

19th Annual Conference of the National Task Force
on CME Provider/Industry Collaboration

Grant Application Procedures

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**Certified CME for Better Patient Care:
Navigating the Regulatory Environment**

Faculty

- Bryan C King – GSK
- Brian Russell – Roche
- Heidi Chandonnet - Shire
- Pamela Mason - AstraZeneca



Disclaimer

The statements, opinions and views expressed in this presentation are those of the respective faculty and do not represent those of their employers.



Topics:

- The Compliance Perspective
- The Grant Review Process
- Expectations for Accountability
- Exhibits
- Independent vs Promotional Education
 - FDA, OIG, CIAs
- Transparency – what it means for grants



Bryan C. King, Pharm.D.
GlaxoSmithKline Pharmaceuticals
Director, Center for Medical Education

- Compliance
 - Organization Eligibility
 - FDA
 - Anti-Kickback Statute
 - Accrediting Body Oversight



Organization Eligibility

- Commercial Supporters must not only consider the merits of the grant proposal, but also who is requesting the funding
- Accreditation status
- Debarment Lists
- General Competency
- Areas of Risk
 - Anti-kickback
 - False-Claims Act



FDA CME Guidance

- Control of content and speakers/moderators
- Disclosures
- Focus of the program
- Relationship between the provider and supporting company
- Provider involvement in sales and marketing
- Provider's demonstrated failure to meet standards
- Multiple presentations
- Audience selection
- Opportunities for discussion
- Dissemination
- Ancillary promotional activities
- Complaints



Anti-Kickback Statute

- The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), prohibits individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid or any other federally funded program (except the Federal Employees Health Benefits Program).



Purpose of Anti-Kickback

- Increased cost to the government-funded programs
- Other:
 - Prevent over-utilization
 - Ensure quality of care for program beneficiaries



Accrediting Body Oversight

- ACCME, AOA, AAFP
- ACPE
- AACN
- Others



Brian P. Russell, RPh, MBA

Director, Medical Education

Roche

Grants Review Process:

What we look for:

- Grant requests that are :
 - **Relevant**
 - **Concise**
 - **Needs-based**
 - **Educationally sound**
 - **Outcome focused**
 - **Reasonable**
 - **Compliant**
 - **Reconciled**



What we look for...

- **Relevant**

- Approximately 40 % of grant requests are declined based on topic
- Do your homework
 - Grant requestors need to match potential companies for support with alignment of needs assessment

- **Concise**

- Literally thousands of grant requests are reviewed annually

- **Needs-based**

- Cornerstone for potential grant support
- All educational objectives based on identified need
- The identified need and the expected end result/outcome should match up



Independent Medical Education: Where Do “Life Cycle Phases” of Therapy Options Fit?



- Increase awareness
- Increase knowledge (MOA, safety, efficacy, clinical data)
- Prepare for change

