

Program Name:	Understanding Canada's Medical Cannabis Regulations
Planning Committee:	Danial Schecter, MA, MD, CCFP Carlene Oleksyn, B.S.P. Pharm Moe Abdallah, BSc, BscPhm, R.Ph
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Learning Objectives

At completion of the program, the participant will be able to:

- Describe key features of the Marihuana for Medical Purposes Regulations (MMPR)
- Counsel patients about how to access medical cannabis under the current regulations
- Collaborate with and support other primary care colleagues with accurate information and resources about the regulations for medical cannabis

Abbreviations:

MMAR = Marihuana Medical Access Regulations (repealed)

MMPR = Marihuana for Medical Purposes Regulations (current)

THC = Delta-9-tetrahydrocannabinol

CBD = cannabidiol

Pre- Course Survey

1. How would you rate your awareness of the Marihuana for Medical Purposes Regulations (MMPR)? (1 = poor; 5 = excellent)
2. How comfortable are you with educating patients about accessing medical cannabis under the MMPR? (1 = not at all comfortable; 5 = very comfortable)
3. How likely are you to recommend medical cannabis for an eligible patient whose condition has not responded to conventional treatments and for which clinical evidence suggests that medical cannabis may be useful? (1 = very unlikely; 5 = very likely)

Introduction

Medical cannabis is increasingly recognized as a valuable therapeutic option for the management of a variety of symptoms. Although pharmacists do not currently write medical cannabis authorizations and pharmacies do not dispense medical cannabis, the pharmacist as a member of the primary care team still plays an important role in supporting and counselling patients who wish to access cannabis for symptom management, and in supporting and collaborating with primary care colleagues in navigating the regulatory environment.

This program will support pharmacists with important knowledge about the legal access to medical cannabis in Canada under the Marihuana for Medical Purposes Regulations (MMPR), which came into effect in June of 2013.

Medical Cannabis Therapeutics

For more information about the therapeutic use of medical cannabis, please see our accompanying

Former Regulations

Marihuana Medical Access Regulations (MMAR): 2001 - 2014

In 2001, Health Canada granted access to patients, with the support of their physicians, to use cannabis for medical purposes. Under the Marihuana Medical Access Regulations (MMAR), patients could obtain a legal supply of cannabis by applying for access to Health Canada's supply of dried cannabis, by applying to produce cannabis for their own use (i.e., personal use licence), or by designating another person to cultivate cannabis on their behalf (i.e., designated person production licence).¹ Since the program's introduction, the number of users grew from <500 in 2001 to >30,000 in 2013.²

Current Regulations

Marihuana for Medical Purposes Regulations (MMPR): 2013 - today

In June 2013, the Government of Canada introduced new regulations, i.e., Marihuana for Medical Purposes Regulations (MMPR), and the Marihuana Medical Access Regulations (MMAR) were repealed on March 31, 2014. During the transition period, both regulations were in force.

As of April 1, 2014, patients are no longer allowed to grow their own cannabis. (A court injunction allows individuals who had a license to grow cannabis under MMAR to continue to do so until the court case is heard or the injunction is appealed. .) Under MMPR, the only way to legally obtain medical cannabis is through licensed producers, companies that are authorized by Health Canada to produce and sell the product. The producers have to demonstrate compliance with regulatory requirements such as quality control standards, record-keeping, and security measures to protect against diversion. Approval of licensed producers by Health Canada is subject to submitting a completed licensed producer application, obtaining necessary personal security clearances, and meeting physical security requirements for cultivation and storage areas.³

Dispensaries and compassion clubs, which developed under a grey area of the MMAR, are not legal under the MMPR.

Health Canada statement due to the injunction (current as of November 19, 2014):

"As a result of ongoing litigation and uncertainty arising from court decisions, Health Canada will treat the following Authorizations to Possess, Personal-Use Production Licences, and Designated-Person Production Licences as extending beyond March 31, 2014 until a decision in Allard is rendered. As per the Federal Court interim injunction, the following criteria must be met:

- Individuals must have held a valid Authorization to Possess under the MMAR on March 21, 2014.

- Individuals must have held a valid Personal-Use Production Licence or Designated-Person Production Licence under the MMAR on, or after, September 30, 2013, where there is also an associated valid ATP as of March 21, 2014.

