Advice to the Profession: Conflicts of Interest and Industry Relationships

Advice to the Profession companion documents are intended to provide physicians with additional information and general advice in order to support their understanding and implementation of the expectations set out in policies. They may also identify some additional best practices regarding specific practice issues.

The practice of medicine can often involve interaction between physicians and industry. These interactions 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, and physicians may find themselves facing ethical dilemmas or conflicts of interest stemming from their relationships with industry. This can have the potential to adversely affect the physician-patient relationship and public trust in the profession.

The *Conflicts of Interest and Industry Relationships* policy does not discourage appropriate physician-industry interactions, but instead aims to assist physicians in managing their relationships with industry appropriately. This companion *Advice* document is intended to provide guidance on how to interpret and effectively discharge the obligations set out in the policy.

General

What circumstances are considered conflicts of interest under the Medicine Act, 1991*?*

In summary, under Part IV of Ontario Regulation 114/94 under the *Medicine Act, 1991*, it is a conflict of interest for physicians to:

- receive any benefit,[1] directly or indirectly, from a supplier (to whom the physician refers patients/specimens or who supplies medical goods or services to the physician's patients);
- rent premises to or from a supplier, except where the rent is normal for the area and the amount of rent is not related to the referral of patients to the landlord;
- sell or otherwise supply any drug, medical appliance, medical product, or biological preparation to a patient at a profit, except:

[1] S. 15 of O. Reg. 114//94 under the *Medicine Act, 1991* defines "benefit."

    - a drug that is necessary
        - for immediate treatment of the patient;
        - in an emergency; or
        - where the services of a pharmacist are not reasonably readily available;
    - an allergy preparation sold or supplied for a price subject to limits;[2]
- order a diagnostic or therapeutic service to be performed at a facility in which they or their family have a proprietary interest, unless the interest is disclosed in advance to the patient, or the facility is a publicly-traded corporation and not owned or controlled by the physician or a member of their family.

When disclosing to a patient the fact that you or a family member has a proprietary interest in a facility where a diagnostic or therapeutic service will be performed, it is important that, at a minimum, the notice is clearly written (e.g., a sign or a form).

How can I appropriately manage conflicts of interest?

In general, it is best practice to avoid conflicts of interest altogether (e.g., by withdrawing or removing oneself from the situation); however, this may not always be possible depending on the circumstances. In addition to disclosing conflicts to patients, making patients aware of alternatives, and offering reassurance that the patient's choice of an alternative will not affect the quality of care, you can also:

- Where applicable, after disclosing the conflict of interest, obtain consent from the patient prior to providing any medical advice or treatment and ensure that the conflict does not affect your decisions about the patient's care.
- Document the details of disclosure and relevant outcomes in the patient's medical record.

In other contexts, such as when participating in continuing medical education or continuing professional development (CME/CPD) activities or conducting research, there are relevant guidelines and/or standards to follow to determine when and how best to disclose and manage conflicts of interest.

It is important to remember that any conflict must be resolved in the best interests of the patient and that you are able to demonstrate that the patient's best interests have been maintained at all times.

[2] S. 16(d)(ii) of O. Reg. 114/94 under the *Medicine Act, 1991*.

The policy defines "conflict of interest" as involving primary and secondary interests. What are examples of these types of interests?

The primary interests of physicians can vary according to the activity they are engaged in. For instance, a primary interest can be providing care in the patient's best interests, conducting unbiased medical research, or fostering high-quality medical education. Patients, the public, research participants, and medical learners need to trust physicians to act in ways that are consistent with these primary interests.[3] Secondary interests can often be in the form of financial gain; however, they can also include the desire for professional advancement or recognition of personal achievement.

Frequently, interests may be described in terms of being direct or indirect, financial or non-financial, and personal or professional. For example:[4]

- **Direct financial interest:** when a physician receives a direct benefit or payment such as industry-sponsored speaking engagements.
- **Indirect financial interest**: when a physician receives an indirect benefit such as industry funding for research.
- **Non-financial interest:** where physicians receive a secondary benefit not related to a payment such as recognition of professional achievement.
- **Personal interest:** where a physician's relative receives a secondary benefit such as referring patients to businesses or facilities in which the relative holds a material financial interest, including diagnostic and/or treatment facilities.

How can I determine whether a primary interest is compromised by a secondary interest?

Whether a primary interest is compromised by a secondary interest is a matter of judgment and depends on the context. Relevant factors to consider in assessing the likelihood and seriousness of a conflict of interest can include:[5]

- **Monetary value:** the greater the value of the secondary interest, the more likely its actual or perceived influence.
- **Scope (duration and depth) of a relationship:** longer and closer associations can increase the risk.
- **Authority and discretion in a role:** certain roles (e.g., Principal Investigator) may afford more discretion and influence in making important decisions.