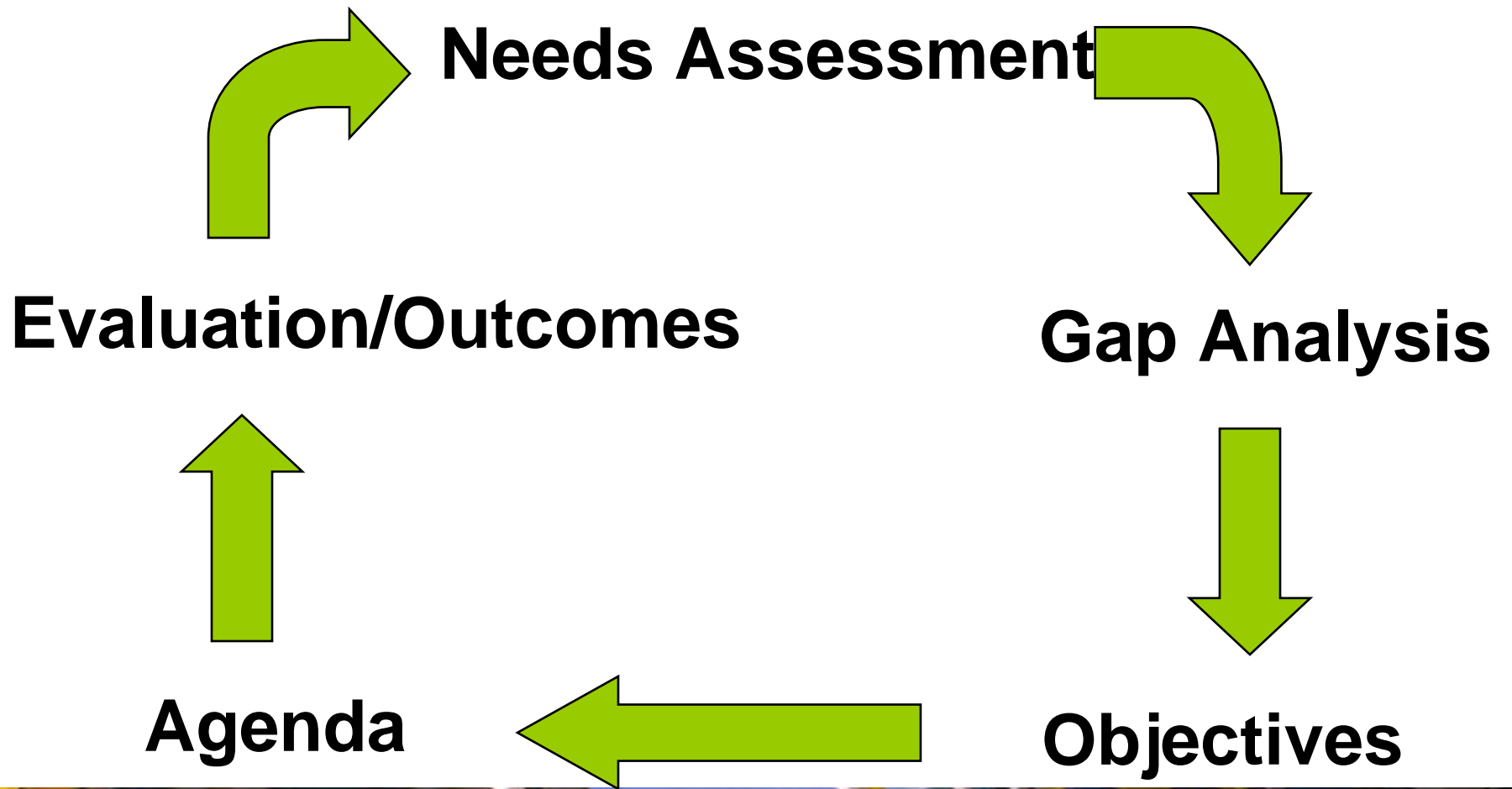
- Validate new approaches
- Incorporate new behaviors in practice
- Identify and resolve barriers

- Communicate supporting guidelines
- Communicate new data (evidence-based medicine)
- Reinforce best practice

Curricular approach to continually address all levels of behavior change readiness



Demonstrate how it all ties together



What we look for...

- **Educationally sound**
 - Strategy grounded in outcomes
 - What do we want the result to be?
 - Increase in knowledge?
 - Change of belief?
 - Change of behavior?
 - How will we define success?
 - Understand and utilize appropriate *methodologies* for educational design and educational effectiveness
 - A model for success
 - ***Who*** do we teach ***what*** and ***when***?



What we look for...

- **Outcome based**
 - Evaluation of effectiveness of education initiatives
 - Commercial supporters and providers alike are trying to demonstrate the value of independent grant funding to their stakeholders
 - “One offs” have little benefit
 - Consider what outcome you are trying to attain



What we look for...

- **Reasonable**
 - Is the budget appropriate for the activity
 - Is it reasonable to accomplish the objectives in the time and with the methodology described in the request
 - Anticipated size of audience
- **Compliant**
 - Main focus is on education
 - Fair market value for honoraria
 - Appropriate faculty expenses (coach airfare, time at venue, etc.)
 - Appropriate venue
 - Modest meals
- **Reconciled**
 - Did the activity take place?
 - Did provider spend the money as described in the grant request?