Individuals with a medical need who do not fall within the scope of this court order and who have the support of a licensed healthcare practitioner may register with a licensed producer under the MMPR.”

For information or updates, contact Health Canada at 1-866-337-7705 or mmap-pamm@hc-sc.gc.ca. Also watch for updates at www.healthcanada.gc.ca/mma.

When the federal appeal has been scheduled, it will be listed on the website of the [Supreme Court of Canada](#).

Background Information

Case study

John, a 38-year old male, has chronic pain resulting from a spinal fracture from a skiing accident he had 15 years ago. The pain limits his day-to-day activities and interferes with his sleep.

John has been prescribed nonsteroidal anti-inflammatory drugs (NSAIDs), anticonvulsants, and tricyclic antidepressants for pain relief, but none of these adequately relieved his pain. His physician is considering treatment with an opioid, but John is hesitant to use opioids because he has heard about their adverse effects.

John asks you if medical cannabis might be a good option for him.

Case Challenge 1

Test your current knowledge

True or false? Medical cannabis can only be authorized for qualifying conditions (indications) listed under MMPR.

- True
- False

Authorized Indications

The MMPR does not specify conditions/indications for which medical cannabis can be prescribed. Under the old regulations, medical doctors had to indicate that the patient had a symptom of a condition that fell within an allowed category. These categories included end-of-life care, multiple sclerosis, spinal cord injury or disease, cancer, HIV/AIDS, arthritis, epilepsy, or a debilitating symptom of another condition.

Under the new regulations, access to medical cannabis is not restricted to any particular indications. Authorization is at the discretion of the authorized doctor or nurse practitioner.

The endocannabinoid system is involved in several physiological and pathophysiological processes, and several experimental and clinical studies have investigated a potential role for cannabis or the cannabinoids in a variety of diseases. Prescription cannabinoids are approved in Canada for patients not responding to conventional treatments for pain management, relief of spasticity, stimulating appetite in AIDS patients with anorexia associated with weight loss, and for the management of nausea and vomiting associated with cancer chemotherapy. However, for many conditions, the data is limited and conclusive evidence for the role of prescription cannabinoids and herbal cannabis may not be available.⁴

Potential Uses

Potential uses of medical cannabis, based on experimental and/or clinical studies, include the following:⁴

- Relief of intractable pain, e.g., neuropathic pain, acute postoperative pain, chronic non-cancer pain, cancer pain, pain associated with arthritic diseases, fibromyalgia pain, headache and migraine
- In palliative care, for relief from pain and other distressing symptoms, and enhancement of quality of life
- Relief from chemotherapy-induced nausea and vomiting
- Stimulation of appetite and facilitating weight gain in patients with AIDS, cancer, or disease related anorexia
- Amelioration of spasticity in multiple sclerosis, amyotrophic lateral sclerosis, spinal cord injury (or spinal cord disease)
- Modulation of neuronal tone and excitability in epilepsy
- Reduction in motor symptoms in movement disorders such as dystonia, Parkinson's disease, and Tourette's syndrome
- Symptom control for some psychiatric disorders such as anxiety, post-traumatic stress disorder (PTSD) and insomnia.
- Reduced disease activity in inflammatory bowel diseases
- Improved colonic compliance in irritable bowel syndrome

Resources

- For an overview of the above indications, including some of the research and information on cannabis and the cannabinoids, see [Health Canada's Information for Healthcare Professionals \(2013\)](#)⁴
- For a list of clinical studies and case reports involving cannabis/cannabinoids, see the [International Association for Cannabinoid Medicines](#).

Patient Selection

As already mentioned, under MMAR, Health Canada provided a list of qualifying medical conditions for medical cannabis. The physician filled out a form confirming the patient's medical condition and Health Canada issued an authorization to possess cannabis.

Now, under the MMPR, there are no specified conditions for which medical cannabis can be authorized, and the medical document (authorization) is prepared by the healthcare practitioner is not sent to Health Canada. Thus it is the healthcare practitioner who decides on patient eligibility for medical cannabis and its dosage, while Health Canada's role is limited to licensing cannabis producers.⁵

Case Challenge 2

Test your current knowledge

At your urging, John talks with his doctor about whether medical cannabis might be a good option to help manage his symptoms. After some evaluation and screening, his doctor agrees to a trial of medical cannabis. Which of the following describes the process by which John must obtain medical cannabis?

