

American Society for Metabolic and Bariatric Surgery review of endobariatric procedures.

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Study Guide: Financial Disclosure and Conflict of Interest in Medical Publishing

This study guide examines the standards and requirements for financial disclosure as established by the American Society for Metabolic and Bariatric Surgery (ASMBS) for the journal *Surgery for Obesity and Related Diseases* (SOARD). It focuses on the definitions of commercial interests, the nature of relevant financial relationships, and the mitigation of bias in medical education.

Key Concepts and Disclosure Requirements

The primary objective of financial disclosure is to ensure that individuals in a position to control the content of an educational activity—such as authors submitting to SOARD—remain transparent about potential influences.

Disclosure Obligations for Authors

Authors must disclose all relevant financial relationships with commercial interests. This requirement extends to:

- **Individual Authors:** Each author must disclose their own relationships.
- **Corresponding Authors:** They may disclose on behalf of the group if no authors have conflicts.
- **Spousal/Partner Relationships:** Financial relationships held by a spouse or partner are considered the same as those held by the author.

Scope of Disclosure

Disclosure is not limited to active employment. It encompasses various roles and financial benefits:

- **Roles:** Management positions, independent contracting (including research), consulting, speaking, teaching, advisory committee membership, and board memberships.
- **Financial Benefits:** Salaries, royalties, intellectual property rights, consulting fees, honoraria, and ownership interests such as stocks or stock options (excluding diversified mutual funds).

Mandatory Disclosures in Manuscripts

Beyond financial relationships, authors are responsible for disclosing specific product usages within their manuscripts:

- Use of devices, products, or drugs that are not FDA-approved.
- Off-label use of approved devices, products, or drugs.
- Unapproved usage of any medical goods or services.

Bias and Revision

The review process serves as a safeguard against commercial influence. If the review determines that bias is apparent within the content of an article, the author will be required to revise the manuscript prior to its publication.

Short-Answer Practice Questions

1. What is the specific look-back period for disclosing relevant financial relationships?

Relevant financial relationships must be disclosed if they occurred within the 12-month period preceding the time the individual assumes a role controlling the content of the activity.

2. Does the ACCME set a minimum dollar amount for a financial relationship to be considered significant?

No. The ACCME has not set a minimum dollar amount. The logic is that any amount creates an inherent incentive to maintain or increase the value of the relationship.

3. Are providers of clinical services directly to patients considered "commercial interests"?

No. According to ACCME definitions, providers of clinical services directly to patients are not classified as commercial interests.

4. What must an author do if their article describes the off-label use of an FDA-approved drug?

The author is responsible for disclosing this off-label usage within the manuscript.

5. Name three examples of ownership interests that must be disclosed.

Stocks, stock options, or other ownership interests (not including diversified mutual funds).

Essay Prompts for Deeper Exploration

1. The Definition and Impact of Conflict of Interest

Explain how the ACCME defines a conflict of interest in the context of continuing medical education (CME). In your response, discuss how the opportunity to affect content regarding a commercial interest's products creates an ethical obligation for the author.

2. Commercial Interests vs. Clinical Services

Analyze the distinction between an entity that produces health care goods and a provider of clinical services. Why does the ACCME exclude direct clinical service providers from the definition of a "commercial interest," and how does this distinction impact the scope of financial disclosure?

3. The Role of the Spouse or Partner in Financial Disclosure

Discuss the rationale behind including the financial relationships of a spouse or partner in an author's disclosure. How does this requirement strengthen the integrity of the peer-review process and the objectivity of the published research?

Glossary of Important Terms

Term	Definition
Commercial Interest	Any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.
Conflict of Interest	Circumstances where an individual has an opportunity to affect CME content regarding products or services of a commercial interest with which they have a financial relationship.
Financial Relationships	Relationships where an individual benefits by receiving salary, royalties, intellectual property rights, consulting fees, honoraria, ownership interests, or other financial benefits.
Relevant Financial Relationships	Financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
Remuneration	Money paid for work or a service; the financial benefit received or expected from various professional roles.
Off-label Use	The use of an FDA-approved drug, device, or product for a purpose or in a manner other than what it was specifically approved for.