Final Thoughts

- **Physicians are**
 - Seeking more personalized programming matched to their level of understanding
 - Seeking self-assessment driven, tiered educational programming
- **Providers must**
 - Develop sequential learning models and curricular approaches to match educational interventions with individual levels of understanding
 - Target education to appropriate audiences
 - Level of understanding
 - Learning preferences



Moving Forward

- Providers need to focus on:
 - Reach
 - Identifying the right audience for the particular educational intervention
 - Frequency of educational interventions
 - Repeated exposure to consistent educational messages is key
 - Multiple opportunities beyond formal CME activity
 - Learning preferences
 - Varied media to address different preferred learning styles
 - Sequential learning models
 - Address stages of behavior change



Heidi Chandonnet

Senior Professional Education Specialist

Shire Pharmaceuticals Inc.

- Accountability
 - Grantor Perspective
- Exhibits



Defining Accountability

- *2. Education.* a policy of holding schools and teachers accountable for students' academic progress by linking such progress with funding for salaries, maintenance, etc.

"accountability." *Dictionary.com Unabridged (v 1.1)*. Random House, Inc. 19 Aug. 2008. <[Dictionary.com
http://dictionary.reference.com/browse/accountability](http://dictionary.reference.com/browse/accountability)>.



Business as Usual?

- Grantors must identify Providers that are in the *business of education*
- Independence can be high risk since Grantors have:
 - No input
 - No medical accuracy review
 - No faculty recommendations
- Can Providers be held accountable when education goes wrong?



Provider's Perspective

- Execute a thorough educational needs assessment
- Select appropriate faculty
- Develop evidence based educational content
- Validate content with annotated references
- Keep Grantor up-to-date
- Seek constructive feedback post activity



Grantor's Perspective

- Thorough screening
 - Staff, policies, procedures, processes, reputation, etc
 - Experience in a given therapeutic area
 - Analyze partnerships – real? paper only?
- Review periodic status reports – ask questions
- Participate in the activity
- Provide constructive, fact based feedback



Exhibits

- Exhibit space should not be included as part of the educational grant request.
 - Is it even OK to ask about exhibit opportunities?
 - What to do about associations linking booth location to total (annual and past) funding?
 - What to do about Providers using only commercial funding for entire activity – education and promotion?



Exhibits

- If promotional staff handle the request, then how is independence reconciled?
 - Possible solutions
 - Educational grant staff triages requests to:
 - The field
 - Convention staff
 - Internal web site
 - Grant recipient is asked to contact their local representative with a reminder to not discuss educational content
 - How effective is the reminder?



Pamela Mason, CCMEP, FACME

Director, Medical Education Grants Office
AstraZeneca

- FDA Guidance
 - Independent vs promotional education
- OIG Guidance to manufacturers
 - Key compliance requirements
- Transparency – What does it mean?
 - Grants



Guidelines, Standards, Codes and Policy

- Dec 1990 ✎ AMA Guidelines on Gifts to Physicians
- Mar 1992 ✎ ACCME Standards for Commercial Support (SCS)
- **Dec 1997** ✎ **FDA Final Guidance on Industry-Supported Scientific and Educational Activities**
- Jul 2002 ✎ PhRMA Code – Interactions with HCPs
- **Apr 2003** ✎ **OIG Compliance Program Guidance**
- Nov 2003 ✎ AdvaMed Code
- Jan 2004 ✎ Revised ACCME SCS
- May 2007 ✎ US Senate Report Ed Grants and Pharma
- Aug 2007 ✎ ACCME Revised Policies
- July 2008 ✎ Revised PhRMA Code – Interactions with HCPs



Independent vs Promotional Education

- **FDA does not differentiate between education and promotion**
- **FDA does not seek to regulate industry-supported activities that are independent and non-promotional**
- **Basically, educational programs that have not been designed independently from company control are categorized as promotional and regulated as such**
- **Must meet the FDA Guidance (12 factors) to be designated as independent.**



