

				Position Statement Seniors Health, Edmonton Zone Regional Palliative Care Program	
Title:		Position Statement Regarding Marihuana Medical Access Regulations			
Date Approved:		Developed 2001; Revised November 2010			
Approved By:		Practice, Development, and Quality Committee			
Contents		Regulations (effective July 30, 2001) and amendments (June 7, 2005) AMA/CMA/CMPA position Medical Evidence (summary) Recommendations for Palliative Care Physicians			

1. Marihuana Medical Access Regulations

Introduction:

Following the case of Mr. Parker, an epileptic who uses marihuana to control seizures and had been charged with possession of marihuana under the Controlled Drug and Substances Act (CDSA), the Court of Appeal of Ontario declared the prohibition of marihuana under the CDSA of no force and effect. The Marihuana Medical Access Regulations (MMAR) were developed to replace Section 56 of the Controlled Drug and Substances Act (CDSA) and came into effect on July 30, 2001.

“The regulations establish a compassionate framework to allow the use of marihuana by people who are suffering from serious illnesses where conventional treatments are inappropriate or not providing adequate relief of the symptoms related to the medical condition or its treatment, and where the use of marihuana is expected to have some medical benefit that outweighs the risk of its use” – Office of Cannabis Medical Access (now Marihuana Medical Access Division) – Health Canada.

This makes Canada the first country to allow the use and growth of marihuana for personal use by people with terminal illness and serious medical conditions.

Since the Regulations came into force in July 2001, Health Canada has received input concerning the MMAR via a variety of mechanisms, including a "1-800" number, a program e-mail address, and letters from patients, physicians and others. In order to improve its marihuana for medical purposes program, Health Canada initiated consultations in 2003 with various stakeholder groups including patients, physicians, pharmacists and law enforcement agencies, to discuss the need for potential changes to the MMAR.

Following a challenge to the constitutionality of the MMAR in October 2003, amendments to the MMAR came into effect on June 7, 2005. The amendments fit within Health Canada parameters¹:

- Marihuana will be accessible on compassionate grounds and its use will be regulated.

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- The Government of Canada will continue to respect the international drug control conventions to which Canada is a Party. These conventions include the requirement for a government agency to have exclusive rights over importing, exporting, selling, and maintaining stocks of marihuana. This means that Health Canada will limit and maintain tight control on marihuana production.
- Marihuana is a drug as defined by the *Food and Drugs Act* and is not a natural health product as defined by the *Natural Health Products Regulations*.
- Health Canada will continue to require the opinion and support of a physician, since physicians are the professionals best positioned to assess medical need. Decisions by the Courts have lent support to the continued involvement of physicians, including specialists.
- Authorized persons will have access to a legal, standardized, quality-controlled source of marihuana.

Health Canada is assessing the feasibility of a pharmacy-based distribution system.

Summary of Amended Regulations¹ (effective July 30, 2001, amended June 7, 2005)

Patient's can apply under one of two symptom categories:

Category 1 symptom: "any symptom treated within the context of compassionate end-of-life care or a symptom set out in column 1 of the schedule that is associated with a medical condition set out in column 2 or with the medical treatment of that condition".

CATEGORY 1 SYMPTOMS

	Column 1	Column 2
Item	Symptom	Associated Medical Conditions
1.	Severe nausea	Cancer, AIDS/HIV infection
2.	Cachexia, anorexia, weight loss	Cancer, AIDS/HIV infection
3.	Persistent muscle spasms	Multiple sclerosis, spinal cord injury or disease
4.	Seizures	Epilepsy
5.	Severe pain	Cancer, AIDS/HIV infection, multiple sclerosis, spinal cord injury or disease, severe form of arthritis

Category 2 symptoms: "a debilitating symptom that is associated with a medical condition or with the medical treatment of that condition and that is not a Category 1 symptom".

To be able to apply for authorization under Category 2, a specialist has to confirm the diagnosis of the person suffering from the debilitating symptom and that conventional therapies are inappropriate or ineffective for the treatment of that patient's symptom(s). The specialist does not have to sign the application, thereby eliminating the need for an applicant to see a specialist for the sole purpose of having the medical declaration signed.

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Both the Applicant's Declaration and the Medical Declaration are revised. Applicants are now asked to acknowledge and declare their acceptance of the risks associated with the use of marihuana for medical purposes in their declaration.

The treating physician, whether or not he/she is a specialist, can sign the medical declaration for both categories.

Physicians are no longer required to make definitive statements regarding benefits outweighing risks, or to make specific *recommendations* regarding the daily dosage of marihuana to be used by the applicant. In the revised medical declaration, the treating physician is required to provide the amount, and form and route of administration of marihuana that the applicant *intends* to use. In addition, the physician is required to provide confirmation only of the applicant's serious medical condition and that conventional treatments are inappropriate or ineffective. Physicians are no longer required to *list* conventional therapies that have been tried or considered, or to provide their reasons for finding those therapies to be ineffective or inappropriate.