- a) John's doctor provides a medical document, which John mails to his chosen licensed producer. John registers with the producer. The producer accepts John as a client and ships the medical cannabis directly to John.
- b) John's doctor provides a medical document to Health Canada. John registers with the producer. The producer ships the medical cannabis directly to John.
- c) John's doctor provides a medical document to Health Canada. Health Canada approves the application and ships the medical cannabis directly to John.
- d) John's doctor provides a medical document to Health Canada and John's chosen licensed producer. John registers with the producer. The producer accepts John as a client and ships the medical cannabis directly to John.

The Process

In order to gain access to medical cannabis, the patient must consult the healthcare practitioner (Figure 1). If a treatment decision is made to use medical cannabis, the healthcare practitioner will provide the patient with a medical document (discussed below). Authorized healthcare practitioners include physicians in all Canadian provinces and territories, and nurse practitioners in provinces and territories where authorizing cannabis for medical purposes is permitted under their scope of practice. Healthcare practitioners should be aware of their provincial college's position on authorizing medical cannabis.

After obtaining the medical document from the healthcare practitioner, the patient must choose a licensed producer and register as a client with the producer. Registration involves providing certain information, including the original medical document. After registering as a client, the patient will be able to order cannabis from the licensed producer. The licensed producer sets the price for the product. The cannabis will be sent directly to the patient by the licensed producer. The label on the cannabis package or the document that accompanied the shipment of cannabis, both of which would contain the patient's information, is considered proof of legal possession of medical cannabis.

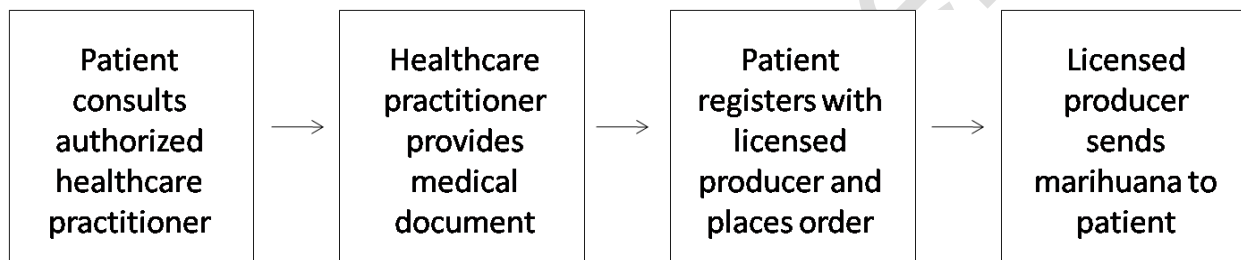


Figure 1. Procedure for patient access to medical cannabis under MMPR

The Medical Document

Under MMPR, a patient requiring medical cannabis should obtain a completed medical document, similar to a prescription, from his/her healthcare practitioner. The medical document should contain the following information:

Patient's given name and surname:

Patient's date of birth (DD/MM/YYYY):

Daily quantity of dried cannabis to be used by the patient: _ g/day

The period of use is ___ day(s) ___ week(s) ___ month(s) (cannot exceed 1 year)

Healthcare practitioner's given name and surname:

Profession:

Healthcare practitioner's business address:

Full business address of the location at which the patient consulted the healthcare practitioner (if different than above):

Phone Number:

Fax Number (if applicable):

Email Address (if applicable):

Province(s) Authorized to Practice in:
Healthcare Practitioner's Licence number:

For a sample medical document, [click here](#).

The **original** medical document must be submitted by the patient directly **to a licensed producer** of the patient's choice along with a registration form provided by the licensed producer and duly completed by the patient. It is advisable for the physician to keep a **copy** of the medical document in his/her files. The medical document **should not be sent to Health Canada**.

