



American Society of Clinical Oncology

POLICY FOR RELATIONSHIPS WITH COMPANIES

Frequently Asked Questions **(Based on April 2013 COI Policy)**

Questions Regarding ASCO COI Policy

Questions Regarding Disclosure

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1. Why did ASCO decide to revise its conflict of interest policy?

ASCO remains committed to maintaining objectivity in all of its scientific and educational pursuits. Since ASCO last revised its conflict of interest (COI) policy in 2005, ASCO has become a much larger and more complex organization. The field of cancer care and research has also evolved rapidly, and ASCO has not been alone in urging responsible management of financial interactions that could create real or perceived COI for scientists, health professionals, and organizations. The Institute of Medicine recently issued a framework report and presented principles for analyzing financial relationships in medical research, education, and practice. In addition, healthcare institutions, professional organizations, and government agencies have implemented systems of disclosure and management. Given these changes in the field and in the organization, ASCO believed the time was right to update its COI Policy, entitled [ASCO Policy for Relationships With Companies](#).

2. What is the goal of ASCO's 2013 COI Policy?

ASCO's 2013 COI policy reaffirms our Society's commitment to transparency and independence in the development and presentation of scientific and educational content. The goal is to provide a platform of integrity for important original research that will educate health-care providers and benefit cancer patients worldwide by analyzing, presenting, and discussing the most important research results with the potential to improve the lives of our patients.

3. When will ASCO's 2013 COI policy take effect? Will I have to do anything differently now?

The disclosure categories and provisions of the new ASCO COI policy are effective immediately with the exception of Section V. A transition period will occur during which participants in ASCO activities will begin to see changes as the new disclosure questions are rolled out. Participants in ASCO activities will not need to make changes to disclosures they have already submitted.

All authors, including the first, last, and corresponding authors, will be required to fully disclose all of their financial relationships with for-profit health care companies, regardless of whether the author believes the relationships to be specifically relevant to their research or ASCO activity. The first, last, and corresponding authors are required to answer additional non-restrictive questions regarding their relationships with the research sponsor for reports on original research.



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4. What are the author restrictions in the new Policy? Are they in effect?

Section V of the new policy deals with significant financial relationships between key research authors and the for-profit health care companies that sponsor their research. The new policy states that a research abstract or manuscript will not be accepted by ASCO if the first, last, or corresponding author has been an employee, major stockholder, or member of the speakers' bureau of the sponsor of the research during the past two years.

The author restrictions outlined in Section V will not be immediately enforced. ASCO will delay enforcement of Section V until it can adequately assess the full impact that the defined authorship restrictions on relationships with companies will have on research publication and presentation with respect to ASCO's educational and scientific offerings as well as the authors and our members.

5. How is the 2013 COI policy different from the 2005 policy?

The new policy introduces new disclosure categories that will allow disclosures to be applied to all ASCO activities, rather than focused on particular ASCO activities. Under the 2005 policy, individuals are to disclose relationships with entities having an interest in "the subject matter under consideration" or "the subject matter in question." Under the 2013 policy, disclosures will be made and reported for all relationships with all healthcare Companies, as defined by the [CMSS Code](#). ("A Company is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients.")

The new ASCO COI policy affirms that institutional interactions with Companies will continue to be transparent. The new policy also highlights the practice of ASCO and its philanthropic affiliate, the Conquer Cancer Foundation (CCF), to publicly disclose financial support of their programmatic activities, including grants, sponsorships, and charitable contributions. ASCO and CCF will publicly disclose the financial relationships held by their directors and officers. The *Journal of Clinical Oncology* and the *Journal of Oncology Practice* will continue to disclose relationships held by their editors.

6. What does "general disclosure" mean? What are the advantages of general disclosure?

General disclosure means comprehensive information about an individual's financial interactions with Companies will be disclosed. Previously, disclosure was related specifically to the subject matter of a particular article, abstract, or volunteer role. Under the new policy, participants will disclose their interactions with Companies and simply confirm or update this information with each new ASCO activity. This will allow for disclosures to apply across all of an individual's concurrent ASCO activities.



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General disclosure will allow participants in ASCO activities to disclose one time, instead of multiple times for each discrete ASCO activity. Simpler for the discloser, this will improve transparency across activities and across other institutions. General disclosure is easier to administer because ASCO will have just one format for receiving disclosures.

7. What will I have to disclose?

The new policy names eight categories of financial relationships that must be disclosed: (1) compensated employment, (2) leadership positions, (3) consulting activities, (4) speaking engagements, (5) expert testimony, (6) ownership interests, (7) research funding, and (8) patents or other intellectual property interests.

All authors, including the first, last, and corresponding authors, will be required to fully disclose all of their financial relationships with for-profit health care companies, regardless of whether the author believes the relationships to be specifically relevant to their research or ASCO activity. The first, last, and corresponding authors are required to answer additional non-restrictive questions regarding their relationships with the research sponsor for reports on original research.

8. Does the ASCO COI policy address only research activities related to clinical trials?

No. In ASCO's view, other kinds of research, such as retrospective studies or health services research, can have an impact on patient care. When funded by a Company, such research can be vulnerable to actual or perceived bias.

9. What is the Physician Payment Sunshine Law? Does this law have any relationship to the new ASCO COI policy?

The Physician Payment Sunshine law, enacted as part of the Affordable Care Act, requires companies to report payments they make to physicians. To administer the law, the Centers for Medicare and Medicaid Services (CMS) established the National Physician Payment Transparency Program. Additional information about the program can be found on the [CMS website](#). ASCO's conflict of interest policy has no direct relationship with the Sunshine Law. ASCO's disclosure questions do not track sunshine categories.

