

STANDARDS OF PRACTICE

Relationships with Industry

Under Review: <u>Yes</u>No Issued By: Council: January 1, 2010



The **Standards of Practice** of the College of Physicians & Surgeons of Alberta ("CPSA") are the **minimum** standards of professional behavior and ethical conduct expected of all regulated members registered in Alberta. Standards of Practice are enforceable under the *Health Professions Act* and will be referenced in the management of complaints and in discipline hearings. CPSA also provides **Advice to the Profession** to support the implementation of the Standards of Practice.

Note: a glossary of terms can be found at

For the <u>purposesend</u> of this <u>document</u>. Glossary terms are indicated in teal with a "G" throughout this document.

PREAMBLE

This standard, "of practice provides direction for regulated members when interacting with industry" means any manufacturer, whether directly engaged in medical and health care innovation, or distributor of when an arm's-length relationship exists. 1 lt must be read in conjunction with the Conflict of Interest and Human Health Research standards of practice.

"Industry" includes the full range of commercial enterprises associated with healthcare products, including pharmaceuticals and medical devices... 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 or education.²

The financial resources and product knowledge contributed by industry coupled with the medical knowledge of regulated members can lead to new procedures, drugs, therapies and treatments that may advance healthcare. However, the fiduciary duty of regulated members remains what is in the best interest of the patient. Conflicts of interest^G related to financial aspects can affect a regulated member's objectivity and the care of patients.³

Terms used in the Standards of Practice:

- "Regulated member" means any person who is registered or who is required to be registered
 as a member of this College. The College regulates physicians, surgeons and osteopaths.
- "Must" refers to a mandatory requirement.
- "May" means that the physician may exercise reasonable discretion.
- $\bullet \text{ ``Patient'' includes, where applicable, the patient's legal guardian or substitute decision maker.}$

¹ From the Canadian Medical Association's Recommendations for Physician Innovators Policy (2021) – accessed Apr. 2025.

² From CPSO's Conflicts of Interest and Relationships with Industry Policy (Mar. 2024) – accessed Apr. 2025. ³ From the World Medical Association's "Statement Concerning the Relationship between Physicians and Commercial Enterprises" (May 2022) – accessed Apr. 2025.



Related standards, additional information and general advice can be found in the companion resources listed at the end of this document.

STANDARD

General

—<u>A regulated member **must**</u> maintain clinical objectivity, ⁴ professional autonomy and independence in any relationship with industry as well as when making decisions regarding patient care to preserve the fiduciary relationship^G.

- 1. A Where possible, a regulated member **must** resolve any conflict of interest resulting from interaction with industry in favor of his/her patients.
- A regulated member must always maintain professional autonomyidentifyautonomy and independence in any relationship with industry.

avoid situations or circumstances that are, may

- 3.1. A regulated member must disclose to a patient any relationship between the regulated member and industry that reasonably could be perceived as having the potential to influence the regulated member's clinical judgment. to be, or may lead to, a conflict of interest.
- Where avoidance is not possible, a regulated member participates in must:
 - a. <u>proactively disclose the details of their interactions with industry sponsored to the relevant parties (e.g., patients, research activities, the regulated member must:</u> participants, institutions, attendees at educational events, etc.); and
 - a. only participate in research activities that are ethically defensible, socially responsible and scientifically valid;

Commented [CD1]: Clause 4 of current version.

Commented [CD2]: Clause 3 of <u>current version</u> with additions from CPSO's <u>Conflicts of Interest and</u> <u>Relationships with Industry</u> Policy to provide clarity.

Commented [CD4]: Clauses related to research will be addressed in a future Health Research Advice to the Profession document.

Terms used in the Standards of Practice:

⁴ From the MCNZ's "Doctors and health-related commercial organisations" Statement (Feb. 2023) – accessed Apr. 2025.

⁵ From CPSO's Conflicts of Interest and Relationships with Industry Policy (Mar. 2024) – accessed Apr. 2025.

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- only participate in research activities that have been <u>formally reviewed</u> <u>and approved</u> by an appropriate ethics review body;
- enroll patients in research activities only after full, informed, competent and voluntary <u>consent</u> of the patient or authorized agent;
- d. protect the patient's privacy in accordance with provisions of applicable legislation;
- b. only resolve conflicts of interest in the patient's best interest, in accordance with the Conflict of Interest standard of practice.
- e. A regulated member must not accept remuneration that covers time and expenses at a reasonable rate;
- f. disclose to research subjects that the regulated member will receive a fee for participation and the source of that fee;
- 4.3. when submitting and/or publishing information in any media, disclose any relationships with industry providing fundingany personal gift of any monetary or other consideration for the research performed or the publication submitted; value from industry.
 - g. avoid entering into agreements that limit the A regulated member's right to publish or disclose results of the study or report adverse events that occur during the coursemember must follow the Human Health Research standard of the study; and
- 4. only participate practice when participating in industry—sponsored surveillance studies that are scientifically valid and expected to contribute research contribute research activities.
- A regulated member must not claim authorship or contribution to the production of educational materials unless they have substantially to knowledge about contributed to the material.

Industry relationships in clinical practice

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Commented [CD3]: Moved to draft *Human Health Research* standard.

Commented [CD5]: From CPSO's Conflicts of Interest and Relationships with Industry Policy: provides additional clarity to above addition.

Commented [CD6]: Simplified with reference to Human Health Research standard: research-related clauses from the current version of the Relationships with Industry standard will be addressed in a future Health Research Advice to the Profession document.

