



Medicare Fraud, Waste and Abuse Training: Impact on Pharmacy Benefit Managers

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Since 2006 all Part D Sponsors have been required by the Centers for Medicare and Medicaid Services (CMS) to provide fraud, waste and abuse (FWA) training to their employees on, at a minimum, an annual basis.

Effective January 1, 2009 this requirement was broadened to require that all Sponsors ensure that employees of first tier, downstream and related entities also receive FWA training on, at a minimum, an annual basis.

On April 15, 2010 CMS released an extensive set of final regulations that among many other issues re-affirmed and clarified this training requirement. This is an important issue to pharmacy benefit managers (PBMs) as Part D Sponsors may wish to delegate the training responsibility in their pharmacy services contract to the PBM.

To Whom Does the FWA Training Requirement Apply?

The scope of the training requirement is all Medicare Advantage programs. In terms of Part D, this includes Medicare Advantage Prescription Drug Plans (MAPD) and stand alone Prescription Drug Plans (PDP). For the balance of this whitepaper, the term Part D Sponsor will be used to represent both MAPDs and PDPs.

A first tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D Sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D. In terms of the Part D program, this would most commonly be a PBM who contracts with the Part D Sponsor.

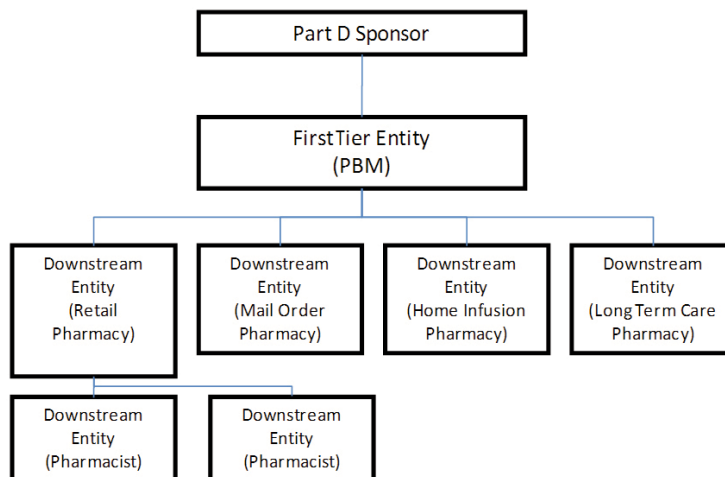
A downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D Sponsor or applicant and a first tier entity. These written arrangements continue

down to the level of the ultimate provider of both health and administrative services. For the Part D program, this would include all of the types of pharmacies needed to have a compliant network (i.e., retail – chain and independent, mail order, home infusion and long term care.)

The term downstream also extends to pharma-

cists employed by the pharmacies.

These relationships are presented in the diagram shown here.



Related entity means any entity that is related to the Part D Sponsor by common ownership or control and:

1. Performs some of the Part D Sponsor's management functions under contract or delegation;
2. Furnishes services to Medicare enrollees under an oral or written agreement; or
3. Leases real property or sells materials to the Part D Sponsor at a cost of more than \$2,500 during a contract period.

It is important to note that the Part D Sponsor does not need to directly train its first tier, downstream and related entities. However, the Sponsor needs to assure that such training has occurred. The first deadline for obtaining that assurance was December 31, 2009. From that point forward, FWA training is at a minimum an annual requirement.

CMS has provided two exceptions for when a Part D Sponsor does not need to assure that the training has occurred:

1. First tier, downstream, and related entities who have met the FWA certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for FWA.
2. First tier, downstream, and related entities who have met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for FWA.

These exceptions are of more use to Part C program requirements since in general, pharmacists will not be covered by either exception.

In the April 15, 2010 set of regulations CMS clarified that "training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member." This expands the scope of the requirement to include new hires at contract initiation in addition to annual training. The regulation specifically references key management and policy making body positions. In 2009, CMS placed a large national managed

care plan on a corrective action plan (CAP) because it was not clear that the plan's board understood its role as it related to oversight of compliance activities.

