Physicians’ Relationships with Industry: Practice, Education and Research

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RELATED TOPICS: Consent to Medical Treatment; Confidentiality of Personal Health Information; Treating Self and Family Members; Practice Guide.


COLLEGE CONTACT: Physician Advisory Service
INTRODUCTION
The practice of medicine often involves interaction between physicians and industry, including pharmaceutical, medical device and technology companies. These interactions have the potential to benefit both physicians and patients by advancing medical knowledge and improving patient care. Such interactions can include physician engagement with industry sales representatives, attendance at industry-sponsored educational events, or participation in industry-funded research.

While industry has a valuable and legitimate role to play in the practice of medicine, its interests and responsibilities may diverge from the professional and legal obligations of physicians. As a result, physicians may find themselves facing ethical dilemmas or conflicts of interest stemming from their relationships with industry. A growing body of empirical evidence demonstrates that patient trust and clinical care can be adversely affected by these conflicts.

This policy is not meant to discourage appropriate physician-industry interactions. It aims to assist physicians in understanding and managing their relationships with industry appropriately.

The expectations set out in this policy are grounded in the principles of medical professionalism set out in the Practice Guide and are based on the best available evidence relating to physician-industry interactions.

PRINCIPLES
The key values of professionalism—compassion, service, altruism and trustworthiness—form the basis for the expectations set out in this policy. Physicians embody these values and uphold the reputation of the profession by:

1. Maintaining their professional autonomy, clinical independence, and integrity;
2. Fulfilling their fiduciary duties by acting in the best interests of their patients;
3. Avoiding or recognizing and appropriately managing conflicts of interest that arise in relation to their professional duties;
4. Being transparent in their interactions with industry, and proactively disclosing the details of those interactions where they may be perceived to influence physician judgment;
5. Participating in self-regulation of the medical profession by complying with the expectations set out in this policy.

PURPOSE AND SCOPE
This policy sets out the College's expectations of physicians who interact with industry.

TERMINOLOGY
Industry: In this document, industry is understood broadly to refer to the full range of commercial enterprises associated with health care. These include, but are not restricted to, the pharmaceutical industry; the biotechnology industry; the medical device industry; and commercial providers of services related to clinical practice, research and education.

Conflict of interest: A conflict of interest is created any time a reasonable person could perceive that a physician's personal interest or relationship with industry is at odds with the physician's professional responsibilities. It is important to note that a conflict of interest can exist even if the physician is confident that his or her professional judgment is not actually being influenced by the conflicting interest or relationship.

In this policy, the term "conflict of interest" should be read broadly and in accordance with the definition above. While sections 15-17 of Ontario Regulation 114/94 under the Medicine Act, 1991 describe some specific situations that constitute conflicts of interest under that regulation, this policy is not limited in its scope to those specific situations described in regulation.

POLICY:
Physicians must comply with the expectations set out in this policy when interacting with industry.

This policy is divided into four sections: the first addresses a physician's interactions with industry in his or her clinical practice; the second addresses physician participation in industry-supported continuing medical education/continuing professional development activities; the third addresses consultation or advisory boards/investigator meetings; and the fourth addresses physician participation in industry-sponsored research initiatives.

1. Practice
Physicians in clinical practice are sometimes approached by industry representatives with offers of product information, drug samples, and other resources that may benefit patient care. While these interactions may have value, physicians are reminded that they must continue to safeguard their clinical objectivity and professional independence and avoid being in a conflict of interest.
Industry Gifts
Research demonstrates that accepting gifts or inducements from industry influences and likely undermines a physician’s independent clinical judgment, even where the physician believes otherwise.¹

Physicians must not request or accept a fee or equivalent compensation from industry in exchange for seeing industry representatives in a promotional or similar capacity. Physicians must not accept personal gifts of any value from industry or industry representatives.