Commented [CD7]: Clause 8 of current version.



- When considering the use of clinical evaluation packages, such as medication samples or medical devices, a regulated member must:
 - a. recognize the influence on the regulated member's prescribing choices;67
 - a.b. use appropriate clinical evidence to determine the choice of medication drug or device; and
 - c. document the type and amount of medication or device in the patient record.
- A regulated member must not receive any form of material gain for themselves, or the practice they are associated⁸ with, based on the choice of product in relation to clinical evaluation packages.
- Notwithstanding clause (9), a regulated member may accept teaching aids⁶ provided by industry if:
 - a. they are satisfied the teaching aids are accurate, balanced, complete and adequately disclose any potential safety concerns;
 - b. primarily entail a benefit to patients with more educational than promotional value^G; and
 - do not have value to the regulated member outside of their professional responsibilities.⁸
- A regulated member must not accept a fee or other consideration from industry in exchange for seeing an industry representative in a promotional or similar capacity.

Continuing professional development

- 5. A regulated member involved in organizing or presenting at a continuing professional development event must:
- 6:10. disclose to participants any financial relationship with industry for products mentioned at the event or with manufacturers of competing products;

⁶ From CMA's Guidelines for Physicians in Interactions with Industry Policy (2021) - accessed Apr. 2025.

⁷ From BMJ "Interactions Between Physicians and the Pharmaceutical Industry Generally and Sales Representatives Specifically and Their Association with Physicians Attitudes and Prescribing Habits: A Systematic Review" (Sep. 2017) – accessed Apr. 2025.

From CPSO's Conflicts of Interest and Relationships with Industry Policy (Mar. 2024) – accessed Apr. 2025.

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Commented [CD8]: Clause 11 of current version.

Commented [CD9]: Clause 12 of <u>current version</u> with acknowledgement of practice from CPSO.

Commented [CD10]: Clause 13 of current version.

Commented [CD11]: From CPSO: provides additional clarity on acceptable teaching aids.

Commented [CD12]: Clause 14 of current version.

Commented [CD13]: Clause 7(a) of <u>current version</u>.



- 11. not A regulated member involved in organizing or presenting at a continuing professional development event must not:
 - a. conduct a seminar or similar event directly or indirectly for industry that
 promotes a product for the purpose of enhancing the sale of that product; andor
 - b. not-accept reimbursement for expenses or honoraria at a rate that could reasonably be perceived as having undue influence.
- 12. A regulated member attending a continuing professional development event must not claim authorship or contribution to accept reimbursement for expenses from industry unless they:
 - a. are in the productionemployproduction of educational materials unless the regulated member has substantially contributed toindustry; or
 - e.b. are directly involved in the material-presentation of the professional development activity.
- 7.<u>13.</u> A regulated member **must** ensure that all industry contributions are declared on educational materials.

GLOSSARY

For

Conflict of interest: a conflict of interest is created any time a reasonable person could perceive that a regulated member'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 regulated member is confident that their professional judgment is not actually being influenced by the conflicting interest or relationship.⁹

8. A regulated member attending a continuing professional development event **must not** accept reimbursement for expenses from industry unless they are in the employ of the industry or are directly involved in the presentation of the professional development activity.

From CPSO's Conflicts of Interest and Relationships with Industry Policy (Mar. 2024) – accessed Apr. 2025.

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Commented [CD14]: Clause 7(b) and (c) of <u>current</u> version.

Commented [CD15]: Clause 10 of current version.

Commented [CD16]: Clause 9 of current version.



-When considering the use of clinical evaluation packages such as samples of medications or devices, a regulated member must:

b. recognize the influence on the regulated member's prescribing choices; more information, please refer to the Conflict of Interest standard of practice and Advice to the Profession document.

Fiduciary relationship: one in which the regulated member acts in good faith and with loyalty toward the patient and never places their personal interests ahead of the patient's.10 11

Promotional value: focus would be on the industry/company (e.g., large logos; references to specific therapeutic agents, services or other products; medical claims of a product; etc.).

Teaching aids: help educate patients on their health conditions, improve their understanding and enhance informed decision-making (e.g., brochures, models, props, videos, etc.) based on the most current and updated clinical evidence.¹²

ACKNOWLEDGEMENTS

CPSA acknowledges the work of the Colleges of Physicians and Surgeons of Ontario in preparing this document.

- use appropriate clinical evidence to determine the choice of medication or device;
- -document the type and amount of medication or device in the patient record;
- -not receive any form of material gain based on the choice of the
- -A regulated member must not accept any personal gift of any monetary or other value from industry.

Terms used in the Standards of Practice:

¹⁰ From CMPA's Glossary – accessed Apr. 2025.

¹¹ From CMPA's "Duty of Care" (Mar. 2023) – accessed Apr. 2025.

¹² From the National Library of Medicine's "Empowering Patients: Promoting Patient Education and Health Literacy" (July 2022) - accessed Apr. 2025.

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11. Notwithstanding clause (12), a regulated member **may** accept teaching aids provided by industry.

A regulated member **must not** accept a fee or other consideration from industry in exchange for seeing an industry representative in a promotional or similar capacity.

RELATED STANDARDS OF PRACTICE

- Conflict of Interest
- Human Health Research
- Informed Consent
- Patient Record Content
- Prescribing: Administration

ADVICE TO THE PROFESSION DOCUMENTS

- Conflict of Interest
- Informed Consent for Adults
- Informed Consent for Minors
- Prescribing: Administration

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