



Compliance Program Implementation

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LifeScience Alley

Agenda

- ▶ Introduction
 - Compliance Requirements: Federal & State
- ▶ How do you approach compliance?
 - What does a company need to do to comply?
- ▶ Example
 - Start-up company (less than 20 employees)
- ▶ Review Best Practices

Federal “Sunshine Act”

- ▶ Government concern about where \$ are going & the accuracy and integrity of “government price” with detailed exploration of
 - ▶ Distribution channels, Contracting relationships, Financial relationships with healthcare providers (HCP), Sales Rep practices, On-Label and Off-Label Promotional Activities
- ▶ Companies must report Physician Payments including:
 - ▶ transfers of value > \$10 and payments >\$100 annually
- ▶ Effective Date: March 31, 2013
- ▶ ***To Comply: Understand specifics and develop a corporate compliance culture (i.e. Code of Conduct)***

State Compliance Reporting

- ▶ Differences exist among states for: payments allowed to health care providers (HCPs), reporting requirements, public disclosure practices, filing fees (\$0-2500/year) and penalties/fines (\$0-10,000)
- ▶ Vermont and Massachusetts appear to have more rigid requirements than the Sunshine Act
- ▶ ***To Comply: Track, flag and report payments in each unique situation and follow Standard Operating Procedures (SOPs)***

EXAMPLE: MN Reporting Requirements

- ▶ Must report if payments exceed \$100 annually for:
 - Payments to sponsors of conferences or other educational programs
 - Reasonable honoraria and expenses for faculty
 - Compensation for consulting services.
- ▶ Payments to HCPs must be less than \$50 total value annually for
 - Gifts
 - Meals
 - Entertainment
- ▶ Must report compensation for substantial:
 - Clinical Trials
 - Research Projects
- ▶ **Tracking these details is expensive & time consuming**



How do you approach compliance?

- ▶ Where do you start?
- ▶ How do you obtain management buy in and get them organized?
- ▶ What's your focus (general corporate v. FDA advertising and promotion/Anti-Kickback/False Claims)? Or All of it?
- ▶ How do you prioritize?
 - Analyzing the enforcement landscape for your business
 - Practical implications of documenting activities
 - The value and importance of monitoring and auditing

Example: OVERVIEW

- ▶ First, discuss concerns
 - bring in trainers to help frame up concerns
 - propose solutions to address concerns
- ▶ Then, develop solutions
 - Written corporate code of conduct documents
 - Slide shows and training tools
 - SOPs based on SOP drafts from various third party vendors (including lawyers)
- ▶ Finally conduct the training and expect compliance
 - Answer questions and retrain as needed
 - Monitor and audit the system to ensure the system is working
 - Continue development of the system

Step 1: Where to Start?

- ▶ Small company started with Code of Conduct
 - Train with multiple vendors to understand “all” issues
 - lawyers, 3rd party vendors, government compliance implementation experts, links to government pricing
 - Develop/Issue written Code of Compliance document
 - Linked to Quality System Standard Operating Procedures
 - Ensure abbreviated code is on website to comply w/CA law
- ▶ Appoint Compliance Officer & Committee Members
 - To oversee compliance program
 - To conduct compliance committee activities
 - To review and improve program as needed

Step 2: Any Concerns?

- ▶ How to invigorate sales force while removing trinkets, meals and entertainment from their toolbox?
 - FOCUS ON PRODUCT - not pens, dinner or sports events
 - COMPLIANCE IS REQUIRED – resistance should be futile
- ▶ How to avoid unnecessary legal battles?
 - Get Standard Operating Procedures (SOPs) in place
- ▶ How to balance tracking effort (cost)?
 - Choose sensible tools/processes (current and future needs)
 - Understand Risk:Benefit ratios
 - Cover the biggest risks and work on the others

Step 3: Specific Valued Items?

- ▶ Gifts
- ▶ Entertainment
- ▶ Travel expenses
- ▶ Consulting fees
- ▶ Research funding or grants
- ▶ Honoraria
- ▶ Charitable contributions
- ▶ Educational funding
- ▶ Direct compensation provided to faculty members of educational seminars
- ▶ Collaborative research
- ▶ Ownership or investment interest held by physician in company
- ▶ Royalties
- ▶ Licensing fees
- ▶ Dividends
- ▶ Profit distribution
- ▶ Stock or stock option grants
- ▶ Additions the Secretary of Health & Human Services deems appropriate.

To Comply: Develop Standard Operating Procedures for each of these

Example: OBSERVATION

- ▶ The trick to preparing written SOPs based on SOP drafts from various third party vendors (including lawyers) was to make the language readable and appropriate for our business. Then, we needed our staff to review and revise the documents to ensure they were compatible with our operations and quality system and finally we needed senior management approval to give the content/program an effective date.

Step 4: Training & Communication

▶ Training

- What is the Code of Conduct?
- How does this training apply to me?
- What do I need to be careful about?
- How do I track my activities?
- Where do I find the SOPs, work instructions and forms when I need them?
- What disciplinary actions might occur if I am not compliant?

▶ Communication

- Ask questions to assess comprehension
 - Answer questions and require compliance
 - Explain changes to the program to all staff as the program evolves
 - Frequently discuss how to maintain compliance and give examples of best practices
- ▶ Compliance officer & committee to discuss emergent issues with senior management as they occur

Example: DOCUMENTATION

- ▶ Many vendors provide services to assist with data collection for compliance issues but these may be cost prohibitive (takes revenue to cover cost; perceived as reducing profit)
- ▶ Getting accurate and timely reporting from the field is CHALLENGING! (requires accurate, verifiable data; documentation takes time away from selling)
- ▶ Small Company may use Excel spreadsheet
 - Capture sales, marketing, management \$ to individual HCPs*
 - Time intensive, no cost to start
 - Plan for future system

*HCP=Health Care Professional who can influence use of the product

Step 5: Monitoring & Auditing

▶ Monitoring

- Monthly roll up reporting may be helpful
- Quarterly management review is recommended
- Annual reporting is required

▶ Auditing

- As with all quality systems, a rigorous program of audits is helpful to ensure accuracy and compliance

Address all discovered issues

Communicate ongoing successes and challenges

Revise, retrain, repeat

Review: Best Practices

Seven Fundamental Elements of a Compliance Program

1. Implementing written policies and procedures
2. Designating a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding promptly to detected problems and undertaking corrective action

– The Office of the Inspector General. “OIG Compliance Program Guidance for Pharmaceutical Manufacturers.” Federal Register Vol. 68, No. 86. May 5, 2003.

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Speaker

- ▶ Joy Frestedt, PhD, RAC, CCTI , President /CEO, Frestedt Inc. (www.frestedt.com), a virtual network with 70+ experts meeting client needs in regulatory, clinical and quality affairs.
- ▶ Dr. Frestedt has a PhD in Pathobiology from the University of Minnesota Medical School and over 30 years scientific, clinical and regulatory experience in the health care, pharmaceutical and medical device industries including work at Johnson and Johnson, AstraZeneca, Medtronic, Mayo Clinical Trial Services, Orphan Medical, BridgePoint, Humanetics and CNS Therapeutics.
- ▶ Dr. Frestedt speaks locally, nationally and internationally on topics related to clinical trials, regulatory negotiations, compliance and quality systems. She is a member of ASCO, AAPS, ACRP and currently Chairs the Ethics Committee for the Regulatory Affairs Professionals Society.

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