[3] Lo, Bernard and Field, Marilyn J. *Conflict of Interest in Medical Research, Education, and Practice.* (2009) Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice.
[4] *Professional Standards Regarding Conflict of Interest*, College of Physicians and Surgeons of Nova Scotia.
[5] Lo, Bernard and Field, Marilyn J. *Conflict of Interest in Medical Research, Education, and Practice.* (2009)

- **Scope of consequences:** conflicts that can impact many patient care decisions (e.g., developing clinical practice guidelines) may have more potential for harm.
- **Extent of accountability:** the availability of accountability measures can reduce the likelihood or severity of harm.

How can I support medical students and postgraduate trainees in avoiding and managing conflicts of interest and interacting with industry appropriately?

Physicians are responsible for modelling professional and ethical behaviour for medical students and postgraduate trainees by acting in accordance with this policy. It is important that students and trainees do not feel pressured to interact with industry where they are uncomfortable doing so and that there be a safe and supportive environment for reporting any concerns around the interpretation of CPSO's policy with physician supervisors/educators.

Industry Relationships in Clinical Practice

Why does the policy prohibit accepting gifts or inducements from industry?

A large body of empirical evidence demonstrates that accepting gifts or inducements of *any* value can influence and undermine a physician's independent clinical judgment, even without the physician's awareness.[6] The expectations contained in this policy are rooted in this research and align with expectations of other stakeholders.

In general, it is important to exercise caution and critically evaluate any information provided by industry representatives. Physicians may sometimes find it helpful to meet with industry representatives to learn about a drug or medical device. However, there is a lack of evidence demonstrating that interactions with industry representatives produce educational benefits. Research indicates that industry representatives may be less likely to discuss a drug's risks and adverse effects than its benefits and has found an association with costlier and lower quality prescribing.[7]

[6] For examples, please see the following articles:
- Katz, Dana, Caplan, Arthur, & Merz, Jon. (2003, June 1). All Gifts Large and Small: Toward an Understanding of Pharmaceutical Gift Giving. *University of Pennsylvania Scholarly Commons – Center for Bioethics Papers*.
- Spurling, GK, et al. Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review. (2010). *PLoS Med*. 7(10), e1000352.
- Brax H, et al. Association between physicians' interaction with pharmaceutical companies and their clinical practices: A systematic review and meta-analysis. (2017) *PLoS One*. 12(4):e0175493.

[7] Spurling, GK, et al.

What is considered a meal of "modest" value?

While CPSO is unable to provide a specific dollar value, physicians can exercise individual judgments and take into consideration the reasonable expectations of their patients in assessing whether a meal is of "modest" value.

What do I need to consider when distributing drug samples to patients?

Samples are primarily used by companies for marketing and promotional purposes, which can raise concerns about their influence on physician prescribing. While samples can be beneficial for patients in certain circumstances (e.g., by allowing physicians to initiate therapy immediately, evaluate clinical performance of medication for a patient, and/or offset costs), they can also lead to the use of medications that are not a physician's first choice and which are costlier than other medications, potentially leading to higher out-of-pocket costs for patients when samples run out.

You must consider the influence of samples on your prescribing and use clinical evidence for therapeutic decisions. This includes taking into account whether the sample is your first choice of treatment and any impact that using samples may have on the patient's current and future costs. If the sample is of a medication which the patient may use on a long-term basis, you may wish to consider discussing with the patient other options for obtaining medications if they are available, for example, through the Ontario Drug Benefit Program or other patient assistance programs.

Continuing Medical Education/Continuing Professional Development (CME/CPD)

Can students/trainees receive funds from industry to attend CME/CPD events?

Scholarships or other funds from industry to permit undergraduate medical students or post-graduate trainees (including fellows) to attend CME/CPD events can be dispensed as long as their academic institution selects the participants for these funds.

Are there expectations I need to know related to unaccredited CME/CPD events?

The *National standard for support of accredited CPD activities* Element 7 sets out responsibilities for organizers of CME/CPD events, specifying that unaccredited CME/CPD events cannot take place at times and locations that interfere or compete with accredited CME/CPD activities and cannot be listed or included within activity agendas, programs or calendars of events (preliminary and final).

Physicians attending informal or non-accredited learning activities with industry involvement will need to approach these activities with caution due to a higher likelihood that such events are promotional in nature. Physicians may wish to follow the guidance set out in the Canadian Medical Association's (CMA) *Guidelines for physicians in interactions with industry*.

Consultation or Advisory Boards

What do I need to be aware of when serving in a consultant or advisory role for industry?