10. Why is there a *Journal of Oncology Practice* exemption for certain types of articles? How will I know if my article qualifies?

The mission of the *Journal of Oncology Practice (JOP)* is to provide oncology professionals with information and tools to enhance practice efficiency and promote a high standard for quality of patient care. Important work in oncology comes from data gathered by Companies involved in managed care, health informatics, and practice management, and the articles are often authored by Company employees. All manuscripts are subject to *JOP*'s rigorous peer review and editorial oversight. Data will still be collected on the author relationships for all manuscript submissions; however no restrictions will be enforced.



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11. If a Company reviews a speaker's slides for legal or regulatory compliance, will this trigger the definition of a speaker's bureau?

No. The ASCO policy defines a speaker's bureau presentation as one where any of the following three criteria are met: "a) a Company has a contractual right to dictate or control the content of the presentation or talk; (b) a Company creates the slides or presentation material and has final approval of the content and edits; or (c) the presenter is expected to act as a Company's agent or spokesperson for the primary purpose of disseminating company or product information." A Company may review a speaker's slides strictly for regulatory or compliance purposes. So long as the speaker has control and approval rights over scientific content and is not acting as the Company's agent or spokesperson, the activity will not fall within the definition of a speaker's bureau. It is important to note that the author restrictions set out in Section V will not be enforced, pending a two to three-year period of data-gathering and analysis.

12. Is additional assistance available if I have any questions about the new ASCO COI policy?

Yes. ASCO remains committed to working with its members and the larger oncology community in fully implementing this new policy. Additional information (including the new and earlier ASCO COI policies) can be found at www.asco.org/rwc. Email specific questions to coi@asco.org.

Questions Regarding Disclosure

13. Does an individual covered by the ASCO Conflict of Interest Policy have to disclose funding received from a contract research organization (CRO) coordinating the research for the sponsor?

Yes. The ASCO policy requires disclosure of all payments associated with the conduct of the research in question if provided by the sponsor or agents employed by the sponsor. The CRO is an agent acting on behalf of the sponsor.

14. If a pharmaceutical company provides research funding directly to a covered individual's academic institution, cooperative group, or clinical division, rather than to the individual directly, should the individual disclose this industry funding to ASCO?

Yes. The ASCO conflicts policy requires disclosure of all payments associated with the conduct of the original research in question. In the first instance, the policy is intended to focus on the personal financial interests of the covered individual. However, in some cases company funds may be paid to the covered individual's *institution, cooperative group, division, or other unit*. Where the covered individual knows that institutional payments associated with the research project (possibly including the researcher's salary) will be covered by the sponsor's funds, it is appropriate to make the disclosure.



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15. Does the ASCO Conflict of Interest Policy require authors of abstracts and manuscripts to disclose financial relationships with government or non-profit entities?

No. When disclosing financial relationships in accordance with the ASCO Conflict of Interest Policy, authors of abstracts and manuscripts should limit their disclosure to for-profit health care companies. This does not include government agencies, charitable foundations, academic institutions and other non-profit entities.

16. Does a researcher have to disclose honoraria received from a third party continuing medical education organizer, NOT the research sponsor – even if the researcher knows that the sponsor is sponsoring the CME event?

No. Honoraria paid directly to the covered individual by the company must be disclosed. A researcher does not need to disclose to ASCO honoraria paid by accredited CME providers, because the CME planning process has other safeguards to avoid conflicts when accepting industry support.

17. What does it mean to disclose “within two years” of submission of an article or abstract?

The ASCO Conflict of Interest Policy requires disclosure of compensation for consultant or advisory services and expert testimony, along with the value of gifts and other remuneration received from a for-profit health care company within two years of the activity. For those who seek to present at any ASCO meeting or to submit an article to an ASCO-sponsored publication, this is intended to encompass a time period beginning two years prior to accrual of the first participant to the original research that forms the basis of an article or abstract, and ending on the date of submission.

18. Who is considered an “immediate family member” according to the ASCO Conflict of Interest Policy?

The ASCO Conflict of Interest Policy requires disclosure of financial interest and other relationships held by “covered individuals.” Under the Policy, covered individuals are those who participate on the ASCO Board of Directors, committees and task forces, and those who seek to present at any ASCO meeting or to submit an article to an ASCO-sponsored publication, as well as their immediate family members. The Policy defines “immediate family member” as a person’s “spouse, dependent child, or adult child employed by the sponsor, or any other relationship involving the sharing of income or assets.” In most instances where disclosure of the interests held by a person’s immediate family member is required by the Policy, disclosure of the interests held by one’s spouse or dependent child is sufficient. However, ASCO recognizes that there are cases in which disclosure on behalf of additional individuals is warranted. ASCO encourages disclosure of the financial relationships of any other person with whom you share income or assets and believe disclosure is relevant.



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19. Does the ASCO Conflict of Interest Policy require disclosure of consulting relationships with investment firms?

Yes. The ASCO policy requires disclosure of all consultant or advisory arrangements with an entity having an investment, licensing or other commercial interest in the bio-medical arena. ASCO interprets this requirement to call for the disclosure of consulting relationships with investment firms and investment firm intermediaries. These relationships should be disclosed because investment firms and investment firm intermediaries may have a commercial interest in advance knowledge of drug trials, due to the impact original research results can have on the stock prices of pharmaceutical and device manufacturers.