Medical Marijuana

Background

In 2001, Health Canada enacted a preliminary set of "marihuana medical access regulations" (MMAR). These were in response to an Ontario Court of Appeal finding that banning marijuana for medicinal purposes violated the Charter of Rights and Freedoms. The MMARs, as enacted, were designed to establish a framework to allow the use of marijuana for the relief of pain, nausea and other symptoms by people suffering from serious illness where conventional treatments had failed.

In developing the preliminary MMARs, Health Canada asked for feedback from key stakeholders, including the Canadian Medical Association (CMA). While recognizing the needs of those suffering from terminal illness or chronic disease, CMA raised strong objections to the proposed regulations. In particular, there were concerns about the lack of evidence on the risks and benefits associated with the use of marijuana. This made it difficult for physicians to properly advise their patients and properly manage doses or potential side effects. Additionally, there were concerns about medico-legal liability, corroborated by the Canadian Medical Protective Association (CMPA).

While acknowledging some of the concerns of the CMA, the regulations were passed in July 2001, without sufficient change to gain CMA’s support. There remained fundamental concerns about quality, safety and efficacy of medical marijuana. The medico-legal liability concerns remained, prompting the CMPA to issue an information sheet for physicians and to encourage those uncomfortable with the regulations to refrain from prescribing marijuana to patients.

In January 2003, the Ontario Superior Court ruled that the MMARs failed to provide a legal supply of marijuana for those persons entitled to possess it for medicinal purposes. Therefore, the regulations were deemed constitutionally invalid with no force or effect. The decision was suspended for six months in order to give Health Canada time to remedy the situation.

Subsequently, in 2003, Health Canada presented an "Interim Policy", which included provisions for the production and distribution of medical marijuana to authorized patients. CMA vigorously opposed this policy, which exacerbated rather than addressed the fundamental concerns of the profession by making physicians part of the supply chain.

The CMA raised strong concerns about the implications of both the original regulations and the interim policy for both patients and physicians, stating that physicians should not be put in the untenable position of gatekeepers for a proposed medical intervention that had not undergone established regulatory review processes as required for all other prescription medicines.
At General Council in 2003, delegates passed the following motions:

*That Canadian Medical Association strongly oppose the use of marijuana for medical reasons in the absence of supporting scientific evidence.*

*That Canadian Medical Association recommends that physicians not participate in the dispensing of medical marijuana under the existing Medical Marijuana Access Regulations.*

New regulations (introduced in June 2005) reduced the onus on physicians to declare the need for, and dose of marijuana, focusing instead on an attestation of diagnosis and failure of conventional therapies. These amendments were seen as an improvement to the previous MMARs as they reduced the obligation of a physician to declare that the proposed therapy was efficacious. While continuing to oppose the medical use of marijuana and recommending that physicians not participate in the program because of the failure of governments and manufacturers to provide adequate information regarding safety, CMA accepts that physicians who feel qualified to recommend medical marijuana to their patients do so in accordance with the regulations.

**Current Situation**

The MMARs have undergone a number of further revisions since 2005. For the most part, these revisions have been in response to decisions from various courts across the country. Courts have consistently sided with patients’ rights to relieve symptoms of terminal disease or certain chronic conditions, despite the limited data on the effectiveness of marijuana. Courts have not addressed the ethical position in which physicians are placed as a result of becoming the gate keeper for access to a medication without full knowledge of its effectiveness, proper dosage, or short and long-term side effects. As of June 2009, there were 4,029 people licensed to possess dried marijuana for medical purposes.\(^3\)

In 2009, General Council passed a resolution urging the CMA to:

a) update its policy on medical marijuana; and

b) ask the federal government to update the medical marijuana access program and regulations following appropriate consultations with stakeholders and scientific advisory committees, and reinstate support for research into the safety and efficacy of medical marijuana and cannabinoids.