Available Dosage Form

The regulations specify the dose and form that patients can receive:

- Licensed producers can only provide dried cannabis to patients. Dried cannabis is typically inhaled or consumed orally. Smoking is not recommended. Dried cannabis can also be used with a vaporizer or in teas.
- The product label will indicate the percentage of THC and CBD for that lot of cannabis.
- Medical cannabis cannot be sold with additives (added substances).
- Medical cannabis cannot be sold in a dosage form, such as in pre-rolled cigarettes or capsules.
- Other forms of cannabis (e.g., edibles or oils), cannot be sold by licensed producers under MMPR.
- In addition to dried cannabis provided under MMPR, two pharmaceutical formulations containing cannabinoids are available in Canada; these are nabilone (Cesamet®), and CBD/THC 1:1 (Sativex®). These formulations are not considered to be medical cannabis, and are sold by prescription through pharmacies, whereas dried cannabis is not.

Case Challenge 3

Test your current knowledge

John's daily dose of medical cannabis, in accordance with the medical document provided by his doctor, is 1g/day. An RCMP officer found John to be in possession of 20mg of medical cannabis. The RCMP officer has contacted the licensed producer to confirm that John is a client. Will the licensed producer be allowed to confirm John's status as a client?

- a) Yes; the licensed producer can confirm John is a client
- b) No; the licensed producer is bound by confidentiality

Legal Disclosures

Patient Information

If a verified member of a Canadian police force provides a licensed producer with the given name, surname, date of birth, and gender of an individual in the course of an investigation under the MMPR or the Narcotics Control Act, the producer must provide within 72 hours indication of whether or not the individual is a client or the designated individual responsible for a client, as well as the daily amount of medical cannabis authorized to that individual. [For more information, refer to section 101 of the full wording of the MMPR:](#)

101. (1) Subject to subsections (2) and (3), if a licensed producer is provided with the given name, surname, date of birth and gender of an individual by a member of a Canadian police force who requests information in the course of an investigation under the Act or these Regulations, the producer must provide as soon as feasible, within 72 hours after receiving the request, the following information to that Canadian police force:

- (a) an indication of whether or not the individual is
 - (i) a client of the producer, or
 - (ii) an individual who is responsible for a client of the producer; and
- (b) the daily quantity of dried marihuana that is specified in the medical document supporting the client's registration.

Verification

(2) Before providing the requested information, the licensed producer must verify in a reasonable manner that the person requesting the information is a member of a Canadian police force.

Use of information

(3) Information provided under this section must be used only for the purposes of the investigation referred to in subsection (1) and for the proper administration or enforcement of the Act or these Regulations.

Case Challenge 4

Test your current knowledge

The RCMP officer has verified that John is authorized to receive and possess medical cannabis. But is John in possession of a legal amount?

- a) Yes; John is within the possession limit for medical cannabis

b) No; John is in possession of too high an amount of medical cannabis

Amount Restrictions

Patients are not permitted to be in possession of medical cannabis in amounts greater than their monthly supply.

- There is a possession limit of 150 grams or 30 times the daily amount, whichever is less.
- MMPR regulations also allow doctors, nurse practitioners and hospitals to accept cannabis on behalf of their patients and transfer it to the patient.
- The usual amount of inhaled or orally ingested cannabis used for medical purposes by most patients is less than 3 grams per day. However, there are no restrictions on the daily amount of medical cannabis that healthcare practitioners may recommend under MMPR.
- A licensed producer must not sell a client a quantity exceeding 30 times the daily amount (up to 150 g) in any 30 day period.
- A quantity of medical cannabis is deemed to be provided on the date that the licensed producer reasonably anticipates it will be received by the client (i.e., date of sale).

Choice of Product and Producer

Under the new regulations, the patient will only be able to buy medical cannabis directly from a licensed producer, instead of from Health Canada as under the old regulations. (It is also no longer legal for patients to grow their own medical cannabis under the new regulations; however, a [court injunction](#) has allowed people who have previously been given permission to grow by Health Canada to continue to grow medical marijuana while a legal challenge is brought forward in the courts.) Licensed producers are now operating across Canada. Patients can choose any licensed producer; they do not need to choose a producer from within their own province.

License

The producer must be legally licensed by Health Canada. Licensed producers adhere to rigorous standards and regulations.

For a list of authorized licensed producers under the MMPR, [click here](#).

Process and Quality Control

To gain a good understanding of the differences in the various licensed producers and their products, it may be beneficial to talk with producers. While pharmacists are not currently authorizing medical cannabis under the MMPR, anyone, including a pharmacist, can call a producer to ask questions and learn more about the producer.

Pharmacists can also support patients by making them aware that by calling the producers (most of which have toll free numbers) and visiting their websites, they can learn more about the producer and their products.

