

Proposed amendments to the *Marihuana for Medical  
Purposes Regulations*

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Canadian Medical Association Submission in response to  
the Canada Gazette publication on the proposed  
amendments to the *Marihuana for Medical Purposes  
Regulations*

July 11, 2014



The Canadian Medical Association (CMA) is the national voice of Canadian physicians.

Founded in 1867, the CMA is a voluntary professional organization representing more than 80,000 of Canada's physicians and comprising 12 provincial and territorial medical associations and 60 national medical organizations.



The Canadian Medical Association (CMA) is pleased to provide this brief in response to Health Canada's consultation on the proposed regulatory amendments to the Narcotic Control Regulations and the Marihuana for Medical Purposes Regulations of the Controlled Drugs and Substances Act, published in the Canada Gazette Part I, on June 14, 2014.

The CMA has already made its position on the Marihuana for Medical Purposes Regulations known to Health Canada (see Appendix A). While recognizing the needs of those suffering from terminal illness or chronic disease, and for whom marijuana may provide relief, the CMA has raised significant concerns and objections to the regulatory framework since it was first proposed in 2001. Put simply, the CMA has significant and grave concerns with the regulatory framework governing medical marijuana. Of particular concern to physicians is the scarcity of evidence-based information about the use of marijuana as medical therapy, including on dosage, risks and benefits, and contraindications.

While several amendments to the regulatory framework have been promulgated since its initial establishment, the CMA's primary concerns have yet to be addressed. In brief, as the CMA's position on the regulatory framework is detailed in Appendix A, the CMA opposes the approach placing physicians in the role of gatekeepers for a product whose medical benefits have not been sufficiently researched. The CMA continues to recommend that marijuana for medical purposes be held to the same standards as prescription pharmaceuticals, including the clinical trial process required for therapeutic products under the Food and Drugs Act and be subject to the same safety and efficacy standards as pharmaceuticals if used for medical purposes.

There remain fundamental concerns about quality, safety and efficacy of marijuana used for medical purposes, and the Canadian Medical Protective Association has advised physicians who are uncomfortable with the regulations to refrain from authorizing marijuana to their patients due to potential liability. The CMA advocates for education and licensing programs, clinical guidance and practice supports for health care practitioners who decide to authorize the use of marijuana for patients.

The CMA recommends that Health Canada further revise the proposed amendments to the Marihuana for Medical Purposes Regulations to:

- 1) Enable consistent and best practice oversight

In the CMA's submission to Health Canada as part of its review of the Controlled Drugs and Substances Act, as well as in parliamentary briefs on the prescription pharmaceutical regulatory

framework, the CMA has recommended high regulatory standards for prescription medication; and even more stringent requirements for controlled substances, both during the approval and the post-approval phases. These recommendations are driven by the potential for harm to patients and the possibility for misuse or abuse of medications, particularly opioids and other such substances.

For these reasons, the CMA advocates for an inter-operable, pan-Canadian system of real-time prescription monitoring and surveillance for controlled substances. Robust monitoring and surveillance programs facilitate professional regulatory bodies' oversight and intervention, by enabling the identification of prescribing outliers which include fraudulent attempts to access controlled medications. Prescription monitoring programs also gather information to improve the understanding of prescription drug abuse and to support the development and adoption of best practices. In order to be streamlined and optimized, such a system should be compatible with existing electronic medical and pharmacy record systems and with provincial pharmaceutical databases, and accessible as a point-of-care tool for health care practitioners.

Currently, marijuana for medical purposes is exempt from the regulatory requirements of the Food and Drugs Regulations that apply to prescription pharmaceuticals in Canada. Under the Marihuana for Medical Purposes Regulations there is no system in place to monitor the authorization of marijuana for medical purposes.

It is in this context that CMA supports the underlying principle of the proposed amendment to the Marihuana for Medical Purposes Regulations which requires licensed producers to provide information to the provincial professional licensing authorities for health practitioners regarding authorizations for marijuana for medical purposes in response to a request by the licensing authority.

However, aligned with the CMA's support of a pan-Canadian prescription monitoring system, the CMA recommends that the provision of relevant information to licensing authorities should be part of required regular reporting procedures for the licensed producers, consistent with the prescription monitoring program requirements of the respective provincial and territorial jurisdictions.

Finally, the CMA recommends that Health Canada support the integration marijuana for medical purposes within provincial/territorial prescription monitoring programs, including facilitating the availability of a point-of-care access tool for health care practitioners.

## 2) Safeguard protection of privacy

As articulated in the CMA's Code of Ethics, physicians consider protecting the privacy of patient information to be paramount, and as such, the CMA has developed policy guidance concerning patient as well as physician information. The CMA's Principles for the Protection of Patients' Personal Health Information (see Appendix B) emphasizes that privacy, confidentiality and trust are cornerstones of the patient-physician relationship. Recognizing that health information is highly sensitive, this policy statement articulates foundational privacy principles that must be adhered to with respect to patient information.