Physicians may accept items from industry that advance disease/treatment education (e.g., patient teaching aids). These items must primarily entail a benefit to patients and not have value to the physician outside of his or her professional responsibilities. The College recognizes that what may be included in or on teaching aids is not necessarily in the control of physicians; however, it is preferable for patient teaching aids to include at most the logo of the donor company, and not refer to specific therapeutic agents, services or other products.

Product Detailing
Physicians are frequently approached by industry representatives with offers to share information regarding their products or services. For products, this may include research studies and clinical information with respect to their use, indications, and adverse effects. Physicians must ensure that they critically evaluate any information provided by industry representatives and do not solely rely on this information when making clinical decisions regarding patient care.

Where industry representatives are providing information about products or services, physicians may accept meals for themselves and appropriate staff where the meal is of modest value. Physicians should note that it is an act of professional misconduct to receive a benefit from a supplier contrary to s. 16(a) of O. Reg. 114/94 under the Medicine Act, 1991. Physicians should have regard to this regulation and the reasonable expectations of their patients in assessing whether a meal is “modest”.

Physicians who provide their patients with industry-produced educational materials (e.g., pamphlets) must first review the materials to ensure that they are accurate, balanced and complete.

Drug Samples
Physicians are permitted to accept drug samples from industry; however, physicians must comply with the expectations set out in the Prescribing Drugs policy. Drug samples must only be given to patients, and not taken by physicians for their own personal use or the use of their family members.²

2. Continuing Medical Education/Continuing Professional Development (CME/CPD)
The primary purpose of CME/CPD activities is to address the educational needs of physicians in order to improve the health care provided to patients.³ As professionals, physicians are obligated to maintain their competence and remain current on advances and trends in medicine and health-care delivery.⁴ CME/CPD may be delivered in a number of ways, including self-learning, courses, workshops, educational rounds, journal clubs, conferences, meetings, and industry-sponsored dinners; they may be in-person or in an electronic format (e-CME/CPD).

Since the interests of industry sponsors of educational activities are not always congruent with the goal of addressing the educational needs of the profession, it is essential that educational content be developed independent from the influence of industry.

CME/CPD Events
Organizers
These provisions apply to physicians who organize industry-supported CME/CPD activities.

Organizers must ensure that:

- Final decisions regarding the content, faculty, educational methods, and materials are made without influence from industry sponsors.
- CME/CPD activities are scientifically valid, objective and contain balanced information relevant to the topic or focus of the event.
- All funds from industry are in the form of an independent

¹ Key evidence from the literature can be found in the following articles:

² Limited exceptions are set out in the Treating Self and Family Members policy.
³ Canadian Medical Association policy – Guidelines for Physicians in Interactions with Industry (Update 2007).
educational grant payable to the institution or organization sponsoring the CME/CPD activity.

- Educational materials and presentations refer to generic names in addition to trade names where a generic name exists.
- Physician presenters are paid an amount that is at fair market value and commensurate with the services provided. Payments may also include reimbursements for reasonable travel, lodging and meal expenses. Payments must be made through the meeting organizers and not the industry sponsor.
- Negotiations for space or for types of promotional displays at CME functions are not influenced by industry sponsorship. Promotional displays from industry must not be in the same room as the educational event.
- Presenters, attendees, and their personal guests pay for the full cost of any pre or post meeting social events.
- There is a mechanism to manage all identified conflicts of interest. Organizers must only accept payments that are at fair market value and commensurate with the services provided. Payments may include reimbursements for reasonable travel, lodging and meal expenses.

Where a CME/CPD activity does not have a formal organizing committee, and where a physician is directly engaged by industry to organize the event, physician organizers must continue to comply with the expectations set out above with the following exceptions: funding for the event, including payments to presenters, may be provided directly by industry, and need not be in the form of an independent educational grant.

Presenters

Presenters are physicians who prepare and present a substantive educational session or physicians who act as Session Chairs and/or Panel Members.