In these roles, it is important to be attentive to the perception of bias when attending meetings and when receiving remuneration. It is generally preferable to attend meetings in your geographic locale or those which form part of a meeting that you would normally attend; however, factors such as the remoteness of your location and the availability of virtual meetings can be taken into consideration. When these arrangements are not feasible, reasonable travel and accommodation expenses may be reimbursed.

What do I need to be aware of if I am developing clinical practice guidelines (CPG)?

The Guidelines International Network's (GIN) *Principles for disclosure of interests and management of conflicts in guidelines*, formulates core principles for disclosing and managing conflicts of interest for physicians involved in CPG development.

Industry-Sponsored Research

What do I need to know when participating in industry-sponsored research?

Physicians participating in industry-sponsored research must continue to meet expectations of all physicians participating in research generally. The principles and responsibilities articulated in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS-2) are broadly applicable to physicians conducting research involving human participants.[8] When conducting research with First Nations, Inuit, and Métis peoples, physicians may refer to Chapter 9 of the TCPS-2 and consider the application of the First Nations Principles of OCAP.

While research involving human participants can result in benefits that positively affect society, often there is little to no direct benefit to individual participants. Research can pose various risks to individuals and impact vulnerable populations. When conducting industry-sponsored research, it is important that the primary objective of research be the advancement of the health of the public rather than the private good of either

[8] *Stirrett v Cheema,* 2018 ONSC 2595, at para. 5; *Barker v. Barker,* 2020 ONSC 3746, at para. 1171.

physicians or industry. Seeking approval from a research ethics board (REB) can minimize the risk to patients. It is also important that the REB operate by appropriate governance and procedures.

What information needs to be disclosed to patients for consent to be informed?

A physician's duty towards research participants can be greater than their duty towards a patient because of the experimental nature of the research and the lack of corresponding therapeutic benefit to the research participant that there would be for a patient. Therefore, obtaining consent for participation in research can require a higher level of disclosure than what is typically required when obtaining consent to treatment.

The TCPS-2 requires researchers to provide prospective participants full disclosure of all information necessary for making an informed decision to participate in a research project. Chapter 3 outlines information that may be required, including:

- the identities of the researcher and the funder or sponsor; and
- information concerning any real, potential or perceived conflicts of interest on the part of the researchers, their institutions, or the research sponsors.

Can I participate in post-marketing surveillance studies?

Physicians must only participate in industry-sponsored research that is ethically defensible and scientifically valid. Post-marketing surveillance studies that are scientifically appropriate for drugs or devices relevant to their area of practice and where the study may contribute to medical knowledge about the drug or device may meet these criteria. However, post-marketing surveillance studies that are clearly intended for marketing or other purposes are not.

What are the authorship criteria for publishing articles reporting research results?

The policy refers to the International Committee of Medical Journal Editors (ICMJE) which has developed Recommendations of best practice and ethical standards in the conduct and reporting of research and other material published in medical journals. The ICMJE recommends that authorship be based on meeting four criteria, related to making substantial contributions to the work, drafting or revising the work, final approval of the version to be published, and agreeing to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

What do I need to know about collecting, using, and/or disclosing personal health information when participating in industry-sponsored research?

Physicians must comply with the *Personal Health Information Protection Act, 2004 (PHIPA)* when collecting, using, or disclosing personal health information (PHI). In general, physicians must only collect, use, or disclose PHI if they have the patient's consent, or if the provisions under *PHIPA* which permit the collection, use, or disclosure of PHI for research purposes without consent have been satisfied. Physicians can seek a patient's consent even if an exception to the consent requirements applies and may wish to make reasonable efforts to obtain a patient's consent before disclosing their information whenever possible.

Relevant resources from the Canadian Medical Protective Association (CMPA) and the Information and Privacy Commissioner of Ontario (IPC) can be found below. Further guidance can also be found in Chapter 5 of the TCPS-2.

Can I respond to industry requests to contact patients directly?

Where third party researchers received PHI from a physician about the physician's patients under s. 44(1) of *PHIPA,* they are prohibited from contacting those patients, either directly or indirectly, unless the physician has obtained the patient's consent to be contacted by the researcher (s. 44(6)(e)). If the researcher obtained information by other means, *PHIPA* does not prohibit the researcher from contacting the individuals.

Resources

Canadian Medical Association

Guidelines for physicians in interactions with industry / Recommendations for physician innovators

Canadian Medical Protective Association

Clinical research
Medical-legal issues to consider with clinical research contracts
Physicians and research: Understanding the legal, ethical, and professional obligations

Information and Privacy Commissioner of Ontario

Consent and your personal health information
Use and Disclosure of Personal Health Information for Broader Public Health Purposes