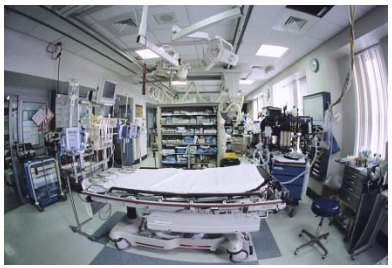
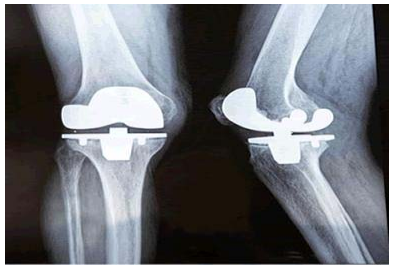
THE TWELFTH ANNUAL Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

TRANSFORMATIONAL LEARNING – EFFECTIVE KNOWLEDGE EXCHANGE

Implementing a CIA: Challenges & Lessons Learned





3:45 p.m. – 4:45 pm

Day II – Thursday, November 3, 2011

Panel Participants

- Daniel Moynihan, Esq., Chief Compliance Officer and Compliance Counsel, EMD Serono
- Scott Memmott, Esq., Partner, Morgan, Lewis & Bockius LLP
- Seth Lundy, Esq., Partner, King & Spalding LLP
- Tracy Mastro, MBA, Director, Huron Life Sciences

Implementing a CIA: Challenges & Lessons Learned

- Covered Persons
- Training and Certifications
- Ineligible Persons Screening
- Policies & Procedures
- Management Certifications
- Board Resolutions
- Compliance Monitoring & Auditing
- Budgeting Plans, Needs Assessments and Fair Market Value
- Key Take-Aways

Implementing a CIA: Challenges & Lessons Learned

- The CIA requirements that will be discussed today are reflective of many of the recent CIAs, but do not reflect any CIA in particular.
- The topics covered today represent the challenges frequently encountered by companies as they prepare for and implement the various requirements of their CIAs.
- Keep in mind most CIAs have a 120-day implementation period, which creates challenges depending on how prepared a company is for its CIA.

Covered Persons

Requirements

- Identify universe of Covered Persons, Relevant Covered Persons and applicable Vendor Covered Persons.
- Important for purposes of providing General and Specific Training, conducting Ineligible Persons screening, and conducting Code of Conduct certifications.

Considerations

- Who will identify Covered Persons, Relevant Covered Persons and get these individuals trained within the specified window of time (generally, 120 days after effective date of CIA)?
- Who will own the process of initial and ongoing identification of a Company's Covered Persons and Relevant Covered Persons?
- Who will own the initial and ongoing identification process of Vendor Covered Persons (i.e., contractors, subcontractors, agents and others who perform Promotional Functions or Product Related Functions "on behalf of" the Company)?
- Who will determine the initial and ongoing identification of Global Employees and Contingent Workers (i.e., part-time or per diem employees, contractors, subcontractors, agents or others, and the 160-hour requirement)?
- Who will identify sources of Covered Persons data (e.g., HR, Line of Business, Procurement, SAP) and compile the necessary information?

Training and Certifications

Requirements

- Develop and deliver training to different audiences (e.g., Board of Directors, employees, vendors)
- Obtain Code of Conduct certifications.

Considerations

- Who is responsible for creating General and Specific Training modules within the required time period (typically 120 days of the CIA Effective date)?
  - Who will be responsible for developing content?
  - Will a vendor be used? If so, who will select vendor?
  - How will training be tailored to different audiences?
- What is the mechanism for delivering the General and Specific training (e.g., is there an electronic delivery system in place)?
  - If so, can the system track those who have completed training?
  - Can it be used to obtain Code of Conduct certifications?
  - Can the system be used to train non-employees (e.g., Vendors)?
- How will training be delivered to Officers and Directors and their certifications obtained?
- How will the company meet ongoing training and certification requirements for new Covered Persons (Company and Vendor), new relevant Covered Persons?

Ineligible Persons Screening

Requirements

- Screen all Covered Persons using Government Exclusion Lists to identify Ineligible Persons.

Considerations

- Who is going to develop the process?
- Who is going to own the process?
- How do you ensure that Vendor Covered Persons are screened?
- What are the procedures for meeting the Removal Requirement?
- Who will be responsible for meeting ongoing screening requirements for new Covered Persons (Company and Vendor) and annual screening requirements?

Policies & Procedures

Requirements

- Review, update and create (where necessary) policies required by the CIA.

