are expired, or have not been stored or handled in accordance with manufacturer and FDA requirements.
- **Prescription refill errors:** A pharmacist provides the incorrect number of refills prescribed by the provider.
- **Illegal remuneration schemes:** Pharmacy is offered, or paid, or solicits, or receives unlawful remuneration to induce or reward the pharmacy to switch patients to different drugs, influence prescribers to prescribe different drugs, or steer patients to plans.
- **TrOOP manipulation:** When a pharmacy manipulates TrOOP to either push a beneficiary through the coverage gap, so the beneficiary can reach catastrophic coverage before they are eligible, or manipulates TrOOP to keep a beneficiary in the coverage gap so that catastrophic coverage is never realized.
- **Failure to offer negotiated prices:** Occurs when a pharmacy does not offer a beneficiary the negotiated price of a Part D drug.



PRESCRIBER FRAUD, WASTE, AND ABUSE

The following section describes examples of prescriber fraud, waste and abuse. Examples of potential fraud, waste and abuse include but are not limited to:

- **Illegal remuneration schemes:** Prescriber is offered, or paid, or solicits, or receives unlawful remuneration to induce or reward the prescriber to write prescriptions for drugs or products.
- **Prescription drug switching:** Drug switching involves offers of cash payments or other benefits to a prescriber to induce the prescriber to prescribe certain medications rather than others.
- **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.
- **Provision of false information:** Prescriber falsifies information (not consistent with medical record) submitted through a prior authorization or other formulary oversight mechanism in order to justify coverage. Prescriber misrepresents the dates, descriptions of prescriptions or other services furnished, or the identity of the individual who furnished the services.
- **Theft of prescriber'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. In the context of e-prescribing, includes the theft of the provider's authentication (log in) information.

WHOLESALE FRAUD, WASTE AND ABUSE

The following section describes examples of wholesaler fraud, waste and abuse. The big concerns here for the pharmacist are wholesalers inserting diverted, counterfeit, or adulterated drugs into shipments to pharmacies. The term "Grey Market" refers to the almost completely eliminated practice of a hospital or non-profit organization purchasing more drugs than they actually need at a discounted price and selling the excess at a profit to middlemen who sell those drugs to chains or other buyers at a price below their regular wholesale cost. Some of these drugs were exported and brought back to the USA. No one knows about the storage conditions or how many hands they went through. If anything looks strange, different or "shop worn," be suspicious and report it.

Examples of potential fraud, waste and abuse include but are not limited to:

- **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 case the pharmaceuticals may be marked up six times before being sold to the consumer.
- **Inappropriate documentation of pricing information:** Submitting false or inaccurate pricing or rebate information to or that may be used by any Federal health care program.



PHARMACEUTICAL MANUFACTURER FRAUD, WASTE AND ABUSE

The following section describes examples of potential or suspect Pharmaceutical Manufacturer fraud, waste and abuse. Examples of potential fraud, waste and abuse include but are not limited to:

- **Lack of integrity of data to establish payment and/or determine reimbursement:** Pharmaceutical manufacturers may be liable under the False Claims Act, civil monetary penalties and/or the Federal Anti-Kickback statute if government reimbursement for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, including rebates, directly or indirectly, and the manufacturer has knowingly failed to generate or report such information completely and accurately.
- **Inappropriate documentation of pricing information:** Manufacturers must maintain accurate and complete documentation of their pricing information.
- **Kickbacks, inducements, and other illegal remuneration:** The Anti-Kickback statute may be implicated by the following types of activities:
 - ◆ 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, including inappropriate discounts, inappropriate product support services, inappropriate educational grants, inappropriate research funding, or other inappropriate remuneration.
- **Formulary and formulary support activities:** Examples of potential fraud and abuse include
 - ◆ Inappropriate relationships with formulary committee members,
 - ◆ Payments to PBMs,
 - ◆ Formulary placement payments in order to have manufacturer's products included on a Plan's formulary.
- **Inappropriate relationships with physicians:** Potentially inappropriate relationships between pharmaceutical manufacturers and physicians include:
 - ◆ "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 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 samples.



MEDICARE BENEFICIARY FRAUD, WASTE, AND ABUSE RISKS

Typically, Medicare beneficiaries tend to be victims, not perpetrators, of fraudulent, wasteful or abusive schemes. However, there are some schemes committed by beneficiaries that may impact payers. The following section describes examples of the types of fraud, waste or abuse that could be perpetrated by beneficiaries in Part D, as well as examples where beneficiaries might be victimized. Examples of potential fraud, waste and abuse include but are not limited to:

