




Medicolegal Aspects of Marijuana for Medical Purposes



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Overview


- Medical marijuana regulations
- College positions
- Medico-legal risks
- Risk mitigation strategies



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Marijuana Medical Access Regulations (MMAR)



- Came into force on July 30, 2001
- Patient applied to Health Canada to obtain authorization to possess or produce
- Required "medical declaration" signed by MD
- Required specialist support for certain categories of conditions

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Marijuana for Medical Purposes Regulations (MMPR)




- Came into force April 1, 2014
- MMAR repealed
- Health Canada no longer produces or distributes marijuana nor does it approve applications

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Marijuana for Medical Purposes Regulations (MMPR)

- Marijuana can now only be obtained from licensed commercial producer upon submission of a "Medical Document"
- Personal production no longer authorized
- However, if authorization to produce was obtained under MMAR patient may continue to produce pending outcome of legal case



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Marihuana for Medical Purposes Regulations (MMPR)

- Categories of symptoms eliminated
- No requirement to obtain specialist support
- Patient must submit Medical Document to licensed producer who then supplies marihuana
- New process analogous (but not identical) to a prescription model
 - Term “prescription” deliberately avoided in MMPR
 - Marihuana not approved or regulated like other prescribed drugs

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Medical Document

Must indicate:

- MD’s name, profession, and coordinates
- License information
- Patient name and DOB
- Address and location where patient consulted MD
- Daily quantity of marihuana to be used by patient
- Period of use (no more than 1 yr)
- CPSA requires patient’s medical condition

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Medical Document - Health Canada

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).

NOTE: The period of use cannot exceed one year

Strength? Composition? Indication?

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Medical Document

NOTE: 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: _____

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

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College Positions

- Guidelines/Policies vary considerably and many impose additional obligations over those in MMPR
- Colleges raise issue of limited evidence on efficacy of medical marihuana
- MDs should only sign medical document when they have necessary clinical knowledge to engage in meaningful consent discussion

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College Positions


THE COLLEGE OF FAMILY PHYSICIANS OF CANADA
LE COLLÈGE DES MÉDECINS DE FAMILLE DU CANADA

Table 1. Province	Requirements Apply	Provinces (Councils)
Conflict of interest		QC NB NL
Must e		
Must e		
Must e		
Must e non-n		
Autho		NL
State p		
Regist		
Disquali		

Authorizing Dried Cannabis for Chronic Pain or Anxiety

PRELIMINARY GUIDANCE

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College Expectations

Additional obligations:

- Determine whether conventional therapies ineffective
- Review prescription databases for medication profile
- Assess addiction risk
- Obtain informed consent
- Evaluating patient regularly
- Providing ongoing care for medical condition


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Colleges

- CPSA requires MD to first register with College and provide copy of Medical Document
- CMQ prohibits MD from providing medical document unless done as part of a recognized research project
- CPSS and CPSPEI requires (CPSO and CPSNB recommends) MD have patients sign written treatment agreements in which they undertake:
 - Not to misuse, abuse, sell or give away the marihuana
 - Not to double-doctor
 - To store the marihuana safely
 - Acknowledge if agreement breached, MD may not complete other medical documents for patient

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Treatment Agreement

Table 2. Sample treatment agreement
 Because we take our responsibilities to authorize and supervise the medical use of marijuana (dried cannabis) very seriously, we ask you to read, understand, and sign this form.

1. I request Dr. _____ MD, to sign a medical document for me under the Health Canada MMMPR legislation, so that I may legally use marijuana to treat my medical condition.
2. I agree to receive a medical document for marijuana only from one physician, Dr. _____ MD.
3. I agree to consume no more marijuana than the doses authorized for me by Dr. _____ MD. I will not request a refill before the agreed-upon refill date.
4. I agree to not distribute my marijuana to any other person, for personal use or for sale. I am aware that redistribution of any marijuana for sale is an illegal activity.
5. I am aware that using marijuana is associated with psychosis in persons who are still undergoing neurodevelopment (brain growth). Therefore, I will ensure that no person under the age of 25 years has access to my marijuana.
6. I agree to the safe storage of my marijuana.

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Colleges

- CPSO and CPSBC consider the medical document equivalent to a prescription
 - Physicians who provide the medical document must comply with the expectations and guidelines for prescribing and dispensing drugs, any other relevant College policies such as the policy on Complementary/Alternative Medicine
- Although *MMPR* requires patient to be 18 years of age, CPSO and CPSBC recommends that patients be over 25
- CPSM, CPSS, CPSNL, CPSBC requires practitioner to be the patient's primary treating physician


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Colleges


- Some prohibit financial interest in producer or becoming licensed producer (CPSA, CPSS, CPSM, CMQ, CPSNL)
 - Even if not specifically prohibited by College policy, likely perceived as conflict of interest to complete medical document and be licensed producer
- Some prohibit dispensing (CPSA, CPSBC, CPSS, CPSM, CMQ, CPSPEI) and others discourage dispensing (CPSNL)
 - Dispensing also creates criminal prosecution risks

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Colleges

- Certain Colleges have restrictions on providing Medical Document via telemedicine
- MD wishing to provide medical document via telemedicine may have to comply with College policy of jurisdiction in which patient is located in addition to the policy of their own jurisdiction



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Completion of the Medical Document

What should physicians tell their patients regarding driving and medical marijuana usage?

