Prescribe with Caution: The Response of Canada's Medical Regulatory Authorities to the Therapeutic Use of Cannabis

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Canada was one of the first countries worldwide to legalize the use of cannabis for therapeutic purposes. The federally regulated cannabis access program has not had the support of medical regulatory authorities, however, and recent changes to federal rules are controversial in imposing responsibility on physicians to prescribe the drug, which is unapproved and illegal outside the medical use laws. This paper analyzes the response of Canada's ten medical regulatory authorities to these legal changes and provides critical commentary on the legal and ethical guidance provided to physicians who treat patients seeking to use cannabis therapeutically. The paper considers the role of doctors as gatekeepers, the profession's concerns about medico-legal risks of cannabis prescription, stigmatization and barriers to care for patients who use cannabis, and the need for research to continue to build

Le Canada a été l'un des premiers pays au monde à légaliser l'utilisation du cannabis à des fins thérapeutiques. Toutefois, le programme d'accès au cannabis, régulé par le gouvernement fédéral, n'a pas obtenu le support des autorités régulatrices médicales et certains changements controversés aux règles fédérales imposent aux physiciens la responsabilité de prescrire cette drogue, malgré son illégalité et un manque d'approbation concernant son utilisation à des fins autres que médicales. Cet article analyse la réponse des dix autorités régulatrices médicales canadiennes à ces changements juridiques et propose un commentaire critique sur les directives juridiques et éthiques fournies aux physiciens traitant les patients qui recherche une utilisation thérapeutique du cannabis. Cet article aborde le rôle que jouent les médecins en contrôlant l'accès au cannabis, les inquiétudes de la

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the evidence base to inform therapeutic prescription of the drug. The Canadian experience provides lessons for other jurisdictions that are considering liberalizing cannabis use laws.

profession concernant les risques médicolégaux associés à la prescription de cannabis, la stigmatisation et les barrières d'accès aux soins pour les patients utilisant le cannabis et la nécessité de continuer la recherche pour mettre en place une base de connaissances sur la prescription de cette drogue à des fins thérapeutiques. L'expérience du Canada fournit des leçons importantes pour les autres juridictions qui considèrent libéraliser les lois sur l'utilisation du cannabis.

Introduction

Countries around the world are liberalizing laws to permit the use of cannabis for therapeutic purposes, with several European countries, Israel, and nearly half of American states permitting medical use,[1] and legislators in other jurisdictions contemplating law reform.[2] In Canada, the *Controlled Drugs and Substances Act* prohibits the production, distribution, and possession of cannabis;[3] despite this, Canada was one of the first countries in the world to develop a national regulatory framework to allow a legal exemption for medical use of the drug.[4] Recent changes to the federal regulations have, however, renewed controversy about medical access to the drug.

Lessons from the Canadian experience can inform law reform initiatives elsewhere. Health and drug policy researchers have recently published analyses of the characteristics and modes of access of medical cannabis users in Canada[5] and of users' experiences with the medical access program,[6]

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1 See Lynne Belle-Isle et al, "Barriers to Access for Canadians Who Use Cannabis for Therapeutic Purposes" (2014) 25:4 Int J Drug Policy 691 at 691; Samuel T Wilkinson & Deepak Cyril D'Souza, "Problems with the Medicalization of Marijuana", Opinion, (2014) 311:23 JAMA 2377 at 2377; Maurizio Bifulco & Simona Pisanti, "Medicinal Use of Cannabis in Europe" (2015) 16:2 EMBO Rep 130 at 130–31.

2 As one example, several Australian states are considering law reform proposals to permit medical cannabis use. The State of Victoria passed the *Access to Medicinal Cannabis Act 2016* in April of that year, and will allow patients to access cannabis for exceptional medical circumstances commencing in early 2017. For background discussion, see e.g. Australia, Victorian Law Reform Commission, *Medicinal Cannabis* (August 2015), online: VLRC <lawreform.vic.gov.au/sites/default/files/VLRC_Medicinal_Cannabis_Report_web.pdf>.

3 SC 1996, c 19, ss 4–5, 7, Schedule II [*CDSA*].

4 See Philippe G Lucas, "Regulating Compassion: An Overview of Canada's Federal Medical Cannabis Policy and Practice", online: (2008) 5 Harm Reduct J 5 at 3 <www.harmreductionjournal.com/content/5/1/5> [Lucas, "Regulating Compassion"].

5 Zach Walsh et al, "Cannabis for Therapeutic Purposes: Patient Characteristics, Access, and Reasons for Use" (2013) 24:6 Int J Drug Policy 511.

6 Philippe Lucas, "It Can't Hurt to Ask; A Patient-Centered Quality of Service Assessment of Health Canada's Medical Cannabis Policy and Program", online: (2012) 9 Harm Reduct J 2 <www.harmreductionjournal.com/content/9/1/2> [Lucas, "Can't Hurt"].

and they have considered implications of the program for cannabis control policy more broadly.[7] This paper adds to the literature by analyzing the responses of Canada's medical regulatory authorities to physicians' roles and responsibilities under the federal medical cannabis program and situating these responses within broader debates about doctors' obligations to patients, the medical profession, and society and about the evidence base to support cannabis use.

The Canadian context involves legal, ethical, and political complexities in that cannabis is not an approved therapeutic product under the *Food and Drugs Act*[8] and the Conservative federal government that set up the medical access program in response to constitutional litigation mostly encouraged doctors not to prescribe the drug.[9] The government has handed over gatekeeping responsibility for determining appropriate therapeutic use of cannabis to health care providers, a move decried by medical regulatory authorities and professional associations. The professional regulators have criticized the medical access program since its inception in 2001,[10] and the

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7 Benedikt Fischer, Sharan Kuganesan & Robin Room, "Medical Marijuana Programs: Implications for Cannabis Control Policy – Observations from Canada", Policy Commentary, (2015) 26:1 Int J Drug Policy 15.

8 RSC, 1985, c F-27. For readers interested in discussion of medical cannabis regulation in the United States, see e.g. George J Annas, "Medical Marijuana, Physicians, and State Law" (2014) 371:11 New Eng J Med 983; Rosalie L Pacula, Priscilla Hunt & Anne E Boustead, "Words Can Be Deceiving: A Review of Variation among Legally Effective Medical Marijuana Laws in the United States" (2014) 7:1 J Drug Policy Anal 1; Jessica Bestrashniy & Ken C Winters, "Variability in Medical Marijuana Laws in the United States" (2015) 29:3 Psych Addict Behav 639.

9 Speaking at the annual meeting of the Canadian Medical Association in August 2014, the federal health minister reportedly stated: "Let me be clear: Health Canada does not endorse the use of marijuana, nor is it an approved drug in this country, nor has it gone through any of the clinical trials that other pharmaceutical products that are approved in this country have gone through." The health minister further remarked that "[t]he majority of the physician community do not want to prescribe it, they don't want to be put in a situation where they're pressured to prescribe it and I encourage them to not prescribe it if they're not comfortable with it" (Sharon Kirkey, "Doctors Should Not Feel Obligated to Prescribe Marijuana, Health Minister Says", *National Post* (18 August 2014), online: NP <news.nationalpost.com/health/doctors-should-not-feel-obligated-to-prescribe-marijuana-health-minister-says>).

10 See Lucas, "Regulating Compassion", *supra* note 4 at 5.

2014 legal changes intensified controversy about the role of medical practitioners in prescribing dried cannabis. Debate over medical cannabis use reportedly "dominated" the 2014 annual meeting of the Canadian Medical Association,[11] and medical regulatory bodies across the country have issued statements to practitioners to provide guidance on their legal, ethical, and professional duties when considering the use of cannabis as a therapeutic option in their practice (see Appendix I). Two commentators have provocatively observed that the legalization of medical use in the absence of regulatory approval of cannabis as a therapeutic medicine amounts to "essentially legalizing recreational marijuana but forcing physicians to act as gatekeepers for those who wish to obtain it."[12]

In challenges to the constitutional validity of the federal regulatory scheme, litigants have argued that doctors' gatekeeping role imposes an arbitrary barrier to accessing cannabis.[13] Courts have, however, accepted the need for medical involvement in decisions about the therapeutic use of a drug, especially one whose safety and efficacy are still under investigation. While "medical oversight is a constitutionally accepted feature"[14] of the Canadian regulatory scheme, physicians' exercise of this role raises legal and ethical concerns for individual doctors and patients, as well as professional regulatory bodies.

Divided views exist in the medical community on the safety and efficacy of the drug,[15] and many doctors are wary of their role in authorizing

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11 Kirkey, *supra* note 9.

12 Wilkinson & D'Souza, *supra* note 1 at 2378.

13 *Hitzig v Canada* (2003), 171 CCC (3d) 18 at 40–41 (paras 64–66), 101 CRR (2d) 320 (Ont Sup Ct) [*Hitzig* Sup Ct], aff'd and var'd on other grounds, 231 DLR (4th) 104, 177 CCC (3d) 449 (Ont CA) [*Hitzig* CA cited to DLR]; *R v Beren*, 2009 BCSC 429 at paras 27–33, 192 CRR (2d) 79 [*Beren*]; *R v Mernagh*, 2013 ONCA 67 at para 23, 276 CRR (2d) 59 [*Mernagh*].

14 *Mernagh*, *supra* note 13 at para 140.