Following the passage of this resolution, the Office for Public Health (OPH) began a review of the published literature on medical marijuana. Evidence exists about pharmaceutically prepared, orally administered marijuana alternatives. Commonly referred to as cannabinoids, these drugs utilize the active ingredient in marijuana, delta-9-tetrahydrocannabinial (THC), and are dispensed in pill or vaporized format.\(^4\) Pharmaceutical cannabinoids have undergone clinical trials to demonstrate safety and effectiveness, and have been approved for use through the Food and Drug Act of Canada. Of note is that in this format, the toxic by-products of smoked marijuana are avoided.\(^5\)

In summary, there remains scant evidence regarding the effectiveness of the herbal form of marijuana (e.g. smoked) as accessed through Health Canada’s MMAR program. The generalizability of the conclusions from published studies are limited by methodology (double blind placebo controlled trials are not possible; previous users of marijuana are often excluded) and very small sample sizes. While it may be the case that medical marijuana is efficacious, scientific evidence comparable to other prescription pharmaceuticals is still lacking. Additionally, there is insufficient information about long-term effects and pharmacodynamics such as interactions with other medications and dose-response curves.

The OPH met with representatives from the Controlled Substances and Tobacco Directorate of Health Canada, which oversees the MMARs. Concerns regarding the limited data on effectiveness, the difficulties with assessing proper dosage, long term health effects of inhaled marijuana and pharmacodynamics were shared.
As previously noted, the Federal government is constrained by the decisions of Canadian courts. They are currently reviewing the MMARs and plan to consult further with CMA regarding research, physician responsibilities and education programs for Canada’s physicians. The OPH met with Margaret Bloodworth, a contractor hired by Health Canada to do a full assessment of the program.

CMA Position:

The CMA has always recognized and acknowledged the unique requirements of those individuals suffering from a terminal illness or chronic disease for which conventional therapies have not been effective and for whom marijuana for medicinal purposes may provide relief. However, there are a number of problems with the current Medical Marijuana access program. In order to find a solution to these outstanding problems, CMA makes the following recommendations.

1. The advancement of scientific knowledge about medical marijuana must be encouraged. Given that there are currently over 4,000 patients receiving medical marijuana from Health Canada, CMA encourages the Government to properly study the safety, efficacy, most appropriate amount to be used, and the most effective delivery mechanism for treatment of specific conditions. The same safety and evidence standards should apply to medical marijuana as to pharmaceutical products under the FDA.

2. With the increasing number of patients being authorized to possess medical marijuana, it is imperative that physicians know and understand the regulations and the use of medical marijuana in their practice settings. As such, CMA calls on the Government to work with the CMA, The College of Family Physicians of Canada, the Royal College of Physicians and Surgeons, and other relevant stakeholders, to develop compulsory education and licensing programs for physicians who authorize the use of marijuana for their patients.

3. Finally, until the problems with the MMARs are rectified, CMA lacks the basis upon which to revise its current policy. Physicians who wish to authorize the use of marijuana for patients in their practices should consult relevant CMPA policy and guidelines in order to ensure appropriate medico-legal protection.

References

CMA POLICY

Principles for the Protection of Patients’ Personal Health Information

The Canadian Medical Association (CMA) Principles for the Protection of Patients’ Personal Health Information are intended to provide physicians (including medical students and physicians in training) with a resource to highlight ethical and practical ways to protect patients’ personal health information, including situations where legislation grants physicians discretion to collect, use and disclose personal health information without consent. The CMA recognizes that physicians are required to comply with applicable privacy law when dealing with their patients’ personal health information. The Principles are not designed to serve as a tool for legislative compliance in a particular jurisdiction or provide a standard of care. Rather, the CMA wishes to provide physicians with guidance and a vision of what physicians might strive for to further their professional and legal obligations in a complex area. The Principles are relevant to physicians practicing in both the public and private sectors.

With the advent of shared electronic records (for example, in provincial/regional Electronic Health Record* (EHR) systems) the physician may not be the custodian of - i.e., control access to - the patient’s records once the health information is collected. Institutions, clinics and physician-group practices may also have responsibility for personal health information and therefore play an important role in ensuring personal health information is protected. The Principles therefore recognize that physicians’ responsibilities as data stewards and custodians of health information must be assessed in the light of this framework. Where the term physician is used, it is meant to refer to the custodian of the medical record which in the case of institutions may not be the treating physician.

Foundational Privacy Principles.

Article 31 of the CMA’s Code of Ethics (Revision 2004) states: Protect the personal health information of your patients.

1. Privacy, confidentiality and trust are cornerstones of the patient-doctor relationship.

Health information is highly sensitive and is confided or collected under circumstances of vulnerability and trust. Trust plays a central
role in the provision of health care and treatment; fulfillment of physicians’ fiduciary obligations enables open and honest communications and fosters patients’ willingness to share personal health information.