- **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.
- **Identity theft:** Perpetrator uses another person's Medicare card to obtain prescriptions.
- **TrOOP manipulation:** A beneficiary manipulates TrOOP to push through the coverage gap, so the beneficiary can reach catastrophic coverage before they are eligible.
- **Prescription forging or altering:** Where prescriptions are altered, by someone other than the prescriber or pharmacist with prescriber approval, to increase quantity or number of refills.
- **Prescription diversion and inappropriate use:** Beneficiaries obtain prescription drugs from a provider, possibly for a condition from which they do not suffer, and gives or sells this medication to someone else. This can also include the inappropriate consumption or distribution of a beneficiary's medications by a caregiver or anyone else.
- **Resale of drugs on black market:** Beneficiary falsely reports loss or theft of drugs or feign illness to obtain drugs for resale on the black market.
- **Prescription stockpiling:** Beneficiary attempts to "game" their drug coverage by obtaining and storing large quantities of drugs to avoid out-of-pocket costs, to protect against periods of non-coverage (i.e., by purchasing a large amount of prescription drugs and then disenrolling), or for purposes of 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 an underlying scheme, such as stockpiling or resale on the black market.
- **Improper coordination of benefits:** Improper coordination of benefits where beneficiary fails to disclose multiple coverage policies, or leverages various coverage policies to "game" the system.
- **Marketing schemes:** A beneficiary may be victimized by a marketing scheme where a Sponsor, or its agents or brokers, violates the Medicare Marketing Guidelines, or other applicable Federal or state laws, rules, and regulations to improperly enroll the beneficiary in a Part D Plan.



In addition to the above mentioned potential schemes, risks, and vulnerabilities, listed below are four other major areas of concern relating to pharmacy:

• **Coordination with State Pharmacy Assistance Programs**

42 C.F.R. § 423.464 requires coordination of benefits with other providers of prescription drug coverage, including State Pharmacy Assistance Programs (SPAPs). SPAPs under Part D will be providing wrap-around benefits in the form of financial assistance by supplementing Part D premiums prior to and for the “coverage gap” portion of the benefit. Oversight of this coordination is essential to:

- ◆ Prevent double billing.
- ◆ Ensure that the Part D Plans remain the primary payer.
- ◆ Ensure that benefits are coordinated so that TrOOP tracking of SPAPs is taken into account.

Additionally, an oversight and monitoring program will also ensure that expenditures by other plans are excluded for the purposes of reaching the beneficiaries true out-of-pocket (TrOOP) expenditures in the TrOOP calculation.

NABP AND NADDI’S LISTS OF SUSCEPTIBLE PHARMACEUTICALS

In February 2004, the National Association of Boards of Pharmacy (NABP) released the updated Model Rules for the Licensure of Wholesale Distributors. The formulation of the updated Model Rules was a collaborative effort among NABP, pharmacy representatives, the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), state regulatory authorities, and the wholesale distributor industry to protect the public from the use of counterfeit drugs and devices. The drugs most vulnerable to counterfeiting are usually single source injectable drugs, are commonly prescribed, have substantial wholesale cost with revenue-generating power, or are in limited supply.

Additionally, the National Association of Drug Diversion Investigators, Inc., (NADDI),⁹⁰ publishes a list of abused pharmaceutical substances. These are narcotics that are most frequently abused or illegally sold/counterfeited.

DRUGS EXCLUDED FROM PART D COVERAGE

Pursuant to section 1927 of the Social Security Act and the final Part D regulations at 42 C.F.R. § 423.100, a Part D drug is:

- Defined as a drug that may be dispensed only upon a prescription;
- Approved by FDA for safety and efficacy;
- A biological product;
- Insulin and medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or
- A vaccine.

A drug is considered to be a Part D drug only if prescribed for a “medically accepted indication.” Drugs may not be covered under Part D if they are not prescribed for a medically accepted indication. Coverage for other than a medically accepted indication is not permitted under the statute because such drugs would not be considered Part D drugs.

In accordance with section 1860D-2(e)(2) of the Act, covered Part D drugs shall specifically exclude drugs or classes of drugs, or their medical uses, which may be excluded or restricted from coverage under the Medicaid program,⁹¹ with the exception of smoking cessation agents. Thus, it is the responsibility of the Part D plans to prohibit the inappropriate payment for these excluded drugs or indications, i.e. edits or prior authorization.



PART B AND PART D COVERAGE ISSUES

Prior to the implementation of the Medicare Modernization Act (MMA), Medicare beneficiaries received coverage for a limited number of drugs provided under Parts A and B. With the implementation of the prescription drug benefit, there is potential for inappropriate duplicate coverage between A, B, and D drugs. While the potential crossover between Parts A and D is unlikely, Medicare Parts B and D contain specific drugs covered under both programs. As a consequence, there is a greater likelihood of crossover between Part B and D drugs; and it will be incumbent on Sponsors to have mechanisms in place to ensure drugs are adjudicated correctly to either Part B or D.

