

## Use of Injectable Ketamine to Treat Psychiatric Illnesses in an Out-of-Hospital Premises in Ontario

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### Summary

Ketamine is a narcotic subject to provisions in the *CDSA* and *NCR*. Physicians are authorized to prescribe narcotics to patients under their professional treatment pursuant s 53(2) of the *NCR*. However, physicians may prescribe a drug only if they have the knowledge, skill and judgment to do so safely and effectively (O Reg 865/93, ss 2(1)(c) and 2(5)). There is no federal or provincial prohibition of off-label use of a drug, and the CPSO does not have a position on the off-label use of ketamine. The Province of Ontario permits physicians to use non-conventional therapies and exempts them from being found guilty of misconduct or incompetence solely on the basis that the physician practises a non-conventional therapy (*Medicine Act, 1991, s 5.1*). Only physicians and certain categories of nurses are authorized to administer ketamine via injection to a patient (*RHPA, ss 27(1) and 27(2)(5)*); *Medicine Act, 1991, s 4(5)*; *Nursing Act, 1991, ss 4(2), 5.1(1)(6) and 5.1(2)*). The procedure may be performed in an out-of-hospital premises approved by the CPSO for that purpose (Part XI of O Reg 114/94).

### Table of Contents

1. [Introduction](#)
2. [Federal Regulation of Ketamine](#)
  - 2.1. [Under the CDSA](#)
  - 2.2. [Under the NCR](#)
    - 2.2.1. [Licensed Dealers](#)
    - 2.2.2. [Practitioners](#)
  - 2.3. [Conclusion](#)
3. [Provincial Regulation of Treatment with Ketamine](#)
  - 3.1. [CPSO Policies](#)
    - 3.1.1. [Complementary/Alternative Medicine policy](#)
    - 3.1.2. [Prescribing Drugs policy](#)
    - 3.1.3. [Off-label Use of Ketamine and Liability](#)
  - 3.2. [Premises](#)
  - 3.3. [Injection Procedure](#)
  - 3.4. [Conclusion](#)

## 1. Introduction

Health care in Canada is in a shared sphere of jurisdiction between federal and provincial governments. The federal authority over health care stems from the federal government's constitutional authority with respect to its spending power, criminal law power, peace, order and good government power, and patent regulation and aboriginal health services powers.<sup>1</sup>

The provinces maintain exclusive jurisdiction over the establishment, maintenance and management of hospitals (except marine hospitals which are exclusively under federal jurisdiction), municipal institutions in the province (e.g., some hospitals, home care and long-term care access services and facilities may be municipally governed), the incorporation of companies with provincial objects (e.g., hospitals tend to be provincial corporations), property and civil rights in the province (e.g., the regulation of physician compensation), and all matters of merely local or private nature in the province.<sup>2</sup>

Federally, ketamine is a narcotic drug approved for medical use in Canada by Health Canada. Access to ketamine is subject to the provisions in the *Controlled Drugs and Substances Act*, SC 1996, c 19 (“CDSA”) and the *Narcotic Control Regulations*, CRC, c 1041 (“NCR”).

In the provincial sphere of jurisdiction, administration of ketamine via injection to patients in the Province of Ontario in an private clinic (out-of-hospital premises) may involve several statutory provisions as well as to policies and procedures set out by the College of Surgeons and Physicians of Ontario (CPSO). Relevant statutes are: *Regulated Health Professions Act, 1991*, SO 1991, c 18 (“RHPA”); *Medicine Act, 1991*, SO 1991, c 30; *Nursing Act, 1991*, SO 1991, c 32; O Reg 114/94, *General*, enacted under the *Medicine Act, 1991*; O Reg 865/93, *Registration*, enacted under the *Medicine Act, 1991*. Relevant CPSO policies include the *Complementary/Alternative Medicine* policy, *Prescribing Drugs* policy, *Consent to Treatment* policy, and other policies that may be applicable to the case.

## 2. Federal Regulation of Ketamine

### 2.1 Under the CDSA

Ketamine (2-(2-chlorophenyl)-2-(methylamino)cyclohexanone) is a controlled narcotic drug listed in s 14(1) of Schedule I to the *CDSA* and s 14(1) of the Schedule to

<sup>1</sup> Halsbury's Laws of Canada (online), *Medicine and Health*, at HMH-1 “Federal authority over health care.”