Examples of subjects that might be relevant to your patient's interests or preferences:

Source: What is the source of their plants? What are the plants' region of origin and genetics? How does this matter? (If a particular strain is desired it may be beneficial to have this information.)

Growing methods: What is the growth medium? Is the medical cannabis grown hydroponically or in soil? What is the water source? Are they organic? What, if any, pesticides are used? What agents are used to nourish the plants as they grow? Is the medical cannabis grown in a greenhouse or in an enclosed room under artificial lighting? (Again, this is a matter of meeting individual patient preferences and needs.)

Processing: What methods do they use (for example, how do they trim the excess leaves from the budding flowers of the plant? What forms of mechanization do they use? What is done by hand and why? How is the medical cannabis dried (or cured)?

Standardization: Is the licensed producer able to guarantee that the medical cannabis received is exactly the same one shipment to the next?

Product availability: Does the producer run out of certain products? Will the patient be able to access continuous supply of their chosen strain from month to month?

Special needs: How well does the producer accommodate special needs or patient requests? If the patient prefers a milled product that they do not have to crumble themselves (due to arthritis in their hands, for example), does the producer make that available to them. Does the producer offer irradiated products for patients who are immunocompromised?

Product recalls: Has the company had any [product recalls](#)? (Since the introduction on the MMPR, three producers have had recalls as of November 2014, one of which is no longer a licensed producer at this time.)

Product Offering

Does the producer have medical cannabis available in several strains and varieties? Different products may have different attributes, and patients have reported effects to differ between strains, but clinical research has not yet established the validity of these claims. Every strain of cannabis ordered will have been tested for the percentage of THC and CBD, the two most medically active compounds in the cannabis plant.

Price & Shipping

Price is set by the producer (not by Health Canada). Additionally, your patient might ask about how long shipping will take and what fees will apply.

If your patient is on a fixed income, disability, or social assistance, or is an eligible veteran, financial assistance may be available through government or insurance healthcare benefit programs or compassionate pricing might be offered by the producer.

Arming your patient against misinformation:

Organizations may be slow to respond to regulatory changes under the new MMPR. Patients may encounter outdated information or expectations when communicating with organizations about their rights or benefits.

Patients should know:

- The old MMAR has been **repealed**
- The current regulations are the **MMPR**
- Patients and/or their doctors **do not** need to contact Health Canada to obtain their medical authorization under the MMPR
- Patients and/or their doctors **do not** need to disclose the medical condition (i.e., the indication) under the MMPR

MMAR = Marihuana Medical Access Regulations (repealed)
MMPR = Marihuana for Medical Purposes Regulations (current)

Support for your Patient

What type of support does the producer offer you and your patient? For example:

- Are they available to answer questions at any time on any day?
- How do they ensure timely registration, to avoid a gap in care?
- Do they have systems in place to make submitting documents easy and secure?
- Do they have representatives who visit and consult with you to provide information and research about medical cannabis? Is this important to you?

Barriers to Medical Cannabis Treatment

The use of cannabis for medical purposes has long been a controversial topic. Cannabis is viewed both as a useful agent that should be given the status of a legitimate pharmaceutical agent and as one with no medical utility.⁹ In general, physicians tend to be less supportive than the general public about the use of medical marijuana.^{10,11} Physicians may be concerned that patients who request medical marijuana may actually use it for recreational purposes.¹² In a survey of family physicians,¹¹ 46% of respondents did not support physicians recommending medical cannabis, and only 19% thought that physicians should recommend it. A minority thought that cannabis conferred significant benefits to physical (27%) and mental (15%) health. Most believed that cannabis poses serious mental (64%) and physical (61%) health risks. A need for education of family physicians on medical cannabis was also cited.

