Medicolegal Aspects of Marihuana for Medical Purposes

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Overview
• Medical marihuana regulations
• College positions
• Medico-legal risks
• Risk mitigation strategies

Marihuana 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

Marihuana for Medical Purposes Regulations (MMPR)
• Came into force April 1, 2014
• MMAR repealed
• Health Canada no longer produces or distributes marihuana nor does it approve applications
• Marihuana 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
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

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

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 is a person licensed, qualified, and appointed under the Health Information Protection Act, 2014, and who practises in a specialty or branch of medicine within the scope of practice. If this document is used, it must contain all of the information below.

Patient’s Full Name and Signature
Date of Birth (DD/MM/YYYY)
Daily quantity of dried marihuana to be used by the patient:
The period of use:

NOTE: The period of use cannot exceed one year

Strength? Composition? Indication?

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

College Positions
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

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

Treatment Agreement

Table 2. Sample Treatment Agreement

Because we take our responsibilities to our patients and society to the highest possible ethical standard, we must act in good faith.

1. I request
2. ________ MD to sign a medical document in accordance with the Health Canada MMPR regulations, or that may legally be considered necessary, and agree:
3. ________ I shall not misuse, abuse, sell or give away the marihuana
4. ________ I will not request a refill before the agreed upon refill date
5. ________ I agree to store the marihuana safely
6. ________ I understand that failure to follow any of the above will result in termination of the agreement

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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

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

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
What should physicians tell their patients regarding driving and medical marihuana 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.

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.

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.

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

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

Marihuana

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

**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

**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

**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.