

II. In-Depth

LIABILITY AND COMPLIANCE ISSUES IN MEDICARE PART D

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As government contractors, health plans that sponsor Medicare Part D plans – either stand-alone prescription drug plans or Medicare Advantage-Prescription Drug plans – should expect scrutiny from government enforcement officials and qui tam relators in the future.

The government and plaintiffs' bar are intently focused on potential fraud in the Medicare prescription drug benefit because of the huge dollars at stake and historical concern and skepticism about marketing and pricing practices in the pharmaceutical industry.

However, pharmaceutical companies and pharmacies do not contract to provide the Part D benefit – health plans do. As the entity with the contract, Part D plan sponsors ("Sponsors") are exposed to substantial risk if they submit inaccurate data to the government. Although health plans face similar concerns with the Medicare managed care program, Medicare Advantage (and its predecessor, Medicare+Choice), there is far more scrutiny for Medicare Part D. The structure of the Part D benefit – with the government paying a portion of costs for reinsurance – heightens the legal risks for Sponsors.

KEY RISK AREAS

Sponsors face a variety of risks under the Medicare prescription drug benefit. These risks stem in large measure from the fact that the government shares risk with Sponsors, and Sponsors submit extensive data on the costs they incur, net of administrative expenses and rebates, in order to administer the risk-sharing arrangement. If that data is not fully accurate, the federal government could end up paying more than it otherwise would because of this payment structure.

Although Sponsors receive a per member–per month payment, Medicare Part D is not fully capitated. The federal government shares risk with Sponsors, through the subsidy in the _____

initial coverage period (estimated to be \$1,400 per beneficiary in 2006) and reinsurance for beneficiaries who incur a catastrophic level of drug costs. The federal government also will provide risk-corridor payments to Sponsors whose costs significantly exceed their estimates (i.e., 5-7.5% greater than their bids). As a result, the federal government is affected if Sponsors overpay providers or fail to prevent, detect or correct fraudulent or wasteful spending, or receive inaccurate data.

There are numerous ways in which data submitted to the government might be inaccurate. Early concerns center around the following areas:

Pharmaceutical Company Remuneration to PBMs. CMS is intensely focused on payments by pharmaceutical companies to pharmacy benefit managers ("PBMs"). In the Final Call Letter for the 2007 benefit year, CMS expressly stated that Sponsors must report any rebates from a pharmaceutical company to a PBM and use the rebates to reduce the Sponsor's drug costs – even if the rebate was not actually paid to the Sponsor. CMS' theory is that PBMs retain these rebates in lieu of charging Sponsors higher administrative costs.

CMS' position presents a number of risks for Sponsors. Sponsors, for example, must find out about rebates paid to PBMs and track and report those rebates to CMS. If a Sponsor does not get accurate or complete information, the rebate data it submits to CMS will be inaccurate. In addition, CMS' position is not limited strictly to reporting of rebates: if a pharmaceutical company is paying other remuneration to a PBM (such as for administrative services, data, funding for educational programs, etc.) there is a real question whether such payments similarly must be reported to CMS and netted from drug costs.

PBM Payments to Pharmacies. In addition, PBMs may pay network pharmacies a different price than they charge the Sponsor. An unresolved question is whether any mark-up the PBM retains will be considered a disguised administrative payment by the Sponsor which must also be tracked and reported to CMS.

Improper Claims Payments. Some entities that have served as government fiscal intermediaries have been sued under the False Claims Act for making payments to providers that the providers were not entitled to. Although the federal government has not focused discussion on these types of theories under Medicare Part D, qui tam relators and government attorneys may apply similar theories to prescription drug claims – particularly if those same claims then are submitted to CMS for reinsurance and risk-corridor payments. As a result, Sponsors should consider their efforts to prevent improper payments and recoup overpayments as a potential compliance issue as well as a business issue.

Reconciliation. Numerous other pieces of data – including enrollment, disenrollment and enrollees' TrOOP calculations – also will need to be submitted to CMS and may affect a Sponsor's payments. Inaccuracies in such data that leads to overpayments from CMS also expose Sponsors to liability.

