ASSOCIATION MÉDICALE CANADIENNE | CANADIAN MEDICAL ASSOCIATION

CMA POLICY

Guidelines for physicians in interactions with industry

See also companion policy Recommendations for physician innovators

Physician–industry relationships are evolving in an increasingly complex health care landscape as new industry sectors assume more prominent roles in medicine. Today, physicians interact with industry in the course of medical practice, research, and education. Appropriate interactions with industry can benefit patients, society, and physicians through the advancement of medical science and practice, effective and safe use of health care products and services, and ultimately by improving patients' opportunities to access the benefits of health care and health outcomes. However, physicians' interactions with industry can influence their professional judgment and potentially conflict with patients' interests in ways that can harm patients and public health. Evidence indicates that physicians may not always be aware of, or be able to accurately self-assess, how their industry affiliations can subconsciously influence their judgment, their assessment or presentation of medical evidence, their clinical decisions and their prescribing.

Physicians have a responsibility to ensure that their participation in collaborative efforts with industry primarily serves the interests of their patients and the public. Physicians must strive first to avoid or second to minimize or manage conflicts of interest. They must always disclose any ties with industry that have, or could be perceived as having, the potential to influence their judgment, including their professional recommendations, clinical decisions, and prescribing.

Conflicts of interest arise when a person in a position of trust has competing professional or personal interests. Conflicts of interest occur where judgments or decisions about a primary interest — in this case, patient well-being, trustworthy medical research and knowledge, and excellent medical education — are unduly influenced by a secondary interest. Secondary

interests can include direct financial gain, professional advancement, and reputational benefits, or other benefits to family, friends, or colleagues and may arise in the context of competing roles that physicians hold (such as clinical, education, research, organizational, administrative, leadership, and advocacy roles). Conflicts of interest may be real, potential, or perceived, and may exist even if no unethical or inappropriate act results from the conflict. Conflicts can persist even after an individual has ceased to benefit directly from a secondary interest.

This document guides physicians in determining how to appropriately interact with industry and effectively mitigate bias and undue influence through the avoidance or management of conflicts of interest. The medical profession leads by example by promoting physician-developed guidelines. The guidelines offer direction on how physicians should interact with industry at an arm's length including when acting as consultants, advisors, or employees, or as recipients or users of industry funding, products, or information. Physicians are also increasingly taking on leadership roles in medical innovation or entrepreneurship enterprises — roles that place the physician within industry.a A companion document to these guidelines, the Recommendations for Physician Innovators, provides recommendations for physicians in navigating conflicts of interest arising from their roles as medical professionals who are also engaged directly in medical and health care innovation.

Relationships between physicians and industry are also guided by the CMA Code of Ethics and Professionalism. Physicians should also be aware of regulatory and legal requirements that govern medical practice and the use of patients' personal health information in the jurisdiction where they practise as well as any additional requirements set out by relevant institutions, research ethics boards, accreditors and publishers, which may be more stringent than these guidelines.

These guidelines are directed primarily to individual physicians across the career life cycle — including learners and practising and retired physicians. They are also relevant to guiding the development of relationships between medical organizations and industry.

GUIDING PRINCIPLES

These principles apply both to these guidelines and to the Recommendations for Physician Innovators. These principles draw on the CMA Code of Ethics and Professionalism.

Well-being of the patient

A physician's primary obligation is to preserve and promote the well-being of the patient. Relationships with industry are appropriate only where they do not undermine the physician's

[a] In these guidelines, industry refers to health-related industries, which include, but are not limited to, manufacturers, developers, or suppliers of pharmaceuticals, therapeutics, medical devices and supplies, health care products and services, wellness and nutritional products and services, biotechnology, information technologies including software (such as for the management of patient data, records, and treatment), and products that may be understood as having a clinical or health benefit.

duty of loyalty to protect and further the patient's best interests and goals of care. Physicians must resolve any conflict of interest between themselves and their patient resulting from interactions with industry in favour of the patient. In particular, they must avoid acting in self-interest in their prescribing and referral practices.

Public trust

Trust is central to the patient–physician relationship and to providing the highest standard of medical care. Patients and the public should be able to trust that physicians prioritize the well-being of patients above all else. Physicians must uphold patients' and the public's trust in physicians, in the profession of medicine and in medical science. Transparency helps promote public trust by facilitating oversight and accountability, as well as facilitating public commentary and advocacy.

