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Highlights from CMS's Final Revised Fraud, Waste, and Abuse Guidance: What Plans and Stakeholders Need to Know

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CMS now has published the final, revised Chapter 9—Part D Program to Control Fraud, Waste and Abuse ("FWA") directed to Medicare Part D prescription drug plan sponsors ("Sponsors").[1]

The Chapter provides interpretive rules and guidelines for Medicare Part D Plan Sponsors on how to implement Medicare Part D Program regulatory requirements under 42 C.F.R. § 423.504(b).

This regulation mandates that every Part D Plan Sponsor have in place a compliance program and a "comprehensive" plan to detect, correct and prevent fraud, waste and abuse in connection with its Part D benefit plan(s). As expected, the revised FWA Chapter clarifies aspects of its prior proposed version of the Chapter.[2]

CMS explained its view on the revisions to the FWA Chapter during a Special Open Door Forum May 2. This article summarizes the key clarifications reflected in the final FWA Chapter and offers our thoughts on the impact of those clarifications on Part D Plan Sponsors and key stakeholders in the Part D industry.

I. The FWA Chapter includes mostly recommendations (the "should" provisions), but also some important mandates (the "shall" provisions) for Part D Plan Sponsors. This suggests that the first step for Sponsors responding to the FWA Chapter should be to implement the "shall" provisions.

An important issue raised by the proposed FWA guidance was whether CMS intended its FWA chapter as recommendations or as directives to its Part D Plan Sponsors on the structure and operations of Part D

[1] A copy of the full text of the Centers for Medicare & Medicaid Services Prescription Drug Manual Chapter 9—Part D Program to Control Fraud, Waste and Abuse is available on CMS's Web site at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.

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[2] Our prior two-part article and analysis of the proposed FWA Chapter appeared in *BNA's Health Care Fraud Report* as ***CMS Draft Part D Fraud, Waste, Abuse Guidance, Part I: A To-Do List for Plans*** (March 15, 2006) and ***CMS Draft Part D Fraud, Waste, Abuse Guidance, Part II: Implementation Issues, Best Practices*** (March 29, 2006).

FWA programs. This was an area where CMS received comments from the industry.

All Part D Plan Sponsors are required by the Part D regulations and by their contract with CMS to establish and operate a ''comprehensive'' FWA program. However, what was not clear was the degree of discretion that Sponsors could exercise over the specific structure and operations of their individual FWA programs. CMS addressed this question in its final FWA Chapter.

In the final FWA Chapter, CMS states that the adoption of the methods suggested in its FWA Chapter on how to implement a comprehensive fraud and abuse program are ''left to the discretion of each Sponsor.''[3] CMS explains that the purpose of the Chapter is to ''assist'' Sponsors in implementing the regulatory requirements and to provide ''recommendations.'' CMS says that the adoption of the approaches suggested in the final FWA Chapter on how to implement a comprehensive fraud and abuse plan is left to the ''discretion'' of each Sponsor ''based on the size, scope and resources of its organization.''[4]

CMS also states explicitly that recommendations made in the chapter are reflected by use of the term ''should,'' whereas statutory or regulatory program requirements are reflected by use of the term ''shall'' or ''must.''[5] Consequently, the first step for Sponsors responding to the final FWA Chapter is to confirm that the ''shall'' provisions are in place at their organization.

A related ''first'' step is to establish internal monitoring or auditing protocols around these mandatory obligations to make sure that they are happening accurately and consistently. Periodic reviews are the best way to attempt to validate compliance.

The second step for Sponsors responding to the final FWA Chapter is to have in place, well documented and archived the assumptions, justifications, sources of authority and/or monitoring or auditing activities as they relate to the areas of ''discretion.'' This also is essential so that there is validation as to reasons for crafting policies and procedures ''based on the size, scope and resources of its organization.''[6]

As to the mandatory provisions, our search of the final FWA Chapter reveals that the following topics discussed in the FWA Chapter include the terms ''shall'' or ''must,'' thereby reflecting mandatory obligations, not mere recommendations:

■ ***P&T Committee composition***—The P&T committee members ***must*** be individuals who are practicing physicians or practicing pharmacist or both. They are charged with developing and reviewing a formulary. The P&T committee ***must*** include at least one practicing physician and at least one practicing pharmacists each of whom is independent and free of conflict with respect to the Sponsor, and at least one practicing physician and one practicing pharmacist who have expertise in the care of elderly or disabled persons (FWA Chapter § 10.1, citing 42 C.F.R. § 423.120(b)(1)).

