Conflicts of Interest and Industry Relationships

Policies of the College of Physicians and Surgeons of Ontario (the "College") set out expectations for the professional conduct of physicians practising in Ontario. Together with the *Practice Guide* and relevant legislation and case law, they will be used by the College and its Committees when considering physician practice or conduct.

Within policies, the terms 'must' and 'advised' are used to articulate the College's expectations. When 'advised' is used, it indicates that physicians can use reasonable discretion when applying this expectation to practice.

Additional information, general advice, and/or best practices can be found in companion resources, such as *Advice to the Profession* documents.

Definitions

Conflict of interest: A conflict of interest is created any time a reasonable person could perceive that a physician's judgments or decisions about a primary interest (e.g., the patient's best interests, unbiased medical research) are compromised by a secondary interest (e.g., direct financial gain, professional advancement). A conflict of interest can exist even if the physician is confident that their professional judgment is not actually being influenced by the conflicting interest or relationship.

Industry: The full range of commercial enterprises associated with health care. These include, but are not limited to, the pharmaceutical industry, the biotechnology industry, the medical device industry, and commercial providers of services related to clinical practice, research, and/or education.

Policy

General

Interactions between physicians and industry have the potential to benefit both physicians and patients by advancing medical knowledge and improving patient care. While industry has a valuable and legitimate role to play in the practice of medicine, sometimes the goals and interests of industry may be at odds with a physician's professional and legal obligations. This policy sets out expectations to help physicians navigate their interactions with industry and manage conflicts of interest which impact patient and public trust in physicians and the medical profession.

1. Physicians **must** maintain their clinical objectivity and professional independence when interacting with industry.

2. Physicians **must** identify situations or circumstances that are, may reasonably be perceived to be, or may lead to, a conflict of interest and avoid or appropriately manage them.

3. Physicians **must** fulfil their fiduciary duties to their patients by acting in good faith and in the patient's best interest when resolving conflicts of interest.[1]

4. Physicians **must** be transparent and proactively disclose conflicts of interest and details of their interactions with industry to the relevant parties (e.g., patients, research participants, institutions) where they may be reasonably perceived to influence the physician's judgment.

Conflicts of Interest under the *Medicine Act, 1991*

5. Physicians **must** avoid and appropriately manage conflicts of interests as set out in Part IV (ss. 15-17) of Ontario Regulation 114/94 ("the General regulation") under the *Medicine Act, 1991*.[2]

6. In addition to complying with the requirements set out in the General regulation when physicians are when ordering a diagnostic or therapeutic service to be performed by a facility in which the physician or a member of their family[3] has a proprietary interest, they **must** communicate to the patient that:
    a. the patient has the option to obtain the diagnostic or therapeutic service elsewhere; and
    b. the patient's choice will not affect the physician-patient relationship, or the quality of health services provided by the physician.

[1] The physician-patient relationship is a fiduciary relationship from which fiduciary duties arise. In this relationship, the balance of knowledge and information favours the physician, so that patients are reliant on their physicians and may be vulnerable. Patients rely on and must be confident that the physician has put the needs of the patient first.

[2] O. Reg. 114/94: GENERAL under Medicine Act, 1991, S.O. 1991, c. 30. The General regulation sets out when it is a conflict of interest for physicians to receive benefits from a supplier for patient referrals or of medical goods or services to patients; to rent premises; to sell or otherwise supply drugs, medical appliances, medical products, or biological preparations to patients at a profit; and to order a diagnostic or therapeutic service to be performed by a facility in which the physician or a member of their family has a proprietary interest. A physician is required to disclose the details of the proprietary interest to the College. The College's Conflict of Interest Declaration Form is available online.

[3] A "member of his or her family" is defined under s. 15 of the *General* regulation.

Industry Relationships in Clinical Practice

7. Physicians **must not** request or accept fees or equivalent compensation, personal gifts, or inducements of any value from industry in exchange for seeing industry representatives in a promotional or similar capacity.
    a. Where industry representatives are providing information about products or services, physicians are permitted to accept meals for themselves and appropriate staff but **must** only accept meals that are of modest value.

8. Physicians **must** critically evaluate any information provided by industry representatives and **must not** solely rely on this information when making clinical decisions regarding patient care.

9. Physicians **must** only distribute patient teaching aids provided by industry that:
    a. primarily entail a benefit to patients (i.e., have more educational than promotional value);[4,5]
    b. they are satisfied are accurate, balanced, and complete; and
    c. do not have value to the physician outside of their professional responsibilities.

Samples

10. Physicians who accept samples of drugs or devices from industry **must** comply with the expectations set out in relevant College policies.[6]

11. Physicians **must** consider the potential influence of samples on their prescribing choices and use clinical evidence to determine the appropriate choice of drug or device in alignment with the patient's best interests.

12. Physicians **must not** obtain any form of material gain for themselves or for the practice with which they are associated (including from selling or trading) when distributing samples.