FRAUD, WASTE AND ABUSE CHAPTER

CMS' Office of Program Integrity recently reinforced some of these concerns in a chapter for the Prescription Drug Benefit Manual that sets high expectations for Sponsors to "ensure" compliance not only by employees of their own organizations but also by their contractors and network pharmacies. The Chapter, issued April 25, 2006, sets a high standard of

accountability for Sponsors and emphasizes Sponsors' responsibilities as the entity contracting with CMS.

Allocation of Responsibility. The Chapter emphasizes that Sponsors ultimately are responsible for all functions, including those that are performed by subcontractors, such as PBMs or marketing companies, as well as by network pharmacies. As a result, Sponsors are responsible for establishing and maintaining a process and procedures to monitor and review the conduct of these third party entities. This is particularly important because Sponsors may rely on subcontractors and network pharmacies for much of the data that must be submitted to the government.

The Chapter allows Sponsors to delegate many aspects of the required fraud, waste and abuse program to subcontractors, subject to the oversight described above. In order to perform that oversight, the Sponsor must have a compliance officer and compliance committee – it cannot delegate those compliance functions.

Sponsors, their contractors, and their network pharmacies will need to consider questions such as the following:

- What compliance functions will each entity be responsible for performing? Are the respective compliance responsibilities clearly set forth?
- What processes and procedures will be in place for Sponsors to review subcontractors' and network pharmacies' compliance?
- What monitoring and auditing will the subcontractors and network pharmacies be subject to, and what information and access will the Sponsor require in conjunction with these oversight activities?

Sponsors should understand that it will be risky to rely on subcontractors to be in compliance and to monitor the conduct of network pharmacies and others. Sponsors will need to carefully consider how to allocate responsibilities and draft contracts to reduce the likelihood that they will later be found to have knowingly or recklessly submitted inaccurate data and claims to CMS – the standard for liability under the False Claims Act.

"Should" versus "Shall." Another key issue in the Chapter is the tension between mandatory requirements and voluntary recommendations. The Chapter has both. According to CMS, where the Chapter states that a Sponsor "shall" or "must" take a certain action, such action is mandatory. However, CMS describes most of the Chapter as "recommendations," indicated by use of the term "should."

Despite CMS' clarification, it is likely that even the non-binding "recommendations" will set a standard that Sponsors and subcontractors will want to consider following. Many of those recommendations are very specific, suggesting that CMS believes strongly that they should be incorporated. For example, in Section 50.2.1.1, CMS states that an effective compliance program "will have a code of conduct that articulates an organization's commitment to ethical behavior." The Chapter further specifies the preferred content of the code: it should clearly articulate the Sponsor's commitment to complying with all applicable statutory, regulatory and other Part D program requirements; delineate the Sponsor's expectations with regard to subcontractors' ethical behavior; and identify ramifications for subcontractors that fail to comply with the expectations. "The written 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."¹

Similarly detailed recommendations are provided regarding the written policies and procedures that Sponsors must adopt, the monitoring and auditing activities that Sponsors should perform, and the types of fraud, waste and abuse that Sponsors and their subcontractors should be looking for with their compliance and anti-fraud activities. For example, the Chapter specifies not only the subject matter, but also, in many instances, the preferred content of the policies and procedures. "Recommendations" include a policy of annually checking employees against lists of individuals excluded from the Medicare program and procedures for ensuring that all CMS reporting requirements for potential conflicts and appropriate lobbying disclosure requirements are satisfied.²

The specificity of the Chapter's "suggestions" raises the question whether such recommendations will become de facto requirements. It is possible that failure to adopt the "recommendations" could increase the risk of liability under the False Claims Act or other laws if subcontractors provide inaccurate data that the Sponsor then submits to the government, or if there is other non-compliance with Part D requirements. Thus, Sponsors should carefully consider which "recommendations" they will implement.