15 For competing medical views, see e.g. David N Juurlink, "Medicinal Cannabis: Time to Lighten Up?", Commentary, (2014) 186:12 CMAJ 897; Meldon Kahan & Anita Srivastava, "New Medical Marijuana Regulations: The Coming Storm", Commentary, (2014) 186:12 CMAJ 895. For other medical views for and against therapeutic use of cannabis, see e.g. Greg T Carter, "The Argument for Medical Marijuana for the Treatment of Chronic Pain" (2013) 14:6 Pain Med 800; Gregory Bunt, "Marijuana Is Not Good Medicine" (2013) 14:6

access to the product. In a 2014 survey of general medical practitioners, nearly 70% of respondents said they are uncomfortable with authorizing cannabis use and they need more information and training about appropriate medical uses.[16] Patients who seek access to the drug typically want to manage symptoms associated with chronic pain, sleep disturbances, and anxiety and mood disorders,[17] and they report problems in finding a doctor who will support them by authorizing therapeutic cannabis use. As a consequence, the vast majority of users resort to illicit sources of the drug.[18]

This article first explains the Canadian legislative framework governing access to cannabis for therapeutic purposes, including a summary of several legal challenges that forced the federal government to make incremental reforms to the medical access program. It then summarizes the main concerns of the medical profession in Canada about this framework, focusing on the 2014 amendments that shifted the responsibility for authorizing cannabis use from the federal health department to doctors. Next, it examines practice standards and policies issued by medical regulatory authorities in all ten Canadian provinces and analyzes doctors' gatekeeping role in the context of their legal and ethical duties. Key provisions of the regulatory policies are summarized in Appendix I. The final section concludes with lessons that can be learned from the Canadian experience.

It is worth noting that physicians may have similar safety and efficacy concerns in relation to so-called complementary and alternative (CAM) therapies, including herbal and botanical products. The medical regulatory bodies across Canada have adopted policies that establish rules governing doctors' incorporation of CAM into their own practices and their relationships with other providers of CAM therapies, as well as expectations for doctors to inform their patients of the possible harms and benefits of CAM. These policies, which are separate from the medical cannabis policies, have

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Pain Med 799; Carol Falkowski, "Why We Need to Be Cautious about Medical Marijuana: Reefer Sadness" (2014) 97:3 Minn Med 39; Jacob Mirman, "One More Potential Therapy: Why We Need to Legalize Medical Marijuana" (2014) 97:3 Minn Med 38.

16 Tony Coulson, "Medical Marijuana in Canada: The Doctor's Dilemma" (2014), *Environics Research* (blog), online: <environicsresearch.com/insights/medical-marijuana-canada-doctors-dilemma/>.

17 Walsh et al, *supra* note 5 at 515.

18 Belle-Isle et al, *supra* note 1 at 694, 697 (reporting that only 7% of the sample obtained their cannabis exclusively from authorized suppliers).

been reviewed elsewhere,[19] and Canadian medico-legal experts have provided recommendations to help physicians meet their legal and ethical duties to patients in relation to CAM.[20] The current controls on the therapeutic use of cannabis under the *Controlled Drugs and Substances Act* distinguish cannabis from non-prescription natural health products.[21] The latter non-prescription products are widely available for purchase and consumer choice to use those products is not subject to compulsory physician oversight. Law reform aimed at decriminalizing cannabis – a pledge made by the new Prime Minister during his 2015 election campaign – will likely increase the general availability and use of the drug and may blur the boundaries between therapeutic and recreational use. For example, without a threat of criminal sanctions, more individuals may "self-medicate" with cannabis, viewing it as a CAM remedy. While this paper does not seek to speculate on drug law reform, the federal government will need to be careful in assessing the impacts of any new rules allowing production, possession, and use of cannabis for recreational purposes on the medical access scheme. Medical regulatory authorities and physicians are key stakeholders in this debate, and the analysis that follows can help inform future discussion of legislative reform and the implications for medical professional regulation and practice.

I. Origins of the Canadian Medical Cannabis Program

The Canadian federal medical cannabis program originated in response to successful court challenges by individuals who sought a legal source of dried cannabis to treat symptoms of their medical conditions, including HIV, multiple sclerosis, spinal cord disease, and epilepsy. In *Wakeford v Canada*,[22] an HIV-positive man brought legal action to obtain an exemption

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19 See Nola M Ries & Katherine J Fisher, "The Increasing Involvement of Physicians in Complementary and Alternative Medicine: Considerations of Professional Regulation and Patient Safety" (2013) 39:1 Queen's LJ 273.

20 See e.g. Joan Gilmour et al, "Referrals and Shared or Collaborative Care: Managing Relationships with Complementary and Alternative Medicine Practitioners" (2011) 128: Suppl 4 Pediatrics S181; Joan Gilmour et al, "Informed Consent: Advising Patients and Parents about Complementary and Alternative Medicine Therapies" (2011) 128: Suppl 4 Pediatrics S187.

21 *Supra* note 3.

22 (1998), 166 DLR (4th) 131, 55 CRR (2d) 56 (Ont Ct Gen Div) [*Wakeford I*], var'd (1999), 173 DLR (4th) 726, 63 CRR (2d) 131 (Ont Sup Ct) [*Wakeford II* cited to DLR].

from statutory prohibitions on the cultivation and possession of cannabis. The applicant gave evidence that he used marijuana with success to control side-effects of his HIV medication, including nausea and cachexia, a wasting syndrome. In response to this litigation, the then-Liberal Minister of Health announced a process for Health Canada to consider applications for exemptions in exceptional circumstances for individuals to use cannabis for medical reasons.[23]

In 1999, ministerial permits became available to exempt medical cannabis users from the operation of the criminal prohibitions. An interim guidance document was published in May 1999 and the first permits were granted that June.[24] In the landmark case of *R v Parker*,[25] the Ontario Court of Appeal ruled that this exemption process was unlawful because it gave the Minister of Health unfettered discretion to determine applications. Moreover, the court held, a regulatory provision in the federal drugs law that contemplated medical prescriptions for cannabis served no real purpose; in the absence of a legal supply of the drug, no doctor could prescribe it.[26] The court ruled that the criminal prohibitions on cannabis cultivation and possession unjustifiably violated the constitutionally protected rights of persons for whom cannabis provided relief from symptoms of serious

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23 The health minister's promises were quoted in the rehearing of *Wakeford I*:

> [T]his government is aware there are Canadians suffering, who have terminal illnesses, who believe that using medical marijuana can help ease their symptoms. We want to help. As a result, I have asked my officials to develop a plan that will include clinical trials for medical marijuana, appropriate guidelines for its medical use and access to a safe supply of this drug.

(*Wakeford II*, *supra* note 22 at 733 (para 9) (quoting the Honourable Allan Rock, speaking during Question Period in Parliament on 3 March 1999) [alteration in original; paragraph break removed].)

24 See Health Canada, Therapeutic Products Programme, "Research Plan for Marijuana for Medicinal Purposes: A Status Report" (9 June 1999) at 8, online: Government of Canada Publications <publications.gc.ca/collections/Collection/H42-2-83-1999E.pdf>.

25 (2000), 188 DLR (4th) 385, 49 OR (3d) 481 (CA) [*Parker* cited to DLR].

26 *Ibid* at 433 (para 127) ("[t]heoretically, a physician could prescribe marihuana under the *Narcotic Control Act*, but since no firm has ever been licensed to produce marihuana, there is no pharmacy to fill such a prescription and thus it is practically not possible to legally possess marihuana pursuant to a prescription").

or life-threatening conditions, such as the claimant, Terry Parker, who used cannabis to control severe epileptic seizures.[27] The court suspended its declaration of constitutional invalidity for one year to give the federal government time to devise a workable regulatory framework for medical cannabis access and use.[28]

In response, the federal government implemented the *Marihuana Medical Access Regulations*[29] in 2001, which established a process whereby individuals with serious illnesses could apply for authorization to possess cannabis for therapeutic use. The regulations imposed strict eligibility conditions and limited the avenues through which cannabis could be lawfully obtained. The drug had to originate from a licensed producer or the individual could obtain a personal licence to cultivate the plant or seek to have a third party designated as a licensed grower.[30] At the time, there was only one licensed producer in the country,[31] and third-party designates could be licensed solely to grow for a single individual.[32] These restrictive provisions were soon the subject of constitutional challenges. Some litigants argued that many medically authorized users living with severe illness or disability were forced to access the black market to buy cannabis seeds or the dried product.[33] It was ruled that an access program that relied on illicit access

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27 See *ibid* at 395–96 (para 10), where the court summarizes its decision:

> I have concluded that the trial judge was right in finding that Parker needs marihuana to control the symptoms of his epilepsy. I have also concluded that the prohibition on the cultivation and possession of marijuana is unconstitutional. … I have concluded that forcing Parker to choose between his health and imprisonment violates his right to liberty and security of the person. I have also found that these violations of Parker's rights do not accord with the principles of fundamental justice.

28 *Ibid* at 396 (para 11).

29 SOR/2001-227, as registered on 14 June 2001 (published in Canada Gazette, pt II, vol 135, no 14, 1330) [*MMAR*].

30 *Ibid*, s 5(1)(e).

31 *Ibid*; see also *Hitzig* CA, *supra* note 13 at 131 (para 58).

32 Lucas, "Regulating Compassion", *supra* note 4 at 7.

33 See *Hitzig* Sup Ct, *supra* note 13 at 36 (para 46), 39 (para 57), 67 (para 176); *Hitzig* CA, *supra* note 13 at 132–34 (paras 66, 68, 71); *Beren*, *supra* note 13 at

violated the rule of law and the constitutional rights of authorized users,[34] thus prompting further regulatory amendments concerning lawful channels for producing and distributing cannabis for the purposes of the federal medical access program.

The regulations required individuals seeking authorization to possess the drug to submit a medical declaration to Health Canada in support of their application. The 2001 scheme created three categories of medical conditions or symptoms for which a physician could support the therapeutic use of cannabis.[35] Category 1 symptoms were defined as symptoms associated with terminal illness or its treatment; Category 2 symptoms were set out in a schedule to the regulations and included, for example, severe nausea related to cancer or AIDS diagnosis or treatment; and Category 3 symptoms were broadly defined to encompass uses not covered in the other categories.[36] The latter two categories required declarations from medical specialists, while a general medical practitioner could support cannabis use under Category 1 for terminally ill patients.[37] The physician was also required to state the daily cannabis dosage recommended for the patient and give the opinion that the benefits of cannabis use would outweigh any risks.[38] Some medical professional and regulatory bodies expressed concern with this system, arguing it was not appropriate for doctors

> to attest to the relative risks and benefits of marijuana (to say nothing of recommended dosages and administration), because the information required to make such a declaration is not available. The safety, quality and efficacy of marijuana as

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para 33; *Sfetkopoulos v Canada (AG)*, 2008 FC 33 at para 19, 166 CRR (2d) 86, aff'd 2008 FCA 328, 382 NR 71.

