

# Implementing a CME Compliance Program to Meet Current and On-going Regulatory Issues in the CME Community

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ACCREDITATION • CLINICAL & MEDICAL AFFAIRS • COMPLIANCE • OUTCOMES

# Presenters

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# Today's Objectives

- Define Compliance and identify the key stakeholders
- Review the basic components of a compliance program
- Identify ways to implement a compliance program in your CME office



## Intersection of CME and Compliance (distinct from achieving Accreditation Criteria)

- Compliance is a key factor and consideration for any company that regardless of whether commercial support of CME is accepted or not
- Accreditation organizations, Commercial Interests, and Federal and State Regulatory Bodies have embraced compliance
- Providers need to put forth and apply new learning and applying new processes



# Why is Compliance Important?

**New California law requires pharma to adopt compliance programs that comply with OIG guidance**

*Combination of new law, unfair competition statutes, California FCA could prove lethal*

**Pfizer Case Signals Tougher Action On Off-Label Drug Use**

**New California law mandating pharma compliance programs riddled with unanswered questions**

*Health care attorneys say new law has broad scope but few specifics*

**OIG 2005 Work Plan puts spotlight on FDA oversight of off-label promotion, DTC advertising**

*Work Plan also looks at Average Sales Price, Part D benefit, and other MMA items*



Ortho Biotech Medical Education and Health Care Compliance 2007 Update.  
Courtesy, M Lemon

# Why Compliance Matters

## Provider world has changed

- Responsibilities to meet accountabilities to accrediting organizations. (ACCME transparency)
- Government inquiries into CME
  - Purpose
  - “Follow the \$\$\$\$”
- Public questioning, pressure on
  - Drug safety, efficacy
  - Prescribing practices
  - Direct to Consumer, Direct to Patient, Health info on the Internet



# Beyond Today: Why Compliance Matters

Initiatives outside of CME provider “control” that impact CME

- Licensure
- Pay for Performance
- Electronic Medical Records

Return on Education (ROE) and getting activities planned, developed, implemented

- Are they effective?
- Do they address real and meaningful healthcare “gaps”?
- Are they compliant?
- Are they needed?



# What is Compliance?

## INTEGRITY and COMPLIANCE go hand-in-hand

- Compliance is a systematic process that establishes processes/protocol, defines appropriate interactions between key stakeholders, and provides for individual and organizational accountability
- It is the **FOUNDATION** for the internal & external policies and procedures that establish and support the foundation for the way you do business (and, yes, CME is a business)



# Compliance Stakeholders for CME Providers - ACCME & other accrediting bodies

## Accrediting Organizations (ACCME, ACPE, AANP, and others)

- Adherence to Essential Areas and Elements
- Policies and Procedures
- Standards for Commercial Support
- Provider Self-Study/Reaccreditation



# Compliance Stakeholders for CME Providers - OIG/FDA

## OIG/FDA

- OIG Compliance Program
- Pharma Code
- AdvaMed Code
- AMA Gifts to Physicians



# Compliance Stakeholders for CME Providers - Commercial Interests

## Commercial Interests

- Corporate Integrity Agreements
- Designated Compliance Officers
- Reporting structures
- On-going auditing



# Compliance Issues for CME Providers: Been Around for a Long Time and Continue to Come

## ACCME (& other accredited bodies)

- 1981-Founded
  - “Identification, development, promotion of standards for quality CME utilized by physicians in their maintenance of competence and incorporation of new knowledge, in order to improve quality medical care for patients and their communities.”
- 1992 Standards for Commercial Support
- 2002 Content Validation
- 2004 Updated Standards for Commercial Support
- 2006 Updated Accreditation Criteria
- 2009 Call for Greater Transparency - pending



# Compliance Issues for CME Providers: Been Around for a Long Time and Continue to Come

## AMA

- 1990 AMA Ethical Opinions
  - Gifts to Physicians from Industry
  - Continuing Medical Education Guidelines
- 2006 Changes in selling prescriber info/data practices

## FDA

- 1997: FDA Guidance on Industry-Supported Scientific and Educational Activities
- Continuing: Regulatory oversight, guidance's