Professional integrity

Physicians must uphold professional integrity when engaging in innovation or entering into associations, contracts, and agreements with industry. Integrity requires maintaining professional autonomy and independence, acting in accordance with professional expectations and the best available medical evidence, adhering to scientific methodology, and safeguarding the interests of the patient or public. Professional integrity also requires humility, honesty, and the transparent disclosure of innovation activities and industry relationships to patients, colleagues, and supervisors when such potential conflict would be viewed by others as relevant to the relationship in question.

Social accountability and equity

Social accountability is central to professional excellence in medicine. Physicians and the profession express social accountability when they respond to the current and future priority health needs of the patients and communities that they serve in their clinical practice, education, research, leadership, and advocacy. Physician interactions with industry and physician-led innovation should be guided by a primary concern for advancing the health and addressing the evolving health needs of Canadians, including by advancing medical practice and science to reduce health inequities and disparities in care.

PART I: PHYSICIAN INTERACTIONS WITH INDUSTRY

A. PRACTICE

Medical practice

1. Physicians should always maintain professional autonomy in interactions with industry. Physicians must remain committed to scientific methodology and to their professional responsibilities.
2. Physicians who are employed by, or affiliated with, industry should not allow their employment or affiliation to influence their clinical judgment and medical practice in ways that do not support the well-being of their patients and the public.
3. Physicians with industry affiliations or with a direct financial interest in health care industry have an obligation to disclose these affiliations, interests, or investments to patients and ensure that they do not affect their decision-making in practice, including with respect to diagnosis, prescribing, and patient care.
4. Physicians should dispense pharmaceuticals or other products only where permitted by applicable law and regulations, including the regulations of their medical regulatory authority, and where they can demonstrate that these cannot be provided by an appropriate other party, and then only on a cost-recovery basis.
5. Physicians who enrol patients into industry-sponsored patient support programs or patient assistance programs in the course of their practice must not accept compensation or benefits from an industry member or representative in return for prescribing a particular agent, recommending a particular device, diagnostic, or service, or enrolling a patient to the program.
6. Physicians should limit the presence of industry representatives in their practice, including ensuring that industry representatives are not present during clinical rounds and confidential conversations or decisions, unless rounds are open to the public.

Clinical practice guidelines (CPGs)

7. This section provides general guidance to which physicians involved in clinical practice guideline (CPG) development should adhere. These principles also apply to the development of clinical care pathways developed in hospitals and health systems to guide care. The *Principles for Disclosure of Interests and Management of Conflicts in Guidelines*[1] developed by the Guidelines International Network serve as an additional source of guidance for physicians and physician organizations involved in guideline development. Physicians should also be aware of guidelines and standards related to CPG development adopted by other bodies, including academic journals.
8. Clinical practice guidelines are used to inform medical practice and education. Owing to their potential to significantly affect practice, CPGs must be developed on the basis of an independent, rigorous assessment of the best available medical evidence by a committee with significant representation of the target audience of the guideline. Financial and non-financial interests held by physicians involved in CPG development can give rise to biases that may lead

to the overestimation of benefits or underestimation of harms associated with a treatment or intervention, which may in turn unduly influence the strength or direction of a practice recommendation.
9. Physicians must be aware of how industry affiliations can influence their judgment and must not allow their affiliations to influence their assessment or presentation of medical evidence.
10. Physicians involved in CPG development should be free of financial and other relevant non-financial conflicts of interest. Where this is not possible, a majority of panel members should be free of conflicts of interest and the panel must adhere to the guidance listed below.
11. Physicians and physician organizations involved in CPG development must disclose all financial and non-financial conflicts of interest in writing, including disclosing the nature of conflict, the name of the business involved, and the amount provided; physicians on a CPG development panel must inform the chair should they develop a new conflict of interest.
12. Physicians chairing a guideline development panel must be free of direct financial or other relevant non-financial conflicts of interest. The chair is accountable for the assessment of conflicts of interest for panel members.
13. Physicians with conflicts of interest may be involved in CPG development by imparting or clarifying medical information only if they have unique expertise that cannot be provided by experts without industry affiliations or other relevant conflicts of interest. In such cases, those developing a CPG should seek a balance of opinion among those involved.
14. Physicians with direct financial conflicts of interest must recuse themselves from adjudication and voting on the strength or direction of a practice recommendation.

