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RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Ten steps to develop and implement effective compliance monitoring of CME activities

By Jane Ruppenkamp

Pharmaceutical funding of accredited CME activities is very much in the cross-hairs of the legislative and legal communities. New enforcement mechanisms being touted by the FDA and Accreditation Council for Continuing Medical Education (ACCME), the recent Senate hearings on CME, and Pfizer's highly restrictive CIA—requiring expanded levels of monitoring—are challenging current standards of compliance monitoring.

Companies are assessing the effectiveness of current monitoring efforts to insure compliance while maintaining required firewalls. Also weighing heavily in this assessment is the increasing need to collect comprehensive objective data and determine if and when a corrective course of action is required for individual activities, as well as for operational policies and procedures.

While auditing of CME activities is a common practice, the operational imperative for medical education compliance has shifted from simply conducting [audits to developing] a systematic approach to collect comprehensive objective data and determine a corrective course of action for individual activities, as well as operational policies and procedures.

Independence, conflict of interest, content validation and off-label discussion are just a few of the risks associated with CME activities over which grantors have no control. When developing a monitoring program for the CME activities supported by educational grants, creating a credible process is essential and defining the core criteria is a critical first step.

Develop the Process

1. Clarify your purpose. [The purpose of the monitoring process] may be to address potential industry criticism, identify necessary changes and/or satisfy regulatory requirements. Perhaps it is to gain insight as to the whether the grant was used as intended (e.g., aligned with needs assessment, or compliant with ACCME Standards and the PhRMA Code.)

2. Develop a comprehensive assessment tool. Based on your objectives, establish criteria and develop a tool that auditors will consistently use to evaluate the criteria. The tool may address logistics (e.g., meals, venue), content (e.g., content validity, balance, objectivity), and/or commercial bias.

3. Develop a training program for the auditors. The training should be a prerequisite for conducting audits, provide the context of the audit and address all of the elements of the assessment tool.

Will the training be conducted live or on-demand?

How will you assess competence?

Will there be a test?

4. Define COI for auditors. The independence and objectivity of the auditors lends credibility to the data collected. Determine what will constitute COI for your auditors – e.g., do internal auditors have a

conflict of interest? Require auditors to disclose their pertinent financial relationships.

5. Determine how activities will be selected for audits. Some companies set goals to monitor a certain percentage of the activities they fund. They may be selected randomly or based on identification of pre-determined risk factors.

Select an Auditor

6. Qualify auditors. The auditor should be proficient with the subject matter as well as regulatory compliance issues. Define qualification criteria. Consider profession, expertise, and experience.

7. Vet the auditors for COI. Just as important as having a process in place to conduct the audits is the responsibility to consider potential conflicts of interest. Require disclosures and apply your definition of conflict of interest (COI).

Follow up Post-audit

8. Make changes as a result of the data collected. Consider what you will do with the data collected. Determine what warrants corrective action and the action to be taken.

Will you report egregious activity to the proper authorities? If so, how will you determine what will be reported?

Will you use the information to make future funding decisions?

9. Measure effectiveness. Revisit your purpose for implementing the process and determine how you will know it is successful. Consider how you will monitor results, measure outcomes and continually improve the process. Periodically review the aggregate data to identify trends and information that may strengthen the compliance program (e.g., objective criteria for grant requests.)

10. Document the process. It is not enough to have a process in place; it must be consistently monitored and documented. Establish who will oversee the process and keep records of the audits as well as improvements made as a result of the findings.

By following these steps, an effective CME compliance monitoring process will be in place that will help drive continual improvement and address growing criticism of pharmaceutical funding of accredited CME activities.

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