

4.02 Compliance Training

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Seven Elements of an Effective Compliance Program

- Implementing written policies and procedures
- Compliance officer and compliance committee
- **CONDUCTING EFFECTIVE TRAINING AND EDUCATION**
- Developing effective lines of communication
- Conducting internal monitoring and auditing
- Enforcing standards through well-publicized disciplinary guidelines
- Responding to problems and undertaking corrective action

Compliance Training

OIG Guidance

“The proper education and training of officers, directors, employees, contractors, and agents, and periodic retraining of personnel at all levels are critical elements of an effective compliance program.”

Summary of Presentation

- Topics
- Personnel
- Format
- Timing
- Documentation

Topics of Training

- General Sessions
- Specific Sessions

Topics of Training

- General Sessions:
 - Your compliance program
 - Written policies and procedures
 - Applicable federal requirements

Topics of Training

- Specific Sessions:
 - Anti-kickback statute
 - Calculation and reporting of pricing information
 - Calculation and reporting of rebate payments

Topics of Training

- How do you know what specific areas to train on?
 - Government enforcement activities
 - Past compliance issues
 - Internal auditing and monitoring activities
 - Helpline / Hotline calls
 - Questions from employees

Topics of Training

- Corporate Integrity Agreements
 - General Training
 - CIA requirements
 - Compliance Program
 - Specific Training
 - Proper methods for promoting, marketing, selling products in accordance with applicable statutes and regulations
 - Personal obligation of each individual involved in marketing and sales to ensure that marketed and sold appropriately
 - Applicable legal rules
 - Examples of proper/improper promotion, marketing, and sales practices

Topics of Training

- Example-centered training
 - Relevancy to job function
 - Engaging content
 - Keep the training fresh

Personnel to Train

OIG Guidance

“The OIG suggests that all relevant personnel (*i.e.*, employees as well as agents of the pharmaceutical manufacturer) participate in various educational and training programs of the company.”

Personnel to Train

- Positions
- Functions
- Responsibilities

Personnel to Train

- Corporate Integrity Agreement – TAP
 - Covered Persons
 - “officers, directors, employees, contract workers, and agents working at TAP’s facilities”
 - “specifically includes all other personnel, apart from those acting under co-promotion agreements, who comprise TAP’s contract sales force, if any.”

Personnel to Train

- Corporate Integrity Agreement – Abbott
 - Covered Persons
 - Directors
 - Officers and employees engaging in marketing and sales
 - Officers and employees of a particular business unit
 - Relevant Covered Persons
 - Covered Persons engaged in the marketing and sales of the product at issue

Personnel to Train

- Corporate Integrity Agreement – AstraZeneca
 - Covered Persons
 - All officers, employees, and contractors/agents whose job responsibilities relate to:
 - Sales and marketing activities for gov't reimbursed products
 - Calculating and reporting of prices
 - Negotiation, implementation, and any reporting related to gov't contracts

Contractor Training

OIG Guidance

“All employees and, where feasible and appropriate, contractors should receive the general training.”

Contractor Training

- Corporate Integrity Agreements – TAP, Bayer & GSK
 - Covered Persons
 - specifically contract sales force

Contractor Training

- Employment Law Issues
 - Differential training
 - Content
 - Detail
 - Train select contractors
 - Sales force – YES
 - Others – DEPENDS

Format of Training

OIG Guidance

“The OIG recognizes that the format of the training program will vary depending upon the size and resources of the pharmaceutical manufacturer.”

Format of Training

- Live
- Computer-based training
- Videotape
- Video/audio conferencing

Format of Training

- Live training – who delivers?
 - Compliance Officer
 - Legal
 - Company trainers
 - Supervisory employees
 - Outside consultants

Format of Training

- Corporate Integrity Agreement – GSK
 - “training and education . . . may be provided by supervisory employees, knowledgeable staff, or GlaxoSmithKline trainers and/or outside consultant trainers”
 - Trainers “shall be knowledgeable about the subject areas of their training”

Format of Training

- Live training – multiple messengers?
 - Consistency of message
 - Competency to answer questions

Format of Training

- Computer-based training vendors
 - Off-the-shelf training
 - Semi-custom
 - Custom

Format of Training

- Other avenues
 - Intranet
 - Newsletters
 - One-on-one (e-mails / voicemails)

Timing of Training

OIG Guidance

“The pharmaceutical manufacturer should train new employees soon after they have started working.”

Timing of Training

- Corporate Integrity Agreements
 - Initial training
 - Within 30 days after beginning employment
 - Bayer / GSK / Abbott
 - Within 60 days after beginning employment
 - TAP / AstraZeneca
 - Annual training
 - Specified amount of time
 - “reasonable and appropriate”

Documentation of Training

OIG Guidance

“The compliance officer should document any formal training undertaken by the company as part of the compliance program.”

Documentation of Training

- Attendance logs
- Descriptions of the training sessions
- Copies of the materials distributed at the training sessions

Documentation of Training

- Certification
 - All employees should certify:
 - Have received the training
 - If based on a policy/procedure, should certify:
 - Received
 - Read
 - Understand
 - Will comply

Documentation of Training

- Corporate Integrity Agreements
 - “Each individual who is required to attend training shall certify, in writing, or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer . . . shall retain the certifications, along with all course materials.”

Questions?

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