Other specific requirements and recommendations in the Chapter include:

- **Policies and Procedures.** The Chapter identifies 16 specific policies, procedures and processes that a Sponsor "should" implement. Examples include policies and procedures to:
 - Confirm that officers, directors and managers do not have a conflict of interest that provides an unfair competitive or monetary advantage to the Sponsor;
 - Identify overpayments and underpayments at any level within the Sponsor's network and properly report and repay, where applicable, such overpayments in accordance with CMS policy;
 - Identify improper coverage determinations, services or enrollment at any level within the network and properly report and repay (where applicable) any overpayments resulting from inaccurate enrollment data;
 - Identify claims that were submitted for drugs that were prescribed by an excluded or deceased provider and report and properly repay any overpayments resulting from inaccurate claims payments;
 - Ensure full disclosure to CMS upon request of all Sponsor pricing decisions for Part D items or services, related data and pricing records. Sponsors' policies should "ensure transparency" in the pricing structure to include all rebate and negotiated price discounts

¹ Centers for Medicare and Medicaid Services, Prescription Drug Benefit Manual, ch. 9, § 50.2.1 (Apr. 2006).

² § 50.2.1.2.

and hold the Sponsor and its subcontractors accountable for accurate reporting of price information; and

- Ensure that the Sponsor's relationships with its vendors, suppliers, and other contractors do not violate the federal Anti-Kickback Statute or other applicable federal or state laws.³
- **Compliance Officer.** The Sponsor must designate a Part D compliance officer, and may not delegate this responsibility. According to the Chapter, the compliance officer "will be responsible" for developing, implementing and monitoring a Sponsor's anti-fraud program and should have the authority to report directly to the board of directors and president and/or CEO. The Chapter also identifies numerous duties expected of the compliance officer, including:
 - Reporting to Sponsor's corporate compliance officer (if one exists), the board of directors, the president and/or CEO and the compliance committee at least quarterly;
 - Coordinating personnel issues with the human resources department to ensure that all employees, officers, directors and managers as well as contractors are not on the exclusion lists maintained by the Office of the Inspector General or General Services Administration; and
 - Ensuring all contractors are aware of and follow the requirements for Medicare Part D sales and marketing activities.⁴
- **Training.** The Chapter sets forth detailed recommendations for employee training. For example, the Chapter provides that training of supervisors should include:
 - Appropriate responses to compliance inquiries and reports of potential non-compliance;
 - Maintaining the confidentiality of inquiries and reports; promoting and enforcing non-retaliation policies; and
 - Knowing when to refer the incident to the compliance officer.⁵

The Chapter also recommends that Sponsors consider making compliance training available to its network pharmacies and other subcontractors, "to the extent that it is feasible and reasonable." However, the Chapter suggests that Sponsors' pharmacies and other subcontractors provide such training if the Sponsors do not do so.

- **Auditing and Monitoring.** Sponsors are advised to develop a strategy and work plan for auditing and monitoring internal compliance and anti-fraud efforts, and included in this work plan should be activities relating to monitoring and auditing subcontractors involved in the administration and delivery of the prescription drug

³ Id.

⁴ § 50.2.2.

⁵ § 50.2.3.

benefit. With respect to auditing subcontractors, Sponsors "should include routine and random auditing as part of their contractual agreement," and "make it a priority to conduct a certain number of on-site audits." The Chapter identifies the type of data and materials that should be evaluated, various methodologies that should be adopted as well as recommendations of additional monitoring efforts that Sponsors should consider adopting.⁶

The Chapter also offers examples of potential fraud, waste and abuse by various parties participating in the Part D benefit, including contractors, pharmacies, providers and beneficiaries.

Sponsors – and the individuals developing and implementing compliance measures for Sponsors, contractors and networks – should take care to review the provisions of the Chapter, the requirements and CMS' recommendations.

CONCLUSION

The launch of the Medicare prescription drug benefit has not been a simple task. It has required significant resources and effort by CMS, Sponsors, their contractors and pharmacies. However, the potential liability and compliance issues indicate the bulk of the work may not be complete yet.

⁶ § 50.2.6.