Independent Certified CME vs. FDA-regulated, Promotional Education

Education	Promotion	Independent
Oversight Guidelines	FDA, OIG, PhRMA	ACCME, AAFP, AOA, (+ FDA, OIG, PhRMA for industry)
Funding	Sponsored by Company	Sponsored by Provider – may be supported by a Commercial interest
Origin of Need	Market driven	Independent assessment documenting learners needs
Content Creator	Company	ACCME accredited provider, AAFP, AOA
Content Focus	Product – limited by labeling	Disease State – limited by scientific data
Fair Balance	Based on Regs – safety & efficacy data	Based on all information - therapy options – peer review
Faculty Selection	Sponsoring company	Provider selects faculty independently
Conflict of Interest	ID by faculty to audience	Resolved by Provider through transparent process
Off label	Faculty may respond to unsolicited question based on experience and state which areas are off-label	Faculty may address off label issues as long as they are evidenced based. Free scientific exchange of information
Learner Motivation	New products, faculty	Learning methods – faculty – CME credits



Addressing concerns & recommendations from the OIG

- ✓ Separate grant decision making function from sales & marketing
- ✓ Establish objective criteria that do not take into account volume or value of purchases made by, or anticipated from, grant recipients
- ✓ No manufacturer control over speaker or content
- ✓ Support bona fide educational activities
- ✓ Maintain documentation
- ✓ Regular monitoring
- ✓ Follow Federal health care program & FDA requirements
- ✓ Support of IME activities that are well intended and transparent and conform to the ACCME Standards for Commercial Support



OIG requirements for grants in recent CIAs

- **2005 Serono CIA**

- Establish policies and internal procedures and controls
- Document agreements in writing
- Retain & track information – make available to OIG
- Establish criteria on grant selection
- Document review & approval process
- Internal audit – report reviewed by Compliance
- External audit
- Respond to suspected violations

- **2007 BMS CIA**

- Support of activities will be transparent
- Quarterly documentation review of 10 randomly selected grants in all TAs
- Assess processes and procedures used to approve grants
- Confirm that the activity actually occurred and funds were used as stated
- Maintain records of CIA review for OIG inspection and include summary report in Annual Report



Recent Agreements & CME (IME)

• Cephalon CIA 2008

- Defines “third party educational activity” = CME, IME, disease awareness or other scientific, educational or professional program, meeting or event (symposia)
- Discloses financial support and any financial relationships with faculty, speakers or organizers at such Activity
- Third party has to agree to disclose as a condition of funding
- Support contingent on provider’s commitment to provide information that is fair-balanced, accurate & not misleading

• Lilly judgment 2008

- Disclose supported grants
- Maintain information on LGO website for at least 2 years
- Readily accessible format for review by the States upon written requests for 5 years
- Separate grant function from sales & marketing
- Contractually require provider to disclose Lilly’s support & any financial relationship with faculty
- Require provider to identify URL of Lilly website as a reference
- If know speakers promoting off-label, then can not provide funding for same program or additional funding



Transparency

- Move towards greater transparency by many companies.
 - Education grants & contributions
 - Eli Lilly posted in May 2007
 - In Feb 2008, Grassley requested positions on transparency from 15 companies
 - Companies responded (letters posted April 2008)
 - 10 companies intended to post;
 - 5 had no plans at this time
 - Some companies have posted (Pfizer, Amgen, AstraZeneca, MedImmune)
 - Other companies have announced their plans to post (Abbott, BMS, J&J, Merck, GSK, etc).



Challenges faced when disclosing

- What information should be disclosed?
 - Amount, Recipient, Title
 - All partners on a MedEd grant? Or just CME provider?
 - Multi-sponsored? Collaborations?
 - Components of grant (Purpose, Needs Assessments, RFPs)?
 - Grant in entirety?
- Informing grant applicants and revising LOAs
- Systems for capturing and reporting
- Data needs to be reviewed before posted
- Mechanics of posting – website, formatting, etc



Other issues with transparency

- Concerns about misuse and misinterpretation of the data leading to unintended negative consequences
- Disclosures are transparent in form but not in substance
- Non-uniform reporting process
 - no common definitions and criteria
- Administrative burden will drive costs up further
- Potential differences between what is posted for this purpose (such as grants with multiple education partners) and other types of potential reports (direct payments to meet state & federal requirements, etc)

