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REPORT

CMS Draft Part D Fraud, Waste, Abuse Guidance, Part II: Implementation Issues, Best Practices

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This is the second article in a two-part series we have authored that summarizes and analyzes the recent publication by the Centers for Medicare and Medicaid Services (''CMS'') of a draft Chapter 9 – Part D Program to Control Fraud, Waste and Abuse, a proposed chapter in the *Medicare Prescription Drug Benefit Manual*.

This second part of our article:

- provides a closer look at the regulatory requirements for a ''fraud, waste and abuse'' (''FWA'') program for Medicare Part D plan sponsors;
- addresses the areas of CMS's draft FWA chapter that raise interesting or complex implementation issues; and
- describes examples of where the Part D compliance guidance may come to reflect ''best practices'' for plans that participate in other federal health care programs.

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I. Regulatory Requirements for Part D Plans to have Fraud, Waste and Abuse Programs

As we discussed in Part 1 of this article, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations require that all organizations under contract with CMS to sponsor a Medicare Part D drug benefit program (''sponsors'' or ''plans'') have a comprehensive plan to detect, correct and prevent fraud, waste and abuse.

In implementing this requirement, the final Part D regulations require each plan to develop a compliance program and specifically list the required elements of each plan's mandatory compliance program. This also applies to the Part D fraud, waste, and abuse program.

In its draft chapter on the elements of a Part D FWA program, CMS includes specific discussion about each of the required elements. A discussion of each element is set forth below.

- ***Written Policies and Procedures***. *The regulations mandate that each 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.*

The draft FWA chapter explains that appropriate written policies and procedures include a Code of Conduct plus additional policies or procedures. CMS is clear that the sponsor's senior management should communicate a ''strong and explicit'' organizational commitment to compliance standards and ethical corporate behavior.

Having written standards in place with this commitment helps mitigate the risks associated with the Part D program. CMS expects that the written code of conduct

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will be approved by the sponsor's governing body or by a committee of the sponsor's governing body.

The written code of conduct also has to be reviewed periodically based on existing codes used in the industry. CMS explains that the code of conduct should: (1) clearly articulate the sponsor's commitment to comply with applicable statutory, regulatory and other Part D program requirements: (2) delineate the sponsor's expectations of employees and subcontractors involved in the Part D business to act in an ethical and compliant manner; and (3) include ramifications for failure to comply.[2] CMS explains that the code of conduct should specify the disciplinary actions that can be imposed for non-compliance, including oral or written warnings or reprimands, suspensions, terminations and financial penalties.

CMS's draft chapter then addresses the 16 areas where Part D sponsors should have written policies and procedures ''at a minimum.'' These 16 areas include a commitment to comply with the False Claims Act, Anti-Kickback Statute, prohibitions on inducements to beneficiaries and other applicable laws, regulations, ''subregulatory guidance'' and other requirements, a process to respond to potential violations of law within 30 days after a determination of potential violation has been made, a process to ''ensure'' that agents and brokers are marketing in full compliance with applicable laws and requirements, procedures for timely responses to data requests from CMS, MEDIC and law enforcement, a process to identify and repay overpayments, a process to ''ensure'' full disclosure and ''transparency'' of pricing decisions, policies for cooperating with CMS, MEDICS and law enforcement, procedures for corrective actions, record retention policies, a policy on commitment to ''legal'' P&T Committee decisions and formulary decisions based on clinical efficacy and appropriateness of drugs over cost considerations and conflict of interest policies for officers and directors and subcontractor officers and directors.

■ ***Compliance Officer/Committee***. *The Part D sponsor must designate a compliance officer and compliance committee that is accountable to senior management.*

CMS recommends that there be a full-time employee at the Part D plans sponsor who is dedicated to overseeing each plan's Part D compliance program operations. According to CMS, the Part D compliance officer should have authority to report directly to the corporate compliance officer (if separate from the Part D compliance officers), the board of directors and the president or chief executive officer.