The statutory definition of “covered Part D drug” states that Sponsors must exclude any drug that would otherwise be considered a Part D drug for which, as so prescribed and dispensed or administered to that individual, payment would be available under Parts A or B.⁹³

The implementation of the Part D benefit does not alter coverage or associated rules for drugs currently covered under Part B. Part B covers drugs in a variety of settings. In almost all of these settings the question of whether coverage should be provided under Part D will not arise because the drugs are being provided in the context of a service or procedure and thus the drugs are covered under Part B. For a limited number of categories, however, pharmacists and infusion providers will have to determine whether to bill Part B or Part D; and Sponsors will need to confirm whether Part D is being billed correctly.

Areas where potential confusion allows schemes are:

- **Home Infusion:** Home infusion pharmacies are often paid delivery and dispensing fees for certain self-injectable medications (e.g., Epogen, Procrit) even if the beneficiary self-administers. As home infusion pharmacies will be part of both Part B and Part D networks, these pharmacies might inappropriately submit the claim for coverage under inappropriate benefit.
- **Duplicate Billing:** Claims could be submitted by a provider under both medical for Part B and pharmacy for Part D. Control mechanisms may include prior authorization processes that identify by diagnosis and other qualifying factors if a drug is covered under Part B or Part D and prevents the claim from being paid by the non-covered component. Additional control mechanisms and retrospective review for duplicate claims may vary between MA-PD and PDP due to different levels of access to medical history and claims.
- **Crossover Drugs:** Some of the medications that will be crossover drugs are traditionally purchased and administered by the physician’s office or clinic. These medications represent a potential revenue stream to the physician’s office. If a PDP or MA-PD carves out purchase of the medications for Part D coverage to a specialty or mail service pharmacy that will deliver patient-specific medication to a physician’s office, this could represent a loss of revenue. In some cases, the patient may be able to purchase the pharmaceutical under the Part D benefit at a community pharmacy and bring it to the physician’s office for administration. In these circumstances, the physicians may inappropriately bill for both the drug and the injection of the drug under Part B.
- **Differential Copays:** Beneficiary may have different cost sharing obligations if a crossover drug is paid under Part B versus Part D, or vice versa. A beneficiary could ‘game the system’ to lower their cost sharing obligations by improperly submitting a claim to the inappropriate payer.

It is incumbent upon the Sponsor to institute a control, such as a prior authorization to ensure that the pharmacy is billing the correct program. Sponsors should have procedures in place to reverse claims in case a pharmacy is paid in error under Part D for what should have been a Part B covered product.



Four additional areas pharmacy staff should have a general understanding of regulations and intents:

The False Claims Act

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. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor, or state Medicaid program.

When submitting claims data to CMS for payment, Sponsors and their subcontractors must certify that the 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. In addition, parties have a continuing obligation to disclose to the government any new information indicating the falsity of the original statement. Since Sponsors maintain ultimate responsibility for adhering to all terms and conditions of its contract with CMS, they must monitor their subcontractors for compliance with all applicable regulations.

The Anti-Kickback Statute 98

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or 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. 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.⁹⁹ 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. Sponsors shall have policies and procedures employed to ensure that illegal remuneration is not permitted and shall specify follow-up procedures if they uncover unlawful remuneration schemes.

The Health Insurance Portability and Accountability Act

Among other things, the Health Insurance Portability and Accountability Act (HIPAA), was enacted for the purpose of improving the efficiency and effectiveness of health information systems through the establishment of standards and requirements for the electronic transmission of certain health information. This purpose has been effectuated through the promulgation of various regulations including those establishing standards for certain electronic transactions, minimum security requirements, and minimum privacy protections for individually identifiable health information that is held by covered entities (i.e., protected health information). Additional rules have or will establish national identifiers under HIPAA for providers, plans and employers. Covered entities include health plans, health care clearing houses and certain health care providers (namely those that conduct covered transactions). The Office for Civil Rights (OCR) is the Departmental component responsible for implementing and enforcing the privacy regulations.¹⁰² The Centers for Medicare and Medicaid Services (CMS) is the Departmental component responsible for implementing and enforcing the other HIPAA regulations. Implementing these standards will improve the efficiency and effectiveness of the nation’s health care system by encouraging the widespread use of electronic data interchange in health care.

The Freedom of Information Act (FOIA)

The Freedom of Information Act (FOIA) is codified at 5 U.S.C. §552. Its basic purpose is to promote the continued existence of an informed citizenry. More generally, FOIA makes information collected by government agencies available to the public. Consistent with our approach under the Part C program, CMS will not release information under the Part D program that would be considered proprietary in nature or that would tend to stifle the availability of discounts or rebates from pharmaceutical manufacturers negotiated by Part D plans or their first tier entities, downstream entities, or related entities. Most FOIA provisions affect how and when CMS is required (or restricted) from releasing information submitted by Sponsors and should not affect how or when Sponsors release information to CMS.