2. Patients have a general right to control the use and further disclosure of their personal health information, and a right of reasonable access to the information contained in their medical record.

The personal health information contained in the medical record belongs to the patient; patients retain an interest in what subsequently happens to it. Patients have a right of reasonable access to any personal health information in a medical record that was used for their care and treatment, regardless of whether the record is electronic or paper. Physicians may provide the patient with access to personal health information in a form that is accessible to the patient (e.g. paper or electronic). Patients generally have a right to request a correction of or addition to the information contained in the medical record and physicians may make the correction or addition if it is determined to be appropriate. Health information may be withheld from a patient if there is a significant likelihood of a substantially adverse effect on the physical or mental health of the patient or substantial harm to a third party.

There are circumstances when a physician must consider whether it is the parent or the child who should have control of personal health information. A young person who is deemed to understand fully the implications of a medical decision is generally also deemed to have control over their personal health information.

3. Physicians must handle personal health information in compliance with the applicable federal and provincial privacy laws and professional regulations.

Physicians may be required to comply with more than one privacy law when dealing with their patients’ personal health information. Where there is uncertainty, physicians should seek advice from their professional liability protection provider (e.g. Canadian Medical Protective Association) and/or their Provincial Regulatory College.

4. Physicians play an important role in educating patients about possible consensual and non-consensual uses and disclosures that may be made with their personal health information.

Prior to the collection of health information, the patient should be informed through means such as websites, letters, posters, flyers or conversations that their personal health information (a) will be shared on a strict need-to-know basis with members of the health care team for the purpose of providing the necessary health care and treatment; (b) will be used to obtain payment for the health services provided; (c) may be used for health system planning and research; (d) may be disclosed to fulfill mandatory reporting obligations (e.g. fitness to drive, communicable diseases, etc.); (e) may be used or disclosed for other purposes where permitted or required by law (e.g. warrants, subpoenas, etc.) and (f) where possible, personal health information may be either de-identified or anonymized for any secondary purposes.

Patients should be encouraged as well to raise any concerns they might have about the uses and disclosures of their health information. Where physicians are not the primary
custodians of personal health information (for example in hospitals, multi-disciplinary clinics, or other group practices), such institutions should assist physicians in making these issues clear to patients.

5. Security safeguards must be in place to protect personal health information in order to ensure that only authorized collection, use, disclosure or access occurs.

Consent

6. Under certain circumstances, physicians may rely on a patient’s implied informed consent to share personal health information.

Physicians may infer a patient's consent to collect, use, disclose and access personal health information for primary therapeutic purposes (i.e. for the purposes of direct patient care and treatment). Thus a physician may infer consent to (a) store personal health information in an electronic or paper medical record; (b) share the necessary personal health information with the appropriate members of the health care team.

7. The patient’s express consent is generally required to disclose any part or all of the patient’s personal health information in response to a third party request (e.g. insurance company, patient’s lawyer) that is not directly related to the patient’s health care or treatment. As discussed further in Principle 9 below, consent is generally not required where disclosure is permitted or required by law.

Patient consent is a fundamental concept in the provision of medical care. Patient consent to share information is crucial for the protection of the right to privacy and for the preservation of trust in the doctor-patient relationship. The principal purpose for the collection of health information is to benefit the patient, who confides or permits information to be collected for this purpose.

Collection, use and disclosure

8. The use or disclosure of patient information within the “circle of care” should be done solely on a need-to-know basis.

This principle limits the sharing of personal health information with members of the health care team to only that information which is necessary for each team member, in accordance with their specific training, skills, responsibilities and terms of employment or other engagement, to provide the patient with direct health care and treatment.

9. Physicians may use or disclose personal health information without consent when it is required by law.

Patient consent is not required to permit physicians to fulfill mandatory reporting requirements such as the duty to report child abuse, fitness to drive, communicable diseases, etc. Patient consent is not required to disclose personal health information to regulatory authorities (Colleges) and billing audit agencies when the information is required by the College/agency to fulfill their respective mandates. Patient consent is not required to permit physicians to disclose personal health information in accordance with a warrant, subpoena, court order, or summons. Physicians must limit the personal health information that is disclosed to only that information which is necessary to fulfill the requirement. Physicians will want to consider if it is appropriate in the circumstances to advise the patient when a disclosure has been made.
10. Physicians may exercise discretion when the use or disclosure of personal health information without consent is permitted, but not required by law.

