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REPORT

CMS Draft Part D Fraud, Waste, Abuse Guidance, Part I: A To-Do List for Plans

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This is the first part in a two-part series of articles summarizing and analyzing the recent publication by the Centers for Medicare & Medicaid Services of its draft Chapter 9–Part D Program to Control Fraud, Waste and Abuse, a proposed chapter in CMS's Prescription Drug Benefit Manual.

Part I – Overview to Part D Plan Fraud, Waste and Abuse Obligations

Introduction

As promised, the Centers for Medicare & Medicaid Programs (''CMS'') issued draft Part D compliance program provisions on Feb. 8, 2006. The provisions are encompassed within CMS's draft Chapter 9—Part D Program to Control Fraud, Waste and Abuse (the ''draft FWA chapter''), a proposed chapter in CMS's Prescription Drug Benefit Manual (''PDP Manual''). The PDP Manual is ''subregulatory'' materials issued by CMS to Part D plans. The draft FWA chapter greatly expands upon CMS's prior published summary guidance entitled ''Review of [Part D] Sponsors' Fraud Waste and Abuse responsibilities Summary Document.'' Comments to the draft Chapter were due March 1 and a revised final chapter is expected shortly.

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The draft FWA chapter is directed to Part D plans that are stand-alone prescription drug plans (''PDPs'') as well as to Medicare Advantage plans (also sometimes called ''Part C Plans'') that offer Part D benefits (''MA-PDs'').

Many Part D plans expected the detailed, sweeping contents of the draft FWA chapter, and already have been knee deep in the progress of modifying their existing compliance programs to take into account the Part D benefit. However, some Part D plans likely underestimated the level of compliance activities and oversight that CMS is expecting. In either case, most Part D plans still have a long ''to-do'' list to accomplish over the next few, short months in the area of Part D compliance.

While we fully expect CMS to consider and respond to the comments that are submitted in response to the draft FWA chapter, any revisions to the guidance are likely to be refinements or clarifications, not wholesale revisions. Thus, Part D Plans are well advised to begin now developing a game plan for bringing their compliance plans up to speed with the draft chapter.

The draft FWA chapter also is important reading for other Part D stakeholders. It specifically discusses potential risk areas for activities conducted by PBMs, pharmacies, prescribers, wholesalers and pharmaceutical manufacturers. Although the draft chapter does not expressly say it, prudence suggests that each of these stakeholder groups review the specific sections of the draft FWA chapter that apply to their activities and take steps to modify their own compliance programs and

Part D activities to avoid raising the issues described in the chapter.

Finally, managed care plans for other federal health care programs, such as Medicare Advantage, Medicaid, and TriCare, also should review the draft FWA chapter. Although technically not applicable to these entities' non-Part D service lines, the draft chapter is an important expression by government regulators of their current policies on compliance issues when federal health care program dollars and beneficiaries are involved. Don't be surprised to find that certain aspects described in the final FWA chapter become ''best practices'' in other federal health care program managed care compliance contexts.

This Part I of this two-part article:

- provides a background to Part D and the draft FWA chapter,
- explains the role of MEDICS in Part D compliance,
- summarizes the provisions of the draft FWA chapter, and
- offers suggestions to Part D plans for the roll-out of a ''comprehensive fraud, waste and abuse program'' of the kind envisioned by the regulators.

A future Part II of this article will:

- provide a closer look at the regulatory requirements for a FWA program for Part D plans,
- address the areas of the draft FWA chapter that raise interesting or complex implementation issues for plans, and
- discuss examples of where the Part D compliance guidance may come to reflect ''best practices'' for plans that participate in other federal health care programs.

I. Background

The Medicare Part D program was established by the Medicare Prescription Drug, Improvement and Modernization Act in 2003 (the ''MMA''). The Part D program, which took effect Jan. 1, 2006, is a program for the delivery of outpatient prescription drugs to qualified Medicare beneficiaries who have enrolled with an organization approved by CMS to provide such benefits. Organizations approved and contracted with CMS for this purposes (''Part D plan Sponsors'' or ''plans'') are subject to a host of statutory, regulatory and sub-regulatory requirements published by CMS.