# Compliance Issues for CME Providers: Been Around for a Long Time and Continue to Come

## Code of Ethics on Interactions with HealthCare Providers

- 2008 PhRMA and 2004 AvaMed

## Office of the Inspector General (OIG) and Dept of Justice (DOJ)

- Inquiries and Pharma settlements on inappropriate marketing and sales practices
  - TAP \$875MM
  - PD-Pfizer \$425MM
  - Serono \$705MM
- *OIG* Guidance Document on Pharmaceutical Marketing



# Compliance Issues for CME Providers: Been Around for a Long Time and Continue to Come

## Senate Finance Committee/Special Committee on Aging

- Letters to pharmaceutical and biotechnology companies on CME Spending
- Letter to ACCME on CME and CME Provider Oversight
- ACCME testimony to U.S. Senate Special Committee on Aging addressing conflicts of interest in continuing medical education (CME).

## Macy and IOM Reports/Recommendations



# Why Go Beyond Accreditation Compliance?

## Integrity

- Demonstrates commitment to “doing the right thing”
- Builds trust between providers, participant healthcare providers, institutions, government, commercial interests, learners

## Helps manage of “Risk areas” and potential consequences, which are now moving targets

- Corporate Integrity Agreements
- Newspaper Articles, Journal, Editorials
- Government Inquires



# And Compliance Programs Can Increase Provider Effectiveness and Productivity

## Increases CME program effectiveness

- “Tone from the top”
- Company-wide policies and procedures and targeted training
- Early problem identification and intervention
  - Activities
  - People

## Addresses roles and responsibilities for internal and external stakeholders

- Firewalls, Responsibilities, Accountabilities
- Documentation

## Increases productivity

- Documentation streamlining and evaluation
- Enhances consistency and reduces “re-dos”



## Risk of Non-Compliance

- Loss of credibility and viability
- Loss of professional accreditations
- Loss of ability to attract participants
- Loss of ability to submit and obtain educational grants
- Loss of independence to being considered an agent of the pharmaceutical company
  - 3<sup>rd</sup> parties that act on behalf of the pharmaceutical company are subject to the same governmental investigation, penalties, etc.



# Elements of an Effective Compliance Program

## Includes:

- Designated staff person responsible for compliance program oversight
- Written policies and procedures
- Staff training and education
- Effective lines of communication including a process for reporting a compliance breach/infraction
- On-going internal monitoring and auditing
- Practices enforced through well-publicized and communicated standards
- On-going communication to external stakeholders
- Prompt responses to detected problems and undertaking corrective action
- Documentation, documentation, documentation and regular **SELF-ASSESSMENT**



# Let's Get Started-

## 1. Designate the staff person responsible for compliance program oversight

- The right person to assume the role has:
  - Competency in accreditation polices, standards and criteria
  - Understanding of regulatory issues outside of accreditation policies
  - Interest and commitment to compliance
  - Personality traits that are most effective for your organization
  - Skills to ensure that compliance issues are addressed and resolved



# Let's Get Started-

## 2. Written policies and procedures

- Not just for "the files"
  - Base them on the requirements and expectations outlined in the Accreditation Criteria, including the Standards for Commercial Support
    - Make them usable and understandable
      - » Translate from "CME speak" to "Organization speak"
    - Align them with other policies and procedures within your organization
    - Include others required by your organization type (hospital, medical association, med ed company non-profit, for profit, etc)
  - Regularly evaluate, update and seek approval from CME Committees and Advisory Boards



# Let's Get Started-

## 3. Staff Training and On-Going Communication

### *Training*

- New employee training
- Regular/As needed staff training
- Re-training and reinforcement following any updated or changed accreditation policy
- Re-training and reinforcement following a major compliance issue ("breach")