When privacy legislation permits the disclosure of personal health information without consent, physicians will want to exercise their discretion to ensure the disclosure is consistent with the duty of confidentiality or otherwise reasonable in the circumstances. For example, in some jurisdictions, medical officers of health may use personal health information for purposes related to the administration of a public health program or services prescribed in regulations. Given the number of factors involved in determining when it is appropriate to exercise discretion to use or disclose personal health information where permitted by law, physicians may wish to consider contacting their professional liability protection provider (e.g. CMPA) and/or Provincial Regulatory College for advice in these instances.

Physicians will also want to consider whether it is reasonable and/or preferable to obtain patient consent. There may be circumstances where it is not reasonable to seek patient consent, such as where the disclosure is required to avoid an imminent risk of harm to the patient or another person or where the disclosure is required to obtain risk management or legal advice. Physicians should limit the personal health information that is disclosed to that information which is necessary for the purpose. Physicians will want to consider if it is appropriate in the circumstances to advise the patient when a disclosure has been made.

11. Physicians should be aware of applicable requirements before collecting, using, or disclosing personal health information for research purposes.

Even if not required to do so by privacy legislation, physicians should obtain the approval of a properly constituted and informed research ethics board (REB) or review committee prior to collecting, using or disclosing patients’ personal health information for research purposes without consent. ***

**Retention**

12. Personal health information should be retained at least for the period required by the provincial or territorial regulatory authority (College) or by any applicable legislation. It may be necessary to maintain personal health information beyond the applicable period where there is a pending or anticipated legal proceeding related to the care provided to the patient.

Physicians should retain, transfer and dispose of records in a safe and secure manner, in accordance with the requirements specified by their regulatory authorities and any applicable legislation.

**Electronic Records***

13. Patients should be informed that the treating physician cannot control access and guarantee confidentiality for an electronic health record (EHR) system.

Every institution with a role to play in the EHR environment (e.g. health authorities, hospitals, clinics and governments) must play a part in educating patients and the public about the use of the EHR to store and share personal health information.

When transfer of patient health information to an interoperable (i.e. provincial or regional) EHR system is legislatively required, patients should be informed of this requirement.
Implementation of an interoperable EHR requires a strict privacy framework, including an access audit “trail” to safeguard against unauthorized access. Patients should be able to access this audit trail.

Patients and the public can be informed through means such as websites, letters, posters, flyers, conversations or public awareness campaigns that their personal health information will be included in an EHR. Options for protecting that information such as opt-out, disclosure directives, masking, or lock-boxes should be available and disclosed to patients.

Where possible, personal health information contained in an EHR should be de-identified before it is used for secondary purposes, such as health-system planning. Physicians may also wish to consult the Provincial Regulatory College in their jurisdiction as to whether patient consent might be required to upload a core segment of the EMR to an EHR.

14. Physicians may wish to consider entering into a Data Sharing Agreement to govern their participation in any shared electronic record (i.e. EMR/EHR)

The CMA and the CMPA have published Data sharing principles for Electronic Medical Record/Electronic Health Record agreements to provide guidance with respect to the main principles that should be addressed when a physician is entering into an agreement for an EMR, where multiple health care providers will have access to personal health information submitted by the physician.

The Data Sharing Agreement should address issues including but not limited to: confidentiality and privacy; security; accuracy; and data quality; record maintenance; quality assurance; and functionality.

**“Electronic health record”** is the health record of an individual that is accessible online from many separate, interoperable automated systems within an electronic network. It is maintained by a hospital, regional health authority or provincial/territorial government and typically includes a wider cross section of information from a number of sources.

**“Electronic medical record”** is essentially an electronic version of the paper record that doctors have long maintained for their patients. It may be a simple office-based system or a more sophisticated and interconnected system that links health professionals through a shared network.

**“Circle of Care”** refers to those members of the health care team directly involved in the clinical care and management of the patient.

In an environment in which the capacity to capture, link and transmit information is growing and the need for fuller accountability is being created, the demand for physician information, and the number of people and organizations seeking to collect it, is increasing.

Physician information, that is, information that includes personal health information about and information that relates or may relate to the professional activity of an identifiable physician or group of physicians, is valuable for a variety of purposes. The legitimacy and importance of these purposes varies a great deal, and therefore the rationale and rules related to the collection, use, access and disclosure of physician information also varies. The Canadian Medical Association (CMA) developed this policy to provide guiding principles to those who collect, use, have access to or disclose physician information. Such people are termed “custodians,” and they should be held publicly accountable. These principles complement and act in concert with the CMA Health Information Privacy Code,1 which holds patient health information sacrosanct.

