

Practising Outside Established Conventional Medicine

The College of Physicians & Surgeons of Alberta (CPSA) provides advice to the profession to support physicians in implementing the CPSA Standards of Practice. This advice does not define a standard of practice, nor should it be interpreted as legal advice.

Advice to the Profession documents are dynamic and may be edited or updated for clarity at any time. Please refer back to these articles regularly to ensure you are aware of the most recent advice. Major changes will be communicated to our members; however, minor edits may only be noted within the documents.

Contents

What is covered by this standard?	2
When should CAM be considered?	
ls off-label use of Schedule 1 or 2 drugs CAM?	4
How do "emerging therapies" fit in?	
Respecting patient autonomy	
Resources	

CPSA has previously referred to this practice as complementary and alternative medicine ("CAM"), but we recognized the need for the standard to be updated to better reflect the current health care context.

All physicians are expected to practice in a manner that is informed by evidence and science and is in keeping with professional, ethical and legal obligations. We recognize there may be a lack of clarity between complementary and alternative medicine ("CAM") and an emerging treatment for which robust, peer-reviewed evidence is not yet available. Physicians should be aware of the best currently available scientific evidence regarding safety and efficacy when practicing outside of conventional medicine.

Any physician offering treatments with limited supporting scientific evidence should be certain of the patient's diagnosis and must also offer conventional treatment options. The patient must be aware of the uncertainties, risks and potential side effects of a non-



Practising Outside Established Conventional Medicine

conventional therapy. This is the same expectation for any physician offering any treatment—good reasoning, clear communication, setting expectations with patients and ensuring <u>informed consent</u>.

A physician considering practicing outside of conventional medicine that it not part of an approved <u>human health research</u> study should consult with the <u>Canadian Medical</u> <u>Protective Association</u> (CMPA). CMPA has <u>resources available</u> to physicians regarding the medico-legal concerns with CAM that should be reviewed prior to offering therapies outside of conventional therapies.

What is covered by this standard?

CAM refers to health care approaches developed outside of mainstream or conventional, medicine that are used for specific conditions or overall well-being¹. CAM is broadly categorized into:

- natural health products, like vitamins, herbs and probiotics, which are regulated by <u>Health Canada;</u>
- mind and body practices, such as acupuncture; and
- other CAM practices, like traditional medicine: "traditional medicine" can refer to the healing practices, products and beliefs of First Nations, Metis and Inuit peoples, but is also a term used for traditional medicine from other cultures or locations, such as Traditional Chinese Medicine and Traditional Medicine of India (e.g., Ayurveda).

When providing medical care, it is important to inquire about the use of "traditional medicine" and the option for Indigenous people to explore traditional medicine as a treatment modality. Indigenous people may choose to use these treatments alongside conventional medicine or use them as the sole treatment: this right must be respected.

It is important to note that simply because a practice is considered CAM does not mean it is not evidence-based and, alternately, a practice being within conventional health care does not guarantee that it is evidence-based. A practice may be considered CAM because of a different philosophy of healing, diagnosis or treatment, regardless of whether there is adequate evidence about its safety or efficacy. As new approaches to health care and

¹<u>https://nccih.nih.gov/health/integrative-health</u>



high quality evidence regarding CAM continue to emerge, definitions and lists of what constitutes CAM can be expected to change over time.

Published evidence of CAM safety and efficacy may be limited, particularly for pediatric, geriatric and other vulnerable populations. Dosing, duration of therapy, long-term outcomes, potential interactions and other key questions may not be known, and awareness of evidence-based resources among many physicians may be limited. Despite this, high-quality evidence about CAM is emerging, and research is increasingly being conducted and published in reputable journals.

When should CAM be considered?

When a physician considers a CAM therapy to be potentially beneficial in patient care, directing or <u>referring</u> the patient to a qualified CAM practitioner may be appropriate after carefully considering and discussing the risks and benefits of the therapy with the patient. In these cases, physicians must ensure patients <u>fully understand and consent</u> to the therapy. A physician's legal obligations of care and duty to the patient, including potential issues of medico-legal liability arising from such referrals, remain regardless of the type of practitioner (conventional or CAM) to whom the referral is made.

If a patient seeks out CAM therapy, that patient's physician should be able to demonstrate requisite training, or if they do not have that training, they can refer the patient to a qualified CAM provider.

