

# LegalUpdate

## **CMS Medicare Part D Fraud, Waste and Abuse Guidance: Impact on Pharmacies**

CMS has issued a fraud, waste and abuse guidance for the Medicare Part D drug benefit. The guidance is available on the CMS website.<sup>1</sup> The 70-page guidance includes “interpretive rules and guidance for Part D plan sponsors” as they implement mandatory fraud waste and abuse compliance programs.<sup>2</sup> This Legal Update provides an overview of the guidance provisions that affect pharmacies.

### **I. Application To Pharmacies**

The guidance is addressed to plan sponsors, not pharmacies. However, the guidance clearly states that plan sponsors may be held liable for violations by “providers” and other “downstream entities.” *See* § 40. Pharmacies and pharmacists are included in the definitions of “providers” and “downstream entities.” *See id. and* § 10.1. Therefore, several provisions of the guidance either require or recommend that plan sponsors place compliance burdens on pharmacies.

### **II. Requirements vs. Recommendations**

The draft guidance was confusing because it was often unclear whether CMS was mandating or merely recommending certain compliance measures. The final guidance make a very important clarification: “recommendations made in this chapter are reflected by the use of the term ‘should,’ whereas statutory or regulatory program requirements are reflected by the use of the term ‘shall’ or ‘must.’” *See* § 20. It is important to note, however, that a plan sponsor can turn a CMS recommendation into a mandatory requirement by adding a mandatory provision to the network contracts that pharmacies sign.

### **III. Exclusions Lists**

The final guidance provides that plan sponsors “should review the HHS OIG and GSA exclusion lists at least once a year, and have processes in place to prevent the payment of claims for services provided by excluded providers.” *See* § 50.2.6.3.3. It also provides that plan sponsors “should” require pharmacies and others to make sure they do not employ persons who have

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<sup>1</sup> [www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual\\_Chapter9\\_FWA.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf)

<sup>2</sup> CMS rules require each plan sponsor to adopt a comprehensive program to prevent, detect, and correct fraud, waste and abuse. *See* 42 C.F.R. § 423.504(b)(4)(vi)(H).

been excluded from participation in Medicare. Section 50.2.1.2 of the guidance provides two examples of policies and plan sponsors “should” adopt:

- “The Sponsor should obtain certifications from first tier entities, downstream entities, and related entities that these entities will review the OIG and GSA exclusions lists upon initially hiring and annually thereafter to ensure that any employee or manager responsible for administering or delivering Part D benefits is not excluded from Federal health care programs. The Sponsor should likewise obtain certifications that if an employee of the first tier entity, downstream entity, or related entity responsible for the administration of delivery of any Part D benefits is on such lists, that employee will immediately be removed from any work related directly or indirectly to all Federal health care programs and the entity will take appropriate corrective actions.”
- “Policies that ensure and document the review of the DHHS OIG and General Services Administration (GSA) exclusion lists for all new employees and at least once a year thereafter to ensure that its employees, board members, officers, and first tier entities, downstream entities, or related entities that assist in the administration or delivery of Part D benefits are not included on such lists. If the Sponsor’s employees, board members, officers, managers or first tier entities, downstream entities, or related entities are on such lists, the Sponsor’s policies shall require the immediate removal of such employees, board members, or first tier entities, downstream entities, or related entities from any work related directly or indirectly on all Federal health care programs and take appropriate corrective actions.”

#### **IV. Conflict Of Interest**

The guidance provides that sponsors “should” adopt several conflict of interest policies. For example, a sponsor “should obtain certifications from first tier entities, downstream entities, and related entities that these entities will require its managers, officers and directors responsible for the administration or delivery of Part D benefits to sign a conflict of interest statement, attestation, or certification at the time of hire and annually thereafter certifying that the manager, officer or director is free from any conflict of interest in administering or delivering Part D benefits.” *See* § 50.2.1.2. Pharmacies are considered “downstream entities” in the guidance.