With regard to compliance, the MMA and implementing regulations mandate that each Part D plan Sponsor establish a ''comprehensive'' plan to detect, correct and prevent fraud, waste and abuse. *See* 42 U.S.C. § 1395W-104 and 42 C.F.R. 423.504(b)(4). This mandate for a compliance program makes Part D plan Sponsors different from most other health industry companies that provide services reimbursed in whole or part by Medicare. Only Part D plans Sponsors and organizations that offer Medicare Advantage (''MA'') plans are required by the federal government, as a condition of their Medicare Program contract with CMS to provide such services, to have compliance programs. For other providers of items or services payable by Medicare, such as hospitals, physicians, and medical equipment companies, compliance programs (although clearly ''best practices'') remain technically voluntary.

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Almost simultaneously with the establishment of the Part D Program, the federal government regulators began speaking and publishing severe warnings against fraud in the Part D Program. Although fraud and abuse always had been an important concern for Medicare regulators, Medicare historically covered only a small number of outpatient prescription drugs. The new Part D Program promised a significant injection of new federal money into an industry that previously had not participated in Medicare to any great extent. Federal regulators, not surprisingly, predicted a matching increase in fraud by various participants and constituencies in the Part D Program.

In addition to requiring the Part D plan Sponsors themselves to detect, prevent and correct fraud, CMS has hired outside companies, called Medicare Drug Integrity Contractors or ''MEDICS,'' to perform specific program integrity functions. CMS describes the MEDICS as its ''designee'' to audit, oversee, and conduct anti-fraud and abuse efforts for the Part D Program.

Although this article focuses on CMS's statements in its draft FWA chapter, we remind our readers that CMS is not the only federal regulatory agency with jurisdiction over fraudulent or abusive tactics affecting the Medicare Part D Program. Violations of the federal False Claims Act (''FCA''), the federal civil monetary penalties provisions (''CMPs''), the federal Anti-Kickback Statute (''AKS'') and other applicable laws also may be investigated or prosecuted by agencies such as the U.S. Department of Justice (''DOJ''), the Department of Health and Human Services Office of the Inspector General (''OIG'') and the Federal Bureau of Investigation (''FBI'').

II. Role of MEDICs in Part D Fraud, Abuse Oversight

As described in the draft Chapter, CMS has contracted with private organizations, called MEDICS, to manage CMS's audit, oversight, and anti-fraud and abuse efforts in the Part D benefit. The main functions of the MEDICS, as explained by CMS in the draft Chapter, include identifying and investigating potential Part D fraud and abuse cases for referral to law enforcement agencies, acting as a liaison to law enforcement and serving as an auditor of part D Plan Sponsors and subcontractor operations.

With regard to prevention activities, among other tasks, MEDICS are charged with reviewing bids submitted from plans, reviewing the FWA components of Part

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D plan Sponsor compliance programs. They also educate entities about potential prescription drug fraud waste and abuse and facilitate intermediate sanctions against plans found non-compliant with Part D program requirements.

On the detection front, MEDICS are charged with activities that include conducting reviews and audits, and complaint investigations, investigating aberrant behavior, identifying potential overpayments, and providing support for law enforcement agencies for investigations of potential fraud and abuse. MEDICS' audit responsibilities include auditing one-third of the Part D plan Sponsors each year on issues such as bids, low-income subsidy payments, direct subsidy payments, rebates, formulary, claims, TrOOP data, and calculation of copays. Other MEDIC audit functions include auditing FWA compliance plans, beneficiary protections audits, P&T Committee audits, retiree drug subsidy audits, and audits of creditable coverage disclosures.

III. Summary of Draft Chapter on Part D Fraud, Waste, Abuse Compliance Programs

After a section on definitions and a discussion of the MEDICS, the draft FWA chapter begins, interestingly, with a section addressing Part D plan Sponsor accountability and oversight of subcontractors. The fact that this section on subcontractors appears so early on the draft FWA chapter reflects how critical subcontractor oversight is to an effective Part D FWA program.