[34] See e.g. *Hitzig* CA, *supra* note 13 at 150 (para 128).

[35] *MMAR*, *supra* note 29, s 1.

[36] *Ibid*.

[37] *Ibid*, s 4(2)(b)–(c). A general practitioner could support the therapeutic use of cannabis for terminally ill patients – defined as having an anticipated life expectancy of less than one year – on the basis that such patients would not face the potential harms of long term cannabis use (*Hitzig* CA, *supra* note 13 at 127–28 (para 47)).

[38] *MMAR*, *supra* note 29, s 6.

> a medicine are unknown because there has not been enough research done in the area.[39]

As discussed later, these worries have intensified under the current regulatory regime.

The regulatory framework was the subject of constitutional challenge in *Hitzig v Canada* and, while generally accepting the appropriateness of medical oversight, the Ontario Court of Appeal ruled that the specific requirement to obtain the support of two specialists for a Category 3 application was an unnecessary and arbitrary barrier that did not accord with the principles of fundamental justice.[40] Following *Hitzig*, the federal government amended the regulations, and under the framework in place from 2005 to 2014, eligibility for Health Canada's medical cannabis access scheme depended on the applicant having a symptom in one of two categories: Category 1 included symptoms of persons in palliative care or experiencing severe pain from conditions such as cancer, spinal cord injury, multiple sclerosis, and HIV/AIDS; Category 2 covered "debilitating" symptoms of any other condition (or treatment of any other condition).[41] The medical declaration signed by a physician had to state the person's diagnosis and symptoms and attest that conventional treatment was ineffective or inappropriate.[42] The doctor was no longer obliged to declare that the benefits would outweigh the risks and, instead of stating a dosage, had to state the daily amount of cannabis the patient proposed to use.[43] While a family physician could sign declarations for both categories, a specialist consultation was required for Category 2 cases if the signing doctor did not have relevant specialist training.[44]

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39 *Hitzig* Sup Ct, *supra* note 13 at 37 (para 49) (referring to the views of "[s]everal medical associations, licensing authorities and the Canadian Medical Protective Association").

40 *Hitzig* CA, *supra* note 13 at 155 (para 145), 157 (para 152).

41 *Regulations Amending the Marihuana Medical Access Regulations*, SOR/2005-177, s 1(2) [*MMAR Amendment* (2005)], amending *MMAR*, *supra* note 29, s 1(1). For a comparison of the medical declaration provisions from 2001 and 2005, see *Mernagh*, *supra* note 13, Appendix A.

42 *MMAR Amendment* (2005), s 4, amending *MMAR*, *supra* note 29, s 6(1).

43 *Ibid*.

44 *MMAR Amendment* (2005), s 4, amending *MMAR*, *supra* note 29, s 6(2).

II. The Current Regulatory Framework

The *Access to Cannabis for Medical Purposes Regulations* (*ACMPR*)[45] came into effect in August 2016, after the writing of this article. The *ACMPR* replace the *Marihuana for Medical Purposes Regulations* (*MMPR*),[46] however they do not change the role of health care practitioners in serving as gatekeepers for individuals who want to use cannabis for therapeutic reasons.[47] The new *ACMPR* were devised in response to the Federal Court decision in *Allard v Canada*,[48] which ruled that limiting access to cannabis through licensed producers unjustifiably violates the Section 7 *Charter* rights of medical users. The *Allard* decision does not affect the requirement to obtain medical authorization to use the drug. In announcing the federal government's decision not to appeal the court ruling, the Minister of Health signalled that regulatory changes would focus only on how users with a medically determined need obtain appropriate access to cannabis: "The Federal Court's concern was that under the current legislation … medical marijuana was not appropriately affordable and accessible to Canadians. And those are the parts of the regulations we are required to address."[49]

Under the *ACMPR*, authorized users of cannabis for medical purposes can access the drug from a licensed producer, register with Health Canada to

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45 SOR/2016-230 [*ACMPR*].

46 SOR/2013-119 [*MMPR*], enacted under authority of the *CDSA*, *supra* note 3.

47 Health Canada, "Fact Sheet: Access to Cannabis for Medical Purposes Regulations", Backgrounder (Ottawa: HC, 11 August 2016), online: HC <news.gc.ca/web/article-en.do?nid=1110409> [Health Canada, "Fact Sheet"].

48 2016 FC 236, 394 DLR (4th) 694. The court accepted that

> [t]he evidence does establish that under the single source system of a Licensed Producer [LP] there is no guarantee that the necessary quality, strain and quantity will be available when needed at some acceptable level of pricing (through such mechanisms as flexible pricing or discount pricing) – due to the structure of the regulations and the characteristics of the market.

(*Ibid* at para 15.) The federal government was given six months to devise new regulations in response to this ruling (*ibid* at paras 296–97).

49 Susan Lunn, "Philpott Won't Appeal Allard Ruling on Right to Grow Medical Marijuana", *CBC News* (24 March 2016), online: <www.cbc.ca/news/politics/medical-marijuana-grow-allard-philpott-no-appeal-1.3506015> (quoting Minister of Health Jane Philpott [ellipsis in original]).

grow small quantities for their own use, or designate a third party to produce the drug for them.[50]

The analysis in this article, while based on the regime implemented in the *MMPR*, is relevant to the new regulations. The *MMPR*, which came into full effect in April 2014, substantially changed the role of Health Canada and the responsibilities of medical practitioners. Importantly, under those amendments, the federal government ended its role in receiving and determining applications to use the drug, eliminated its list of specified medical conditions that qualified a person to access cannabis, and shifted the eligibility determination entirely to health care practitioners. Under the *MMPR*, and now the *ACMPR*, individuals must obtain a "medical document" from a doctor or a nurse practitioner that states the person's medical condition and cannabis dosage.[51] With this document – in effect, a prescription – the patient is entitled to access cannabis through the approved means noted above. A sample medical document is reproduced in Appendix 2.

The practitioner who completes the medical document, which is valid for up to 12 months, must specify a daily cannabis dose instead of simply stating the amount the patient intends to use.[52] The regulations do not prescribe a maximum daily amount, however Health Canada notes that one to three grams per day is commonly reported by users in peer reviewed studies.[53] The regulations authorize practitioners to obtain cannabis from a licensed producer to dispense to a patient.[54] Individuals may not legally possess more than 150 grams of dried cannabis.[55]

The 2014 amendments eliminated an individual's right to cultivate their own cannabis, and compelled personal-use growers to destroy their existing

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50 Health Canada, "Fact Sheet", *supra* note 47.

51 *MMPR*, *supra* note 46, s 129; *ACMPR*, *supra* note 45, s 8(1).

52 *ACMPR*, *supra* note 45, s 8.

53 Health Canada, *Information for Health Care Professionals: Cannabis (Marihuana, Marijuana) and the Cannabinoids* (February 2013), online: HC <www.hc-sc.gc.ca/dhp-mps/marihuana/med/infoprof-eng.php [Health Canada, *Information*].

54 *MMPR*, *supra* note 46, s 128(1)(a); *ACMPR*, *supra* note 45, s 7(1)(a).

55 *MMPR*, *supra* note 46, s 5(c); *ACMPR*, *supra* note 45, s 76(1)(d).

plants.[56] Over 200 individuals filed legal challenges seeking permission to grow their own cannabis, and a judicial injunction suspended this plant-destruction provision.[57] In June 2015, the Supreme Court of Canada held as unconstitutional the rules restricting medical access to cannabis in its dried form.[58] As a consequence, licensed producers can now supply fresh cannabis leaves and buds and derivatives such as cannabis oil to individuals for therapeutic uses.[59]

Some patients seeking to use cannabis within the confines of the previous federal rules expressed distrust of the government and frustration with a complicated and burdensome application process that, at one point, required completion of a 33-page application form.[60] Removing the governmental role, as the current regulations do, may assuage these concerns. Additionally, eliminating the scheduled list of approved conditions arguably better reflects the reality of therapeutic cannabis use, since "a large contingent" of medical users in Canada say that they use the drug for health conditions not previously included in the federal regulatory scheme.[61] These users – who previously had to obtain the drug from unauthorized sources – may now seek medical authorization to enable them to access cannabis through legal avenues. Yet, as will be discussed below, these ostensible benefits of the current federal framework may not be realized due to heightened concerns among medical regulatory authorities that enabling access to an unapproved drug is at odds with doctors' legal and ethical responsibilities.

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56 *MMPR*, *supra* note 46, s 236, amending *MMAR*, *supra* note 29, s 33.

57 See *Allard v Canada*, 2014 FCA 298, 248 ACWS (3d) 430.

58 *R v Smith*, 2015 SCC 34, 386 DLR (4th) 583. The Court held that restricting the medical use exemption to dried cannabis was not adequately connected to the state's interest in preventing diversion of cannabis to illegal markets. Moreover, the Court noted that smoking dried cannabis carries risks for medical users, and that oral or topical administration may be preferred for treatment of some conditions and symptoms.

59 *ACMPR*, *supra* note 45, s 22(4)(a).

60 L Belle-Isle & A Hathaway, "Barriers to Access to Medical Cannabis for Canadians Living with HIV/AIDS" (2007) 19:4 AIDS Care 500 at 503; Lucas, "Can't Hurt", *supra* note 6 at 7–8.

