50.3 – Element III: Effective Training and Education (Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12) (Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-

42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

12)

The sponsor must establish, implement and provide effective training and education for its employees, including the CEO, senior administrators or managers, and for the governing body members, and FDRs.

The training and education must occur at least annually and be made a part of the orientation for new employees, including the chief executive and senior administrators or managers, governing body members, and FDRs.

FDRs 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 fraud, waste, and abuse.

Effectiveness of Training and Education

Effectiveness of training, education, compliance policies and procedures, and Standards of Conduct will be apparent through sponsor's compliance with all Medicare program requirements. Sponsors must ensure that employees are aware of the Medicare requirements related to their job function.

50.3.1 – General Compliance Training

(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

The sponsor's employees (including temporary workers and volunteers), and governing body members, must, at a minimum, receive general compliance training within 90 days of initial hiring, and annually thereafter. The following are examples of how sponsors may satisfy the general compliance training requirements:

- Classroom training;
- Online training modules; or
- Attestations that employees have read and received the sponsor's Standards of Conduct and/or compliance policies and procedures.

Sponsors must be able to demonstrate that their employees have fulfilled these training requirements. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.

Sponsors must ensure that general compliance information is communicated to their FDRs. The sponsor's compliance expectations can be communicated through distribution of the sponsor's Standards of Conduct and/or compliance policies and procedures to FDRs' employees. Distribution may be accomplished through Provider Guides, Business Associate Agreements or Participation Manuals, etc.

Sponsors should review and update, if necessary, the general compliance training whenever there are material changes in regulations, policy or guidance, and at least annually.

The following are examples of topics the general compliance training program should communicate:

- A description of the compliance program, including a review of compliance policies and procedures, the Standards of Conduct, and the sponsor's commitment to business ethics and compliance with all Medicare program requirements;
- An overview of how to ask compliance questions, request compliance clarification or report suspected or detected noncompliance. Training should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of suspected or detected noncompliance or potential FWA;

- The requirement to report to the sponsor actual or suspected Medicare program noncompliance or potential FWA;
- Examples of reportable noncompliance that an employee might observe;
- A review of the disciplinary guidelines for non-compliant or fraudulent behavior.
 The guidelines will communicate how such behavior can result in mandatory
 retraining and may result in disciplinary action, including possible termination
 when such behavior is serious or repeated or when knowledge of a possible
 violation is not reported;
- Attendance and participation in compliance and FWA training programs as a condition of continued employment and a criterion to be included in employee evaluations;
- A review of policies related to contracting with the government, such as the laws addressing gifts and gratuities for Government employees;
- A review of potential conflicts of interest and the sponsor's system for disclosure of conflicts of interest:
- An overview of HIPAA/HITECH, the CMS Data Use Agreement (if applicable), and the importance of maintaining the confidentiality of personal health information;
- An overview of the monitoring and auditing process; and
- A review of the laws that govern employee conduct in the Medicare program.

See Appendix B for other examples of laws and regulations that may be discussed in training.

50.3.2 – Fraud, Waste, and Abuse Training

(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

The sponsor's employees (including temporary workers and volunteers), and governing body members, as well as FDRs' employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs), and annually thereafter. Additional, specialized or refresher training may be provided on issues posing FWA risks

based on the individual's job function (e.g., pharmacist, statistician, customer service, etc.). Training may be provided:

- upon appointment to a new job function;
- when requirements change;
- when employees are found to be noncompliant;
- as a corrective action to address a noncompliance issue; and
- when an employee works in an area implicated in past FWA.

Sponsors may choose to tailor the training in response to circumstances surrounding potential FWA and specific functions performed by FDRs.

Sponsors must be able to demonstrate that their employees and FDRs have fulfilled these training requirements as applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.

Sponsors must provide the FWA training directly to their FDRs or provide appropriate FWA training materials to their FDRs.

To reduce the potential burden on FDRs, CMS has developed and provided a standardized FWA training and education module. The module is available through the CMS Medicare Learning Network (MLN) at http://www.cms.gov/MLNProducts. Using CMS' training module is optional and a sponsor may use another method. However, this training meets CMS' FWA training requirements so sponsors should accept FDRs' use of this FWA training option. For details on accessing the FWA training and education on the MLN website, see the May 8, 2012, HPMS memo regarding Fraud, Waste and Abuse Training and Education Guidance.

Topics that should be addressed in FWA training include, but are not limited to the following:

- Laws and regulations related to MA and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.);
- Obligations of FDRs to have appropriate policies and procedures to address FWA;
- Processes for sponsors and FDR employees to report suspected FWA to the sponsor (or, as to FDR employees, either to the sponsor directly or to their employers who then must report it to the sponsor);
- Protections for sponsor and FDR employees who report suspected FWA; and

Types of FWA that can occur in the settings in which sponsor and FDR employees work.

Sponsors are accountable for maintaining records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered to their employees, and must require FDRs to maintain records of the training of the FDRs' employees.

FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are deemed to have met the FWA training and education requirements. No additional documentation beyond the documentation necessary for proper credentialing is required to establish that an employee or FDR or employee of an FDR is deemed. In the case of chains, such as chain pharmacies, each individual location must be enrolled into Medicare Part A or B to be deemed. See examples of such entities in Pub. 100-16, Medicare Managed Care Manual, chapter 6 §70.