The requirement for FWA training is not limited to clinical staff. CMS has made it clear that the requirement includes all staff, including administrative and clinical personnel. To the extent that first tier, downstream or related entities use contractors to complete any of their responsibilities, then those contractors are also "downstream" and fall within the requirements for FWA training.

A Part D Sponsor may delegate responsibility for the training to a PBM or other entity, but the Sponsor may never delegate accountability. The Part D Sponsor is accountable to CMS for all compliance and compliance-related activities. When delegation occurs, Part D Sponsors must have an audit process in place to assess compliance with the training requirements. PBMs should have a structure in place for responding to such audits. A Part D Sponsor being audited by CMS must be able to prove that the required training has taken place. Proof of training may be completed attestations or logs from training sessions. Depending on who and how training is conducted, individual sign-off sheets may be completed or an organization-wide attestation may be completed.

Failure of a Part D Sponsor to prove the required training will result in the Sponsor being placed under a corrective action plan by CMS. A special challenge for PBMs is that they often contract with multiple Part D Sponsors. If they have a single client who fails a CMS audit, CMS might decide to complete ad hoc audits of other clients of the PBM and broaden the compliance concerns.

Compliance Program Requirements and FWA Training

CMS requires all Part D Sponsors have a compliance program in place and that all Sponsor employees receive training on the program. The requirement for the first tier, downstream and related entity FWA training program sits within the training requirement of the overall compliance program.

Chapter 9 of the Prescription Drug Benefit Manual provides guidance for Part D Sponsors regarding the seven elements of a compliance program. The elements are:

- 1. Written policies, procedures, standards of conduct and a plan to identify and respond to FWA issues.**

The Part D Sponsor must have written policies, procedures and standards of conduct that state the Sponsor's commitment to comply with all applicable Federal and State and other requirements related to the Medicare program. CMS considers this documentation to be a critical component of a comprehensive program to detect, prevent and control FWA. The Sponsor's senior management should communicate a strong organizational commitment to compliance standards and ethical corporate behavior. CMS believes that having written standards in place along with a strong commitment by senior management can help mitigate the risks associated with the Part D program.

2. Designation of a compliance officer and compliance committee.

The Part D Sponsor must designate a compliance officer and compliance committee that is accountable to senior management. Sponsors must have a compliance officer and compliance committee in place and this function may not be subcontracted.

3. Effective training and education.

The Part D Sponsor must provide effective training and education between the Part D Compliance Officer and organization employees, subcontractors, agents, directors, first tier, downstream and related entities who are involved in the Part D benefit.

4. Effective lines of communication.

The Part D Sponsor must have a system in place to receive, record, and respond to compliance questions, or reports of potential or actual non-compliance from employees, contractors, agents, directors and first tier, downstream and related entities while maintaining confidentiality, allowing anonymity if desired (e.g. through telephone hotlines or mail drops), and ensuring non-retaliation against callers. Sponsors must establish a system that fosters effective lines of communication between the Compliance Officer and the organization's employees, subcontractors, agents, directors, first tier, downstream and related entities and members of the compliance committee

regarding how to report compliance concerns and suspected or actual misconduct. An organization that fosters open communication can be highly effective at identifying, reporting and mitigating misconduct under the Part D benefit.

5. Enforcement of standards through disciplinary actions.

The Part D Sponsor must enforce standards through well-publicized disciplinary guidelines. Enforcement of standards is an essential element of a compliance plan and is essential to the Sponsor's efforts to prevent, detect, and reduce FWA.

6. Internal monitoring and auditing procedures.

The Part D Sponsor must maintain effective internal monitoring and auditing procedures. An internal monitoring and auditing program will help protect the Medicare program and beneficiaries from Part D FWA and may help reduce the Sponsor's, first tier, downstream, and related entities' liability resulting from potentially fraudulent, abusive or wasteful activities. Procedures for internal monitoring and auditing should test and confirm compliance with the Part D benefit regulations, CMS guidance, contractual agreements, and all applicable state and federal laws, as well as internal policies and procedures to protect against potential FWA.