61 Walsh et al, *supra* note 5 at 515.

III. Concerns of the Medical Profession

Medical regulatory authorities in Canada have uniformly criticized the new legal framework for authorizing the use of cannabis for therapeutic purposes. The College of Family Physicians of Canada asserts that the regulations put "physicians in an unfair, untenable and to a certain extent unethical position by requiring them to"[62] judge whether to authorize the use of an unapproved and otherwise illegal product. They argue the evidence base is inadequate to inform sound clinical judgment about the use of cannabis and that doctors must address patients' requests for cannabis "in a relative vacuum of evidence or information."[63] Unlike other prescription drugs, there are no standardized doses of cannabis and users are exposed to varying amounts of active compounds in the drug depending on the mode and frequency of use. The Collège des médecins du Québec, the provincial regulatory college for physicians and surgeons, states that the legal changes oblige

> the medical profession to prescribe this product outside the usual framework for prescribing prescription drugs and without the necessary evidence-based scientific data to ensure good medical practice. This creates a unique, unprecedented situation, with certain risks for patients and possible medico-legal implications for the prescribing physician.[64]

Legal risks are heightened, regardless of whether the practitioner decides to prescribe or not. If a doctor refuses, patients may complain to the Collège that the practitioner has unreasonably prevented their access to can-

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62 College of Family Physicians of Canada, "The College of Family Physicians of Canada Statement on Health Canada's Proposed Changes to Medical Marijuana Regulations" (February 2013) at 1, online: CFPC <www.cfpc.ca/uploadedFiles/Health_Policy/CFPC_Policy_Papers_and_Endorsements/CFPC_Policy_Papers/Medical%20Marijuana%20Position%20Statement%20CFPC.pdf>.

63 College of Family Physicians of Canada, "New CPFC Release: Dried Cannabis Preliminary Guidance" (September 2014), online: CFPC <www.cfpc.ca/Release_Dried_Cannabis_Prelim_Guidance>.

64 Collège des médecins du Québec, "Guidelines Concerning the Prescription of Dried Cannabis for Medical Purposes" (April 2014, updated 1 May 2015), cl 1, online: CMQ <www.cmq.org/publications-pdf/p-1-2014-04-01-en-directives-concernant-ordonnance-cannabis-seche-fins-medicales.pdf> [Québec College Guidelines].

nabis. Patients may also seek out the product illegally and blame the doctor if caught. Conversely, practitioners who authorize cannabis for therapeutic reasons may face allegations of negligence if a patient suffers harm from using the drug. The legally required standard of care is ambiguous when a health care professional endorses cannabis use in the absence of accepted indications and dosing and with uncertainty about long-term risks.[65] The British Columbia College of Physicians and Surgeons cautions that "[p]hysicians may be the subject of accusations or suggestions of negligence, including liability if the use of marijuana produces unforeseen or unidentified negative effects."[66]

IV. Policies of Medical Regulatory Authorities

A. Status of policies

All ten provincial medical regulatory bodies in Canada have issued statements on the therapeutic use of cannabis (see Appendix I). However, the force of such documents varies. Practice standards or bylaws in some provinces set out compulsory rules, and non-compliance may put a practitioner at risk of disciplinary action.[67] Other regulators have issued guidelines that recommend best practices but are not binding. Some regulatory authorities say it is premature to adopt mandatory practice standards, as doing so might improperly legitimize cannabis use.[68] In addition to these

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65 As the Supreme Court of Canada stated in *Ter Neuzen v Korn*, [1995] 3 SCR 674 at 693, 127 DLR (4th) 577, "[i]t is well settled that physicians have a duty to conduct their practice in accordance with the conduct of a prudent and diligent doctor in the same circumstances." Ambiguity arises, however, if there is not yet scientific agreement about what a prudent doctor would do in regard to a therapeutic product like cannabis.

66 College of Physicians and Surgeons of British Columbia, "Professional Standards and Guidelines: Marijuana for Medical Purposes" (revised 30 July 2015) at 1, online: CPSBC <www.cpsbc.ca/files/pdf/PSG-Marijuana-for-Medical-Purposes.pdf> [BC College Guidelines].

67 For example, in Alberta, a contravention of a standard of practice is unprofessional conduct, on the grounds of which a health practitioner may be investigated and penalized: *Health Professions Ac*t, RSA 2000, c H-7, ss 1(1)(pp)(ii), 62, 80, 82.

68 For example, the College of Physicians and Surgeons of Newfoundland and Labrador states: "The College believes it is premature at this time to publish

policies that focus specifically on cannabis, practitioners who treat patients seeking medical authorization to use the drug must also consider other applicable policies, including codes of ethics, conflict-of-interest policies, policies on moral or religious beliefs affecting health care provision, and policies on dispensing medications. Regulatory college policies acknowledge that doctors may have conscientious objections to providing certain types of care, but they must nonetheless assist the patient, for example, by advising of the option to consult another care provider.[69] Moreover, a doctor who systematically excludes from her practice patients who seek cannabis for therapeutic purposes may contravene legislated protections against disability-based discrimination.[70]

B. No obligation to provide "unproven therapy"

At the same time, regulatory authorities make it clear that a practitioner is not obliged to accede to a patient's request for authorization to use cannabis and, as with all therapies, practitioners must exercise professional judgment in determining an appropriate treatment. This exercise of judgment is complicated by the current state of evidence, however, and almost all policies note a lack of high-quality research findings to support therapeutic benefits of cannabis use. For instance, the College of Physicians and Surgeons of British Columbia's guideline on marijuana for medical purposes states there is a "paucity of evidence to support the use of marijuana for

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standards of practice regarding the facilitation by physicians of access to marihuana for medical purposes, as this could be interpreted as the College supporting or legitimizing this practice": College of Physicians and Surgeons of Newfoundland and Labrador, "Advisory to the Profession and Interim Guidelines: Marihuana for Medical Purposes" (March 2014), online: CPSNL <www.cpsnl.ca/userfiles/file/CPSNL%20%20Medical%20Marihuana%20%20March%202014%20rev%201_0.pdf> [NL College Interim Guidelines].

69 See e.g. College of Physicians and Surgeons of British Columbia, "Professional Standards and Guidelines: Access to Medical Care" (November 2012) at 2, online: CPSBC <www.cpsbc.ca/files/pdf/PSG-Access-to-Medical-Care.pdf> [CPSBC, "Access to Medical Care"]. For a discussion of conscientious objection policies, see Jacquelyn Shaw & Jocelyn Downie, "Welcome to the Wild, Wild North: Conscientious Objection Policies Governing Canada's Medical, Nursing, Pharmacy, and Dental Professions" (2014) 28:1 Bioethics 33.

70 See e.g. CPSBC, "Access to Medical Care", *supra* note 69 at 1 (discussing discrimination generally with respect to health care provision).

medical purposes."[71] The regulatory bylaws of the Saskatchewan college describe cannabis as "an unproven therapy with an unproven record of safety and efficacy."[72] The Newfoundland and Labrador college's advisory to the medical profession implies an absence of evidence, stating that "physicians should not be expected to facilitate patient access to a substance, for medical purposes, for which there is no body of evidence of clinical efficacy or safety."[73]

C. Try conventional therapies first

Some policies stipulate that cannabis should only be considered where conventional treatments have been tried and have proved unsuccessful in easing the patient's symptoms (see Appendix I). Practitioners must document that conventional therapy has been ineffective. The policies emphasize the importance of discussing with patients the risks of cannabis use and the uncertainty about its clinical efficacy and of comprehensively documenting these discussions in patient records. Where indicated, approved therapeutics containing cannabinoids should also be considered instead of authorizing the patient to use dried cannabis. In Canada, three cannabis-based drugs are approved medicines: Sativex® (nabiximols), approved to treat pain in persons with multiple sclerosis or advanced cancers; Marinol® (dronabinol), approved to treat AIDS-related anorexia or cachexia and severe nausea and vomiting in persons receiving chemotherapy; and Cesamet® (nabilone), also approved for severe chemotherapy-related nausea or vomiting.[74]

D. Cannabis authorization only through primary treating practitioner

Most policies seek to avoid the problem of "doctor shopping" by stipulating that a patient may only obtain authorization to use cannabis through their primary treating practitioner. In British Columbia, for instance, the

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71 BC College Guidelines, *supra* note 66 at 2.

72 Saskatchewan College of Physicians and Surgeons, *Regulatory Bylaws for Medical Practice in Saskatchewan* (1 July 2016), s 19.2(n), online: SCPS <www.cps.sk.ca/iMIS/Documents/Legislaion/Legisation/Regulatory%20Bylaws%20-%20July%202016.pdf> [Saskatchewan College Bylaws].

73 NL College Interim Guidelines, *supra* note 68 at 1.

74 Health Canada, *Information*, *supra* note 53 at 29.

medical practitioner should only complete a medical document if he has a "longitudinal treating relationship with the patient" or is directly consulted by another practitioner who has such a relationship and both agree on the use of cannabis for medical purposes.[75] The College of Physicians and Surgeons of PEI explicitly prohibits doctors from using telehealth to complete a medical document authorizing therapeutic cannabis use.[76] Several policies advise the doctor to provide regular follow-up with the patient; for instance, the colleges in Alberta and Québec require quarterly appointments with patients after a stable cannabis dosage has been established.[77] These requirements are in place to ensure that access to the drug occurs in the context of a *bona fide* doctor–patient relationship. Data collected in American states reveal the problems of some physicians gaining a reputation for liberal prescription of cannabis; for example, the practice of some Colorado doctors is described as consisting "principally or exclusively in recommending medical marijuana."[78]

E. Informed consent details

Some policies deal with the content of informed consent discussions, specifying that in addition to discussing the possible harms and benefits of cannabis use, practitioners must counsel patients about cannabis impairment, activities that must be avoided (e.g., driving), and any legal obligation on the doctor to report to a regulatory or licensing authority if a patient using cannabis works in a safety-sensitive occupation or poses a public

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75 BC College Guidelines, *supra* note 66 at 2.

76 See College of Physicians and Surgeons of Prince Edward Island, "Prescribing of Medical Marijuana" (amended September 2014), cl 3, online: CPSPEI <cpspei.ca/wp-content/uploads/2014/12/Marijuana-Prescribing-revised-May-1313-April-314May-2614-amended-Sept-2014.pdf>. (Telehealth or telemedicine refers to information and communication technologies that allow health care services to be delivered when the patient and doctor are in separate locations.)