CMS then provides 15 specific duties that should be included in the job description for the Part D compliance officer. Some of the specific duties include developing Part D written policies and procedures, reporting at least quarterly to the board of directors, participating in employee and subcontractor training, ensuring compliance with sales and marketing requirements, developing methods for reporting of suspected fraud, responding to reports of potential instances of fraud, conducting internal investigations into reports of potential Part D fraud, coordinating personnel issues, maintaining documentation for each report, and having authority to seek advice from legal counsel.

A compliance committee for Part D also should be convened, either within the existing structure of the compliance committee or separately. CMS then lists eight responsibilities for the Part D compliance committee.

These include developing strategies to promote compliance, overseeing internal controls, supporting the Part D compliance officer's staff and resource needs, ensuring up-to-date compliance policies, ensuring that the plan has a system for employees to report potential FWA confidentially without fear of retaliation, reviewing reports of monitoring and auditing of areas at risk for fraud, waste or abuse.

CMS makes clear that the compliance officer and compliance committee functions may not be subcontracted out to another organization, affiliated or not.

■ ***Effective Training***. *The Part D Sponsor must provide effective training and education between the Part D Compliance Officer and organization employees, subcontractors, agents and governing board directors who are involved in the Part D benefit.*

According to CMS, all persons involved with the Part D benefit, including subcontractors' employees, should receive general compliance training. Subcontractors should be permitted to attend the Part D plan sponsor's training or they must agree to conduct their own Part D compliance training.

General compliance training of at least two hours in length should be provided upon initial hire, at the time of contracting or upon initial adoption of a compliance program, and annually thereafter as a condition of employment or contract.

In addition, annually specialized training at a minimum of four hours in length must be provided for employees, subcontractor employees, directors and agents engaged in certain functions, such as marketing, appeals, calculating TrOOP, making negotiated prices available to members, payment reconciliation, submitting data to CMS, negotiating rebates with manufacturers, and other areas.

■ ***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.*

CMS explains that Part D sponsors must have a system in place to receive, record and respond to compliance questions and reports of (potential or actual) noncompliance from employees and contractors. The system must maintain confidentiality and allow anonymity if desired, without fear of retaliation. Hot lines or mail drops are examples given of such systems.

Effective communication about how to report compliance concerns and actual or suspected misconduct also

[2] According to CMS's draft FWA chapter, each Part D plan sponsor's code of conduct also should inform contractors, employees, and governing body members of their obligation, at times, to report ''violations of law and policy'' to CMS, its responsible designee such as the Medicare Drug Integrity Contractors (MEDICs) (an organization that has contracted with CMS to perform specific Part D program integrity functions, auditing and antifraud and abuse efforts) and/or law enforcement (we discussed the role of the MEDICs in more detail in Part 1 of our article). *See* draft FWA chapter at section 50.2.1.1. CMS also states that sponsors should notify MEDICs of ''potential'' fraud, waste or abuse following the conduct of a ''reasonable inquiry'' but not later than 30 days after the determination is made that a ''violation'' may have occurred. *See* draft FWA chapter at section 50.2.8.2. It is not clear what standard CMS intends to apply to self-reporting of Part D fraud.

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needs to run between employees, subcontractors, agents, directors and members of the compliance committee. Sponsors must have prompt follow-up investigation procedures in response to hotline inquiries and other complaints and a complaint tracking system. CMS states that sponsors must provide education to enrollees on FWA, as well.

■ ***Discipline***. *The Part D sponsor must enforce standards through well-publicized disciplinary guidelines.*

To help communicate the organization's commitment to compliance, CMS explains, the sponsor's CEO and senior management should be directly involved in developing standards for conduct.

In addition, the organization should use various methods, such as newsletters, staff meeting topics, postings, to encourage reporting of unethical or noncompliant behavior. Clear and specific disciplinary policies must be established.

According to CMS, all employees and subcontractors should be told that violations of the Part D plan's standards may result in termination of their specific relationship with the plan.