The draft FWA chapter is clear that the Part D plan Sponsor maintains ''ultimate responsibility'' for fulfilling the terms and conditions of its contract with CMS, regardless of whether the plan engages subcontractors to perform functions on its behalf. CMS states ''[t]o that end, Sponsors will be held liable for the failure to meet contractual requisites performed by subcontractors working on their behalf to meet contractual requisites.'' *See* Draft FWA Chapter at page 11 citing 42 C.F.R. 423.505(i).

The draft FWA chapter explains that a ''first tier entity'' means a party that has a written arrangement with a Sponsor to provide administrative or health care services to Part D eligible individuals, which in most cases, CMS states, will be a pharmacy benefit manager (''PBM''). A ''downstream entity'' means any party that enters into a written arrangement below the level of a first tier entity, down to the level of ''ultimate provider'' of either administrative or health care services, such as network pharmacies that contract with PBMs or the pharmacists that contract with the network pharmacies.

CMS provides a diagram titled ''stakeholder relationship flow chart'' to illustrate the relationships between the CMS contractor/Part D plan Sponsor and first tier and downstream entities, which in the flow chart include a PBM, pharmacies, a quality assurance firm, a claims processing firm, and a health care marketing consultant. CMS then describes the responsibilities of plans and first tier and downstream entities, which it generally refers to as ''subcontractors.''

CMS makes clear that the Part D Compliance Officer and Compliance Committee functions *may not* be delegated or subcontracted by a Part D plan. CMS further states that a Part D plan's contract with subcontractors must include ongoing monitoring performed by or on behalf of the Sponsor to assess whether all subcontractors are ''in compliance'' with all Part D provisions. *See* Draft FWA Chapter at p. 14 citing 42 C.F.R. 423.505(i)(4)(iii).

Part D plan Sponsor contracts with subcontractors must include certain provisions, such as inspections, enrollee protections, Sponsor accountability, delegation, and record retention. In reality, most Part D plan contracts with PBMs probably already include these basic regulatory requirements. However, such contracts were negotiated last year as Part D plans were working feverishly to submit bids, formularies and basic networks to CMS for approval, *i.e.*, before many plans had time to develop adequately their organizational strategies for auditing and oversight of their PBM contractors. CMS's draft FWA chapter is a stern reminder that review and modification of PBM contracts should be a top priority for Part D plans.

The draft FWA chapter then proceeds to address the ''basics'' and ''benefits'' of FWA programs. CMS suggests that Part D plan Sponsors may implement their FWA programs as an addition to other required compliance programs (*e.g.*, as a separate program) or by ''integrating'' the FWA provisions into each element of the Sponsor's existing compliance plan. CMS states its preference in this regard, in that it believes ''it would be most efficient'' for Sponsors to integrate a FWA program into its existing compliance program.

We discuss below some of the factors that a plan may wish to consider in making its determination of whether to operate a ''separate'' or ''integrated'' FWA program. *See* Draft FWA Chapter at p. 16.

CMS then discusses in detail each of the specific regulatory requirements of a compliance plan. Part II of this article will discuss each of these specific regulatory requirements in more detail. For purposes of this overview, we list each of the regulatory requirements below:

- ***Written Policies and Procedures***: The Part D Sponsor must have written policies, procedures and standards of conduct that articulate the Sponsor's commitment to comply with all applicable Federal and State standards.
- ***Compliance Officer/Committee***: The Part D Sponsor must designate a compliance officer and compliance committee that is accountable to senior management.
- ***Effective Training***: The Part D Sponsor 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.
- ***Effective Communication***: The Part D Sponsor must have effective lines of communication between the Compliance Officer and the organization's employees, subcontractors, agents, directors and members of the Compliance Committee.
- ***Discipline***: The Part D Sponsor must enforce standards through well-publicized disciplinary guidelines.
- ***Auditing and Monitoring***: The Part D Sponsor must have procedures for effective internal monitoring and auditing.
- ***Fraud Reporting***: Sponsors must have a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse. The fraud and abuse plan should include procedures voluntarily to self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.