In addition to the provision of patient information, authorizations include physician information. The CMA's Principles Concerning Physician Information (see Appendix C) specify 11 conditions that must be met including with respect to the collection, use, access, storage and disclosure of physician information.

The CMA recommends that the proposed amendments to the Marihuana for Medical Purposes Regulations be reviewed and revised as necessary to ensure it meets the standards of the CMA's Principles for the Protection of Patients' Personal Health Information and the CMA's Principles Concerning Physician Information.

The CMA is concerned with the fact that licensed producers, not Health Canada, are the custodians of patient and licensed health practitioner information, in that they collect, use, have access to or disclose this information. For example, security safeguards, written privacy policies and designated accountable privacy officers, must be in place to protect personal health information and licensed practitioner identification in order to ensure that only authorized collection, use and disclosure or access occurs. The text of the proposed amendment addresses "secure transmission" of data, but it must also address secure storage. Safeguards must ensure that there is the same rigour as required for pharmacies as custodians of sensitive private information. The proposed period of record retention of two years should be reviewed in consultation with the professional licensing bodies, to ensure it is sufficient or if it should be extended.

In recognition of the importance of health information privacy, including privacy of patient and physician information, the CMA strongly reiterates its recommendation that Health Canada undertake a privacy impact assessment of the proposed amendment. It is of the utmost importance that the proposed amendments to the Marihuana for Medical Purposes Regulations must conform to privacy laws, and protect patient confidentiality while enabling oversight by

licensing authorities. The CMA recommends Health Canada to engage stakeholders as part of its consultation process as part of this privacy assessment.

### 3) Clarify and enforce consumer advertising requirements

Regarding direct-to-consumer advertising, while marijuana for medical purposes is exempt from the Food and Drug Regulations, it is subject to requirements specified in the Narcotic Control Regulations and the Food and Drug Act. The CMA is concerned that licensed producers are circumventing existing direct-to-consumer advertising legislative and regulatory standards.

Marijuana for medical purposes is subject to the following sections of the Food and Drugs Act:

3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

(2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Marijuana for medical purposes is subject to the following section of the Narcotic Control Regulations:

70. No person shall

(a) publish or cause to be published or furnish any advertisement respecting a narcotic unless the symbol “N” is clearly and conspicuously displayed in the upper left-hand quarter thereof or, if the advertisement consists of more than one page, on the first page thereof;

(b) publish or cause to be published or furnish any advertisement to the general public respecting a narcotic; or

(c) advertise in a pharmacy a preparation referred to in section 36.

While the legislative and regulatory requirements appear consistent with the requirements governing the advertising of prescription and non-prescription medication, it appears that licensed producers are in gross contravention of these standards. The CMA recommends additional effort and action on the part of Health Canada to ensure compliance and enforcement of direct-to-consumer advertising provisions of the Food and Drugs Act and Narcotic Control Regulations. To this end, the CMA recommends that Health Canada issue guidance documentation outlining compliance with these standards and ensure enforcement of these regulations.

The CMA welcomes the consultation and review of the amendments to the Marihuana for Medical Purposes Regulations with the view of promoting quality care to improve patient safety and public health. The CMA encourages further consultation and welcomes the opportunity to discuss these issues in greater detail.

## Overview of recommendations

1. The CMA recommends that the provision of relevant information to licensing authorities should be part of required regular reporting procedures for the licensed producers, consistent with the prescription monitoring program requirements of the respective provincial and territorial jurisdictions.
2. The CMA recommends that Health Canada support the integration of marijuana for medical purposes within provincial/territorial prescription monitoring programs, including facilitating the availability of a point-of-care access tool for health care practitioners.
3. The CMA recommends that the proposed amendments to the Marihuana for Medical Purposes Regulations be reviewed and revised as necessary to ensure it meets the standards of the CMA's Principles for the Protection of Patients' Personal Health Information and the CMA's Principles Concerning Physician Information.
4. The CMA recommends that Health Canada undertake a privacy impact assessment of the proposed amendments to the Marihuana for Medical Purposes Regulations.
5. The CMA recommends additional effort and action on the part of Health Canada to ensure compliance and enforcement of direct-to-consumer advertising provisions of the Food and Drugs Act and Narcotic Control Regulations.
6. The CMA recommends that Health Canada issue guidance documentation outlining compliance with these standards.

## List of Appendices:

- Appendix A – CMA Policy Statement: Medical Marijuana
- Appendix B – CMA Policy Statement: Principles for the Protection of Patient ' s  
Personal Health Information
- Appendix C – CMA Policy Statement: Principles Concerning Physician Information