Presenters must:

- Ensure the scientific validity, objectivity and completeness of the information they present. For example, if mentioning specific products or services, a presenter must provide a balanced presentation of the prevailing body of scientific information on the product or service, and if reasonable, alternative products or services.
- Disclose where any presentation materials, including presentation slides, have been developed by industry.
- Refer to generic names in addition to trade names where a generic name exists.
- Only accept payments that are at fair market value and commensurate with the services provided and that are made through the meeting organizers and not the industry sponsor. Payments may also include reimbursements for reasonable travel, lodging and meal expenses.

Where a CME/CPD activity does not have a formal organizing committee, presenters must continue to comply with the expectations set out above with the following exceptions: payment may be accepted directly from the industry sponsor provided it is at fair market value and commensurate with the services provided. Payments may also include reimbursements for reasonable travel, lodging and meal expenses.

Attendees

Physicians who attend CME/CPD events must not accept payment or reimbursement for travel, lodging, or meal expenses from industry; however, physicians may accept meals provided at a CME/CPD event where the meal is of modest value.

Physicians must only dispense scholarships or other funds from industry to undergraduate medical students or postgraduate trainees (including fellows) to attend CME/CPD events where the selection of recipients is made by their academic institutions.

When physicians attend CME/CPD events with their students, physicians are responsible for modelling ethical behaviour by acting in accordance with this policy.

Disclosure

Organizers must fully disclose industry sponsorship of the event and make this information publicly accessible prior to the meeting.

5. For organizers, these mechanisms could include disclosing the conflict of interest or excluding themselves from planning activity content in which they have a conflict of interest. For presenters, these mechanisms could include disclosing the conflict of interest, requiring the presenter to attest that they have divested themselves of their financial relationship, refraining from making recommendations regarding products or services, or recommending an alternative presenter for the planning committee’s consideration. Other options include: the provision of time during the activity for peer challenge of content through interactivity or question and answer periods (such as those seen during oral platform sessions at congresses); and the provision of evaluation forms to the audience that explicitly ask about bias in content.

6. Example of such an event: “industry dinner”.

7. Physicians should note that it is an act of professional misconduct to receive a benefit from a supplier contrary to s. 16(a) of O. Reg. 114/94 under the Medicine Act, 1991. Physicians should have regard to this regulation and the reasonable expectations of their patients in assessing whether a meal is “modest”.
Organizers and presenters must disclose to the attendees at the event all conflicts of interest. Such disclosure must include, but is not limited to:

- Current or past relationships with manufacturers of products mentioned at the event or with manufacturers of competing products;
- Any direct financial payments from industry;
- Investments in industry (excluding mutual funds);
- Membership on advisory boards;
- Grants or clinical trials funded by industry; and
- Any other significant (paid or unpaid) relationships with industry.

3. Consultation or Advisory Boards/Investigator Meetings

Physicians who are asked by industry to sit on advisory or consultation boards, or to serve as individual advisors or consultants, must adhere to the following expectations:

- There must be a written agreement setting out the details of the arrangement. The purpose of the arrangement must be exclusively for the physician to impart specialized medical knowledge that could not otherwise be acquired by the hiring company.
- While in this position, physicians must not engage in promotional activities on behalf of the company.
- While in this position, physicians may provide educational activities on behalf of the company; however, their relationship with industry must be disclosed and they must ensure that all information presented is accurate, complete and balanced.
- Remuneration must only be accepted if it is at fair market value and commensurate with the services provided.
- Meetings must be held in the geographic locale of the physician or as part of a meeting which he/she would normally attend. When these arrangements are not feasible, reasonable travel and accommodation expenses may be reimbursed.

Physician researchers who attend Investigator Meetings where researchers meet for the purpose of developing research protocols or discussing research results must adhere to the following expectations:

- Remuneration must only be accepted if it is at fair market value and commensurate with the services provided.
- Meetings must be held in the geographic locale of the physician or as part of a meeting which he/she would normally attend. When these arrangements are not feasible, reasonable travel and accommodation expenses may be reimbursed.