<sup>2</sup> Halsbury's Laws of Canada (online), *Medicine and Health*, at HMH-2 “Provincial authority over health care.”

the *NCR*. Hence, under the *CDSA*, it is an offence: to possess ketamine, except as authorized under the regulations (s 4(1)); to seek or obtain ketamine, or an authorization to obtain it, from a practitioner, unless the person discloses to the practitioner particulars relating to the acquisition of ketamine and every authorization to obtain it (s 4(2)); to traffic or possess ketamine for the purpose of trafficking (s 5(1) and (2)).

Except as authorized under the regulations to the *CDSA*, it is prohibited to import ketamine to or export it from Canada, as well as to possess ketamine for the purpose of exporting (s 6(1) and (2)). The production of ketamine is also prohibited (s 7(1)). It is also an offence to possess, produce, sell, import or transport anything intending that it will be used to produce (except if lawfully authorized) ketamine or traffic in it (s 7.1(1)). An exemption from the applications of the provisions in the *CDSA* or the regulations may be obtained from the Minister under s. 56.

## 2.2 Under the NCR

Pursuant s 3(1) of the *NCR*, a person may obtain authorization to possess ketamine (a narcotic) under some circumstances. The relevant parts of that section to this case are quoted below:

- 3 (1) A person is authorized to possess a narcotic if the person has obtained the narcotic in accordance with these Regulations ... or from a person who is exempt under section 56 of the Act from the application of subsection 5(1) [trafficking in a controlled substance] of the Act with respect to that narcotic, and the person
- (a) requires the narcotic for their business or profession and is
    - (i) a licensed dealer,
    - (ii) a pharmacist, or
    - (iii) a practitioner who is registered and entitled to practise in the province in which they possess the narcotic;
  - (b) is a practitioner who is registered and entitled to practise in a province other than the province in which they possess the narcotic for emergency medical purposes only;
  - ...
  - (d) has obtained the narcotic for their own use
    - (i) from a practitioner,
    - (ii) in accordance with a prescription that was not issued or obtained in contravention of these Regulations, or
    - (iii) from a pharmacist under section 36;
  - ...
  - (h) is not a practitioner of medicine referred to in paragraph (e) or an agent or mandatary referred to in paragraph (f), is exempted under section 56 of the Act with respect to the possession of that narcotic and their possession is for a purpose set out in the exemption; or
  - ...

### 2.2.1 Licensed dealers

Pursuant s 8(1) of the *NCR*, a licensed dealer is authorized to produce, assemble, sell, provide, transport, send, deliver, import or export ketamine. A qualified person in

charge, or an alternate, must be present at the site where the licensed dealer conducts activities in relation to a narcotic (s 8(2)). An additional permit is required to import, export or possess for the purpose of exporting (s 8(3) and (4)).

Licensed dealers may sell ketamine to other licensed dealers (s 25), to a practitioner (s 25.2(1)) or to a person who is exempted under s 56 of the *CDSA* to possess ketamine (s 25.4). The word “sell”, defined in s 2(1) of the *CDSA*, “includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.”

Dealer’s licences are regulated in ss 9 to 17.1 of the *NCR*.

### **2.2.2 Practitioners**

Section 53(2) of the *NCR* permits that a practitioner administer, prescribe, sell or provide narcotics to a patient that is under the practitioner’s professional treatment, and the narcotic is required for the condition for which the person is receiving treatment. Otherwise, practitioners must not administer, prescribe, sell or provide a narcotic substance to a person.

“Practitioner” is defined in s 2(1) of the *CDSA* as “a person who is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons prescribed as a practitioner.”

### **2.3 Conclusion**

Ketamine is a narcotic drug of restricted access under the *CDSA* and the *NCR*. While it is illegal to possess, seek to obtain, traffic and produce narcotics, some specific categories of persons, including exemptees under s 56 of the *CDSA*, licensed dealers and practitioners, may perform specific activities in relation to ketamine. In the case of practitioners, they may prescribe, sell or provide ketamine (narcotic) to patients under their professional treatment.

## **3. Provincial Regulation of Treatment with Ketamine**

Professional regulation is considered to be law in relation to “property and civil rights in the province”, pursuant to s 92(13) of the *Constitution Act, 1867*<sup>3</sup> and therefore is under provincial jurisdiction. In the province of Ontario, the intravenous, subcutaneous or intramuscular administration of ketamine in an out-of-hospital

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<sup>3</sup> Halsbury’s Laws of Canada (online), *Medicine and Health*, at HMH-19 “Jurisdiction of licensing authority.”

premises such as a private clinic can be regulated by provisions found in several statutes, regulations and policies, including: *Regulated Health Professions Act, 1991*, SO 1991, c 18 (“RHPA”); *Medicine Act, 1991*, SO 1991, c 30; *Nursing Act, 1991*, SO 1991, c 32; *Pharmacy Act, 1991*, SO 1991, c 36; O Reg 114/94, *General*, enacted under the *Medicine Act, 1991*; O Reg 865/93, *Registration*, enacted under the *Medicine Act, 1991*. It is also subject to CPSO policies, including the *Complementary/Alternative Medicine* policy, *Prescribing Drugs* policy, *Consent to Treatment* policy, and all other policies that are applicable to the case.

