DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4-23-07
Baltimore, Maryland 21244-1850

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Date: December 28, 2015

To: All Medicare Advantage Organizations and Prescription Drug Plan Sponsors

From: Gerard Mulcahy, Director
Medicare Parts C and D Oversight and Enforcement Group

Subject: Additional Guidance – Compliance Program Training Requirements and Audit Process Update

On June 17, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a Health Plan Management System (HPMS) memo entitled "*Update - Reducing the Burden of the Compliance Program Training Requirements.*" The memo provided guidance about the requirement to accept completion of CMS' compliance training module on the Medicare Learning Network (MLN) as meeting the Compliance Program Effectiveness (CPE) training requirement effective January 1, 2016.

CMS continues to receive inquiries and concerns from sponsors and first tier, downstream and related entities (FDR) regarding the difficulties with adopting CMS' compliance training module to satisfy the compliance program training requirement. Many Medicare Advantage (MA) and Part D Sponsors identify most or all of their vendors as FDRs requiring Medicare compliance training. In addition, each of those sponsors has organization or FDR-specific compliance training that they require their contracted entities to take as a term of their contract. Therefore, FDRs are still being subjected to multiple compliance trainings, but now have an additional burden of taking CMS training and reporting completion back to the sponsor or sponsors with whom they contract. Therefore, the industry has indicated that the requirement implemented intending to reduce the training burden has instead potentially increased the burden for some providers and sponsors.

In response to these concerns, and in order to allow sufficient time to implement and adjust to this new requirement, CMS is suspending review of the training certification element in the CPE program audit protocol (Element #3). Sponsors will not be required to provide the documentation requested in the 2015/2016 Part C and D CPE Audit Process and Data Request – *VII. Sponsor's Accountability For and Oversight of FDRs – Bullet # 6.* All other elements of the CPE protocol will continue to be audited.

In addition, CMS is also providing guidance, allowing flexibility in the implementation of the new compliance training requirement.

What are the Compliance Program Training Requirements?
Sponsors must ensure their FDRs receive general compliance training as well as fraud, waste, and

abuse (FWA) training. The CMS compliance program training was designed to ensure: (1) Sponsors' FDRs have at least a basic knowledge and understanding of compliance program requirements; and, (2) Sponsors' FDRs are knowledgeable about compliance and FWA issues and how to appropriately address them.

CMS developed a web-based compliance training module, which was recently redesigned. The general compliance and FWA training courses now offer the ability to earn continuing education credit, provide separate content for compliance and FWA, and provide web-based and downloadable versions. The training content is generic since various entities (e.g., health plans, labs, hospitals, etc.) complete the training. A certificate of completion is generated upon passing a short test with a score of 70% or higher at the end of the training module. Training courses will be available on the CMS MLN: http://www.cms.gov/MLNProducts

Methods for Completing the Training

Sponsors and/or FDRs will have three (3) options for ensuring FDRs have satisfied the general compliance training requirement:

(1) FDRs can complete the general compliance and/or FWA training modules located on the CMS MLN. Once an individual completes the training, the system will generate a certificate of completion. The MLN certificate of completion must be accepted by Sponsors.

(2) Sponsors and FDRs can download and incorporate the content of the CMS standardized training modules from the CMS website into their organizations' existing compliance training materials/systems.

(3) Sponsors and FDRs can incorporate the content of the CMS training modules into written documents for providers (e.g. Provider Guides, Participation Manuals, Business Associate Agreements, etc.).

Although the training content cannot be modified, CMS will allow modifications to the appearance of the content (i.e. font, color, background, format, etc.). Additionally, organizations may enhance or wrap around the CMS training content by adding topics specific to their organization or the employee's job function. At the Sponsor's request, FDRs must submit an attestation confirming that the organization has completed the appropriate general compliance and FWA training. Attestations must include language specifying the entity complies with CMS compliance and FWA training requirements and the training provided includes CMS content. The format of the attestation may vary depending on the Sponsor. FDRs should check with Sponsors for options on how to submit attestations, as the sponsor may have a specific process or document to be completed.

Who Must Complete The Training?

Section 40 of the Compliance Program Guidelines, located in Pub. 100-18, Chapter 9 of the *Medicare Prescription Drug Manual* and Chapter 21 of Pub. 100-16, the *Medicare Managed Care Manual* has an enumerated list of factors to consider in determining whether an entity is an FDR.

We strongly encourage Sponsors to use discretion when developing the criteria for determining whether an entity is an FDR. Further, while FDRs are required to comply with CMS requirements, including the compliance program training requirements, CMS does not expect an FDR's entire staff would necessarily be subject to the requirement.

In order to prevent unnecessary burden on FDRs, Sponsors should work with their FDRs and specify which positions within an FDR must complete the training. There will be certain FDRs where not every employee needs to take the training based on their duties.

Below are examples of the critical roles within an FDR that should clearly be required to fulfill the training requirements:

Positions/Roles

- Senior administrators or managers directly responsible for the FDR's contract with the Sponsor (e.g. Senior Vice President, Departmental Managers, Chief Medical or Pharmacy Officer);

- Individuals directly involved with establishing and administering the Sponsor's formulary and/or medical benefits coverage policies and procedures;

- Individuals involved with decision-making authority on behalf of the Sponsor (e.g. clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims);

- Reviewers of beneficiary claims and services submitted for payment; or,

- Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA.

Please note, FDRs deemed to have met the FWA training and education certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are NOT exempt from the general compliance training requirement.

When Should The Training Be Completed?
The training must occur within 90 days of initial hiring and annually thereafter. The annual training can be completed any time between January 1 – December 31 of any given contract year.

To reiterate, CMS is suspending review of the training certification element in the CPE audit protocol until further notice to allow time for Sponsors and FDRs to modify systems and processes to comply with this training requirement.

Please direct additional questions, comments or inquiries related to this guidance to: Parts_C_and_D_CP_Guidelines@cms.hhs.gov.