4. Industry-sponsored Research

This section clarifies the College’s expectations of physicians who participate in industry-sponsored research.

Physicians must only participate in research that is ethically defensible, scientifically valid, and that complies with relevant national guidelines, including the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS-2). 8

In accordance with the TCPS-2: 9

- Physicians must only participate in research involving human participants, including post-marketing surveillance studies (phase IV clinical research), that has the approval of a research ethics board. This includes research that only involves the use of personal health information (PHI). 10
- Physicians must only participate in clinical trials that have been registered prior to the enrolment of the first participant in a web-accessible research registry.

Consent Obligations under the Personal Health Information Protection Act

The College expects physicians to comply with their legal obligations under the Personal Health Information Protection Act, 2004 (PHIPA) when collecting, using or disclosing personal health information in relation to all research initiatives, including those sponsored by industry. 11

An overview of the relevant legal requirements is outlined below. Should physicians require guidance with respect to specific circumstances, or have questions about their obliga-

9. Physician must adhere to the Tri-Council Policy Statement: Ethic Conduct for Research Involving Human s (TCPS-2) regardless of whether they are receiving funding from one of Canada’s three federal research agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), or the Social Sciences and Humanities Research Council of Canada (SSHRC).
10. For the definition of “personal health information”, see S. 4 of the Personal Health Information Protection Act, 2004, S.O. 2004, c.3, Sched. A (PHIPA)
11. Grant-funded research would be subject to the same privacy and consent requirements as set out in this section, as would marketing and market research. Physicians should be aware that funding agencies may also stipulate requirements with respect to consent and privacy.
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A) When is consent required?

1. Use of patient information for research conducted by the physician

Physicians sometimes undertake industry-sponsored research initiatives using their own patients as participants. This research may involve the physical participation of the patient, such as for a new drug or treatment, or may simply involve the use or analysis of patient data. In this case, the research is conducted by the physician himself/herself, and does not involve disclosing patient information to any third party researcher.

Physicians in these circumstances have specific obligations under PHIPA with respect to using patients’ personal health information. Physicians must only use patient information if they have the patient’s consent, or if the provisions under PHIPA which permit the use of information for research purposes without consent have been satisfied. Physicians should note, however, that using patient information for research without the patient’s consent is only permissible in limited circumstances: where research ethics board approval has been granted for the research and the board has found that it is impractical to obtain a patient’s consent.

Physicians are not permitted to use personal health information for research purposes if other information will serve the purpose and physicians are not permitted to use more personal health information than is reasonably necessary for the purpose.

2. Disclosing patient information to third party researchers

Physicians are sometimes approached by industry with requests to identify eligible patients for participation in research studies, or to release general patient data, where the research will be conducted by third party researchers.

Under PHIPA physicians must obtain patient consent before disclosing the patient’s information to researchers, unless the provisions permitting the disclosure of information without consent apply. There are limited circumstances in which physicians will be permitted to disclose patient information to researchers without the patient’s consent: a research ethics board who has approved the research must have concluded that it is impractical to obtain patient consent.

If the physician has obtained consent, or has satisfied the relevant PHIPA requirements and can disclose information without consent, physicians are reminded only to disclose personal health information where no other information will do, and to disclose as little personal health information as possible to meet the research needs.

Before personal health information may be disclosed to a third party researcher by the physician, PHIPA requires that the researcher submit a written application to the physician, along with a copy of the research plan and the research ethics board approval. Researchers are required to enter into a written agreement with the physician in which the researcher agrees to comply with the conditions and restrictions, if any, that the physician imposes relating to the use, security, disclosure, return or disposal of the information.

Physicians should note that a third party researcher may not contact the physician’s patients, either directly or indirectly, unless the physician has obtained the patient’s consent to be contacted by the researcher.

B) What are the elements of consent?

PHIPA requires that consent to the use or disclosure of personal health information for research purposes must:

- be the consent of the individual to whom the information relates;
- be knowledgeable;
- relate to the information; and
- not be obtained through deception or coercion.