Considerations

- Who will coordinate process for identifying all policies that are relevant to CIA and perform a gap analysis on the existing policies? Who will determine what new policies need to be created?
- Who will update existing policies and procedures to reflect CIA requirements? Who will write new policies?
- How will the policies and procedures be implemented and distributed to all Covered Persons (Company and Vendor) within the timeframe required by the CIA?
- How will process and business changes needed to meet the requirements of existing policies and/or new policies be implemented and by whom?
- How will relevant employees be trained on new and revised policies and procedures?

Management Certifications

Requirements

- Identify members of management team who must certify on an annual basis to compliance with all applicable Federal healthcare program requirements, FDA requirements and the obligations of the CIA.
- Determine the information/documents/data (e.g., audits) on which each individual will base their certification of compliance.

Considerations

- Who will identify, notify and train appropriate management Certifying Employees?
- What is the scope of “all applicable” Federal healthcare program and FDA requirements? Does it include pricing, GxP, etc.?
- Who will identify the appropriate types and amount of information to provide Certifying Employees in order to get them comfortable making their certifications, which are “being provided to and relied upon by the United States”?
- Who owns the process?
- How will the Company handle departures of Certifying Employees during the Reporting Period?

Board Resolutions

Requirements

- Annually, the Board (or a committee of the Board) must adopt a resolution summarizing the Board's review and oversight of the Company's compliance with federal healthcare program requirements, FDA requirements and the obligations of the CIA.

Considerations

- Who will develop an effective Board Resolution timeline that addresses the entire Reporting Period?
- What is the scope of "applicable" Federal healthcare program and FDA requirements?
- What constitutes a "reasonable and due inquiry"? What are the appropriate types and amount of information to provide Directors in order to get "each individual member" of the Board comfortable in signing the resolution?
- Who owns the process?

Compliance Monitoring & Auditing

Requirements

- Create compliance monitoring and auditing programs for certain activities (e.g., speaker programs, consultant arrangements, records reviews, research-related activities, medical education grants, etc.) as required by CIA.
- Execute compliance auditing and monitoring plans throughout the Reporting Period in order to meet designated number of activities to be monitored each year as required by CIA.

Considerations

- Who will developing the necessary monitoring and sampling protocols?
- Who will developing the monitor templates and appropriate reporting templates to capture and report observations?
- Are there adequate resources in compliance who can actually conduct the monitoring and auditing required by the CIA (in addition to any other monitoring activities it might already be conducting)?
- Does the CIA permit the use of outside vendors?

Examples of Monitoring Requirements in 2010 and 2011 CIAs

Company	Speaker Programs	Ride-Alongs	Records Reviews	Publication Activities	Consultant Arrangements	Grants
UCB	30	20	Not Specified	5	30	30
Novo Nordisk	50	20	3 Products	N/A	30	30
EMD Serono	50	N/A	2 Products	N/A	40	15
Norvartis	125	50	3 Products	25	50	30
Synthes	Not Specified	30	N/A	N/A	N/A	N/A
Forest Labs	175	40	3 Products	30	30	30
Allergan	75	30	3 Products	25	30	30
Ortho-McNeil Janssen	40	30	3 Products	N/A	N/A	N/A
AZ	250	75	3 Products	50	70	60

Budgeting Plans, Needs Assessments and Fair Market Value

Requirements

- Create annual/semi-annual budgeting plans and needs assessments certain activities involving HCPs/HCIs.
- Create process for reviewing and approving Needs Assessments for activities involving HCPs/HCIs.
- Pay all HCPs/HCIs based on a centrally managed, pre-set rate structure based on fair market value ("FMV").

Considerations

- Who will create templates for Budget Plans, Needs Assessments?
- Who will work with the business to create a process for obtaining annual Budgeting Plans and Needs Assessments, including template documents, review and approval procedures, etc.?
- Who will create a centrally managed HCP rate structure and how will FMV be determined (e.g., by physician specialty? By activity type? By experience level?).
- Who will be responsible for training, communicating and implementing the budgeting, needs assessment and FMV processes?
- How will deviations from approved annual needs assessments be addressed?

Key Take-Aways

- Start early.
- Socialize all Company personnel (including senior leadership) to the impact of the CIA on all employees and vendors.
- Identify and assign personnel with responsibilities for certain aspects of CIA implementation.
- Identify additional resources that will be needed in Compliance and in other departments.
- Conduct gap assessment of policies and procedures against recent CIAs and develop new policies as needed and/or enhance existing policies.
- Assess current compliance monitoring and auditing activities (if any) and initiate new/additional activities based on potential compliance risks.

Questions?

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