"These amendments establish a more appropriate sharing of responsibility for the decision to use marihuana as an alternative treatment between the applicant and the physician" – Health Canada.

The regulations further state that when:

1. Obtaining marihuana, a patient can:
 - grow his/her own supply
 - designate someone else to grow marihuana for his/her use
 - purchase from a supplier licensed by Health Canada (Prairie Plant Systems Inc. has been awarded the Health Canada contract to cultivate and supply marihuana).
2. Possessing marihuana, a patient is allowed a maximum of a 30-day supply at any given time.
3. Growing marihuana, a person has to be eighteen years or older, has to be a resident of Canada and has to be able to maintain a certain level of security. A grower will be given a production license and a photo identification card. Marihuana can be grown indoors or outdoors. A grower will be allowed to be in possession of 30 day supply (which will depend on the daily prescribed dose). Growers can obtain seeds to start production.

Patients are issued a photo identification card, which does not contain any medical information.

Health Canada provides an application form and an attached information bulletin to help physicians fill in the form.

"While over three hundred Canadian physicians have supported applications for authorization to possess marihuana for medical purposes, some physicians have chosen not to do so. The decision to support an application and to sign or not to sign a medical declaration is clearly within the professional purview of the physician. A physician whose clinical assessment and judgment prevents him or her from signing a medical declaration must be able to state that and be free of the risk of negative consequences for doing so" – Health Canada.

Regulatory Impact Analysis Statement: (Health Canada) ¹

The claims and uses of marihuana are named; a legal and international perspective is given; the impact on different sectors is discussed (e.g. hospitals: institutions are allowed to make their own decisions regarding possession/use on their premises); cost factors are examined

(e.g. Health Canada could look at a registration fee in the future); issues raised by various groups are addressed (e.g. “smoking marihuana for medical purposes in a public setting, thereby potentially exposing others to the drug’s effects, is unacceptable. Patients are therefore expected to use common sense when using this drug”).

2. Alberta/Canadian Medical Association (AMA/CMA) and Canadian Medical Protective Association (CMPA) position ²

In a letter to Mr. Rock (Minister of Health at the time), dated July 26, 2001, then-AMA President Dr. Clayne Steed stated: “These regulations announced by Health Canada are unacceptable because there has not been thorough and rigorous scientific testing. This, in turn, may negatively affect the physician-patient relationship. Patients may believe that they could benefit from the use of marihuana for one of a number of conditions or that they may be able to obtain marihuana for recreational use through their physicians.”

The AMA objections include:

- a) Use of marihuana is not evidence-based and there has been no rigorous testing regarding long-term implications
- b) There are no clinical practice guidelines in place, including appropriate dosages
- c) Physicians do not know product potency or consistency
- d) The regulations place physicians in an untenable position.

The AMA suggests the following:

- a) Consider any potential contraindications
 - b) Think twice before filling out Health Canada application forms
 - c) Apply caution when filling out forms from any source other than Health Canada
- “Though the AMA remains opposed to the medicinal use of marihuana under these regulations, the AMA is very willing to continue to work with Health Canada and other stakeholders in order to resolve this issue in a positive manner. “

In October 2005, the CMPA recommended that physicians who complete the medical declaration ask the applicant to sign the CMPA’s “release from liability” form, available at the CMPA website www.cmpa-acpm.ca. This message was reinforced by the CMPA in May 2008.

The College of Physicians and Surgeons of Alberta, the Alberta and Canadian Medical Associations, and the Canadian Medical Protective Association have cautioned physicians against prescribing marihuana or procuring and distributing marihuana for patient use because insufficient information exists to support its use, and several properly studied and effective alternative treatments exist for the same indications.

3. Summary of medical evidence

There are very few clinical trials on smoked marihuana available in the literature ^{3,4,5} and none are in palliative patients.

There are many studies on the cannabinoids and there is possible evidence for its use in chemotherapy-induced nausea and vomiting ^{5,6,7} in glaucoma ⁸, in spasticity associated with multiple sclerosis and in certain neuropathic pain syndrome ^{9,10,11,12} in anorexia/cachexia associated with HIV/AIDS and cancer ^{13,14,15} in asthma ¹⁶ and in Alzheimer’s disease ^{17, 18}. At

present the indications for commercially available synthetic oral cannabinoids are for chemotherapy-associated nausea and for the wasting syndrome associated with AIDS. A new oromucosal spray containing delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) is now available in Canada and is indicated for relief of symptoms of multiple sclerosis (MS) and for treatment of severe neuropathic-related cancer pain.

4. Recommendations

Research in the palliative population is urgently needed as the regulations have outstripped research in this area, due to restrictions on smoked marihuana.

Until such time that stronger evidence is available, the Edmonton Regional Palliative Care Program will not support the application for permission to use marihuana for medicinal purposes under the new regulations.

5. References

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