We expect physicians will do the following prior to incorporating CAM therapies or emerging therapies into their practice:

- 1. Attend accredited <u>continuous professional development</u> to learn about the new treatment modality, its indication, benefits, risks, etc.;
- 2. When learning a new procedure or therapeutic treatment, arrange a period of mentorship with a qualified colleague and seek feedback from that colleague to ensure they are competent to perform the procedure independently in their own practice;
- 3. Where possible, obtain certification or appropriate credentials for the treatment modality (e.g., acupuncture); and



4. Once performing the treatment independently, put quality assurance mechanisms into place to ensure the procedure is being performed to the highest possible standard (e.g., Infection Prevention and Control Standards, monitor complications).

Physicians should consider evidence for effectiveness, evidence with regard to harms, as well as cost to the patient, patient preference, respecting patient autonomy and that health related beliefs, preferences, values and culture have tremendous impact on treatment adherence and patient outcome.

Is off-label use of Schedule 1 or 2 drugs CAM?

Off-label use of medications where there is insufficient peer-reviewed evidence to support its use is **not** considered CAM. CPSA recommends, whenever possible, physicians consider such treatments only within the confines of an ethics-approved research study in accordance with the <u>Human Health Research</u> standard of practice.

It is important to ensure the proposed "off-label" use is aligned with widely accepted opinions of peers and field experts; otherwise, off-label use should be done only in an approved, scientifically rigorous study.

How do "emerging therapies" fit in?

Emerging therapies refer to therapies that are developed within mainstream conventional medicine with support from human health research but lacking in rigorous peer reviewed evidence; this may include pharmacological and non-pharmacological practices, products, procedures and other interventions. CPSA strongly recommends that if a physician is considering offering an emerging therapy, they only do so in the context of a <u>human health</u> research study. If the emerging therapy is not being done as part of a human health research study, the therapy being considered for use should be within the physician's usual field of expertise², and there are peers and evidence to support its use for a clinical indication.

Respecting patient autonomy

A patient who inquires about or requests a CAM therapy should be counselled about therapeutic options, both conventional and CAM, weighing the known risks and benefits of

² Family physicians or specialists considering an emerging therapy that is within their generally accepted field of expertise.



each therapy and providing sufficient information and opportunity for discussion in order for the patient to make informed decisions. Acknowledging the limitations of evidence supporting safety and efficacy of all potential therapies is an important aspect of these discussions. The physician should use appropriate and non-judgemental language in advising the patient and offer easily accessible, evidence-based, comprehensive resources when possible. Coercive language or tone must be avoided, and the patient must understand that s/he is free to decline any aspects of care <u>without unduly affecting their therapeutic relationship</u> with the physician³.

For patients who are minors and not autonomous decision makers, the physician must always employ a conventional medical approach before offering any CAM therapy and act in the best interest of the patient. For patients considered mature minors, physicians must practice in a manner that is consistent with the *Informed Consent* standard of practice⁴.

Physicians should make their training and professional experience with the CAM therapy known to their patient. It is also important to discuss the expected course of the CAM therapy, including:

- number of treatments;
- duration;
- costs;
- potential adverse effects and how they may be managed, mitigated or avoided;
- any additional tests (e.g., screening, intermittent blood tests); and
- goals for therapy, such as end-point of treatment.

The physician must ensure the costs of the CAM therapy are <u>consistent with current</u> <u>accepted standards</u> and should consider the <u>patient's resources</u> to sustain a reasonable course of therapy without undue financial pressures. Additionally, physicians should disclose all real and potential <u>conflicts of interest</u> in the provision of CAM therapy, including financial or personal and endeavour to resolve the conflict with the patient

³ See "Informed Consent: Advising Patients and Parents about Complementary and Alternative Medicine (CAM) Therapies"

⁴ For more information, please refer to the <u>Informed Consent for Adults</u> and <u>Informed Consent for Minors</u> Advice to the Profession documents.



before embarking on the therapy.

Resources

CPSA team members are available to speak with physicians who have questions or concerns. Please contact <u>standardsofpractice@cpsa.ab.ca</u>.

RELATED STANDARDS OF PRACTICE

- Advertising
- Charging for Uninsured Professional Services
- <u>Conflict of Interest</u>
- Human Health Research
- Informed Consent
- Patient Record Content
- Practising Outside of Established Conventional Medicine
- <u>Referral Consultation</u>

COMPANION RESOURCES

- <u>Advice to the Profession:</u>
 - o Advertising
 - o Charging for Uninsured Professional Services
 - o <u>Conflict of Interest</u>
 - o Informed Consent for Adults
 - o Informed Consent for Minors
- <u>Canadian Medical Association's Complementary and Alternative Medicine policy</u>
 <u>document</u>
- <u>Canadian Medical Protective Association's Duties and Responsibilities: Alternative</u> <u>medicine - what are the medico-legal concerns?</u>