7. Procedures to ensure prompt response and corrective action for detected offenses.

The Part D Sponsor 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 regardless of where the misconduct occurred, i.e., at the level of the Sponsor or its first tier, downstream, or related entities. Potential instances of FWA may come to the attention of the Part D Compliance Officer or other members of senior management through a number of sources (e.g., employee or beneficiary complaints, audits).

What FWA Training Should Include

Every entity that is involved with the Part D program should adopt and implement its own compliance program that reduces the risk of FWA. The actual compliance program can be scaled to the size of an organization. For example, a large multi-state chain of retail pharmacies will have a more layered compliance structure vs. a single site local retail pharmacy. The actual requirements are no different for the large retail chain as compared to the local pharmacy.

CMS has clarified that Part D Sponsors may either provide the FWA training directly, provide appropriate training materials to its delegated and contracted entities or delegate training to the downstream entity. As stated previously, regardless of how training is structured, the Part D Sponsor is responsible for ensuring that the training meets CMS requirements and that it gets done.

Topics that should be addressed in a FWA training program include:

- Laws and regulations related to FAW (i.e., False Claims Act, Anti-Kickback statute, Beneficiary Inducement, HIPAA, etc);
- Obligations of the first tier, downstream, and related entities to have appropriate policies and procedures to address FWA;
- Process for reporting to the Part D Sponsor suspected FWA in first tier, downstream, and related entities;
- Protections for employees of first tier, downstream, and related entities who report suspected FWA;
- Types of FW that can occur in first tier, downstream, and related entities.

This represents a broad list of topics and is not intended to include all topics that could be addressed in FWA training. Additional topics that are generally included in FWA training are facts about the Part D Sponsor's compliance program such as purpose, scope, etc., real world examples of FWA and penalties and sanctions related to FWA. Because the scope of potential FWA activities is very broad, the examples can include FWA based on actions taken by providers, beneficiaries, Part D Sponsors and suppliers.

While CMS mandates training in the FWA subject area, CMS has not mandated a particular level of exhibited proficiency. For comparison, independent sales agents are only permitted to sell Medicare Advantage products if they have completed training and passed an exam showing proficiency of 85% or greater. In the FWA area, in lieu of a particular score, upon completing a course, students may be tested on their understanding of the material and then acknowledge that they will comply with the policy. What's more, an organization might consider going beyond the minimum requirements to ensure that course material was truly understood.

To date, CMS has not certified or given a "seal of approval" to any FWA courses. Some vendors have indicated that their courses are "certified". This means that the vendor, not CMS, has certified the content of the courses. CMS has been asked to consider developing a Web-based compliance course, but has not committed to doing so.

How to Handle the Redundancy?

As many first tier and downstream entities have relationships with multiple Part D Sponsors, CMS has recognized the potential burden associated with taking training from multiple organizations. Most markets include a dozen or more national and local Part D Sponsors. CMS allows Sponsors to either provide the training or obtain attestations that each required individual has received the needed training. If attestations are used, the Sponsor needs to be assured that the training included the required scope. Some Sponsors have included the scope as part of the attestation document. Training logs and attestations must be available for audit by CMS.

To reduce redundancy, a structure that allows cooperation across Part D Sponsors and PBMs is appropriate. This would require multiple organizations to agree on content and then have a structure so that attestations can be shared. The managed care industry already has an existing structure for this type of cooperation. Certification Verification Organizations (CVO) exists so providers do not need to provide the same credentialing support documentation multiple times. A similar structure could be used for managing the first tier, downstream and related entity FWA training and attestation process.

Resources

Online Information Resources

- CMS Prescription Drug Benefit Manual – Chapter 9
http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf

- Code of Federal Register (see 42 CFR 422.503 and 42 CFR 422.504)
<http://www.gpoaccess.gov/cfr/>

- Office of the Inspector General
<http://www.oig.hhs.gov/fraud.asp>

- Medicare Learning Network (MLN) Fraud & Abuse Job Aid
http://www.cms.gov/MLNProducts/downloads/110107_Medicare_Fraud_and_Abuse_brochure.pdf

PBMI and Kaplan EduNeering Relationship

The Pharmacy Benefit Management Institute (PBMI) and Kaplan EduNeering formed an alliance to provide online learning solutions for professionals involved in the delivery of drug benefit programs.