77 College of Physicians & Surgeons of Alberta, "Marihuana for Medical Purposes" (3 April 2014), cl 4(b), online: CPSA <www.cpsa.ca/standardspractice/marihuana-medical-purposes/>; Québec College Guidelines, *supra* note 64, cl 7.

78 Abraham M Nussbaum, Jonathan A Boyer & Elin C Konrad, "'But My Doctor Recommended Pot': Medical Marijuana and the Patient–Physician Relationship" (2011) 26:11 J Gen Intern Med 1364 at 1366.

safety risk. Laws regulating certain workers in transportation sectors (e.g., aeronautics, railways, and shipping), as well as motor vehicle licensing and occupational health and safety laws, impose reporting duties on physicians who have a reasonable belief that a patient with an impairment may place third parties at risk of harm.[79] It is unclear, however, how often doctors who authorize cannabis use report patients to these regulatory or licensing bodies; some research indicates doctors rarely report medically unfit drivers to motor vehicle licensing authorities, even when such reporting is legally compulsory.[80] Lastly, several policies advise the doctor to screen the patient for addiction risk using a standardized assessment tool (see Appendix I).

F. Treatment agreements

Some policies prescribe formal obligations for documentation including, in certain cases, a requirement for a patient to consent to a written treatment agreement. The Regulatory Bylaws of the Saskatchewan College of Physicians and Surgeons specify the terms to include in such an agreement:

> A physician who prescribes marihuana may only do so after the patient signs a written treatment agreement which contains the following:
>
> (i) A statement by the patient that the patient will not seek a prescription for marihuana from any other physician during the period for which the marihuana is prescribed;
>
> (ii) A statement by the patient that the patient will utilize the marihuana as prescribed, and will not use the marihuana in larger amounts or more frequently than is prescribed;
>
> (iii) A statement by the patient that the patient will not give or sell the prescribed marihuana to anyone else, including family members;

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79 For a summary of such reporting requirements, see e.g. College of Physicians and Surgeons of Ontario, "Policy Statement #6-12: Mandatory and Permissive Reporting" (last updated September 2012), online: CPSO <www.cpso.on.ca/CPSO/media/uploadedfiles/policies/policies/policyitems/mandatoryreporting.pdf>.

80 See e.g. Donald Redelmeier, Vikram Vinkatesh & Matthew B Stanbrook, "Mandatory Reporting by Physicians of Patients Potentially Unfit to Drive" (2008) 2:1 Open Med e8.

(iv) A statement by the patient that the patient will store the marihuana in a safe place;

(v) A statement by the patient that if the patient breaches the agreement, the physician may refuse to prescribe further marihuana.[81]

Guidelines from the College of Physicians and Surgeons of New Brunswick state that matters discussed for informed consent purposes "are best documented in a treatment agreement,"[82] including risks of cannabis use and cautions made to patients to obtain the drug only from licensed producers and not to give their medical supply to other people. The doctor should also explain and document the "circumstances [that] would result in a discontinuation of marijuana prescribing by the physician."[83] In its March 2015 policy update, the College of Physicians and Surgeons of Ontario also recommends that patients sign a written treatment agreement.[84]

None of the Canadian policies prescribe a template for a cannabis treatment agreement. However, the College of Family Physicians of Canada as well as clinician-researchers in the United States have published model treatment agreements for patients using cannabis for chronic pain.[85] Under the terms of such agreements, patients state that they understand and agree to various conditions under which they are authorized to use cannabis. For instance, they agree to access cannabis only through one doctor, not to di-

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81 Saskatchewan College Bylaws, *supra* note 72, s 19.2(d).

82 College of Physicians and Surgeons of New Brunswick, "Guidelines: Medical Marijuana" (April 2014), online: CPSNB <www.cpsnb.org/english/Guidelines/MedicalMarijuana.htm>.

83 *Ibid*.

84 College of Physicians and Surgeons of Ontario, "Policy Statement #1-15: Marijuana for Medical Purposes" (last updated March 2015) at 5, online: CPSO <www.cpso.on.ca/CPSO/media/documents/Policies/Policy-Items/Marijuana-for-Medical-Purposes.pdf>.

85 College of Family Physicians of Canada, "Authorizing Dried Cannabis for Chronic Pain or Anxiety: Preliminary Guidance" (September 2014), online: CFPC <www.cfpc.ca/uploadedFiles/Resources/_PDFs/Authorizing%20Dried%20Cannabis%20for%20Chronic%20Pain%20or%20Anxiety.pdf> [CFPC Guidance]; Barth Wilsey et al, "The Medicinal Cannabis Treatment Agreement: Providing Information to Chronic Pain Patients through a Written Document" (2015) 31:12 Clin J Pain 1087.

vert cannabis or engage in other criminal activities, and to receive follow-up monitoring as required by the physician.[86] The College of Family Physicians' agreement requires patients to acknowledge that Health Canada has not approved cannabis as a therapeutic product and that some risks of the drug may be unknown. Moreover, the patient must "accept full responsibility for any and all risks associated with the use of marijuana, including theft, altered mental status, and side effects of the product."[87] In the US, a group of authors has published a sample treatment agreement explaining the risks and responsibilities in simple language, such as: "I know that some people cannot control their use of cannabis. One example is using cannabis for … getting stoned. This may lead to not going to work, or not doing my household chores. I agree to discuss this with my doctor if this happens."[88]

Treatment agreements are arguably not legally actionable contracts for various reasons, chief among them the power imbalance between a physician who has the authority to give or withhold access to treatment and a vulnerable patient who is often suffering from chronic and severe symptoms.[89] Violations of an agreement may nonetheless have consequences. For example, the regulatory bylaws of the Saskatchewan college require a patient to acknowledge in writing that the physician may refuse further doses of cannabis if the patient breaches the agreement.[90] Some commentators criticize this type of punitive response: "The physician's ethical obligation not to abandon a patient is contrary to many pain contracts/agreements that describe the conditions under which a patient will be 'fired' if the patient violates any or all of the terms set forth."[91] Another commentator contends that "[i]t is foolish to deny the hard reality of problem patients" who may

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86 See e.g. CFPC Guidance, *supra* note 85 at 10, tbl 2 (Sample Treatment Agreement).

87 *Ibid*.

88 Wilsey et al, *supra* note 85 at 1093 ("Tenet 2" of the sample agreement). See also the discussion *ibid* at 1088.

89 See Martin Cheatle & Seddon Savage, "Informed Consent in Opioid Therapy: A Potential Obligation and Opportunity" (2012) 44:1 J Pain Symptom Manage 105 at 107.

90 Saskatchewan College Bylaws, *supra* note 72, s 19.2(d)(v).

91 Richard Payne et al, "A Rose by Any Other Name: Pain Contracts/Agreements" (2010) 10:11 Am J Bioeth 5 at 11.

abuse or divert drugs such as cannabis or opioids, and states that it is ethically

> fair to tell the patient that if he or she chooses not to become partners [with the doctor in managing his or her health], then the patient must bear the consequences, including ultimately the loss of physician aid. This is not intended to be paternalistic, but as part of patient/physician dialogue it should be seen as a sign of respect for the patient and expectation of the patient.[92]

Abuse of medically authorized cannabis and diversion to the recreational-use market are two dominant concerns that may be addressed in a treatment agreement. Defending its repeal of the law allowing users to grow their own cannabis, Health Canada estimated that, in 2013, three million plants grown by users with federal permission "produced 190 000 kg of dried marijuana – enough for each authorised user to roll 54 to 90 cigarettes a day."[93] This volume of production suggests that some portion is diverted to non-medicinal use. From the experience of treatment agreements for opioid therapy, there is little evidence regarding the effectiveness of agreements in preventing diversion and abuse.[94]

G. Recording and reporting data on cannabis authorizations

Practitioners in some jurisdictions must maintain a register of patients for whom they have authorized cannabis use, and the regulatory college may inspect this log as part of quality assurance or disciplinary investigations. The register typically includes basic patient details and information about the purpose for and amount of the authorized cannabis use. In Alberta, the legal obligation is more stringent in that physicians who wish to authorize cannabis use for their patients must register with the College of Physicians and Surgeons of Alberta and submit a copy of each patient's cannabis au-

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92 Robert L Fine, "The Physician's Covenant with Patients in Pain" (2010) 10:11 Am J Bioeth 23 at 24.

93 Owen Dyer, "Canadian Court Decision Challenges New Rules on Medical Marijuana", News, (2014) 348 Brit Med J g2369 at g2369.

94 Joanna L Starrels et al, "Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients with Chronic Pain" (2010) 152:11 Ann Intern Med 712 at 715–18.

thorization document to the College within a week of issuing it. The College states that the purpose of this reporting requirement is to detect cases where patients are seeking cannabis authorization or supply from multiple doctors or licensed producers.[95] In Saskatchewan, doctors who authorize cannabis use must submit their patient register to the regulatory college every six or 12 months depending on the number of prescriptions made.[96]

The new *ACMPR* require licensed producers to report, at the request of a health profession's regulatory college, any information obtained under the *ACMPR* about health practitioners who have provided medical documents authorizing a client to use cannabis.[97] Information to be disclosed includes the prescribing practitioner's name, basic patient information, the daily amount of cannabis authorized, and the duration of the authorization. This information is similar to that collected as part of provincial monitoring programs for prescription narcotics. Health Canada previously asserted a need for this type of reporting provision, claiming that "healthcare licensing authorities do not have the tools to effectively monitor the practices of their members as they relate to marihuana for medical purposes."[98] As noted above, some regulatory colleges have, in fact, mandated reporting, but reports from licensed producers would allow the colleges to confirm whether the patient who received a medical authorization to use cannabis subsequently obtained the drug from a licensed producer. While a system of mandatory reporting enables monitoring of physician practices and creates opportunities to identify and correct inappropriate prescribing, it may further stigmatize cannabis use and heighten doctors' fears that they may be subject to audit and investigation. In turn, both patients and doctors may be deterred from participating in the legalized access system.