Another example listed by CMS is a policy to ensure that a sponsor’s “officers, directors and managers do not have a conflict that provides a potential unfair competitive or monetary advantage as a result of the Sponsor performing the Medicare contract (e.g., ... ownership, control or contractual arrangement with a first tier entity or downstream entity that would create an incentive to use that entity, etc.).” *See* § 50.2.1.2. Since pharmacies are “downstream entities” this suggests CMS is interested in limiting arrangements that steer beneficiaries to particular pharmacies.

## V. Training And Education

The guidance provisions on training and education are not completely clear when it comes to determining whether pharmacy personnel must receive fraud, waste and abuse compliance training. Section 50.2.3 of the guidance begins by stating that a plan sponsor “must provide effective training and education” for its “employees, subcontractors, agents and directors who are involved in the Part D benefit.” It adds that “All persons involved with the Sponsor’s administration or delivery of the Part D benefit should receive general compliance training. To the extent that it is feasible and reasonable, first tier entity, downstream entity, and related entity staff should be permitted to attend the Sponsor’s training or agree to conduct their own Part D compliance training in accordance with the guidance provided below.” Remember that pharmacies and pharmacists are “downstream entities.”

The section on general compliance training provides that “Sponsors should also consider requiring that any first tier entities, downstream entities, and related entities with any Part D responsibilities on behalf of the Sponsor to have their own training, or where there are sufficient organizational similarities, the Sponsor may choose to make its training programs available to these entities.” *See* § 50.2.3.1.

The section on specialized compliance training provides that “employees that have specific responsibilities in Medicare Part D business areas should receive specialized training on issues posing compliance risks based on their job function (e.g., pharmacist ....” *See* § 50.2.3.2. But that section does not clarify whether this applies only to employees of the sponsor. However, that section of the guidance adds that “sponsors should require that any first tier entities, downstream entities, and related entities with any Part D responsibilities on behalf of the Sponsor to have their own specialized compliance training, or where there are sufficient organizational similarities, the Sponsor may choose to make its training programs available to these entities.” The guidance does not say whether network pharmacies are downstream entities “with any Part D responsibilities on behalf of the Sponsor....”

Finally, this section of the guidance discusses “offering” training to pharmacies and other downstream entities:

Sponsors should consider offering training and education to their first tier entities, downstream entities, and related entities. In the case of chain pharmacies and large PBMs, Sponsor-held training and education may supplement existing training programs. This may include web-based tools, intranet sites and videotaped presentations. Independent pharmacies, which in general have fewer resources, may appreciate the access that a training program affords to critical Part D information....

Some first tier entities, downstream entities and related entities may be providing services to multiple Sponsors, and it may become cumbersome for them to attend training at the various Sponsor locations. Rather, first tier entities and downstream entities that provide services to multiple

Sponsors may prefer to host their own Part D training that meets CMS training recommendations.

## **VI. Audits By Plan Sponsors**

Pharmacies that submit claims data to CMS must certify the “accuracy, completeness, and truthfulness of that data,” and plan sponsors are “responsible for exercising oversight of Part D data generated or submitted by [pharmacies] to ensure the accuracy of that data so that the Sponsor receives accurate payments.” *See* § 40.2. As a result, the guidance includes numerous auditing requirements and recommendations that impact pharmacies.

Section 50.2.6.1.3 includes an extended discussion of audits. It provides that plan sponsors “must have a plan in place to monitor and audit” pharmacies and other downstream entities:

Sponsors should include routine and random auditing as part of their contractual agreement with first tier entities, downstream entities, and related entities. Sponsors should include in their workplan the number of first tier entities, downstream entities, and related entities that will be audited each year, how the entities will be identified for auditing, and should make it a priority to conduct a certain number of on-site audits. Sponsors must ensure their contracts with first tier entities, downstream entities, and related entities require record retention and provide rights of access to these records to CMS or its designee.

Audits should include a review of documentation such as prescriptions, invoices, pharmacy licenses, claim transaction records, signature logs, purchase records, and negotiated prices, as well as verification that network providers are in compliance with the minimum standards pharmacy practice as established by the States, and verification that network pharmacies post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request and exception if they disagree with information provided by a pharmacist. Audits should also include a review of first tier entity, downstream entity, and related entity contracts, as well as rebate, discount, and all other relevant agreements (and supporting data). Additionally, Sponsors should conduct interviews with first tier entity, downstream entity and related entity staff to gauge whether applicable Part D requirements are being followed.

