Pitfalls and Lessons Learned:

Advanced Implementation Strategies for a Compliant Grant Process

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Companies should consider implementing enhancements in the following areas, if they have not already, to minimize compliance risks:

- **Infrastructure**

- **Proposal submission process**

- **Review and approval/denial process**

- **Notification process**

- **Monitoring and reconciliation process**

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Infrastructure

- Separate Sales & Marketing from the Grant process, as recommended by OIG and new PhRMA Code update.

  – Grant funding budgets should be separate from Sales & Marketing budgets.

  – Sales & Marketing personnel should not have influence over review activities or funding decisions.

  – Sales personnel should have only limited involvement in facilitating submission of grant requests through:

    • Provision of telephone numbers and/or Web sites through which grants are submitted

    • Provision of contact information for Medical Science Liaisons or other appropriate Company personnel

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Infrastructure (cont'd)

- **Develop and/or update policies and procedures that outline process for each type of grant separately**

  – **Clearly define each type of grant (e.g., CME, charitable contribution, research) to ensure grant is funneled through appropriate process**

  – **Require tracking of all grant requests**

  – **Require consistent application of decision criteria**

  – **Require documentation of approval/denial decisions**

- **Train relevant personnel on new and/or revised policies and procedures**

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Infrastructure (cont'd)

- **Establish annual budget for each type of grant**

- **Establish budget for grant spending by product or disease state**

  - **Limit the number or percent of educational grants awarded to for-profit organizations**

  - **Monitor magnitude and distribution of past grant spending**

- **Define or establish criteria/topics/research areas that may be funded for the coming year**

- **Consider establishing criteria for any limits on awards to specific individuals or organizations**

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Submission Process

- **Establish a centralized process (e.g., Web-based, central office) through which grant requests are submitted.**

- **Provide transparency to the process by posting:**
  - **Forms**
  - **Instructions**
  - **Checklists**
  - **Deadlines**
  - **Company contacts**
  - **Other information to facilitate submission of requests**

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Submission Process (cont'd)

- **Develop an application checklist for requestors to ensure applications are complete and accurate.**
  - **Grant request letter**
  - **Tax ID number**
  - **Location and date of activity**
  - **Intended audience/participants and anticipated number**
  - **The topic(s), objective, and description of the activity for which the grant is requested.**
  - **The name of the organization to which the check should be made payable**
  - **Itemized budget**

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Submission Process (cont'd)

- **For CME Events**
  - **Needs Assessment**
  - **The agenda or proposed agenda (sample agenda) of the activity**
  - **Itemized budget**
  - **Evaluation procedures**
  - **W-9 Form**
  - **Evidence of accreditation (e.g., ACCME)**
  - **Completed grant information request form**

- **For Non-CME Events**
  - **The agenda or proposed agenda**
  - **Itemized budget**
  - **W-9 Form**
  - **Completed grant information request form**

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Review and Approval/Denial Process

- **Establish a Grants Review Committee(s) that is independent of Sales & Marketing, and includes Compliance and/or Legal.**
  - **Document membership and roles**
  - **Types of grant(s) to be reviewed**
  - **Frequency of meetings/reviews**
  - **Decision criteria used by Committee during its reviews**

- **The Committee should review requests to verify that:**
  - **Content is aligned with the needs assessment and learning objectives of the proposal**
  - **Content is aligned with company scientific/medical objectives**
  - **Information to be presented is fair and balanced**
  - **Proposal is compliant with relevant laws, regulations, and company policies**

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Review and Approval/Denial Process (cont'd)

- **Establish grant review criteria that are objective, do not consider the recipient's current or future use of product, and ensure:**
    - Funded activities are *bona fide* activities
    - Providers are eligible providers
    - There is a firewall for providers who could also potentially be involved in promotional activities with the company
    - CME programs are accredited
    - Speakers paid at Fair Market Value ("FMV")
    - Audiences are appropriate (e.g., physicians, nurses, pharmacists)
    - Eligible therapeutic areas of interest
    - Ineligible requests (e.g., retroactive support, stand-alone entertainment or social activities) are denied funding

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Review and Approval/Denial Process (cont'd)

- **Require documentation of all grants and grant decisions, including those that are denied by the Company**

- **Establish good document management system to track entire process**

- **Establish an acceptable turnaround time for review of requests, including timeframes for:**
  - **Initial screening of request for completeness**
  - **Review process**
  - **Decision notification**
  - **Award pay-out**

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Review and Approval/Denial Process (cont'd)

When making decisions regarding educational grant awards, the Company should not:

- **Influence the development of educational content**

- **Select or influence educational methods, venue or frequency of educational events**

- **Influence selection of presenters or moderators**

- **Determine educational needs or objectives**

- **Influence selection of individuals who would be in a position to control or influence content**

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Notification Process

- Verify requests by sending a written letter

- Ensure requesters are notified about all decisions on a timely basis and that notification is documented

- Consider the need for an escalation process for decision making process

- Payments are paid directly to appropriate recipient organization

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Monitoring, Reconciliation and Auditing Process

- **Establish a monitoring and reconciliation process to verify that activity or program actually occurred**
  - **Final activity report (e.g., number of estimated and actual attendees, credit hours issued)**
  - **Final agenda**
  - **Final invitations**
  - **Final handout materials**
  - **Participant evaluation summaries**
  - **Faculty evaluation summaries**
- **Require providers to provide reconciliation of actual expenses vs. estimated expenses**
  - **If funds were not used for intended use that was approved by Company, then provider must return unused funds to Company**

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Monitoring, Reconciliation and Auditing Process (cont'd)

- **Areas that may be audited**

  - **Grants compliance**

  - **Grants review committee(s) responsibilities**

  - **Grant payment determination (itemized budgets, agenda and schedule are reviewed and deemed reasonable)**

  - **Grant payment process**

Additional Thoughts…

When should your company exercise control?

- It is acceptable to attach some strings to funding:

  - Require program independence

  - Require compliance with PhRMA Code, ACCME Guidelines, and applicable law (not just FDCA, but Anti-Kickback)

  - Ensure that educational provider is responsible for providing objective, scientifically valid content

  - Ensure non-promotional disclosure of financial support

  - Require budget reconciliation

Additional Thoughts… (cont'd)

- **Require that a written contract be in place before educational grant money is paid out.**

  - **Contract templates should be reviewed periodically by Legal department.**

  - **Incorporate relevant current ACCME criteria.**

    - **Note that effective January 1, 2008, commercial supporter may not specify *the manner* in which the provider will fulfill the ACCME requirements.**

- **Consider (and exercise) audit rights of awardees or vendors**

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