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95 College of Physicians and Surgeons of Alberta, "Medical Marihuana: What Do You Need to Know Before Signing a Medical Document?" (1 May 2014), online: CPSA <www.cpsa.ca/medical-marihuana-need-know-signing-medical-document/>.

96 Saskatchewan College Bylaws, *supra* note 72, s 19.2(h).

97 *ACMPR*, *supra* note 45, ss 123–24.

98 Communication of Information (Regulatory Impact Analysis Statement): *Regulations Amending the Narcotic Control Regulations and the Marihuana for Medical Purposes Regulations*, (2014) C Gaz I, 1503 at 1507.

H. Conflicts of interest

Some colleges have set out rules to prevent conflicts of interest (see Appendix I). For instance, a medical practitioner must not have a financial stake in a licensed cannabis producer, nor may he or she charge a fee to, or accept compensation from, a producer for providing a medical authorization to a patient.[99] Although the federal regulations permit practitioners to receive cannabis from a licensed producer on behalf of a patient, several policies state that doctors should not take on this dispensing role.

I. Research use only

The Québec Collège des médecins has the most restrictive policy on authorizing medical use of cannabis out of all of the Canadian physician regulatory colleges.[100] As dried cannabis is not an approved therapeutic product in Canada, Québec medical practitioners may authorize it only as part of a research study.[101] Furthermore,

> [a] physician who prescribes dried cannabis must collaborate, in the context of a research project or otherwise, with the Collège des médecins and its partners in the collection of scientific data in order to improve knowledge and practices with respect to the use of cannabis for medical purposes and to ensure patient safety.[102]

To this end, the Collège is collaborating with the Canadian Consortium for the Investigation of Cannabinoids in a province-wide pharmacosurveillance study to collect data on safety and effectiveness from among the estimated 3000 individuals in the province using medical marijuana.[103] In Minnesota, a 2014 law that approved therapeutic cannabis use also requires the Depart-

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99 See e.g., Saskatchewan College Bylaws, *supra* note 72, s 19.2(j)–(l).

100 See Québec College Guidelines, *supra* note 64.

101 *Ibid*, cls 2, 6.

102 *Ibid*, cl 10.

103 Brian Owens, "Quebec Doctors Aim to Fill Marijuana Knowledge Gaps", News, (2014) 186:9 CMAJ 657.

ment of Health to collect research data on all patients authorized to use the drug.[104]

V. Doctors as Gatekeepers

Court rulings in favour of a legal right to use cannabis for medical purposes forced the federal government to establish a system of regulated access to the drug.[105] The constitutional litigation has centred on the rights of individuals with serious health conditions and has not grappled with the legal and ethical position of health practitioners. The result is a regulatory framework developed on a piecemeal basis through legal adversarialism. The medical regulatory authorities have consistently criticized the federal rules out of concern that it makes doctors part of the cannabis "supply chain"[106] as gatekeepers between patients and an unapproved drug. Political disputes between medical regulators and the government should not, however, detrimentally impact patient access to health services or constrain doctors from providing appropriate and compassionate care.

A troubling conclusion is that the ongoing concerns of the medical profession have contributed to only a minority of medical cannabis users accessing the drug through the legalized regime. Despite the existence of the federal government's medical access program for over a decade, recent research indicates that fewer than 10% of Canadian medical cannabis users obtain the drug solely from legal sources.[107] Unregulated, illicit access to

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104 *Medical Cannabis Therapeutic Research Act*, 2014 Minn Laws ch 311, s 7 (codified as Minn Stat § 152.27). See Suzy Frisch, "Medical Cannabis: US Researchers Battle for Access to the Plant" (2014) 349 Brit Med J g6997 at 3. This article reports that the state initially planned a double-blind, placebo-controlled trial, but the numerous regulatory approval hurdles required for cannabis research resulted in a decision to collect observational data only (*ibid*). For more details on the state's medical cannabis program, see Minnesota Department of Health, "Medical Cannabis", online: MDH <www.health.state.mn.us/topics/cannabis/index.html>.

105 Regarding this litigation, see *supra* note 13 and accompanying text.

106 Canadian Medical Association, "CMA Policy: Medical Marijuana" (2011) at 1, online: CMA <policybase.cma.ca/dbtw-wpd/Policypdf/PD11-02.pdf> (referring to "the fundamental concerns of the profession [arising from] making physicians part of the supply chain").

107 See Belle-Isle et al, *supra* note 1 at 697 *et passim*.

the drug persists. Barriers for those seeking cannabis to relieve symptoms of illness include the stigma associated with its use[108] and practitioners' reluctance to support patient access to the drug.[109] The negative response of medical regulators to the profession's new prescribing role suggests that legal access to cannabis may continue to be the exception instead of the rule. This result is worrying, especially for vulnerable patients with chronic and, in some cases, terminal conditions.

Moreover, patients appear to have little prospect of success if they attempt to challenge physicians' gatekeeping role. A patient could complain to a medical regulatory authority, arguing that an individual doctor unjustifiably withheld access to cannabis. However, this type of complaint may be difficult to make out when college policies typically view cannabis as an unproven therapy of last resort. A doctor who has reasonable concerns about cannabis use for a particular patient (for example, due to medical contraindications or concerns about addiction or diversion risk) or who counsels the patient to exhaust conventional therapies first will likely find support in their college's policies.

Charter challenges to the medical gatekeeping role as a systemic barrier to access have also failed. In *Hitzig v Canada*, for example, individuals seeking to use cannabis therapeutically argued that the requirement to obtain a medical declaration imposed an overly restrictive condition on access. The Ontario Court of Appeal disagreed, stating that a medical gatekeeping role is justified: "Just as physicians are relied on to determine the need for prescription drugs, it is reasonable for the state to require the medical opinion of physicians here, particularly given that this drug is untested."[110] In *R v Beren*, the BC Supreme Court again rejected the argument that physician gatekeeping imposes an arbitrary and constitutionally unjustifiable barrier to accessing cannabis for therapeutic purposes.[111] The court stated that the risks of cannabis use among persons with serious illnesses "remain very real and unstudied. Further, these issues are essentially medical issues and thus, while the drug remains unapproved and research into its medicinal

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108 See Joan L Bottorff et al, "Perceptions of Cannabis as a Stigmatized Medicine: A Qualitative Descriptive Study", online: (2013) 10 Harm Reduct J 2 <www.harmreductionjournal.com/content/10/1/2>.

109 See Belle-Isle et al, *supra* note 1 at 697.

110 *Hitzig* CA, *supra* note 13 at 153 (para 139).

111 *Beren*, *supra* note 13 at paras 95–97.

efficacy for any particular medical condition is still preliminary, there is ample justification for the requirements or hurdles to access"[112] cannabis under the federal regulations.

Courts have also considered arguments that medical opposition to cannabis makes it practically very difficult for patients to establish relationships with physicians who will provide medical declarations. In *Hitzig*, the court was satisfied that a sufficient number of doctors were participating in the medical access program, but stated that "if in future physician co-operation drops to the point that the medical exemption scheme becomes ineffective, this conclusion might have to be revisited."[113] More recently, the plaintiff in *R v Mernagh*, a man with fibromyalgia, scoliosis, epilepsy, and depression, argued that widespread refusal by doctors to provide medical declarations in support of cannabis use had resulted in an illusory scheme that, in practice, failed to support the constitutionally protected rights of seriously ill people.[114] As in *Hitzig*, the Ontario Court of Appeal in *Mernagh* rejected the assertion that doctors have massively boycotted Health Canada's medical access program,[115] noting instead the federal government's evidence showing a slow but steady increase in the number of physicians who had signed off on medical declarations.[116]

Despite the prevalence of illicit access to cannabis by medical users, the fact that some portion of Canadian doctors are willing to support therapeutic use provides a degree of constitutional protection for the federal program, particularly as the courts have recognized a need for medical oversight. The courts have also commented on doctors' role in exercising their professional judgment based on scientific evidence and, in both *Hitzig* and *Mernagh*, have acknowledged differing judicial and scientific evidentiary standards concerning therapeutic use of cannabis. Canadian courts have relied "on evidence of individuals' personal experiences and anecdotal evidence [to determine] that some seriously ill persons derive substantial medical benefit

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112 *Ibid* at para 95.

113 *Hitzig* CA, *supra* note 13 at 153 (para 139).

114 *Mernagh*, *supra* note 13.

115 *Ibid* at paras 12–13. The court noted that "the documentary evidence relied on by the trial judge was insufficient to establish a boycott" (*ibid* at para 83) and also faulted the trial judge for using hearsay evidence to support a finding of a boycott (paras 84–87).

116 *Ibid* at para 44.

from" cannabis use.[117] In contrast, "scientists, who approach questions of medical benefit and risk quite differently than do the courts, remain uncertain" of the potential benefits and harms of cannabis use and "regard the anecdotal evidence relied on by the courts as sufficient reason to conduct proper scientific inquiries … but not as justifying any conclusions as to the benefit of the drug."[118] Expert evidence presented in constitutional challenges concerning medical use of cannabis has generally concurred "that further research [is] needed and should be carried out in every area" of potential therapeutic benefit.[119] Physicians, in turn, are trained to apply scientific evidence in their diagnoses and treatments; as the court in *Mernagh* recognized, they are "fixed with the responsibility of being gatekeepers, but they remain bound by their own ethics and codes of conduct."[120]

Indeed, physicians are responsible for promoting the well-being of their patients and treating them with dignity and respect when providing care.[121] Yet, doctors' duties conflict to some degree when they are asked to authorize access to a therapy with limited or low-quality evidence as to its effectiveness. As regulators of the profession and guardians of public safety, the provincial colleges of physicians and surgeons aim to help physicians fulfill their legal and ethical obligations to patients, to the profession, and to society generally. In examining the content of the colleges' medical cannabis policies, it is important to consider how the conduct that is mandated or recommended in these policies will further these objectives.

