College of Physicians and Surgeons of Newfoundland and Labrador

Advisory to the Profession and Interim Guidelines

Marihuana for Medical Purposes

Preamble

This document is an advisory and guideline of the College of Physicians and Surgeons of Newfoundland and Labrador.

Effective April 1, 2014, provisions of the federal *Marihuana for Medical Purposes Regulations*, will implement a number of changes regarding the distribution of dried marihuana to individuals seeking this substance for medical purposes. As a result of these changes, medical practitioners in this Province may be requested to issue a medical document that will enable individuals to obtain dried marihuana from a licensed producer. Individuals will no longer have to apply to Health Canada for approval to obtain marihuana for medical purposes. The federal *Regulations* will have the effect of putting physicians in the position of "gate keeper" for individuals seeking marihuana for medical purposes.

College's Position on Marihuana for Medical Purposes

This College, and the other Colleges of Physicians and Surgeons across Canada, have expressed to Health Canada their concerns about the federal *Regulations*. In the view of the College, those concerns have not been addressed.

The College believes that physicians should not be expected to facilitate patient access to a substance, for medical purposes, for which there is no body of evidence of clinical efficacy or safety. As well, medical standards and guidelines for prescribing of marihuana, addressing issues such as standardized dosage or quality control, are lacking. The amount of active ingredients in marihuana varies significantly, depending on the origin and method of production of the substance. Also, many uncertainties remain about the effects, whether considered beneficial or harmful, of marihuana use.

In light of these concerns, the College believes physicians will be at increased risk of allegations of negligence and malpractice if they facilitate an individual's access to marihuana for medical purposes, as compared to the prescribing of drugs and treatments for which there is a recognized scientific body of evidence of clinical efficacy or safety.

The College is monitoring the approaches being developed by medical regulators across Canada regarding this issue. The College believes it is premature at this time to publish standards of practice regarding the facilitation by physicians of access to marihuana for medical purposes, as this could be interpreted as the College supporting or legitimizing this practice. Despite these concerns, however, the College has an obligation to advise physicians regarding the College's expectations, if they are considering undertaking this "gate keeper" role.

College's Expectations Regarding Prescribing of Marihuana

The word "prescribing" in this Guideline is used to summarize the procedure for access to marihuana for medical purposes provided for in the federal *Marihuana for Medical Purposes Regulations*.

The College's primary expectation is that physicians should not prescribe any substance for their patients without knowing the risks, benefits, potential complications and drug interactions associated with the use of that agent. For the reasons discussed above, these factors are particularly difficult to assess for the use of marihuana for medical purposes.

Bearing in mind the concerns and caution expressed above, the College expects that a physician would only consider prescribing marihuana if <u>all</u> of the following conditions are met:

- The physician is expected to first review, and be thoroughly familiar with, the *Marihuana for Medical Purposes Regulations* and the materials identified in the References section below.
- The physician is expected to first thoroughly educate himself or herself about the risks, benefits, potential complications and drug interactions associated with the use of marihuana for medical purposes.
- The physician is expected to document in the patient record the conventional therapies for the condition that the physician has used in the management of the patient's medical condition and whether or not these therapies have been effective.
- The physician is expected to assess the patient for risk of addiction using a standardized addiction risk tool and retain a copy of this assessment in the patient record.
- The physician is expected to establish an individualized written protocol for the periodic reassessment of a patient receiving marihuana, including processes to identify any misuse/abuse/diversion by the patient. A copy of the written protocol must be kept with the patient record, and any breaches or departures from the written protocol must be documented in the patient record.
- The physician is expected to have discussed with the patient, and charted in the patient record, the physician's assessment of the patient-specific risks, benefits, potential complications and drug interactions associated with the use of marihuana.
- The physician is expected to adhere strictly to the requirements of Marihuana for Medical Purposes Regulations with respect to the issuance of a "medical document" for access to marihuana for medical purposes. A sample medical document is appended to this Advisory and Guideline. The physician must retain a copy of the completed and signed medical document in the patient record.

 The physician should only issue a medical document to a patient if the physician is the primary treating physician for that patient, and only if the physician is actually treating the patient for the medical condition for which marihuana for medical purposes is prescribed.

