

Field Force Monitoring

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Agenda

- Background Legislation
- Recent Corporate Integrity Agreement Requirements
- Field Force Monitoring Program Elements
- Potential Future Areas of Required Field Force Monitoring

Background Legislation



Background Legislation

- **False Claims Act** (31 U.S.C. §§ 3729 – 3733)
 - Makes it illegal to defraud the government (i.e. sale of “adulterated” products, over-charging the government, etc.)
- **Federal Anti-Kickback Statute** (42 U.S.C. § 1320a – 7b(b))
 - Makes it illegal to pay or receive anything of value in exchange for business related to federal healthcare programs (i.e. Medicare, Medicaid)
- **Food, Drug and Cosmetic Act** (21 U.S.C. § 301, *et.seq.*)
 - Makes it illegal to sell or offer to sell “adulterated” products (i.e. off-label promotion, expired products, temperature controlled products)
- **Prescription Drug Marketing Act** (P.L. 100 – 293, 102 Stat. 95)
 - Makes it illegal to introduce substandard, ineffective, or counterfeit drugs into the stream of commerce (i.e. expired, counterfeit, or adulterated products)

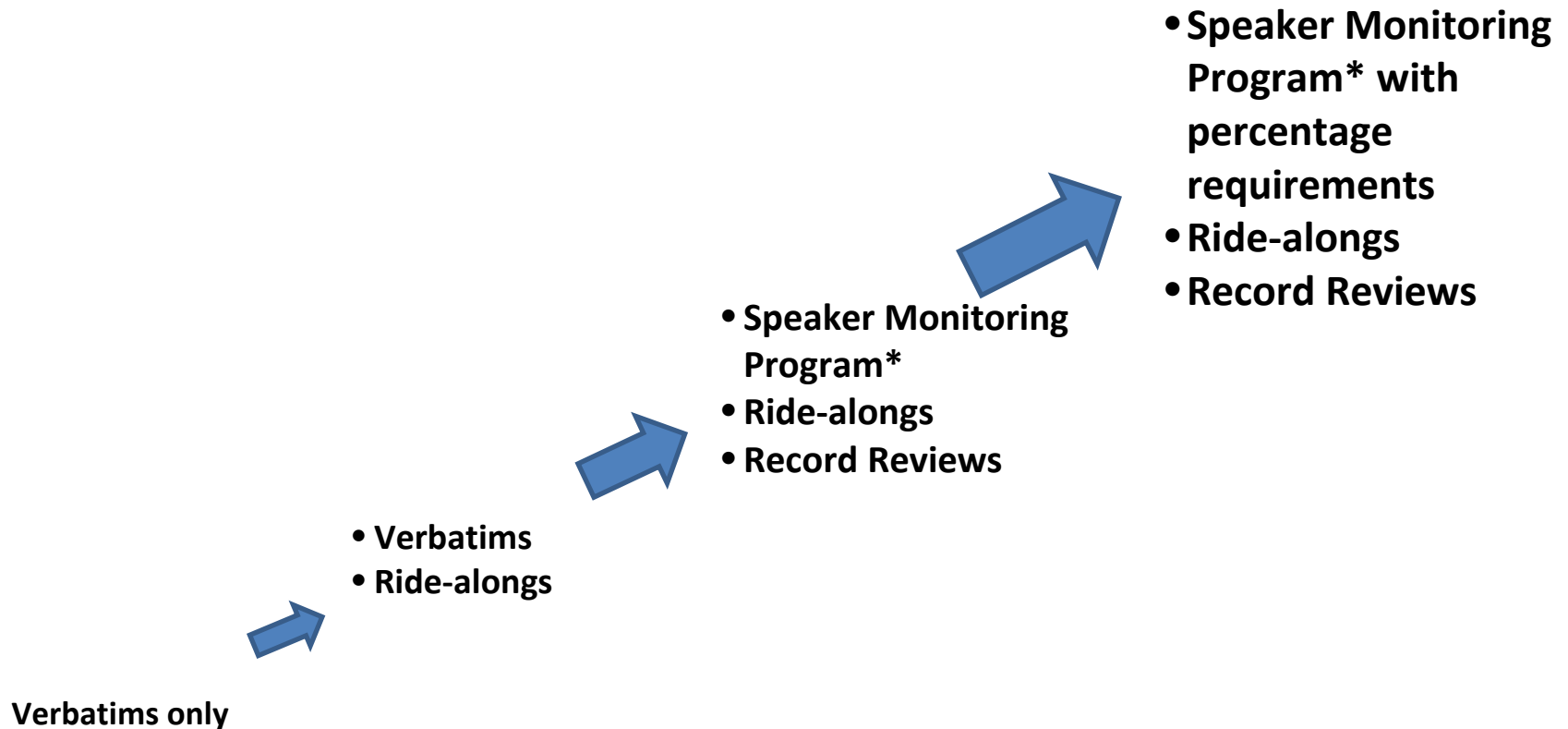
Recent Corporate Integrity Agreement Requirements