### *Establish Effective Lines of Communication*

- Emails
- "One-on-ones"
- Compliance problems are not best solved via emails



# Let's Get Started-

## 4. Establish a Process for reporting a compliance breach/infraction

- Institute means of identifying that there may be a compliance issue
  - Eg, Documents with "ATTENTION-COMPLIANCE REVIEW REQUESTED" or "ATTENTION-COMPLIANCE INQUIRY"
- Ensure confidentiality - a "Safe-Harbor" for reporting and inquiry or breach
- Institute an anonymous reporting structure for those reluctant to communicate



## Let's Get Started-

### 5. On-going internal monitoring and auditing

- Institute an internal Quality Assurance/Quality Control process (staff, dean, course chairs)
- Implement an external review process (CME Committee, Advisory Boards)
- Establish a Compliance Committee with key stakeholders in your organization to review compliance issues and corrective action taken to resolve
- Analyze systems and procedures in terms of workflow and man hours
- Evaluation of planning process to ensure standards are met



## Let's Get Started-

### 6. Practices enforced by well publicized and communicated standards

- Create a policy and procedure handbook and ensure each staff member has access (hard copy, electronic)
- Publish policies and procedures on company website
- Ongoing communication on updated policies issued by Accrediting bodies, external stakeholders

*Remember, you are the source of information for the organization!*



# Let's Get Started-

## 7. Ongoing communication to external stakeholders

- Discuss during planning meetings (Course Chairs, faculty/authors, content collaborators)
- Include in agreement forms and contracts
- Issue press releases and publish on website
- Include as an agenda item (CME committee and advisory board meetings)



## Let's Get Started-

### 8. Prompt responses to detected problems/undertaking corrective action

- Ensure you acknowledge you are in receipt of the inquiry/breach and provide "next steps" course of action
- Gather information and documentation from stakeholders involved
- Review against established policies and processes
- Communicate with key stakeholders a formal "course of action" plan



## Let's Get Started-

### 9. Documentation, Documentation, Documentation!

- The key to demonstrating policies and procedures are followed and compliantly implemented
- Enables you to “tell the story”
  - Remember a compliance issue can arise from years’ past
- Create a systematic process for archiving documentation and ensure you have access



## Enhancing Compliance by CME Providers: Checklist Criteria

- ✓ Staffed sufficiently to meet needs of CME Program
- ✓ Uses faculty and CME professionals expertise to support and enhance activity
- ✓ Develops activities based on gaps in healthcare needs, outcomes and evidence-based content
- ✓ Applies evident quality improvement principles and practices
- ✓ Uses outcomes and outcomes research methods to enhance quality of activities and program
- ✓ Engages audiences in data generation and assessment



# The Compliant CME Provider: Checklist Criteria

- ✓ Is highly visible to and impactful on parent organization
  - Reporting Structure of Officer; Compliance Committee
  - Annual summary report of compliance developments and response by organization
  
- ✓ Staff and organization provide services and support to the CME community
  - Internal and External
  
- ✓ Demonstrates Active participation in relevant organizations (Alliance, NAAMECC, SACME, others)
  
- ✓ Motivates employees to hold leadership positions in service organizations
  - ACME, SACME, ACCME site surveyors, etc.



# Metrics Measurement: Evaluating Compliance Efforts

## Example of Reportable Internal Compliance

- Quantify the number of internal requests for information regarding compliance issues - is the message getting through to the organization?
- Analyze systems and procedures in terms of workflow and man hours
- Evaluation of planning process
  - Ensuring are all steps in place to ensure the tools are available?



# Integrating Compliance into your Organization

- Think positively about compliance. Include compliance in your personal mission statement
- Design your business procedures for both internal and external stakeholders to allow things to be done correctly the first time through
- Acknowledge and reward compliance
  - Build into you organizations culture
- Create “ownership” of the compliance process
  - Think about it
  - Monitor it
  - Measure it



# What External Stakeholders Should Expect from CME Provider Compliance Programs

## CME Provider Compliance Programs

- On-going implementation
- Multi-department involvement with Compliance
- Regular and pro-active self-assessment
- Risk Assessment
  - CME provider
  - Commercial Interests
- Effective policies and procedures to *demonstrate and document* that actions are taken based on *the provider's* policies and direction



Thank you!

# Questions/Comments

