Strategies for a Compliant Grant Process

CIA Monitoring Obligations

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Disclaimer

The opinions expressed herein are my own, are based on my research and experience in the industry, and do not necessarily represent the views or practices of my current employer.

CIA Readiness

Risk Assessment >>>Strategic Planning	
Systems/Infrastructure	SWOT Analysis
•People	•Strengths
•Processes	•Weakness
•Technology	•Opportunities
	•Threats

OIG Guidance - Recommendations

- Separate grant making functions from their sales and marketing functions
- Establish objective criteria for making grants that do not take into account purchases
- Ensure that funded activities are *bona fide*
- Manufacturer should have no control over the speaker or content of the educational presentation
- Compliance with such procedures should be documented and regularly monitored

CIA Readiness

Focus Areas/Reference	
Policy & Procedure	OIG Guidance
Application/Request Forms	Other CIAs
Review & Approval	P*h*RMA Code
Automated Applications	ACCME Standards
Process Owners	Audit – Grant Process

CIA Readiness

Supporting Documentation	Other Issues
Operating Procedures	*Administration*
Requests & Applications	*Training*
Criteria for Review	*Communication*
Types of Review	*Monitoring*
Strategy Development	*Database*
Approval Authority	*Systems*
Contracts & Agreements	*Information to Capture*
Repository	*Access & Privileges*

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Written Standards – Policies & Procedures

- Sponsorship or funding of grants (including educational grants)
  - Policies and procedures designed to ensure that the Company complies with all applicable Federal health care programs and FDA requirements
- Funding or participation in Third Party Educational Activity
  - Policies and procedures designed to ensure that such programs satisfy all applicable Federal health care programs and FDA requirements

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Specific Requirements for Third Party Educational Activities (TPEA)

1. *Financial disclosure by BMS*
2. *Financial disclosure by TPEA Provider*
3. *Financial disclosure by faculty, speakers or organizers*
4. *Activity have an educational focus*
5. *Content, organization and operation of the TPEA be independent of company control*
6. *Support only TPEA that is non-promotional in tone/nature*
7. *Support of TPEA be contingent on the provider's commitment to provide information that is fair, balanced, accurate and not misleading*

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Independent Medical Education & Grants Review

- Quarterly reviews to determine whether grants to support IME were approved and handled consistent with policies and procedures
- Specific testing requirements:
  - Written agreement
  - Records collected, tracked and maintained
  - Funding properly approved
  - Content, speakers, presenters, moderators
  - Responses & actions
  - Occurrence
  - Use of funds

Review Methodology

- Validate Universe
  - *Grants records with Financial records*
- Select Sample
  - *Utilize software to generate random sample*
- Perform the Work
  - *Gather documentation: application; agreement; communication; review and approval records; payments and financial reconciliations*
  - *Test specific attributes*
  - *Analyze testing results*
  - *Confirm findings*
- Reporting & Follow-up
  - *Document & communicate findings*
  - *Corrective action as appropriate*

Evaluate Funding & Providers

- Does the arrangement have a potential to interfere with or skew clinical decision-making
- Does it have a potential to undermine the clinical integrity of a formulary process
- Is the information provided to decision-makers, prescribers or patients complete, accurate and not misleading
- Does the arrangement have a potential to increase costs to federal health care programs, beneficiaries or enrollees
- Does the arrangement have the potential to be a disguised price discount
- Does the arrangement have a potential to increase the risk of over utilization or inappropriate utilization
- Does the arrangement raise patient safety or quality of care concerns

Summary

- Risk Assessment
  - Internal: *Policy, Process, Activities, Controls*
  - External: *Legal, Regulatory, Public Forums*
- Strategic Planning
  - Anticipate change
  - Use output of RA to update plans
- Metrics
  - Establish success criteria
  - Analyze trends
- Monitor process
  - Conduct transactional reviews
  - Analyze spend
  - Provider evaluation

About Presenter

Augusta Monica Jonhart is Director - U S Pharmaceuticals Compliance at Bristol-Myers Squibb. She is responsible for creating and implementing processes and procedures which satisfy auditing and monitoring obligations required by the company's CIA with HHS-OIG. Ms. Jonhart has extensive background in auditing, monitoring and internal controls. She has experience in various auditing, accounting, regulatory and controllership functions; beginning her professional career with the U. S. Department of Treasury where she served as an Internal Revenue Agent. Ms. Jonhart is a Certified Public Accountant. She received a Bachelor of Science in Commerce from DePaul University and a MBA from Creighton University.