As NACDS requested, the guidance does include limit “extrapolation audits”. Plan sponsors must “utilize statistical methods” when “randomly selecting ... pharmacies, provider claims and other areas for review” and when “extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe.” *See* § 50.2.6.1.2.

Section 50.2.6.1.3 of the guidance seems to suggest that pharmacies may be able to perform their own audits in lieu of audits by plan sponsors: “In the event that first tier

entities, downstream entities, and related entities perform their own audits related to the prescription drug benefit, Sponsors should seek written assurances from these entities that they have an adequate audit workplan in place. Sponsors should regularly receive these audit results with respect to their enrollees, and likewise seek assurances that corrective actions are taken by the entity when appropriate.”

The guidance also provides examples of policies and procedures that CMS believes sponsors “should” have in place. One example is “a process to identify overpayments and underpayments at any level within the Sponsor’s network and properly report and repay, where applicable, such overpayments” and “a process to identify improper ... services ... at any level within its network and properly report and repay, where applicable, and overpayments....” *See* § 50.2.1.2. The guidance also lists several types of reports that plan sponsors “should” receive from pharmacies, such as payment reports and drug utilization reports. *See* § 50.2.6.1.3.

## **VII. Audits By Government**

The guidance provides that CMS or its designees (such as MEDICS) may audit plan sponsors or their “subcontractors.” *See* § 50.2..6.4. During those audits “CMS may inspect and audit any pertinent contracts, books, documents, papers, and records...” CMS audits may review “any information needed to determine compliance with the Part D contract and the Part D regulation, such as copies of prescriptions, invoices, pharmacy licenses, claims records, signature logs, purchase records, contracts, rebate and discount agreements, as well as, interviews of the staff.”

## **VIII. Edits**

Section 50.2.6.3.1 of the guidance discusses edits. It provides that plan sponsors “should have systems capability to establish an edit on a given provider and use that edit to automatically deny a claim or suspend payment on a claim when appropriate.” CMS lists several examples of recommended edits, such as:

- Controls on early refills
- Limits on the number of days before a refill is permitted
- Edits to prevent payment for statutorily excluded drugs
- Limits on the number of times a prescription can be refilled
- Brand name versus generic drugs
- Excessive claims for controlled substances
- Step therapy edits

## **IX. Investigations and Remedies For Violations**

The guidance provides that plan sponsors “must conduct a timely, reasonable inquiry into any conduct where evidence suggests there has been misconduct related to payment or delivery of prescription drug items or services under the Part D contract.” *See* § 50.2.7.1. If misconduct is identified it should be reported to a MEDIC. *See* § 50.2.8.3. Reporting of potential fraud that occurs at pharmacies and other “downstream entities” is “especially encouraged.” *See* § 50.2.8.2.

Sponsors must take corrective action when any misconduct is identified. The guidance provides that “when developing corrective actions for misconduct committed by a Sponsor’s first tier entity, downstream entity, or related entity the elements of the corrective action should be detailed in a written agreement with the entity that includes ramifications should the subcontractor fail to satisfactorily implement the corrective action.” *See* § 50.2.8.1. In addition, the guidance states that a plan sponsor “should have a provision in its contract with first tier entities, downstream entities, and related entities that violations may result in termination of the contractual relationship with the Sponsor.” *See* § 50.2.5.3.

#### **X. Examples of Pharmacy Fraud**

Section 70.1.3 of the guidance provides examples of fraud, waste and abuse by pharmacies. Pharmacies would be wise to review this list because it provides a good indication of the types of abuses that are of particular interest to CMS. The categories of examples listed by CMS are:

- Inappropriate billing practices
- Prescription drug shorting
- Bait and switch pricing
- Prescription forging or altering
- Dispensing expired or adulterated prescription drugs
- Prescription refill errors
- Illegal remuneration schemes
- TrOOP manipulation
- Failure to offer negotiated prices