Dried cannabis is not sold through pharmacies, and a criticism of MMPR has been the lack of a dispensary model, i.e., a place where patients can pick up their medical cannabis and obtain information (including administration, adverse effects, precautions and drug interactions) about it. Medical cannabis must also meet patient expectations, and a dispensary model would facilitate obtaining patient feedback and help in determining acceptable quality levels.¹³ Furthermore, with MMPR, Health Canada no longer provides guidance on indications for medical cannabis, thereby shifting the onus on to healthcare practitioners to authorize medical cannabis.⁵

Physicians are unhappy about being the sole "gatekeepers" for medical cannabis, and the College of Family Physicians of Canada (CFPC) initially issued a statement calling on the federal government to continue to play its role in providing clear, accessible and reliable information to family physicians.¹⁴ Further, the CFPC has now issued a guidance document for the authorizing of medical cannabis for either chronic pain or anxiety, which recommends considering authorizations for dried cannabis only in the case of neuropathic pain that has failed to respond to standard treatments (not for other forms of chronic pain commonly seen in practice) and advising that medical cannabis "is not an appropriate therapy for anxiety."¹⁵

A 2011 statement from the Canadian Medical Association mentions concerns about medico-legal liability, which were corroborated by the Canadian Medical Protective Association (CMPA) and prompted the CMPA to issue an information sheet for physicians, encouraging those uncomfortable with MMAR regulations to refrain from authorizing cannabis to patients.¹⁶ However, a new 2014 CMPA article (Revised October 2014) outlines the Health Canada regulatory changes and the current college guidances since the MMPR.

Patients also face various barriers for access to medical cannabis. Under MMPR, the prices of medical cannabis are set by licensed producers, which may make it unaffordable for some patients.^{17,18} Under MMAR, patients could legally grow their own cannabis, but nevertheless, may have been challenged by law enforcement authorities.¹⁹ On the other hand, many users relied on illegal sources for their supply. A 2005 survey (n=197) of people living with HIV/AIDS found that 86% respondents who reported using cannabis as medicine obtained their supply from sources such as compassion clubs and illicit suppliers.²⁰ Patients cited lack of information, product quality concerns, and an onerous, confusing application process among other problems mentioned with the MMAR.

Key Learning Points

- To access medical cannabis under the MMPR, the patient must obtain a medical document (authorization) from an authorized healthcare provider. The patient must register as a client with a licensed producer. Medical cannabis ordered by the patient is sent directly to the patient by the licensed producer.
- Healthcare practitioners authorized to write medical documents (authorization) include physicians in all Canadian provinces and territories, and nurse practitioners in provinces and territories where authorizing cannabis for medical purposes is permitted under their scope of practice. (Healthcare providers are encouraged to check the policies of their provincial regulatory bodies to ensure compliance, as each province is slightly different.)
- Producers must be legally licensed by Health Canada. Licensed producers adhere to rigorous standards and regulations and can only provide dried cannabis to authorized patients.
- The MMPR does not specify conditions for which medical cannabis can be authorized.

Discussion Forum

1. What is your main concern about talking with patients about medical cannabis treatment? How do you manage that concern?
2. Do you currently make recommendations to physicians regarding medical cannabis? How do you facilitate communication with physicians on this topic?

Resources

- [Canadian Consortium for the Investigation of Cannabinoids](#)
- [Health Canada](#)
- For product recalls, see: Health Canada: Recalls and Alerts: [Recall of Medical Marijuana for Medical Purposes](#)
- [International Association for Cannabinoid Medicines](#).
- [The Marijuana for Medical Purposes Regulations \(SOR/2013-119\) \(full wording\)](#)

Post-Test

1. Under MMPR, the maximum period for which medical cannabis can be authorized with a single medical document is

- a) 1 week
- b) 1 month
- c) 1 year
- d) 5 years

2. True or false: MMPR allows patients to purchase their medical cannabis from any compassion club, dispensary, or pharmacy.

- a) True
- b) False

3. Regarding the maximum daily amount of medical cannabis that healthcare practitioners may recommend under MMPR:

- a) There are no restrictions on the daily amount that can be recommended.
- b) The maximum daily amount is 1 g/day.
- c) The maximum daily amount is 3 g/day.
- d) The maximum daily amount is 5 g/day.

4. Which of the following statements about the possession limit for medical cannabis is correct?

- a) There is no possession limit for medical cannabis.
- b) The possession limit is 100 grams.
- c) The possession limit is 50 grams or 10 times the daily amount, whichever is more.
- d) The possession limit is 150 grams or 30 times the daily amount, whichever is less.

5. The price of medical cannabis

- a) is fixed at a discounted rate by the government.
- b) is fixed by the producer.
- c) will vary depending on the patient's income.
- d) is reimbursed by the provincial health plan.

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