STANDARD

Unproven and Unconventional Treatment

STATUS:	APPROVED
Confirmed by Council:	February 2011
Amended:	June 2016
To be reviewed:	June 2021

Under **The Medical Professions Act, 1981** in order to protect the public, the College of Physicians and Surgeons of Saskatchewan is obliged to maintain, or set, the basic standards for the practice of medicine by its members. The standards are those of conventional medicine in the prevention and diagnosis of disease, the treatment of disease and the assessment of the results of treatment.

It is unethical to engage in or to aid and abet in treatment which has no acceptable scientific basis, may be dangerous, may deceive the patient by giving false hope, or which may cause the patient to delay in seeking proper care until his or her condition becomes irreversible.

DIAGNOSIS

The physician must use recognized generally accepted methods to establish diagnosis. Unconventional or unproven methods of diagnosis can only be used as an adjunct to generally accepted methods. The patient must be informed of the unproven nature of such a diagnosis method.

TREATMENT

The physician must offer the most effective generally accepted treatment to the patient. Treatment options, including potential risks and benefits, must be explained to the patient. The potential risks of refusing treatment must be explained. If a physician elects to use other than an accepted standard treatment, that physician should be able to demonstrate that standard methods have been offered and explained to the patient and that the non-standard treatment option has been selected by the physician and the patient. The patient must be informed that the treatment is unconventional and unproven. The physician may consider unconventional treatment if there is no proven, accepted remedy for the patient's condition or if conventional treatment has been ineffective. Such unconventional treatment must be either harmless or the potential benefits must outweigh the risks. The deliberate avoidance by the physician of conventional or potentially curative treatment in the management of acute illness is unacceptable.

RISKS

One of the risks of using unconventional treatment is that more appropriate treatment may be delayed. If there is an unfavourable outcome, the physician using unconventional therapy will be at risk in litigation by a patient, and of discipline by the College.

All physicians must monitor the results of treatment, whether it is conventional treatment or not. The College of Physicians and Surgeons strongly urges physicians who are contemplating the use of non-standard therapy to take part in organizing clinical trials approved by or under the auspices of a university faculty of medicine. Council requires a clinical trial protocol be approved by The Biomedical Research Ethics Board of the University of Saskatchewan, the Behavioural Research Ethics Board of the University of Saskatchewan or other relevant ethics committee before a physician begins using non-standard therapy.

The same standards of care that are expected in conventional diagnosis and treatment apply to the use of unconventional treatment. A physician should not provide an unconventional therapy simply because the patient demands it.

EXPERIMENTAL AND INVESTIGATIONAL TREATMENT

Experimental treatment is the use of an unproven therapy or modality that has not yet been shown to be effective in the human subject. Normally, experimental treatment is offered to patients for whom all standard treatment has been ineffective. Experimental treatment is in need of further study via clinical trials to establish efficacy and safety. Investigational treatment is a therapy that has preliminary data (laboratory or similar) and is approved by Health Canada for testing in humans. The protocol for the proposed trial of experimental/investigational treatment will have had approval from an Ethics Committee and the results will be subjected to scientific scrutiny. All the human subjects will have given informed consent based on a full detailed description of the proposed treatment including any potential risks. At every stage of experimental or investigational treatment, the principles of the World Medical Association (the Declaration of Helsinki) Ethical Principles for Medical Research Involving Human Subjects must be adhered to. An investigational treatment may be approved for use in one disease condition but still considered investigational in other diseases or conditions.

ACCEPTED TREATMENT

a) This is treatment that has been shown to be better than no treatment, or has been shown to be equivalent to or better than previous treatments, either in effectiveness or in reduced side effects.

b) Is supported in the mainstream scientific literature.

UNPROVEN, NON-STANDARD, UNCONVENTIONAL TREATMENT

a) May be Stage I of a Clinical Trial. See **Experimental Treatment and Investigational Treatment**. This is acceptable to the College.

b) May be a standard recognized treatment used for unconventional purposes or in non-standard dosage. This is only acceptable to the College in the context of a Clinical Trial.

c) May be a treatment that is not generally accepted, that has not been subjected to a Clinical Trial, or clinical trials have not shown an effect. Preliminary laboratory data suggesting a possible effect may

be absent or suspect. Reports of efficacy are usually anecdotal. The use of such is unacceptable to the College unless the principles under **Diagnosis, Treatment, Risks** and **Fees** are met.

FEES FOR EXPERIMENTAL, INVESTIGATIONAL, UNCONVENTIONAL, UNPROVEN, AND NON-STANDARD THERAPY

The ethical physician will provide experimental, investigational, unconventional, unproven or non-standard treatment in accordance with the established fee code.

COLLEGE BYLAW RELATING TO PROVIDING UNCONVENTIONAL TREATMENTS

Regulatory Bylaw 8.1 defines unprofessional conduct related to unconventional treatment in the following terms:

(b) *The following acts or failures are defined to be unbecoming, improper, unprofessional or discreditable conduct for the purpose of Section 46(p) of the Act. The enumeration of this conduct does not limit the ability of Discipline Hearing Committees to determine that conduct of a physician is unbecoming, improper, unprofessional or discreditable pursuant to Section 46(o):*

(ix) Failing to maintain the standard of practice of the profession.

(xv) Utilizing any remedy, treatment or device in connection with the physician's medical practice which is not generally accepted as having therapeutic value by the medical community unless:

1. *The remedy or device is utilized in connection with a bonafide clinical trial authorized by a reputable medical organization; or*
2. *The physician demonstrates to the satisfaction of the Discipline Hearing Committee that there was a reasonable scientific basis to utilize the remedy or device, or:*
3. *The Council has given permission to the physician to utilize the remedy or device on such terms as the Council may believe are in the interest of the public.*

OTHER RESOURCES

College of Physicians and Surgeons of Saskatchewan – *Guideline – Informed Consent*
Canadian Medical Protective Association *Alternative Medicine –what are the medico-legal concerns?*
https://www.cmpa-acpm.ca/-/alternative-medicine-what-are-the-medico-legal-concerns-