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117 *Hitzig* CA, *supra* note 13 at 115 (para 9). The court in *Mernagh* clarified this statement:

> [F]or the purposes of judicial fact-finding, anecdotal evidence has been used to establish the general proposition that marihuana can have some medical benefit for some people. Anecdotal evidence, in a sense, compensates for scientific evidence that might otherwise have been used for that purpose. In the absence of more and better studies about the therapeutic value of marihuana, anecdotal evidence may be a reasonable substitute.

(*Mernagh*, *supra* note 13 at para 64.)

118 *Hitzig* CA, *supra* note 13 at 115 (para 10).

119 *Beren*, *supra* note 13 at para 37.

120 *Mernagh*, *supra* note 13 at para 88.

121 See Canadian Medical Association, "CMA Policy: CMA Code of Ethics" (updated 2004, last reviewed March 2015), arts 1–2, online: CMA <policybase.cma.ca/dbtw-wpd/PolicyPDF/PD04-06.pdf>.

The medical cannabis policies of all of the Canadian colleges take the position that more evidence is needed to establish the safety and efficacy of cannabis as a medical therapy and to send a clear message that doctors should be cautious in authorizing cannabis use for their patients. Some critics contend the policies are overly conservative, but acknowledge that doctors' training, the ethical principle of non-maleficence, and the contemporary emphasis on evidence-based practice "incline[] [doctors] toward caution and circumspection."[122] These factors likely contribute to the fact that the policies mostly provide *procedural* guidance to assist doctors in working with patients for whom cannabis may be a suitable option. That is, the policies focus on matters to be discussed, documented, and reported, with an underlying concern for minimizing the legal risks of authorizing access to an unapproved drug.

This procedural, risk-management focus has its place, as doctors who treat patients seeking access to cannabis need clear guidance on best practices for managing informed consent; patient assessments (e.g., for risk of addiction); documentation, including treatment agreements specific to cannabis use; and appropriate monitoring and follow-up. This is particularly important as conditions for which cannabis may be used are often chronic, and long-term use of the drug may result in dependence and produce withdrawal symptoms upon cessation. A comprehensive and well-documented informed consent discussion is necessary to ensure that patients are aware of the state of the evidence on the use of cannabis for their condition, the potential benefits and harms of use, and the risks arising from drug impairment. A robust consent process is also crucial to reducing legal liability risks. While some of the colleges' policies provide useful guidance on these latter points, they offer little or no counsel on when cannabis may be therapeutically appropriate.

There is a pressing need for more research into the therapeutic use of cannabis to help regulatory and professional bodies to develop *substantive* guidance for health care professionals and their patients. The objection raised by all medical regulatory bodies and physicians who refuse to authorize cannabis use is that there is not enough evidence about the risks and possible benefits of using the drug therapeutically. Some experts criticize this position as overly cautious and argue there is sufficient evidence to support cannabis use for some conditions, such as neuropathic pain and

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[122] Craig Jones & Andrew D Hathaway, "Marijuana Medicine and Canadian Physicians: Challenges to Meaningful Drug Policy Reform" (2008) 11:2 Contemporary Justice Rev 165 at 166.

AIDS-related muscle spasticity and wasting.[123] Yet, as long as cannabis retains its status as an unregulated drug, it seems that medical colleges and many doctors will remain guarded about its use.[124] When treating patients who seek access to cannabis, health care professionals require high quality, up-to-date, and easily accessible evidence to inform their clinical decisions.

To help fill this gap, the College of Family Physicians of Canada has issued preliminary guidance on authorizing dried cannabis, though this guideline covers only therapeutic use for chronic pain and anxiety.[125] Health Canada has published a document for health professionals that summarizes peer-reviewed literature on potential indications and risks of cannabis. However, this 150-page report is not a clinical practice guide, and the government stresses on the opening page that the document should not be regarded as an endorsement of cannabis use.[126]

A system of regulated access to cannabis provides an opportunity to collect pharmacovigilance data and to continue to strengthen the evidence base to inform therapeutic use. The research model adopted by Québec's medical regulatory body is a useful example, and Health Canada recently approved six clinical trials to investigate therapeutic cannabis use in patients with conditions such as post-traumatic stress disorder, osteoarthritis, and HIV infection.[127] In addition to investigating the use of cannabis, further study is needed into other cannabinoid-based pharmacologics. As the editor of the *Canadian Medical Association Journal* observes, "[m]arijuana is a drug

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123 See Stephanie Lake, Thomas Kerr & Julio Montaner, "Prescribing Medical Cannabis in Canada: Are We Being Too Cautious?", Commentary, (2015) 106:5 Can J Public Health e328.

124 For example, Dr. Charles Webb, president of the British Columbia Medical Association, reportedly agreed that cannabis may have therapeutic benefit in controlling symptoms of some illnesses, but cautioned that "many physicians will remain reticent to prescribe it until Health Canada comes out with guidelines on dosage, concentration and best practices for administering the drug" (quoted in Mike Hager, "Researchers Urge Medical Marijuana over Opioids to Treat Neuropathic Pain", *The Globe and Mail* (9 October 2015), online: GM <www.theglobeandmail.com/news/british-columbia/researchers-urge-medical-marijuana-over-opioids-to-treat-neuropathic-pain/article26733746/>).

125 CFPC Guidance, *supra* note 85 at IV.

126 Health Canada, *Information*, *supra* note 53 at ii.

127 Shannon Lough, "Growing the Evidence Base for Medical Cannabis", News, (2015) 187:13 CMAJ 955.

that is at a similar stage of development to poppy and foxglove in the 19th century. Although doctors may have prescribed those drugs then, in the 21st century we prescribe morphine and digoxin."[128]

Conclusion: Learning from the Canadian Experience

Lawmakers in other jurisdictions considering drug law reform to allow therapeutic cannabis use must ensure that medical access programs work for both patients and their health care providers. Canada's legal framework for therapeutic use of cannabis and the responses of medical regulators provide instructive examples for other countries, and future research should assess how recent changes to federal law and the regulators' policies affect patient access to the drug and relationships among practitioners, patients, cannabis producers, and regulatory authorities. As more jurisdictions are liberalizing access to cannabis for therapeutic purposes, comparative legal and policy research is needed to gain knowledge about the operation of differing drug and medical practice regulations and to elucidate their impacts on doctors and patients.

This article's concluding exhortations are as follows: a call to governments contemplating law reform to allow medical cannabis use to carefully consider the legal responsibilities imposed on health care practitioners and the impact of regulatory frameworks on the practitioner–patient relationship; a call to medical researchers, clinicians, and regulators to collaborate in the continuing development of evidence-based guidelines on the therapeutic use of cannabis; and a call to those in positions of power to reduce the barriers to care and the stigma experienced by vulnerable patients who seek relief from debilitating symptoms through responsible cannabis use. The promise of medical access programs may be undermined if legal and ethical fears deter doctors from authorizing cannabis use for those patients to whom it may offer therapeutic benefits, with the result that patients may continue to access the drug through informal and illicit channels.

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[128] John Fletcher, "Marijuana Is Not a Prescription Medicine", Editorial, (2013) 185:5 CMAJ 369 at 369.

Appendix I. Policies of Canadian Provincial Medical Regulatory Authorities on Therapeutic Use of Cannabis

Current to September 2016

College of Physicians and Surgeons of British Columbia

***Marijuana for Medical Purposes*, Standard – May 2015 (revised 30 July 2015)** (mandatory)

www.cpsbc.ca/files/pdf/PSG-Marijuana-for-Medical-Purposes.pdf

- There is a "paucity of evidence to support the use of medical marijuana" and known contraindications exist
- Practitioner shall:
  - only authorize cannabis if prescribing or referring doctor has "longitudinal treating relationship" with patient
  - document that conventional treatments were tried and unsuccessful and that risks of cannabis were discussed
  - assess patient's addiction risk using standardized tool
  - review patient's medication profile (via online prescription information system)
  - conduct clinical follow-up every three to six months and assess for misuse issues

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College of Physicians & Surgeons of Alberta

***Marihuana for Medical Purposes*, Standard of Practice – 3 April 2014** (mandatory)

www.cpsa.ca/standardspractice/marihuana-medical-purposes

- Practitioner who authorizes cannabis use must:
  - register with College and submit a copy of all patient medical documents
  - determine that conventional treatments are ineffective
  - assess patient's addiction risk using standardized tool (e.g., Drug Abuse Screening Test, Opioid Risk Tool)
  - ensure informed consent
  - review patient's medication profile (via online prescription information network)
  - provide regular in-person follow-up at least every three months after stable cannabis regimen established

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College of Physicians and Surgeons of Saskatchewan

***Standards for Prescribing Marihuana*, Regulatory Bylaw 19.2 – 1 July 2016** (mandatory)

www.cps.sk.ca/iMIS/Documents/Legislation/Legislation/Regulatory%20Bylaws%20-%20July%202016.pdf

- Dried cannabis "is an unproven therapy with an unproven record of safety and efficacy" (Bylaw section 19.2(n))
- Practitioner may only prescribe cannabis for conditions for which she or he is the treating physician
- Patient must agree in writing to not seek cannabis from another doctor, use cannabis only as prescribed, store cannabis safely, and not provide cannabis to anyone else
- Practitioner may refuse to re-prescribe cannabis if patient breaches agreement
- Patient's medical record must include specified information, including other treatments tried and their outcomes and cannabis risk disclosure details
- Practitioner shall:
  - document medical opinion that patient is likely to benefit from cannabis use
  - maintain record of all cannabis prescriptions with basic patient information, which must be available for inspection by the College
- Practitioner must:
  - not consult with patients at premises of licensed cannabis producer
  - not have any conflict of interest in relation to licensed producer

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College of Physicians & Surgeons of Ontario

***Marijuana for Medical Purposes*, Policy #1-15 – March 2015 update** (mandatory)

www.cpso.on.ca/policies-publications/policy/medical-marijuana

- "While conclusive evidence regarding the safety and effectiveness of dried marijuana as a medical treatment is limited, many patients, physicians, and researchers have voiced support for the cautious and compassionate use of dried marijuana"
- Practitioner must:
  - assess patient for addiction, substance diversion, and mental disorder risks
  - not prescribe cannabis for persons under age 25 unless all other conventional therapies have been exhausted, in light of evidence of higher cannabis-use risks for younger persons
  - specify quantity of dried product and percentage of the psychoactive compound tetrahydrocannabinol