College's Position on Dispensing of Marihuana

The College strongly discourages physicians from dispensing marihuana to their patients. Under the federal *Regulations*, patients who have been issued a medical document by a physician can make arrangements with a licensed producer for supply of the prescribed marihuana directly to them. Physicians who dispense marihuana could become the target of break-ins and thefts.

Physicians are reminded that they may only consider dispensing marihuana for medical purposes if the expectations for prescribing marihuana set out above are met, and in accordance with the College's *Guideline on Dispensing of Medications by Medical Practitioners* (the "Dispensing Guideline"). In addition to meeting all other conditions for dispensing, physicians would be expected to strictly comply with the requirements for secure storage set out in the *Dispensing Guideline*.

The *Dispensing Guideline* states that physicians may charge for the cost of a medication plus a reasonable professional fee for dispensing. By this Marihuana for Medical Purposes Guideline, the College expresses the further expectation that any costs and fees charged for dispensing marihuana should be no more than what is necessary to reimburse the physician for the actual, documented costs for providing this service, and should not generate any profit.

The College, after further review of the matter, may impose further restrictions on dispensing of marihuana.

College's Position on Financial Interest in the Prescribing of Marihuana

Physicians should not charge any fee to, or accept any compensation from, a licensed producer for providing prescribing or dispensing services for marihuana.

Physicians should not operate, be a partner in, or otherwise benefit financially from the operation of a licensed marihuana production facility as this would place the physician in an unacceptable conflict of interest that is detrimental to the provision of responsible and safe care to patients.

Effect of this Guideline with respect to professional conduct

Physicians are reminded of the following provisions of the Section 4 of the College's By-law No. 5 – Code of Ethics:

Professional Misconduct

- 4. Professional misconduct for the purposes of sections 34 to 51 of the Act [sections 39 to 56 of the Act, effective May 31, 2011] shall include:
- (k) Prescribing to a patient without establishing an appropriate doctor-patient relationship.
- (I) Prescribing to a patient contrary to a standard of practice, policy or guideline of the College or a guideline or standard of practice generally accepted by the profession, and including but not limited to those outlined in Schedule "A" to this By-Law, unless
- (i) in the case of departure from any standard of practice, policy or guideline it can be demonstrated by the medical practitioner that there was a reasonable basis for that departure;

Future steps

The College will continue to review the developing practices, policies and information on this issue, and may amend or augment the foregoing expectations, and may impose stricter guidelines and standards, based on its continuing review.

The College may, by questions on renewal on licensure, require physicians to provide the College with information regarding the issuance of medical documents for marihuana. Information regarding such practices, obtained on renewal or otherwise, may become the subject of a quality assurance review by the College's quality assurance committee.

References

Canadian Medical Association

CMA policy: medical marihuana. circa 2011 http://policybase.cma.ca/dbtw-wpd/Policypdf/PD11-02.pdf

Statement from the CMA on new regulations on Medical Marihuana June 10, 2013 http://www.cma.ca/multimedia/CMA/Content Images/Inside cma/Media Release/2013/State ment Medical Marijuana regulations en.pdf

CMA Response: Health Canada's Medical Marihuana Regulatory Proposal Submitted to the Office of Controlled Substances Health Canada February 28, 2013

http://www.cma.ca/multimedia/CMA/Content Images/Inside cma/Submissions/2013/Propose
d-Medical-Marihuana-Regulations en.pdf

Canadian Medical Protective Association

Medical marihuana: medical declaration and release from liability forms. Revised January 2011. https://oplfrpd5.cmpa-acpm.ca/en/legal-and-regulatory-proceedings/-/asset_publisher/a9unChEc2NP9/content/medical-marijuana-medical-declaration-and-release-from-liability-forms

Marihuana medical access regulations. In: Medico-legal handbook for physicians in Canada. 7th ed. Ottawa: Canadian Medical Protective Association, 2010. https://oplfrpd5.cmpa-acpm.ca/en/medico-legal-handbook

Health Canada

Government of Canada Announces New Steps to Help the Medical Community with Marihuana for Medical Purposes http://news.gc.ca/web/article-en.do?mthd=tp&crtr.page=1&nid=832889&crtr.tp1D=1

Medical use of marihuana. Last updated June 2013.

http://www.hc-sc.gc.ca/dhp-mps/marihuana/index-eng.php

Information for health care professionals: cannabis (marihuana, marihuana) and the cannabinoids. Last updated February 2013.

http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/infoprof-eng.php

Marihuana for medical purposes regulations June 2013. http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/ 2013/2013-79bk-eng.php

About the Marihuana Medical Access Program June 20, 2013. http://www.hc-sc.gc.ca/dhp-mps/marihuana/about-apropos/index-eng.php

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Canada. Department of Justice

Marihuana medical access regulations. Consolidation. Current to February 2012. http://laws-lois.justice.gc.ca/PDF/SOR-2001-227.pdf

NOTE: The Questions and Answers below should be considered in the overall context of the College's guidelines on this issue.