Recent CIA Requirements

	CCO	Compliance Committee	BOD Resolution	BOD Compliance Expert	Written Standards	Training	IRO Review	Disclosure Program	Field Force Monitoring	Monitoring of Non-Promotional Activities	Physician Payment Reporting	Additional Transparency Requirements
Lilly	✓		✓		✓	✓	✓	✓	✓ (INCL VERBATUMS)		✓	
Pfizer	✓	✓	✓		✓	✓	✓	✓	✓ (INCL HQ MONITORING)		✓	✓
Biovail Valeant	✓	✓	✓		✓	✓	✓	✓	✓ (VERBATUMS ONLY)		✓	
Cephalon	✓	✓	✓		✓	✓	✓	✓	✓ (INCL VERBATUMS)		✓	
AZ	✓	✓	✓		✓	✓	✓	✓	✓ (INCL VERBATUMS)	✓	✓	✓
NPC	✓	✓	✓	✓	✓	✓	✓	✓	✓ (INCL VERBATUMS)	✓	✓	✓
Allergan	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Forest	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Elan	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
UCB	✓	✓	✓		✓	✓	✓	✓	✓ (INCL VERBATUMS)	✓	✓	✓

CIA Requirements Progression



* - May include Verbatims, if applicable

Field Force Monitoring Program Elements



Field Force Monitoring Program Elements

- Speaker Monitoring Programs
 - » Qualification requirements for approved speakers
 - » Agreements in place
 - » Speaker training
 - » Fee determination (FMV), including hierarchy
 - » Control over speaker materials
 - » Track & evaluate speaker performance (compliance)
 - » Manage speaker use
 - » Aggregate speaker fee caps
 - » Venue
 - » Event cost
 - » Attendee lists (number, specialty, frequency, etc.)

Field Force Monitoring Program Elements

- Observations – Sales Rep Ride-Alongs
 - » Product statements made to HCPs
 - » Handling of HCP inquiries
 - » Potential exchanges of value
 - Approved educational items
 - Approved promotional materials / kits
 - Reimbursement assistance
 - » Handling of samples
 - Frequency
 - Consistency with PI
 - Management of inventory
 - » Handling & use of promotional materials

Field Force Monitoring Program Elements

- Record Reviews

- » Documentation completeness
 - Speaker programs
 - Samples
 - Expense reports
- » Requests for medical information
- » Tutorials & preceptorships
- » Verbatims
- » Sales rep call notes
- » Email & other electronic records
- » Management records



“Connecting the dots”

Potential Future Areas of Required Field Force Monitoring



Potential Future Areas of Required Field Force Monitoring

- Sample Vendor Compliance / Management
- Sample Investigations Process
- E – Detailing
- Vendor Management (Contract Sales Force)
- Reimbursement Services
- Account Team Interactions with Formulary Decision-makers
- Use & Interactions with RMLs / MSLs
- Use of Social Media

Questions / Discussion