IV. ''Stakeholder'' Risk Areas

One of the most interesting sections of the draft FWA chapter is section 70, where CMS provides examples of

potential schemes, risks and vulnerabilities to the Part D benefit by stakeholder—namely, Part D plans, PBMs, pharmacies, prescribers, wholesalers, pharmaceutical manufacturers and Medicare beneficiaries. CMS states that, given Sponsors' ultimate responsibility for delivery of the Part D benefit, Sponsors should review these risks and develop their FWA programs accordingly. We identify some of these stakeholder risk areas below.

Although not discussed by CMS, we would expect these other ''stakeholders'' involved with the Part D benefit to be reviewing this section and modifying their own compliance program accordingly. CMS also repeats several times throughout this discussion that the examples provided are not an exhaustive list of potential fraud, waste or abuse risk areas so stakeholders and Sponsors need to consider other potential risk areas, so stakeholders and Sponsors need to be considering other potential risk areas.

The draft FWA chapter identifies 21 different examples of Sponsor fraud, waste and abuse, ranging from failure to provide medically necessary services and marketing schemes, to improper bid submission, payment for excluded or non-compendium drugs, inappropriate formulary decisions, inappropriate enrollment/ disenrollment, incorrect handling of appeals, false or inaccurate data, duplicative or excessive premiums, incorrect calculation of TrOOP, failure to disclose rebates, discounts or ''price concessions,'' ''bait and switch'' pricing and manipulation of low-income subsidy enrollees. CMS also offers examples of PBM fraud in the draft FWA chapter. CMS notes that for Part D plan Sponsors that own PBMs or that operate in-house PBM functions, this list may apply in addition to the list cited above for Sponsors themselves. The examples include: prescription drug switching, unlawful remuneration, inappropriate formulary decisions, prescription drug ''shorting,'' and failure to offer negotiated prices.

CMS also offers examples of potential fraud, waste and abuse by pharmacies, prescribers, pharmaceutical manufacturers and other ''stakeholders.'' Examples of pharmacy fraud include inappropriate billing practices, prescription drug ''shorting,'' ''bait and switch'' pricing, prescription drug forging or altering, dispensing of expired or adulterated prescription drugs, prescription refill errors, illegal remuneration schemes to switch patients, influence prescribers or steer patients, TrOOP manipulation, and failure to offer negotiated prices.

Examples of prescriber fraud, waste and abuse provided are: illegal remuneration schemes to reward the writing of prescriptions, prescription drug switching, ''script mills,'' provision of false information, or theft of a provider's DEA number or prescription pad.

Examples of pharmaceutical manufacturer fraud are: lack of integrity of data to establish payment or determine reimbursement, inappropriate documentation of pricing information, kickbacks and other illegal remuneration, formulary and formulary support activities, inappropriate relations with physicians, illegal ''off-label'' promotion and illegal use of free samples. These examples serve as recommendations of areas where Part D Plans should strongly consider implementing policies, procedures and training for their employees and subcontractors.

V. Suggestions for Part D Plans on How to Move Forward

One of the first steps for Part D plans is the determination whether to establish a separate Part D FWA program or to integrate the Part D elements into the plan's existing compliance program. As discussed above, CMS offers the possibility either way, but expresses the belief that it would be more ''efficient'' to integrate the FWA program as a component of an existing compliance program.

MA-PDs may be inclined to adopt the integrated approach, since they already should have well established MA compliance programs. In contrast, PDPs may be more interested in considering a separate Part D FWA program, depending on how well developed their current compliance program is for their non-health care business service lines.

As a practical matter, many plans may opt for a combined approach. For example, plans may not want to convene an entirely new Compliance Committee just for Part D, but they might decide to follow CMS's ''strong recommendation'' to designate a single person whose sole job it is to serve as the Part D Compliance Officer. Whether a designated Part D Compliance Officer would report to the existing Corporate Compliance Officer or directly to the existing Compliance Committee would be a company judgment, taking into account factors such as how significant the company's Part D line of business is compared to other service lines, how many additional responsibilities that current Compliance Officer can take on and how well the current Compliance Officer communicates with the Compliance Committee.