Pelorus Management Consultants

Pelorus Management Consultants (PMC) serve as the subject matter experts for a number of Kaplan EduNeering's Medicare, HIPAA and compliance courses. PMC also works with many Medicare and Medicaid health plans on a range of issues including start-up, expansion, training, CMS mock audits, corrective action plans, proposal responses and regulatory interaction.

More information regarding PMC LLC may be obtained from the PMC web site: www.pmcinfo.com, or by sending an e-mail to Albert@pmcinfo.com or calling 973.992.2626. PMC consultants are prepared to help organizations meet CMS and state regulatory requirements and deadlines. They have done so for over 40 clients ranging from start-up health plans to national firms with millions of members.

Kaplan EduNeering Healthcare Compliance Training

Kaplan EduNeering's award-winning Web-based Platform includes a learning management system and a variety of learning tools used by more than 40 healthcare organizations to help them achieve these benefits:

- Meet compliance with changing regulatory requirements;
- Foster a workplace learning culture, focused on individual performance improvement;

Resources (Continued)

- Gain access to audit-ready reports for audits and inspections;
- Improve global partner, subcontractor and supplier performance;
- Increase operational efficiency;

Through the Kaplan EduNeering Platform, compliance and training managers can distribute training simultaneously to all recipients according to a client-determined schedule. The system simplifies the training management process for administrators and trainers, as it automates refresher assignments and enables trainers to build curricula of tasks for end users, managers and even suppliers.

Kaplan EduNeering's Healthcare libraries include:

- **General Compliance Library:** training to meet federal requirements for healthcare organizations, while supporting the need for a consistent corporate message, dependable employee performance, and adherence to company policies and procedures.
- **Medicare Advantage Library:** training for Medicare Advantage Organizations (MAOs) to meet regulatory and corporate policy requirements and goals.
- **HIPAA Library:** training for compliance with requirements of the federal Health Insurance and Portability Accountability Act of 1996.
- **Medicare Part D Library:** training for compliance with requirements of The Centers for Medicare & Medicaid Services and the US Department of Health and Human Services Office of Inspector General; helps employees perform their department-specific functions successfully.
- **Ethics & Corporate Responsibility Library:** training for compliance with Code of Conduct, Conflict of Interest, Federal Sentencing Guidelines, and other best practices for corporate conduct.

Pharmacy Benefit Management Institute

The Pharmacy Benefit Management Institute (PBMI) provides research and education to help drug benefit plan sponsors work effectively with pharmacy benefit managers to improve benefit performance.

Kaplan EduNeering's compliance training libraries are available through the PBMI web site (www.pbmi.com) to individuals and small groups who may not have access to enterprise-wide training.

PBMI's conference and Webcast programs also help professionals involved in managing Medicare Part D and commercial group drug plans to improve their benefit programs while achieving compliance with government regulations. Other PBM resources include benchmarking research reports and white papers.

About Kaplan EduNeering

Kaplan EduNeering (www.kaplaneduneering.com) is part of Kaplan, Inc., a worldwide education services leader and a subsidiary of The Washington Post Company (NYSE: WPO). Kaplan EduNeering develops technology-enabled knowledge solutions for improving business performance and assuring regulatory compliance.

For more than 27 years, the company has served corporate and government clients in the life sciences, healthcare, energy and industrial sectors using proprietary platforms that integrate business, learning and technology. Additionally, Kaplan EduNeering maintains several unique partnerships with its clients, including a Cooperative Research and Development Agreement with US Food and Drug Administration.

Headquartered in Princeton, NJ, Kaplan EduNeering has offices in Houston, TX; Bloomsburg, PA; and the UK.

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