Samples

15. A sample is a unit of a pharmaceutical product, therapeutic agent, or medical device intended for patient use provided to a physician free of charge for the purpose of evaluating the product, agent, or device. Samples can also be referred to as clinical evaluation packages.
16. Physicians should only accept samples they request and should not accept unsolicited samples distributed at conventions, displays, meetings, or learning programs.
17. Physicians who accept samples or other health care products are responsible for recording the type and amount of medication or product dispensed; ensuring their age-related quality, appropriate storage and security prior to dispensing; and ensuring proper disposal if the items are outdated and still in the physician's possession.
18. Physicians who accept samples must determine whether samples are appropriate and dispense them on the basis of clinical evidence, their own clinical judgment, and in accordance with the principles of professional integrity, social accountability, and equity. This includes taking into account whether the physician considers that the sample is their first choice of treatment, and any impact that the patient's use of samples may have on the patient's costs, including when such samples are no longer available.
19. Physicians must avoid distributing samples, including pharmaceutical products and devices, for which they, or any practice they are associated with, would receive any form of material gain.
20. Where industry provides physicians with software (including applications) for clinical evaluation for patient use, physicians should adhere to the guidance in this section.

Gifts

21. Physicians must not accept a fee, gift, meal, or equivalent benefit from industry, including in exchange for interacting with them in a promotional or similar capacity. Physicians should be aware that acceptance of gifts of any value, even minor, has been shown to influence clinical and therapeutic decision-making.
22. Physicians may accept patient teaching aids (also known as service-oriented items) appropriate to their area of practice provided that the aids: (i) hold no personal value to the physician; (ii) are not connected to any stipulation that the physician prescribe a particular medication or use a particular medical device; and (iii) carry at most the logo of the donor company and do not refer to specific therapeutic agents, medical devices, diagnostic tests, or other products or services.

Promotional activities

23. This section provides guidance about the promotion of industry products or services that may be understood as having a clinical or health benefit by physicians, in their capacity as physicians, through any private or public medium, including through social media.
24. The promotion of products or services, whether or not they are directly related to health care or wellness, is at a high risk of creating a conflict with the physician's primary obligation to the well-being of the patient and to the maintenance of public trust.
25. Physicians should carefully reflect on the potential impact of the information they share via social media on both the intended and potential future audiences, especially as information can be easily circulated further without their knowledge or control.
26. Physicians must avoid using their role as a physician to promote services (except their own medical services) or products to patients or the public for commercial gain outside of their treatment role.
27. Physicians should not accept positions from industry to conduct seminars or similar promotional events aimed at enhancing the sale of industry products or services to other physicians. This also applies to third-party contracting, including participation in speaker's bureaus, on behalf of industry.
28. Physicians must disclose all relevant relationships with industry and real or perceived conflicts of interest in a way that is obvious to any relevant audience where discussing products and services. They should refer to relevant medical evidence, not overstate benefits or understate harms, not mislead patients or others about a product or service's impact, and be guided by a primary concern for patient well-being. Disclosure should be done in a serious manner and in such a way that the audience has sufficient time to absorb the information being disclosed.
29. Physicians should not display industry-developed advertisements or informational materials with logos, except for teaching aids, in clinics or hospitals, nor accept payments or donations in return for displaying industry-sponsored materials.

Advisory boards and consulting

30. Physicians may be asked to become members of advisory or consultation boards or to serve as advisors or consultants for industry organizations. Physicians should be mindful of the potential for these relationships to influence their clinical decision-making, research, and

teaching.
31. The expected deliverables of all consulting or advisory arrangements should be clearly set out in writing in the form of a contractual agreement. Physicians should avoid informal consulting arrangements.
32. Remuneration of the physician should be commensurate with the work performed and take into account the extent and complexity of the physician's involvement.
33. Whenever possible, meetings should be held in the geographic location of the physician or as part of a meeting that they would normally attend. Basic travel and accommodation expenses may be reimbursed to a physician advisor or consultant who is required to travel. Hospitality and other arrangements must not be reimbursed for personal guests of the advisor or consultant, including spouses or family members.
34. Physicians must disclose their participation on advisory boards or as consultants where relevant in the course of their practice, research, or teaching.

B. EDUCATION

Continuing professional development (CPD)

35. This section of the guidelines primarily addresses accredited/certified CPD activities, including activities referred to as continuing medical education (CME), for practising physicians, including regular scheduled series, rounds, journal clubs, and small groups. The same general principles apply to live, in-person CPD events and accredited online or electronic CPD (eCPD) content, or any other written, curriculum-based CPD modules. Physicians should also refer to this guidance when considering attendance at informal or non-accredited learning activities with industry involvement. Physicians should approach non-accredited learning activities offered by industry with caution, recognizing that there is a higher likelihood that such events are promotional in nature.
36. CPD provider organizations and presenters must also follow all applicable laws and regulations and the guidance outlined by relevant accrediting bodies. These guidelines are complementary with the National Standard for Support of Accredited CPD Activities;[2] should discrepancies arise, the more stringent of the two standards should be followed.
37. The purpose of accredited CPD activities is to address the educational needs of physicians and other health care providers to improve patient care. Financial and in-kind support by industry should not be considered necessary or desirable for CPD activities but may be accepted as outlined in the national standard. Non-accredited learning activities offered by industry are considered promotional in nature and are not considered as CPD.
38. Physician presenters must disclose to participants any financial affiliations with manufacturers or providers of products and services mentioned at the event, financial affiliations with manufacturers of competing products, and any other related relationships with for-profit and non-for-profit organizations over the previous two years.
39. A reference list for studies cited in CPD activities and modules should be made available to participants to allow them to evaluate the quality of the evidence discussed.
40. Generic names should be used. Where trade names are required, generic names must also be included.