If the determination is made to hire a new person for the Part D Compliance Officer role, then an interim Part D Compliance Officer or ''FWA Program Coordinator'' would need to be designated to oversee the plan's initiatives to implement the FWA program until the Part D Compliance Officer is installed. This interim person would need to develop a FWA workplan and be responsible for setting and meeting deadlines for implementing the various aspects of the FWA program.

Another necessary step for Sponsors is to conduct a ''gap'' analysis to determine the areas where the plan's current compliance program falls short of the FWA guidance provisions.

This analysis would require a thorough review and cataloguing of current compliance policies that need to be updated for Part D, as well as Part D policies to be drafted from whole cloth. Training materials for current employees and subcontractor staff would need to be assessed in this manner as well. Interviews with various department heads and other staff also may be required to determine the level of knowledge regarding Part D currently in existence, so that training materials can be tailored to the plans' specific needs. Another important task is to review of the Sponsor's current internal audit agenda and modify the workplan for Part D.

With regard to MEDICS, given how new the Part D Program is, it is untested how well the MEDICS will perform their various functions. However, Part D plans now need to build into their FWA programs a strategy for interfacing with MEDICS.

For MA-PDs, this aspect of participation in a federal health care program is not new. MA-PDs have experience on the Medicare Part C side with various CMS au-

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dits (*e.g.*, CMS ''site visits'') and OIG audits on behalf of CMS (*e.g.*, ACR audits). Any strategy for interfacing with MEDICS on Part D issues should be built on the same ''best practices'' that have evolved out of the Part C experience. For example, appointing a single staff person well-trained on the Part D Program to serve as ''MEDIC coordinator'' might be appropriate. This might be the Part D Compliance officer or it might be another person who has some responsibility for the Part D benefit within the plan.

A key piece of any effective Part D FWA program is arrangements with subcontactors, like PBMs and others. These arrangements should be reviewed and, no surprisingly, contracts with subcontractors may need to be amended.

The MEDIC coordinator function would include serving as principal contact for all MEDIC interfaces with the plan, maintaining a log of all communications with MEDIC staff, responsibility for complying with and meeting deadline for MEDIC requests for documents or data, organizing discussions between plan staff whose input on general or specific MEDIC issues is necessary (*e.g.*, actuarial staff, claims processing staff, PBM representatives, the internal audit department, the corporate compliance officer and senior management). The person handling the MEDIC coordinator also should review and be familiar with CMS's request for proposal published to solicit entities to serve as MEDIC contractors.

A key piece of any effective Part D FWA program is arrangements with subcontactors, like PBMs and others. These arrangements should be reviewed and, no surprisingly, contracts with subcontractors may need to be amended.

Oversight and auditing of subcontractors is a key element discussed in detail in the draft FWA chapter. If a subcontractor purports to have an existing compliance program that it wishes to modify for Part D, then the Part D plan Sponsor should provide information to help the subcontractor's compliance plan meet the Part D requirements and the plan's own FWA program objectives.

Also, Sponsors should be forewarned that a subcontractor's compliance program may look good on paper, but the real question is whether the program operates effectively as required to protect the Part D plan from liability. A Part D plan should be confidant that its subcontractor's compliance ''culture'' matches the plan's own culture–where employees feel free to ask questions and report suspected compliance concerns without fear of retaliation. The draft FWA chapter is clear that the plan remains ultimately liable for compliance and performance of the Part D requirements, regardless of whether aspects of the plan's Part D obligations have been subcontracted.

The Part D plan should develop a clear code of conduct and protocols on what it expects from its subcontractors, the extent to which the subcontractor will be allowed to use its own compliance plan policies, training, auditing and reporting elements, and the degree to which the subcontractor will be required to participate directly in the plan's FWA program.

If the Part D plan already has the clear contractual right to dictate compliance performance by the PBM, then the Part D plan might wish to issue a policy or other directive to its PBM that sets forth its expectations in detail with regard to how the PBM's compliance efforts will interface with the plans' efforts and what specific oversight activities are expected. Otherwise, formal contract amendments may need to be negotiated.