We have seen above that, in Canada, practitioners are allowed to administer, prescribe, sell or provide ketamine (narcotics) to patients under their professional care pursuant s 53(2) of the *NCR*. However, the procedure through which ketamine is administered to a patient falls under provincial regulation. In Ontario, the College of Physicians and Surgeons of Ontario (CPSO) has determined that procedures involving intra-nasal or oral administration of ketamine are not captured by the Out-of-Hospital Premises Inspection Program (OHPIP). Intravenous, subcutaneous or intra-muscular administration (injection) of ketamine are included in the *General, O. Reg. 114/94*<sup>4</sup> and the OHPIP and are subject to inspection by the CPSO. Every out-of-hospital premises is required to be familiar with and comply with the OHPIP standards. Physicians are expected to practice within their scope of practice and to be familiar with and comply with all CPSO policies, including the *Complementary/Alternative Medicine*, *Consent to Treatment* and *Prescribing Drugs* policies.<sup>5</sup>

The next subsections address: CPSO policies that are applicable to off-label use of ketamine to treat psychiatric illness, out-of-hospital premises, and who can perform procedures involving ketamine.

### 3.1 CPSO Policies

Practitioners in Ontario are subject to the policies passed by the CPSO. Not excluding the application of other policies, two policies are particularly relevant for the treatment of psychiatric illnesses using ketamine. They are the *Complementary/Alternative Medicine*<sup>6</sup> policy and the *Prescribing Drugs*<sup>7</sup> policy.

#### 3.1.1 [Complementary/Alternative Medicine policy](#)

<sup>4</sup> O Reg 114/94, *General*, enacted under the *Medicine Act, 1991*, SO 1991, c 30.

<sup>5</sup> Email communication with the CPSO, May 5, 2021.

<sup>6</sup> College of Physicians and Surgeons of Ontario, “Complementary/Alternative Medicine.” Available online at <https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Complementary-Alternative-Medicine>, accessed May 6, 2021.

<sup>7</sup> College of Physicians and Surgeons of Ontario, “Prescribing Drugs”, available online at <https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Prescribing-Drugs>, accessed May 6, 2021.

Complementary/Alternative Medicine (CAM) is defined as “a group of diverse medical practices and products that are not generally considered part of conventional medicine.” Boundaries between CAM and conventional medicine are not absolute and, sometimes, some specific CAM practices may become incorporated into conventional medicine.

The CAM policy says that “[p]atients have the right to make health care decisions that accord with their own values, wishes and preferences. This includes decisions to pursue complementary/alternative medicine either as an adjunct to conventional medicine, or instead of conventional medicine.” This statement is in accordance with s 7 of the *Charter* and jurisprudence such as *R v Smith*.

According to s 5.1 of the *Medicine Act, 1991*, physicians shall not be found guilty of professional misconduct or incompetence under ss 51 or 52 of the *Health Professions Procedural Code* solely on the basis that they practice a therapy that is non-traditional or departs from the prevailing medical practice. The CAMP notes that physicians practising complementary/alternative medicine are still expected to practise the profession in a manner that is informed by evidence and science and is in keeping with professional, ethical and legal obligations. They are also expected to comply with all of their legal, professional and ethical obligations.

Principles and obligations of ethics and professionalism are binding obligations on physicians’ conduct: obligations to *act in patients’ best interests*, to *respect patient autonomy*, to *refrain from exploiting patients*, and to *manage conflicts of interest*.

Specific expectations for physicians who practise CAM, either as a primary focus of their practice or as a component of their conventional practice, are:

- i. *Clinical Competence*. Physicians must always act within the limits of their *knowledge, skill and judgement* and never provide care that is beyond the scope of their clinical competence (O Reg 865/93<sup>8</sup>, ss 2(1)(c) and 2(5); *Changing the Scope of Practice* policy; *The Practice Guide*).
- ii. *Clinical assessment and diagnosis*. All patient assessments and diagnoses must be consistent with the standards of conventional medicine and be informed by evidence and science.
- iii. *Therapeutical options and informed consent*. Physicians must always have valid informed patient consent to authorize therapeutic intervention. Physicians must also evaluate and analyze all available therapeutic options.

