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Implementing Controls Around Grants, Consulting Agreements, CME, Preceptorships, and Other Promotional Practices

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The Challenge:

How can a manufacturer purchase goods or services from, or make a grant to, a customer without violating the Anti-Kickback statute or the Medicaid Rebate statute?

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The Answer:

Bona Fide

From Latin: *In Good Faith*

Payments must be good, and company must have faith that its employees are acting appropriately.

What makes payments “good”: The Top 10 Considerations

1. Is the proposed arrangement a true “consulting” arrangement?
2. Is there a written agreement between the company and the consultant specifying the nature of the services to be performed and the basis for payment?
3. Does the consulting relationship have a commercially reasonable business purpose that has been identified in advance?
4. Have the consultants been chosen based on their expertise and skills?
5. Who is responsible for selecting the consultants?

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What makes payments “good”: The Top 10 Considerations

6. Is the number of consultants to be used reasonable in light of the scope of the task and the importance of the services?
7. Will the information generated by the consultants be used?
8. Is the remuneration to be offered at fair market value, without taking into account the number or value of referrals or other business generated?
9. Will any meeting be held at an appropriate venue and under appropriate circumstances?
10. Will the consultants be engaged in “white coat marketing”?

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Special Issues in Managed Care

- Concern Over Influencing Formulary Decisions
- OIG Warning re: Dual Benefit/Dual Purpose

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Special Considerations re: Government Employees

- VA, DoD
- 20/50 Rule
- Appearance of Conflict

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Procedural Safeguards: Controlling a Large Organization

“Trust, but verify.”

-Ronald Reagan

OIG Compliance Program Guidance

1. Code of Conduct, policies and procedures
2. Compliance officer and committee
3. Regular, effective training
4. Effective lines of communication
5. Monitoring
6. Discipline and non-retention of excluded individuals
7. Investigation and reporting instances of non-compliance



The Key: Verify

- Faith is important, but so is verification
- Need to look, listen, and ask hard questions



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Lessons from CIAs

- Bring in a fresh pair of eyes
- Focus on areas of greatest risk
- Be systematic and regular
- Evaluate, correct, and report (as necessary)