41. If specific products or services are mentioned, there should be a balanced presentation of the prevailing body of peer-reviewed scientific information on the product or service and of reasonable alternatives. If unapproved, “off-label” uses of a product or service are discussed, presenters must inform the audience of this fact.
42. Physicians acting as authors of accredited eCPD modules should have special expertise in the relevant clinical area and must declare any relationships with the sponsors of the module or any competing companies. Authors are ultimately responsible for the content and validity of eCPD modules and should ensure that they are both designed and delivered at arm’s length of any industry sponsors.
43. Physicians should only accept travel and accommodation arrangements and attend venues and social events for CPD activities receiving financial sponsorship from industry for accredited/certified activities in keeping with the arrangements that would normally be made without industry sponsorship. For example, the industry sponsor must not pay for travel or lodging costs or for other personal expenses of physicians attending a CPD event. Physicians must not accept subsidies for hospitality outside of modest meals that are held as part of a conference or meeting. Hospitality and other arrangements must not be subsidized by sponsors for personal guests of attendees or faculty, including spouses or family members.
44. Participants must not accept payment or subsidies to participate in an accredited CPD activity, but they are not precluded from claiming or receiving compensation from residency programs, employers, or provincial CPD support funds. However, presenters at CPD events may accept reasonable honoraria and reimbursement for travel, lodging, and meal expenses. All participants at an event cannot be designated presenters.

Medical students and residents

45. The principles in this section apply to learners as well as to medical educators.
46. Academic institutions and training environments should provide guidance for, and supervision of, learners in their interactions with industry. Medical curricula should deal explicitly with these guidelines by including educational sessions on conflicts of interest, detecting bias, and physician–industry interactions in the context of medical education, practice and research.
47. All lecturers and those educating or training medical learners should fully and consistently disclose to both learners and their educational institutions any relationship with industry, including financial and non-financial conflicts of interest.
48. Learners should carefully examine involvement in extracurricular activities, non-accredited events, and clubs that receive financial support from industry, no matter how informal, in light of the principles and guidance in these guidelines. They should avoid events or activities that have the potential to create bias or a conflict of interest. Industry ties in this context may include industry sponsorship or a training component provided by industry.
49. In very limited circumstances, industry can play a role in providing training to residents specific to the use of medical devices, pharmaceutical delivery methods, or skills or techniques developed by industry. Such training should only be considered where there is no means of providing the training internally. If training is provided by faculty with industry relationships, all conflicts of interest should be examined and managed, including through careful review by the educational institution and disclosures to learners and the institution. Drug detailing should

only be provided by faculty or lecturers without industry relationships.
50. Sponsorships of learners, scholarships, and bursaries funded by industry should be managed, evaluated, and selected centrally by educational institutions. There should be no industry sponsorship of, or scholarships for, travel to attend conferences. There should be no expectation that recipients should provide any benefit to, or enter into any relationship with, industry.

C. RESEARCH

Industry-sponsored research

51. Physicians who conduct research have the primary responsibility to ensure that research involving humans meets high scientific and ethical standards that respect and protect the dignity and welfare of participants consistent with standards and guidelines that govern the ethical conduct of research involving humans.
52. Physicians participating in industry-sponsored research must comply with all laws, policies, standards and guidelines governing research involving humans, including the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2);[3] the *International Conference on Harmonisation Guideline for Good Clinical Practice* (ICH/GCP),[4] as set forth in *Division 5 under the Canadian Food and Drugs Act*;[5] and all relevant privacy legislation.
53. Physicians must avoid remuneration for conducting or collaborating in research studies that could influence their judgment, decision-making, or actions. Remuneration may cover reasonable time and expenses and should be approved by the relevant research ethics board. Research subjects must be informed if their physician will receive a fee for their participation and by whom the fee will be paid.
54. Physicians must ensure that agreements with industry protect the physician's right to publish or disclose complete and accurate study data and results or report adverse events that occur during the course of the study.
55. Physicians should participate only in post-marketing surveillance studies that are scientifically appropriate for drugs or devices relevant to their area of practice and where the study may contribute substantially to medical knowledge about the drug or device. Studies that are clearly intended for marketing or other purposes must be avoided.