■ ***Auditing and Monitoring***. *The Part D sponsor must have procedures for effective internal monitoring and auditing.*

CMS's position is that sponsors must have an internal monitoring and auditing program to protect against Part D fraud, waste, and abuse and to help mitigate the sponsor's and subcontractors' liability. There should be developed a workplan to assure adequate monitoring and auditing activities.

The workplan should include information regarding all necessary aspects, such as internal audit department requirements, schedule and methodology for audits, and types of audits to be carried out. CMS's position is that any sponsor that does not have an internal audit department should consider establishing one.

Audits should include desk and on-site audits, as well as unannounced spot checks. Risk areas should be identified for this purpose. Response to audits and corrective action to audit results must occur.

CMS is clear that the workplan should include a strategy for monitoring and auditing the activities of subcontractors, as well. This will prove to be very challenging for the plans.

In particular, CMS recommends that audits should include a review of documentation such as prescriptions, invoices, pharmacy licenses, claims transaction records, signature logs, purchase records, negotiated prices, minimum standards for pharmacy networks under state laws, as well as subcontractor contracts, rebates, discounts, and other relevant data.

Sponsors should conduct interviews with subcontractor staff to gauge whether applicable Part D requirements are being met.

Other aspects of the monitoring and auditing program discussed in the draft FWA chapter include use of data in oversight analysis, claims processing system recommendations, identifying providers with a history of complaints, denying claims for drugs prescribed by an excluded provider, developing prompt responses to detected offenses and corrective action plans, conducting timely and reasonable inquiry of detected offenses.

In this discussion, CMS also addresses recommended procedures for sponsors to report fraud, waste, or abuse to MEDICS. CMS encourages sponsors with special investigation units to investigate potentially fraudulent activity so they can make a determination whether potential fraud or misconduct has occurred.

Where the sponsor has limited resources and cannot make such a determination whether conduct has risen to the level of potential fraud, CMS says that the sponsor still should refer the suspect activity to the MEDIC for investigation. CMS also encourages sponsors to consider reporting conduct to government authorities such as the Department of Health and Human Services Office of Inspector General (OIG) or Department of Justice (DOJ).

■ ***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.*

CMS states that self-reporting of fraud, waste and abuse is a ''critical element'' to an effective compliance plan. According to CMS, if, after conducting a reasonable inquiry, the Part D sponsor determines that ''potential'' fraud or misconduct has occurred, the conduct should be referred to the MEDIC promptly, but no later than 30 days after the plan has made a determination that a violation ''may have occurred.''

This means that the plans need to act quickly and have sound decisionmaking procedures so that such determinations are made timely for timely reporting. Sponsors also are encouraged to report the conduct to other government authorities such as the OIG or DOJ.

II. Key Implementation Issues Arising Under the Draft FWA Chapter

Based on the level of detail specified by CMS in the draft FWA chapter, we suggest that Part D plans develop a ''matrix'' that breaks down the draft FWA chapter requirements into action items. The matrix also needs to assign staff and set forth a time table for completion of each item.

Each item needs a ''team leader'' who ultimately is responsible for keeping items on track and for reporting progress to the compliance officer (or senior management or whoever the plan determines needs to be kept apprised of developments). The compliance officer should be the one responsible for identifying and resolving any implementation challenges as the project unfolds. There needs to be clear accountability for this process.