■ ***Overview of FWA Chapter***—A Sponsor ***must*** have policies and procedures to address fraud, waste and abuse at both the Sponsor and ''third party'' levels (FWA Chapter § 20).

■ ***Sponsor Accountability and Oversight***—Written arrangements with related entities, contractors, subcontractors, or pharmacies that involve delegation of Part D responsibilities by the Sponsor ***must*** provide for revocation of the delegation or specify other remedies in instances where CMS or the Sponsor determine that performance is not satisfactory (FWA Chapter § § 40, 40.2, citing 42 C.F.R. § 423.505(i)(4)(ii)).

Contracts with third parties ***must*** include specific provisions including, but not limited to, inspections, enrollee protection, accountability, delegation and record retention (FWA Chapter § 40, citing 42 C.F.R. § 423.505(e)(2), (i) and (j)).

Contracts with first tier entities, downstream entities, and related entities ***must*** include a requirement for ongoing monitoring by the Sponsor to assess compliance with Part D provisions (FWA Chapter § 40.2, citing 42 C.F.R. § 423.505(i)(4)(iii)).

■ ***The Basics of a Program to Control Fraud, Waste and Abuse***—By statute, Part D Plans ***must*** have in place a program to control fraud, waste and abuse (FWA Chapter § 50.1, citing 42 U.S.C. § 1392 w-104).

Benefits of an Effective Program to Detect, Prevent and Control Fraud, Waste and Abuse—Sponsors ***must*** comply with the compliance plan requirements in the regulations to develop effective and efficient programs that detect and prevent fraud, waste and abuse in their Part D plans (FWA Chapter § 50.1, citing 42 C.F.R. § 423.504(b)(4)(vi)). Each Sponsor ***must*** determine what method for implementing a FWA program is best based on its size, structure and resources (FWA Chapter § 50.1).

Written Policies and Procedures—Sponsors ***must*** have written policies, procedures and standards of conduct that articulate the Sponsor's commitment to comply with all applicable federal and state standards (FWA Chapter § 50.2.1, citing 42 C.F.R. § 423.504(b)(4)(vi)(A)).

Sponsors ***shall*** require the immediate removal of employees, board members, first-tier entities, downstream entities, or related entities from any work directly or indirectly on all federal health care programs, and take appropriate corrective actions, in the event such persons or entities are on the OIG or GSA exclusions lists (FWA Chapter § 50.2.1.2).

■ ***Compliance Officer and Committee***—Sponsors ***must*** designate a compliance officer and compliance committee that is accountable to senior management. These functions may not be subcontracted (FWA Chapter § 50.2.2, citing 42 C.F.R. § 423.504(b)(4)(vi)(B); *also* FWA Chapter §§ 50.2.2.1, 50.2.2.2).

Compliance Officer—Sponsors ***must*** have a compliance officer in place (FWA Chapter § 50.2.2.1, citing 42 C.F.R. § 423.504(b)(4)(vi)(B)). The Sponsor ***must*** ensure that the Part D compliance officer does not hold other responsibilities that could lead to self-policing of his/her activities, *e.g.*, the Part D Compliance Officer should not also be, or be subordinate to, the chief financial officer (FWA Chapter § 50.2.2.1).

Compliance Committee—Sponsors ***must*** have a compliance committee in place (FWA Chapter § 50.2.2.2, citing 42 C.F.R. § 423.504(b)(4)(vi)(B)). The Sponsor's governing body ***shall*** establish a compliance committee that is overseen by the Part D compliance officer, advises the part D compliance officer and assists in implementation of the Part D compliance program (FWA Chapter § 50.2.2.2).

[3] FWA Chapter § 10.
[4] FWA Chapter § 20.
[5] FWA Chapter § 20.
[6] FWA Chapter § 20.

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■ ***Training and Education***—Sponsors ***must*** provide effective training and education between the Part D compliance officer and organization employees, subcontractors, agents, and directors who are involved in the Part D benefit (FWA Chapter § 50.2.3, citing 42 C.F.R. § 423.504(b)(4)(vi)(C)).

■ ***Effective Lines of Communication***—Sponsors ***must*** have effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors and members of the compliance committee (FWA Chapter § 50.2.4, citing 42 C.F.R. § 423.504(b)(4)(vi)(D)).

Each Sponsor ***must*** establish a system that fosters effective lines of communication regarding how to report compliance concerns and suspected or actual misconduct (FWA Chapter § 50.2.4.1, citing 42 C.F.R. § 423.504(b)(4)(vi)(D).