Approved by the CMA Board of Directors August 2021
See also companion policy Recommendations for physician innovators

[1] Schünemann HJ, Al-Ansary LA, Forland F, et al. Guidelines International Network: The principles for disclosure of interests and management of conflicts in guidelines. *Ann Intern Med* 2015 Oct 6;163(7):548-53. Available: https://www.acpjournals.org/doi/10.7326/M14-1885 (accessed 2021 Jul 27).

[2] Royal College of Physicians and Surgeons of Canada (RCPSC), The College of Family Physicians of Canada (CFPC), Collège des Médecins du Québec QMC). *National standard for support of accredited CPD activities*. Ottawa: RCPSC, CFPC, QMC; 2017 Aug 29. Available: https://www.royalcollege.ca/rcsite/cpd/providers/tools-resources-accredited-cpd-providers/national-standard-accredited-cpd-activities-e (accessed 2021 Jul 27).

[3] Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council. *Tri-council policy statement: ethical conduct for research involving humans*. Ottawa: Government of Canada; 2018 Dec. Available: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html (accessed 2021 Jul 27).

[4] International Council for Harmonisation (ICH). *ICH harmonised guideline integrated addendum to ICH E6(R1): Guideline for good clinical practice ICH E6(R2) ICH consensus guideline*. Geneva: ICH; 2016. Available: https://ichgcp.net/ (accessed 2021 Jul 27).

[5] Health Canada. *Guidance document: Part C, Division 5, of the Food and Drug Regulations 'Drugs for Clinical Trials Involving Human Subjects' (GUI-0100).* Ottawa: Government of Canada; 2019 Aug 20. Available: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html (accessed 2021 Jul 27).

SELECTED BIBLIOGRAPHY

Canadian Medical Association (CMA). *CMA code of ethics and professionalism* [policy]. Ottawa: The Association; 2018. Available: https://policybase.cma.ca/en/permalink/policy13937 (accessed 2021 Jul 27).

Canadian Medical Association (CMA). *Recommendations for physician innovators* [policy]. Ottawa: The Association; 2021. Available: https://policybase.cma.ca/en/permalink/policy14454 (accessed 2021 Sept 01).

Fickweiler F, Fickweiler W, Urbach E. Interactions between physicians and the pharmaceutical industry generally and sales representatives specifically and their association with physicians' attitudes and prescribing habits: a systematic review. *BMJ Open* 2017;7:e016408. Available: https://bmjopen.bmj.com/content/7/9/e016408.long (accessed 2021 Jul 27).

Fleischman W, Agrawal S, King M, et al. Association between payments from manufacturers of pharmaceuticals to physicians and regional prescribing. *BMJ* 2016;354:i4189. Available: https://www.bmj.com/content/354/bmj.i4189.long (accessed 2021 Jul 27).

Food and Drug Regulations, CRC, c 870. Available: https://canlii.ca/t/7wlw (accessed 2021 Jul 27).

Food and Drugs Act, RSC 1985, c F-27. Available: https://canlii.ca/t/7vgh (accessed 2021 Jul 27).
Institute of Medicine Committee on Conflict of Interest in Medical Research, Education, and Practice. *Conflict of Interest in Medical Research, Education, and Practice*. Washington (DC): National Academies Press; 2009. Available: https://www.ncbi.nlm.nih.gov/books/NBK22942/ (accessed 2021 Jul 27).
Larkin I, Ang D, Steinhart J, et al. Association between academic medical center pharmaceutical detailing policies and physician prescribing. *JAMA* 2017;317(17):1785–1795. Available: https://jamanetwork.com/journals/jama/fullarticle/2623607 (accessed 2021 Jul 27).
Mintzes B, Lexchin J, Sutherland JM, et al. Pharmaceutical sales representatives and patient safety: a comparative prospective study of information quality in Canada, France and the United States. *J Gen Intern Med* 2013;28:1368–1375. Available: https://link.springer.com/article/10.1007%2Fs11606-013-2411-7 (accessed 2021 Jul 27).
Traversy G, Barnieh L, Akl EA, et al. Managing conflicts of interest in the development of health guidelines. *CMAJ* 2021;193(2):E49-E54. Available: https://www.cmaj.ca/content/193/2/E49 (accessed 2021 Jul 27).
Wazana A. Physicians and the Pharmaceutical Industry: Is a Gift ever just a gift? *JAMA* 2000 Jan 19; 283(3):373-80.