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[4] It is preferable that patient teaching aids include at most the logo of the donor company and not refer to specific therapeutic agents, services, or other products.
[5] Section 33 of the *Personal Health Information Protection Act, 2004* (*PHIPA*) prohibits the collection, use, or disclosure of personal health information (PHI) for the purpose of marketing or market research unless the patient expressly consents. For example, physicians would not be permitted to use the PHI of their patients to determine which patients would benefit from receiving marketing information in respect of particular goods, service, products, equipment and devices without their express consent.
[6] Including the *Prescribing Drugs*, *Physician Treatment of Self, Family Members, or Others Close to Them*, and *Medical Records Documentation* policies.

Continuing medical education/Continuing professional development (CME/CPD)

Accredited CME/CPD

13. Physicians participating in industry-sponsored accredited CME/CPD activities and events **must** comply with guidelines outlined by relevant accrediting bodies, including the *National standard for support of accredited CPD activities*.

Unaccredited CME/CPD

14. Physicians who organize and/or present at industry-sponsored unaccredited CPD/CME activities and events **must** only accept reasonable honoraria and reimbursement for hospitality (i.e., travel, lodging, and/or meal expenses).

15. Physicians who attend industry-sponsored unaccredited CPD/CME activities and events **must not** accept reimbursement or subsidies for hospitality, outside of modest meals or social events that are held as part of the activity or event.

Consultation or advisory boards

16. Physicians who sit on advisory or consultation boards or who serve as individual advisors or consultants to industry organizations **must**:
    a. enter into a written agreement setting out the details of the arrangement;
    b. only agree to impart specialized medical knowledge that could not otherwise be acquired by the organization;
    c. not engage in promotional activities on behalf of the organization while in this position;
    d. ensure that all information presented is accurate, balanced, and complete where relevant in the course of their practice, research, or teaching, and when providing educational activities on behalf of the company; and
    e. only accept compensation that is reasonable and commensurate with the services provided.[7]

[7] Reasonable compensation can be at fair market value. Parameters such as time, expenditure, and complexity of the work required may be relevant considerations in determining compensation amount.

Industry-sponsored research

17. Physicians **must** only participate in industry-sponsored 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), regardless of the source of funding.
    a. Physicians **must** have the approval of a research ethics board when participating in research involving human participants, including post-marketing surveillance studies (phase IV clinical research) and research that only involves the use of personal health information.

18. Physicians **must** ensure that patients are provided full disclosure of all information necessary to make an informed and voluntary decision to consent to participate in a research project,[8] including, but not limited to:
    a. the relative probability of harms and benefits of participating and all risks, including those which are rare or remote, especially if they entail serious consequences;[9]
    b. the nature of the benefit (i.e., the type of benefit and amount of any compensation) the physician will receive for recruiting the patient for participation in the research study; and
    c. that they have the right to decline to participate or to withdraw from the study at any time, without prejudice to their ongoing care.

19. Physicians **must** 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.[10]

Compensation

20. Physicians **must** only accept compensation for participation in industry-sponsored research, including attending Investigator Meetings, that is reasonable and commensurate with services provided.

21. Physicians **must** only accept compensation for recruiting patients into a research study if the physician was required to undertake activities beyond their normal

[8] For more on the consent process and information generally required for informed consent see Chapter 3 of the TCPS-2 and the *Advice to the Profession*.
[9] *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.); *Weiss v. Solomon* (1989), 48 C.C.L.T. 280 (Qc. Sup. Ct.).
[10] For the definition of "personal health information", see section 4 of *PHIPA*. For more information about the legislative and regulatory requirements under *PHIPA*, see the *Advice to the Profession*.

practice (e.g., meeting with patients, discussing the study, and obtaining knowledgeable consent for the disclosure of personal health information).[11]

a. Physicians **must not** accept finder's fees (i.e., payments for identifying or recruiting a patient into a trial, whereby the sole activity performed by the physician is to disclose the names of potential research participants).

Dissemination of research results

22. Physicians **must** only be included as an author of a published article reporting the results of industry-sponsored research if they meet the authorship criteria set out by the International Committee of Medical Journal Editors (ICMJE).[12]

    a. Physicians **must** only agree to be published as author if all contributors are identified as authors, if applicable, or acknowledged as contributors.

23. Physicians **must** make reasonable efforts to disseminate the analysis of data and interpretation of research results in the spirit of good science and in the interest of contributing to the existing body of knowledge, including by **not** knowingly being involved in concealing research results or presenting them in a misleading fashion.[13]

[11] Consent is considered knowledgeable if it is reasonable to believe that the individual knows the purpose of the disclosure and knows that they can give or withhold consent.

[12] Specifically, the criteria found in the ICMJE Recommendation *Defining the Role of Authors and Contributors*.

[13] For more on dissemination of research results, see Article 4.8 of the TCPS-2.