We propose that, given the breadth of the FWA program elements described by CMS in the draft FWA chapter, it might be helpful to Part D plans to break down the elements into a few broad categories of requirements. Each of the broad elements comprising the draft FWA chapter then needs to be reviewed under the draft FWA chapter to determine what actions should be taken in order for the Part D plan to satisfy the requirements set forth by CMS.[3]

Breaking down the draft FWA elements also might help determine who at each plan needs to take respon-

[3] We discussed in more detail in Part 1 of this article other suggestions for Part D plans on how to move forward, including considerations for staffing the Part D compliance officer function, conducting a ''gap'' analysis for Part D compliance, developing protocols for interactions with the MEDICs, and initial thoughts on addressing the subcontractor oversight requirements.

sibility for the various activities. We suggest the following four general categories as a framework for this purpose: (1) updating code of conduct, policies and procedures, and training activities, (2) developing and implementing auditing and workplan activities, (3) addressing subcontractor requirements, and (4) establishing internal investigation and voluntary reporting procedures. Other categories or subcategories also might be applicable, depending on the particular plan's structure.

For example, updating the code of conduct and developing Part D training materials might require the time and attention of the plan's compliance department staff, while developing auditing and workplan agendas likely would involve the plan's internal audit department.

Addressing subcontractor oversight necessarily requires the contracts staff to be involved, along with other relevant operational unit staff, such as pharmacy claims and appeals staff if the subcontractor is a PBM.

Establishing internal investigation and reporting procedures likely needs direction from the compliance committee and also might require input from in-house or outside health care regulatory counsel. Developing disciplinary measures for employee non-compliance needs the attention of the human resources department, while responsive measures for subcontractor non-compliance sounds like an issue for the contracts department to address.

On the issue of timetable for completion, we would hope that CMS will provide more direction in its revised final published chapter, which we hope will be published shortly.

An important issue that needs clarification from CMS is the extent to which a Part D plan seeking to renew its Part D contract with CMS will be required to have implemented a completed FWA program as a condition of being awarded a 2007 benefit year contract renewal, or whether CMS will be satisfied with plans that have developed an adequate ''game plan'' for implementing their FWA program over a reasonable, but more extended, time period.

On this issue of timetable, we note that CMS recently published ''DRAFT 2007 MA, MA-PD and PDP Call Letters'' (draft Call Letters) to Part D plans that state, among other things, that CMS will issue contract renewal notices to Part D plans sponsors prior to May 1, 2006, to those sponsors that ''we have determined continue to be qualified to hold a contract during 2007.''

CMS explains that Part D plan sponsors are not required to apply for a contract renewal, as CMS will make the determination based on an evaluation of each sponsor's ''compliance with its contract.'' As Part D plans are required by regulation to establish FWA programs, and now that CMS has published its draft FWA chapter, the question raised is the extent to which CMS will be reviewing plans' FWA compliance programs in connection with its review for 2007 contract renewals.

CMS's draft Call Letters provide some additional guidance in this regard. The draft Call Letters include a section on compliance and monitoring where CMS states that, beginning January 2007, CMS will specify key elements that must be included within the required components of a compliance plan as described in the regulations at 42 C.F.R. 423.504(b)(4)(vi).

CMS adds that compliance plans will be reviewed for these requirements as part of the regular monitoring/auditing of plans. The draft Call Letters then re-state the required elements of a Part D compliance program, which we discussed above in connection with the draft FWA chapter.

III. Part D FWA as Potential 'Best Practices' for Plans Offering Other Federal Health Care Programs

There are other federal health care programs that rely on private health plans to administer health benefits similar to the Medicare Part D program. Examples that come to mind include Medicaid managed care plans, FEHBP plans, and plans under the Tri Care program.

Each of these other federal programs, in its own way, has discussed compliance or program integrity obligations. Some provide more detail than others. However, the draft FWA chapter just issued by CMS includes an even greater level of specificity as it relates to having an ''effective'' corporate compliance program under these circumstances.

Therefore, such other plans may want to review these CMS pronouncements with an eye towards using the final FWA chapter as a potential best practice.

For example, CMS has an extensive discussion in the draft FWA Chapter about the need for Part D plan oversight and contractual controls over subcontractors as well as subcontractor training There appears to be an effort to do more than merely include contractual promises to comply.

There is emphasis on monitoring and auditing a subcontractors' performance. This may be an area other plans may want to focus on in order to improve their own compliance effectiveness even under these other federal government health programs.

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