Mechanisms used by a Sponsor such as hotlines, suggestion boxes, employee exit interviews, emails and other forums that promote information exchange ***must*** be easily available and accessible (FWA Chapter § 50.2.4.1).

Sponsors ***must*** provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Sponsor or any other entity or individual through whom the Sponsor provides covered benefits under any Part D plan that it offers (FWA Chapter § 50.2.4.2, citing 42 C.F.R. § 423.564(a)).

Sponsors ***must*** follow the grievance procedures in 42 C.F.R. Subpart M and the procedures for reporting enrollee complaints outlined in the Medicare Part D reporting requirements (FWA Chapter § 50.2.4.2 at footnote 56).

■ ***Enforcement of Standards***—Sponsors ***must*** enforce standards through well-publicized disciplinary guidelines (FWA Chapter § 50.2.5, citing 42 C.F.R. § 423.504(b)(4)(vi)(E)).

■ ***Monitoring and Auditing***—Sponsors ***must*** have procedures for effective internal monitoring and auditing (FWA Chapter § 50.2.6, citing 42 C.F.R. § 423.504(b)(4)(vi)(F)).

Sponsors ***must*** have a plan in place to monitor and audit first tier entity, downstream entity and related entity responsibilities and activities with respect to the administration and delivery of the drug benefit (FWA Chapter § 50.2.6.1.3).

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 (FWA Chapter § 50.2.6.1.3, citing 42 C.F.R. § 423.505(i)(2).

Sponsors ***must*** follow instructions regarding prescription drug claims processing as dictated by CMS (FWA Chapter § 50.2.6.3.1 footnote 66).

Sponsors ***must*** deny claims for drugs that are prescribed by a provider excluded by either OIG or GSA (FWA Chapter § 50.2.6.3.3, citing 42 C.F.R. § 1001.1901).

Sponsors ***must*** be prepared to allow CMS to audit its financial records, including data relating to Medicare utilization and costs (FWA Chapter § 50.2.6.4 citing 42 C.F.R. § 423.504(d)).

Sponsors ***must*** allow access to any auditor on behalf of the federal government or CMS to conduct and onsite audit (FWA Chapter § 50.2.6.4 citing 42 C.F.R. § 423.504(e)(3))

Sponsors, first-tier entities, downstream entities, and related entities ***must*** provide records to CMS or its designee and should cooperate in allowing them access to their facilities as requested (FWA Chapter § 50.2.6.4).

■ ***Conducting a Timely and Reasonable Inquiry of Detected Offenses***—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 (FWA Chapter § 50.2.7.1, citing 42 C.F.R. § 423.504(b)(4)(vi)(G)(1))

■ ***Corrective Actions***—Sponsors ***must*** conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to potential violations (FWA Chapter § 50.2.8, citing 42 C.F.R. § 423.504(b)(4)(vi)(G)(2))

■ ***Referrals to MEDICS***—Sponsors ***shall*** furnished information requested by a MEDIC within 30 days, unless the MEDIC otherwise specifies (FWA Chapter § 50.2.8.3)

■ ***Implementing a Comprehensive Program to Detect, Correct and Prevent fraud, Waste and Abuse and Procedures to Voluntarily Self-Report Potential Fraud and Misconduct***—Sponsors ***must*** have a comprehensive fraud and abuse plan to detect, correct and prevent fraud and abuse (FWA Chapter § 60, citing 42 C.F.R. § 423.504(b)(4)(vi)(H)).

■ ***Examples of Risks for Fraud, Waste and Abuse*** (FWA Chapter § 70)

Examples of Part D Plan Sponsors Fraud, Waste and Abuse—Sponsors ***must*** ensure that they only provide coverage for ''covered Part D drugs,'' as listed in their approved formularies, and in accordance with 42 U.S.C. § 1860D-2(e)(2) (FWA Chapter § 70.1.1, citing 42 C.F.R. § 423.100)).

Pharmaceutical Manufacturer Fraud, Waste and Abuse—Manufacturers ***must*** maintain accurate and complete documentation of their pricing information (FWA Chapter § 70.1.7)).

Drugs Excluded from Part D Coverage—In accordance with 42 U.S.C. § 1860D-2(e)(2), 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 programs, 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 (FWA Chapter § 70.2.5)).

Part B and Part D Coverage Issues—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 Medicare Parts A or B (FWA Chapter § 70.2.4, citing 42 U.S.C. § 1395w-102; 42 C.F.R. § 423.100).

■ ***Other Part D Sponsor Federal Compliance Considerations***—Sponsors, first tier entities, downstream entities and related entities ***must*** ensure that legal/ethical standards are met. Sponsors will need to continually monitor and update their compliance program to incorporate any modifications to applicable regulations and contractual requirements.