Physicians have legitimate interests in what information about them is collected, on what authority, by whom and for what purposes it is collected, and what safeguards and controls are in place. These interests include privacy and the right to exercise some control over the information; protection from the possibility that information will cause unwarranted harm, either at the individual or the group level; and assurance that interpretation of the information is accurate and unbiased. These legitimate interests extend to information about physicians that has been rendered in non-identifiable or aggregate format (e.g., to protect against the possibility of individual physicians being identified or of physician groups being unjustly stigmatized). Information in these formats, however, may be less sensitive than information from which an individual physician can be readily identified and, therefore, may warrant less protection.

The purposes for the use of physician information may be more or less compelling. One compelling use is related to the fact that physicians, as members of a self-regulating profession, are professionally accountable to their patients, their profession and society. Physicians support this professional accountability purpose through the legislated mandate of their regulatory colleges. Physicians also recognize the importance of peer review in the context of professional development and maintenance of competence.

The CMA supports the collection, use, access and disclosure of physician information subject to the conditions outlined below.

1. Purpose(s): The purpose(s) for the collection of physician information, and any other purpose(s) for which physician information may be subsequently used, accessed or disclosed, should be precisely specified at or before the collection. There should be a reasonable expectation that the information will achieve the stated purpose(s). The policy does not prevent the use of information for purposes that were not intended and not reasonably anticipated if principles 3 and 4 of this policy are met.

2. Consent: As a rule, information should be collected directly from the physician. Subject to principle 4, consent should be sought from the physician for the collection, use, access or disclosure of physician information. The physician should be informed about all intended and anticipated uses, accesses or disclosures of the information.

3. Conditions for collection, use, access and disclosure: The information should:
   a. be limited to the minimum necessary to carry out the stated purpose(s),
   b. be in the least intrusive format required for the stated purpose(s), and its collection, use, access and disclo-
4. **Use of information without consent:** There may be justification for the collection, use, access or disclosure of physician information without the physician’s consent if, in addition to the conditions in principle 3 being met, the custodian publicly demonstrates with respect to the purpose(s), generically construed, that:
   - the stated purpose(s) could not be met or would be seriously compromised if consent were required,
   - the stated purpose(s) is(are) of sufficient importance that the public interest outweighs to a substantial degree the physician’s right to privacy and right of consent in a free and democratic society, and
   - that the collection, use, access or disclosure of physician information with respect to the stated purpose(s) always ensures justice and fairness to the physician by being consistent with principle 6 of this policy.

5. **Physician’s access to his or her own information:** Physicians have a right to view and ensure, in a timely manner, the accuracy of the information collected about them. This principle does not apply if there is reason to believe that the disclosure to the physician will cause substantial adverse effect to others. The onus is on the custodian to justify a denial of access.

6. **Information quality and interpretation:** Custodians must take reasonable steps to ensure that the information they collect, use, gain access to or disclose is accurate, complete and correct. Custodians must use valid and reliable collection methods and, as appropriate, involve physicians to interpret the information; these physicians must have practice characteristics and credentials similar to those of the physician whose information is being interpreted.

7. **Security:** Physical and human safeguards must exist to ensure the integrity and reliability of physician information and to protect against unauthorized collection, use, access or disclosure of physician information.

8. **Retention and destruction:** Physician information should be retained only for the length of time necessary to fulfill the specified purpose(s), after which time it should be destroyed.

9. **Inquiries and complaints:** Custodians must have in place a process whereby inquiries and complaints can be received, processed and adjudicated in a fair and timely way. The complaint process, including how to initiate a complaint, must be made known to physicians.

10. **Openness and transparency:** Custodians must have transparent and explicit record-keeping or database management policies, practices and systems that are open to public scrutiny, including the purpose(s) for the collection, use, access and disclosure of physician information. The existence of any physician information record-keeping systems or database systems must be made known and available upon request to physicians.

11. **Accountability:** Custodians of physician information must ensure that they have proper authority and mandate to collect, use, gain access to or disclose physician information. Custodians must have policies and procedures in place that give effect to the principles in this document. Custodians must have a designated person who is responsible for monitoring practices and ensuring compliance with the policies and procedures.

**Reference**