12. S. 37(1)(j) and 37(3) of PHIPA provide that physicians who do not have patient express consent may use their patients’ personal health information only if they comply with the provisions of PHIPA at s. 44(2) – (4) and 44(6)(a) – (f), which require the submission of a research plan for research ethics board approval. Additional requirements for research plans are set out in s. 16 of the Ontario Regulation 329/04 under PHIPA. Similar obligations apply to the collection of patient personal health information for research purposes, as set out in s. 29(a) and s. 36(1)(a) and (d) of PHIPA.

13. S. 44 (3)(d) of PHIPA.

14. S. 30 (1) and (2) of PHIPA.

15. S. 30 (1) and (2) of PHIPA.

16. S. 44 (1) – (6) of PHIPA.

17. S. 44 (6)(e) of PHIPA.

18. S. 18 (1)(a)–(d) of PHIPA.

19. If an individual is incapable of consenting to the collection, use or disclosure of information, PHIPA sets out the persons who can consent on behalf of the individual. PHIPA S. 23 (1) 3.
As in all circumstances relating to consent, the individual must have the capacity to consent.20

Consent is considered to be knowledgeable if it is reasonable in the circumstances to believe that the individual knows the purposes of the collection, use or disclosure of the information and that the individual knows that they may either give or withhold consent.21

A physician should document evidence of consent in the medical record before the subject's participation in the research study commences, and the withdrawal of consent where applicable.

C) What information must be disclosed to patients? Whenever engaging in research involving human participants, physicians must inform the potential participant about the relative probability of harms and benefits of participating as a research participant and must disclose all risks, even those which are rare or remote, especially if they entail serious consequences.22 Physicians must also advise prospective participants that they have the right to decline to participate or to withdraw from the study at any time, without prejudice to their ongoing care.

Physicians must inform their patients of the nature of the benefit the physician will receive for recruiting the patient for participation in the research study.23 Physicians must also disclose any affiliations (e.g., with the pharmaceutical company or researcher) that may impact on the patient’s decision to provide consent.

Compensation
Physicians must only accept compensation for participation in industry research at fair market value, commensurate with services provided.

Physicians must only accept compensation for recruiting patients into a research study (including post-marketing surveillance studies) if:

• Recruiting patients requires the physician to undertake activities beyond his or her normal practice, including, but not limited to, meeting with patients, discussing the study, and obtaining informed consent for the disclosure of patient information (for example, physicians must not accept “finder’s fees”, whereby the sole activity performed by the physician is to disclose the names of potential research participants); and
• Compensation is at fair market value and commensurate with the services provided.

Publication of Research Findings

Authorship
Physicians must only be included as an author of a published article reporting the results of industry-sponsored research if they have contributed substantively to the study or the composition of the article.24 Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Physicians must not agree to publish as author any article written in whole or part by the employees or agents of industry (“ghostwriting”) unless contributions are clearly disclosed by authorship or acknowledgment.

Disclosure of Relationships
When submitting industry-sponsored research to medical journals or for public consumption, physicians must fully comply with the disclosure requirements of the receiving publication.

Physicians must clearly disclose any relationship they have to industry where it has provided funding or other support for the studies or where it makes the products that are the subject of the study, whether or not the publications require such disclosure.

Publishing Negative Findings
Physicians must seek to publish negative as well as positive results in the spirit of good science, and in the interest of contributing to the existing body of knowledge.

Physicians must not enter into agreements that would limit their right to submit research results for publication, disclose the results of a study, or report adverse events.

Physicians must not knowingly be involved in concealing research results or presenting them in a misleading fashion.

20. S. 21 and 23 of PHIPA.
21. S. 18 (5) of PHIPA.
23. Informing patients of the “nature” of the benefit involves disclosing the type of benefit that may be received. It also includes disclosing the amount of any compensation the physician will receive.
24. The criteria for authorship that must be met are those set out by the International Committee of Medical Journal Editors (http://www.icmje.org)