Questions and Answers

Marihuana for Medical Purposes

What doses of medical marihuana are typically used in large cohorts of patients studied in other countries?

In published tracking data for over 5,000 patients in the Dutch cannabis program (2003-2010), the average dose of dried cannabis was 0.68 grams daily (range 0.65 grams to 0.82 grams). In Israel's medical marihuana program average daily use was 1.5 grams (2011-2012).

How much medical marihuana can be dispensed to a patient at a time?

The new Regulation limits the total amount of marihuana that can be administered (dispensed) to a patient in a 30-day period to no more than 30 times the daily quantity specified in the medical document or 150 grams, whichever is less.

My patient wishes to use medical marihuana but is in a safety-sensitive occupation.

Health Canada advises that patients using cannabis should be warned not to drive or to perform hazardous tasks such as operating heavy machinery. Depending on the dose, impairment can last for over 24 hours after last use because of the long half-life of $\Delta 9$ -THC. Pending data that says otherwise, the College suggests that the same applies to safety-sensitive occupations such as health professions and the supervision of children.

What are the contraindications to the use of marihuana for medical purposes?

Under the heading *Precautions*, Health Canada's authoritative, comprehensively referenced *Information for Health Professionals* document (http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/infoprof-eng.php) states that cannabis should not be used in patients under the age of 18 or those with severe cardiopulmonary disease, severe liver disease, severe renal disease, a personal history of psychiatric disorders (especially schizophrenia), or a family history of schizophrenia. Pregnancy and breastfeeding are regarded as contraindications. Women in their reproductive years should use reliable contraception. Caution is advised for people with a history of substance abuse or concomitant use of psychoactive drugs. Patients with mania or depression should be monitored by a psychiatrist. Patients with asthma or chronic obstructive pulmonary disease (COPD) should not smoke marihuana.

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My patient wants me to accept delivery of dried marihuana on his/her behalf. Do I have an obligation to do so?

No. Physicians are under no obligation to accept delivery of dried marihuana on behalf of their patients. Patients should be advised to seek alternative delivery arrangements from the supplier. Physicians who are willing to accept delivery on behalf of their patients are reminded that they may not charge a fee for that service.

My patient prefers not to smoke marihuana. What advice can I give my patient?

The Health Canada document *Information for Health Care Professionals* (http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/infoprof-eng.php#chp40) is quite explicit. There are no clinical studies on the use of cannabis edibles (e.g. cookies, baked goods) or topical for therapeutic purposes.

Adopted from the Guideline of the College of Physicians and Surgeons of British Columbia, with kind acknowledgement and thanks.

Sample Medical Document for the Marihuana for Medical Purposes Regulations

This document may be completed by the applicant's authorized health care practitioner as defined in the Marihuana for Medical Purposes Regulations. An authorized health care practitioner includes physicians in all provinces and territories, and nurse practitioners in provinces and territories where prescribing dried marihuana for medical purposes is permitted under their scope of practice. If another document is used, it must contain all of the information below.

Patient's Given Name and Surname	
Patient's Date of Birth (DD/MM/YYYY)	
Daily quantity of dried marihuana to be used by the patient:	g/day
The period of use is day(s) week(s) month(s).	The period of use cannot exceed one year.
Health care practitioner's given name and surname	
Profession:	
Health Care practitioner's business address:	
Full business address of the location at which the patient consulted the health care practitioner (if different than above):	
Phone Number:	
Fax Number (if applicable):	
Email address (if applicable):	
Province(s) Authorized to Practice in:	
Health Care Practitioner's Licence number:	

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By signing this document, the health care practitioner is attesting that the information contained in this document is correct and complete.

Health Care Practitioner's Signature:

License Number:

Date Signed (DD/MM/YYYY)

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