The False Claims Act—When submitting claims data to CMS for payment, Sponsors and their subcontractors

must certify that the claims data is true and correct to the best of their knowledge and belief. 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 (FWA Chapter § 80.1, citing 42 C.F.R. §§ 423.505(k)(3)) and 505(k)(4).

The Anti-Kickback Statutue—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 (FWA Chapter § 80.2, citing 42 C.F.R. §§ 423.504(b)(4)(vi)(A)&(G)).

II. Proper oversight of subcontractors remains integral to an effective Part D FWA program.

Although the term ''subcontractor'' that appeared in the proposed FWA Chapter largely has been removed from the final version, CMS' expectations around the concept of Sponsor oversight responsibilities remain clear. Sponsors have significant oversight responsibilities for others involved in the administration of the Part D Benefit.

In particular, the FWA Chapter now uses the terms downstream entity, contractor and first tier entity instead, which are defined terms. Significantly, a first tier entity in most cases is the PBM, and downstream entities are likely pharmacies and pharmacists who contract through the PBM to participate in the delivery of Part D drugs to the Sponsor's enrollees.

Other entities that provide items or services to a Sponsor also may be included within this group of subcontractors. CMS asserts in the final FWA Chapter that first tier, downstream entities and related entities may be subject to applicable civil and criminal laws for fraud perpetrated in the delivery of the Part D benefit, such as the False Claims Act and the Anti-Kickback Statute (FWA Chapter § 40).

CMS also asserts that effective implementation of the Part D drug benefit relies on Sponsors' compliance with applicable laws. Given that Sponsors are ''ultimately liable'' for adhering to their Part D contracts with CMS, Sponsors ***must*** monitor their subcontractors for compliance with applicable requirements (*see* FWA Chapter § 80.1). CMS's mandates on Part D Sponsor's arrangements with first tier and downstream entities are highlighted above in Section I of this article.

In addition, CMS has revised the FWA Chapter to recommend that Sponsors obtain certifications from first tier entities, downstream entities and related entities that such entities will perform certain activities, namely, review of OIG and GSA exclusion lists and removal of excluded persons and execution of conflict of interest forms by managers, officers and directors responsible for administration or delivery of the Part D benefit (FWA Chapter § 50.2.1.2).

CMS also has added a recommendation that Sponsors encourage first tier entities, downstream entities and related entities to adopt and follow a code of conduct particular to their own organization that reflects a commitment to detecting, preventing and correcting fraud, waste and abuse (FWA Chapter § 50.2.1.3).

While these are ''shoulds'' instead of ''***musts***,'' sponsors need to take some type of affirmative actions to make sure that these first tier, downstream entities and related entities act in a compliant manner vis-à-vis their involvement in the administration of the Medicare Part D benefit.

III. Conclusions

The final revised FWA Chapter's distinction between ''should'' provisions and ''***shall***'' provisions means that Part D Plan Sponsors ***must*** should start looking now at their organization's compliance with the mandated provisions identified by CMS.

These ''***shall***'' (or ''***must***'') provisions affect the Sponsors' activities, as well as those of PBMs and other contracted and downstream entities involved in the administration and delivery of the Part D benefit. As one can see from the ''***must***'' list cited above this will not be an easy task.

Sponsors need to assess both their and their contractors' current compliance and effectiveness, as well as building mechanisms for monitoring and auditing for ongoing compliance. This likely will involve a review of current contractual arrangements by and among all of the persons and organizations in the contracted network.

For example, a Sponsor might want to review its PBM's contracts with network pharmacies to determine whether the required contractual provisions are included in these downstream contracts and also to determine what rights the PBM has in the event of noncompliance.

A Sponsor also may want to review the Part D compliance training provided to the pharmacies and pharmacists to determine whether it is satisfied with the level of training.

Even where the Sponsor decides to rely on certifications of compliance with specific elements from its contractors, prudence would suggest that the Sponsor consider developing and implementing a plan for auditing the contractor's mechanisms for delivering such certifications to the Sponsor to determine whether the contractors should have a good faith basis for certifying compliance, which the Sponsor reasonably could rely on.

As to the ''discretionary'' provisions of the FWA Chapter, Sponsors still need to dedicate time and resources even as to these obligations. This includes documentation as to why provisions or strategies are adopted and then such provisions or strategies need to be tested.

Both the ''musts'' and the ''shoulds'' will require dedicated time, focus and resources applied on a continual basis.

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