(College of Physicians & Surgeons of Ontario, continued)

- Practitioner should start with low dose and incrementally increase if necessary
- Written treatment agreement is recommended

Collège des médecins du Québec

***Guidelines Concerning the Prescription of Dried Cannabis for Medical Purposes* – 1 May 2015** (mandatory)

www.cmq.org/publications-pdf/p-1-2014-04-01-en-directives-concernant-ordonnance-cannabis-seche-fins-medicales.pdf?t=1444356766552

- Practitioner may only prescribe cannabis for patients in a research study
- Before considering research use of dried cannabis, other treatments must be considered, particularly including other forms of cannabinoids authorized as pharmaceuticals by Health Canada
- Practitioner must:
  - complete a medical assessment using a form required by the College, which includes assessment of patient's addiction risk
  - provide regular follow-up with patient/research participant at least every three months after stable cannabis regimen established
  - maintain register of all patients/research participants using cannabis and submit to the Collège on request
  - collaborate with the Collège in data collection regarding safety and efficacy of cannabis use
  - not supply patient with cannabis or be a licensed cannabis producer

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College of Physicians & Surgeons of Nova Scotia

***Standard Regarding the Authorization of Marijuana for Medical Purposes* – 26 June 2014** (mandatory)

www.cpsns.ns.ca/DesktopModules/Bring2mind/DMX/Download.aspx?PortalId=0&TabId=129&EntryId=52

- Brief document stating that cannabis authorization is akin to prescribing and therefore a clinical act requiring sound evidence
- Practitioners must
  - prescribe only during in-person patient consultation
  - not charge fees for cannabis prescription
- Practitioners are encouraged to follow medico-legal guidance from organizations such as the Canadian Medical Protective Association

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College of Physicians and Surgeons of New Brunswick

***Medical Marijuana*, Guidelines – April 2014** (best practice)

www.cpsnb.org/english/Guidelines/MedicalMarijuana.htm

- "[S]trong medical evidence to support any particular use [of cannabis] remains lacking"
- Cannabis prescription by any practitioner other than the patient's primary physician must be based on in-person patient assessment in consultation with the primary physician
- Written treatment agreement is recommended
- Practitioner should:
  - discuss risks of cannabis, including safety for activities such as driving
  - warn patient about accessing cannabis only through licensed producer, not diverting cannabis to others, and safe storage
- Practitioner must not have conflict of interest in relation to production and supply of cannabis

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College of Physicians and Surgeons of Newfoundland and Labrador

***Marihuana for Medical Purposes*, Advisory to the Profession and Interim Guidelines – March 2014** (best practice)

www.cpsnl.ca/default.asp?com=Policies&m=340&y=&id=98

- "[P]hysicians should not be expected to facilitate patient access to a substance, for medical purposes, for which there is no body of evidence of clinical efficacy or safety"
- Practitioner is expected to:
  - self-educate on potential harms, benefits, and side-effects of cannabis
  - document informed consent discussions
  - document the conventional therapies that were tried and their outcomes
  - assess patient's addiction risk using standardized tool
  - set and comply with written protocol for regular follow-up of patient, including assessment for cannabis misuse
- Practitioner should only prescribe cannabis for conditions for which she or he is the treating practitioner
- Practitioner is discouraged from dispensing cannabis to patients
- Practitioner must not have conflict of interest in relation to production and supply of cannabis
- College may require information from practitioner on cannabis prescribing as part of licensure and quality assurance reviews

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College of Physicians and Surgeons of Prince Edward Island

***Prescribing of Medical Marijuana*, Policy – 26 May 2014 (updated September 2014)** (mandatory)

cpspei.ca/wp-content/uploads/2014/12/Marijuana-Prescribing-revised-May-1313-April-314May-2614-amended-Sept-2014.pdf

- "There is little verified scientific evidence supporting the use of the dried form of cannabis"
- Practitioner shall:
  - prescribe only for medical indications as listed on Health Canada website
  - never use telehealth technology to prescribe cannabis
  - document that conventional therapies have been ineffective
  - document informed consent discussions and include caution about lack of efficacy evidence
  - inform patient of practitioner's duty to report drivers with impairment to provincial road safety authority
  - obtain consent from patient to report specified details to the College (name, medical condition, details of cannabis prescription)
  - not accept delivery of cannabis for patient or dispense cannabis to patients

Yukon Medical Council

***Marijuana for Medical Purposes*, Standard of Practice – September 2015** (mandatory)

www.yukonmedicalcouncil.ca/pdfs/Marijuana_for_Medical_Purposes.pdf

- This Practice Standard adopts the wording of the Alberta College's policy, with the modification that a Yukon physician must submit a patient's medical document to the Medical Council on request, instead of within a week of signing the document as is required of Alberta physicians

Appendix II. Sample Medical Document for the *Access to Cannabis for Medical Purposes Regulations**

Health Canada / Santé Canada

Your health and safety... our priority. / *Votre santé et votre sécurité... notre priorité.*

Sample Medical Document for the Access to Cannabis for Medical Purposes Regulations

This document may be completed by the applicant's health care practitioner as defined in the Access to Cannabis for Medical Purposes Regulations (ACMPR). A health care practitioner includes medical practitioners and nurse practitioners. In order to be eligible to provide a medical document, the health care practitioner must have the applicant for the medical document under their professional treatment. Regardless of whether or not this form is used, the medical document must contain all of the required information, (see in particular s. 8 of the ACMPR).

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

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 that above): _____

Phone Number: _____

Fax Number (if applicable): _____

Email Address (if applicable): _____

Province(s) Authorized to Practice in: _____

Health Care Practitioner's Licence number: _____

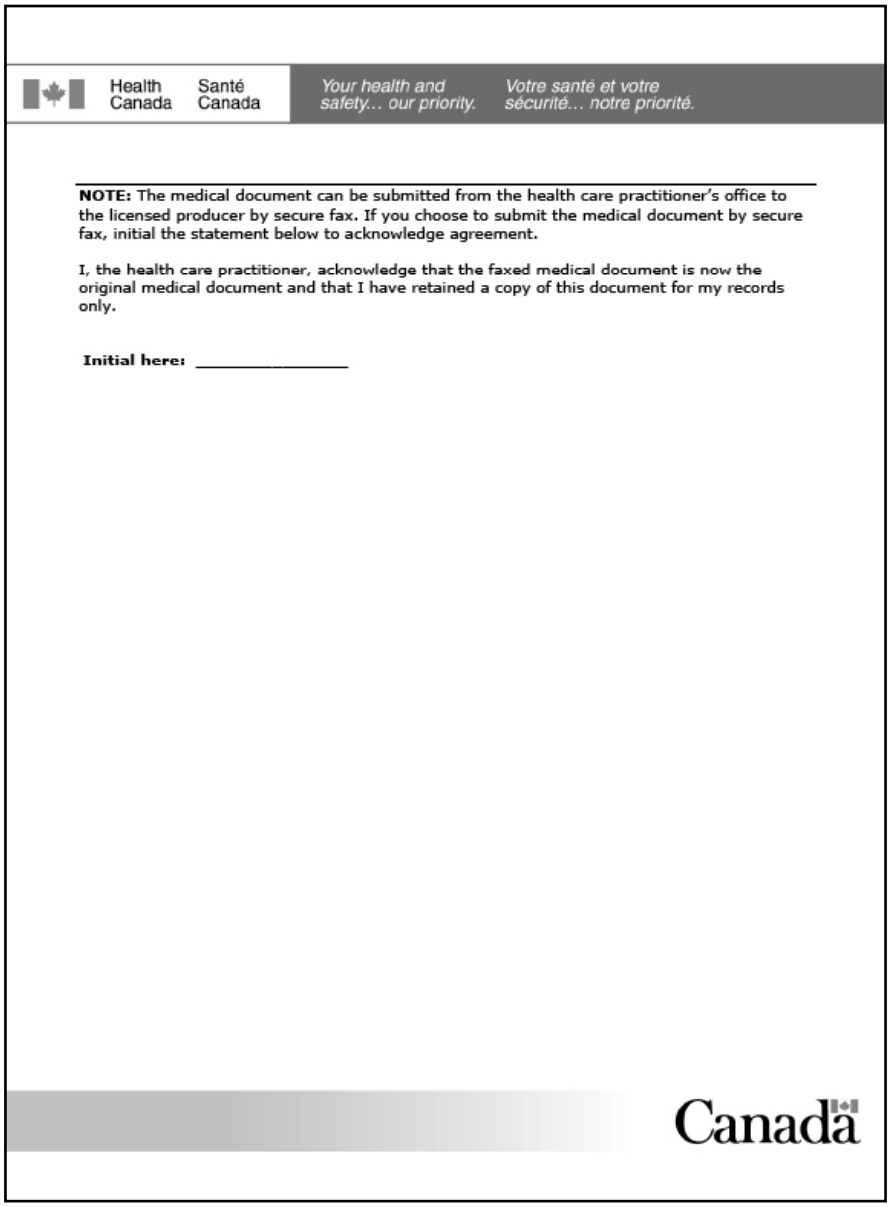
By signing this document, the health care practitioner is attesting that the information contained in this document is correct and complete.

Health Care Practitioner's Signature: _____

Date Signed (DD/MM/YYYY): _____

Canada

* Health Canada provides this sample document on its website: http://www.hc-sc.gc.ca/dhp-mps/marihuana/info/med-eng.php



Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

NOTE: The medical document can be submitted from the health care practitioner's office to the licensed producer by secure fax. If you choose to submit the medical document by secure fax, initial the statement below to acknowledge agreement.

I, the health care practitioner, acknowledge that the faxed medical document is now the original medical document and that I have retained a copy of this document for my records only.

Initial here: _____

Canada