This is part of the consent discussion and would likely be similar to information given to patient in the context of prescribing benzodiazepines or narcotics



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Completion of the Medical Document

Can patients be charged a fee for completion of the document?

A number of Regulatory Authorities consider authorization to be a clinical act and an insured service for which physicians must not bill the patient.



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Completion of the Medical Document

Are physicians required to keep a list of patients for whom they have provided a Medical Document?

MMPR does not require this but some regulatory authorities do (CPSS, CPSM, CMQ). May be prudent for physicians to do so.



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Medico-Legal Issues Informed Consent

- Sufficient information and knowledge to properly advise patients of the potential risks and benefits of marijuana
 - Limited or no studies on efficacy, risks, benefits, dosing, and drug interactions
- Elimination of Health Canada's role in approving applications places greater emphasis on MDs as gatekeepers



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Medico-Legal Issues

Civil Action – MD will be liable if

- MD is in breach of the **standard of care** in providing or refusing to provide a medical document, or in obtaining informed consent
 - e.g. dosage, strength was inadequate, drug interactions, not indicated for condition, or did not disclose all relevant information
- Patient suffered **harm** due to the breach of the standard of care

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Marihuana

- **To Rx, or not to Rx, that is the question.**
 - Is there evidence for use in the condition?
 - Do benefits outweigh the risks?



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If saying "Yes",

- Document consent discussion
- Develop follow-up plan
- Advice about driving
- Assess addiction risk
- Treatment agreement
- Be aware of College policies
- "Release from Liability" not advised



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If saying "No"

- Thoroughly document thought processes and reason for decision
- Subject to College restrictions, if the refusal is based on the MD's insufficient knowledge may consider referring the patient to a physician that has experience in that area



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Vignette

- **Dr Z has signed a Medical Document . Asked by patient to receive shipment of marihuana on their behalf. Should Dr Z agree to this?**
 - *MMPR* allows Dr Z to receive marihuana from producer on behalf of patient
 - *MMPR* also allows Dr Z to transfer or administer marihuana , but not sell it, to patient
 - However, some Colleges do not permit members to dispense marihuana, despite *MMPR*. Dr Z should first check with College.
 - *CPSA expressly prohibits receipt and transfer*

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Vignette

- **Dr A is asked to sign Medical Document in form prepared by a licensed producer. Should Dr A complete the form or provide own document?**
 - Can use producer's form but should only provide information required by *MMPR*
 - *CMPA* has also seen forms that use the term "**prescriber**". Dr A will want to cross out term and write "health care practitioner".
 - Health Canada has a sample medical document on its website that is suitable. Dr A may use that instead if concerned about producer's form.

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Most Recent Court Case

- Decision rendered June 11, 2015
- *R. v. Smith*— Supreme Court of Canada ruled it was unconstitutional to restrict medical marihuana patients to using only dried cannabis

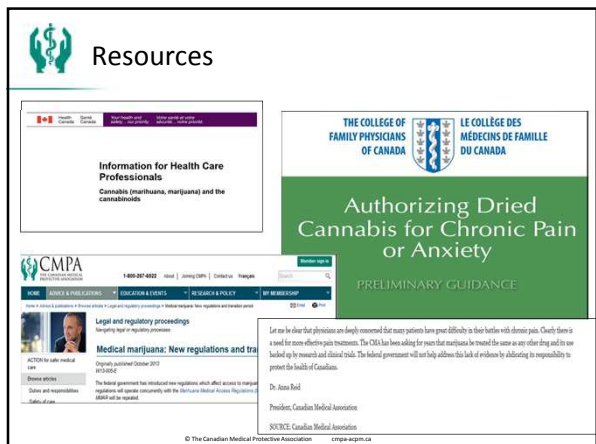
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Risk Mitigation

- Have sufficient clinical knowledge
- Inform of limitations of current evidence
- Document all consent-related discussions in patient record
- Follow College guidelines and policies
- Consider written consent form where patient acknowledges discussion of risks
- Consider developing handouts

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Resources

Information for Health Care Professionals
Cannabis (Marijuana, Marjjuana) and the cannabinoids

THE COLLEGE OF FAMILY PHYSICIANS OF CANADA / **LE COLLÈGE DES MÉDECINS DE FAMILLE DU CANADA**

Authorizing Dried Cannabis for Chronic Pain or Anxiety
PRELIMINARY GUIDANCE

Legal and regulatory proceedings
New regulations and tr...

Medical marijuana: New regulations and tr...
Depends on when...

Dr. Anna Reid
President, Canadian Medical Association

SOURCE: Canadian Medical Association

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CMPA GOOD PRACTICES GUIDE

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