### **3.1.2 Prescribing Drugs policy**

<sup>8</sup> O Reg 865/93, *Registration*, enacted under the *Medicine Act, 1991*, SO 1991, c 30.

In Ontario, physicians are allowed to prescribe, dispense, sell or compound a drug, subject to the terms, conditions and limitations imposed on his or her certificate of registration (*Medicine Act, 1991*, s 4(8)). Under certain conditions, registered nurses may prescribe controlled substances within the meaning of the *CDSA* (O Reg 275/94<sup>9</sup>, s 17(2)).

The CPSO *Prescribing Drug* policy says that physicians must comply with the requirements for prescribing drugs that are set out in the policy as well as those contained in other relevant CPSO policies and legislation, including, but not restricted to, the *Food and Drugs Act, RSC, 1985, c F-27*; the *Controlled Drugs and Substances Act, SC 1996, c 19* (“CDSA”); the *Narcotics Safety and Awareness Act, 2010, SO 2010, c 22*; and the *Drug and Pharmacies Regulation Act, RSO 1990, c H.4*.

Physicians must only prescribe a drug if they have the knowledge, skill and judgement to do so safely and effectively (O Reg 865/93, ss 2(1)(c) and 2(5); *Changing Scope of Practice* policy; *The College’s Practice Guide*).

In regard to the prescription of narcotics, the *Prescribing Drugs* policy says that special consideration is necessary given that they are susceptible to diversion, misuse and/or abuse, and many carry a risk of dependence and overdose. Paragraph 33 of the policy says that, when prescribing narcotics or controlled substances, physicians must meet the general requirements set out in the policy as well as any other relevant policies and legislation. They must consider any relevant practice standards, quality standards, and clinical practice guidelines, and apply them as appropriate. Where these resources do not exist, physicians must consider any available indirect evidence, clinical trials, evidence-based research or consensus recommendations, and general best practices.

Ketamine is a narcotic drug, listed in Schedule I to the *CDSA* and in the Schedule to the *Narcotic Control Regulations, CRC, c 101*. Therefore, all the cautionary measures in the *Prescribing Drugs* policy apply to the prescription of ketamine for treatment of psychiatric illnesses.

### **3.1.3 Off-label Use of Ketamine and Liability**

Recently, intranasal ketamine (Spravato<sup>®</sup>) has been approved by Health Canada for the treatment of major depressive disorder. However, intravenous, intramuscular or subcutaneous application of ketamine for the treatment of psychiatric illnesses is an off-label use of that drug.<sup>10</sup>

<sup>9</sup> O Reg 275/94, *General*, enacted under the *Nursing Act, 1991*, SO 1991, c 32.

<sup>10</sup> College of Physicians and Surgeons of British Columbia, “Ketamine and major depressive disorder”, *College Connector* 8(5), October 2020. Available online at <https://www.cpsbc.ca/for-physicians/college-connector/2020-V08-05/05>, accessed May 9, 2021.

In Canada, doctors have broad prescribing authority, whether for an on-label or off-label use. Doctors play a role in identifying effective off-label uses and it may lead to innovative drug applications. As of 2005, there are no provincial statutes pertaining directly to off-label prescribing. Provincial colleges have regulated off-label use of drugs only indirectly. In Ontario, the CPSO does not have a specific policy on off-label prescribing. However, provincial policies such as the Ontario Drug Benefit may deter off-label use as they may reimburse only the cost of drugs when prescribed for an approved indication.<sup>11</sup>

The CPSO does not currently have a position on the off-label use of ketamine. However, with the exception of oral and intra-nasal ketamine, the CPSO requires that ketamine administered via intra-muscular and/or intravenous must be administered in accordance with OHPIP, regardless of whether it is an off-label use.<sup>12</sup>

The use of ketamine in the form of injection involves the off-label use of that drug and is a non-conventional medical therapy to treat psychiatric illnesses. Non-traditional medical therapies are not illegal in Ontario and, pursuant s 5.1 of the *Medicine Act, 1991*, “[A] member [of the CPSO] shall not be found guilty of professional misconduct or of incompetence under section 51 or 52 of the Health Professions Procedural Code solely on the basis that the member practises a therapy that is non-traditional or that departs from the prevailing medical practice unless there is evidence that proves that the therapy poses a greater risk to a patient’s health than the traditional or prevailing practice.”

In *King v Gannage*, 2020 ONSC 7967, the co-founder of a collective of autistic adults engaged in advocacy on autism-related issues in Ontario that opposes the off-label use of chelation therapy for children with autism made a complaint to the Incidents, Complaints and Reports Committee (ICRC) of the CPSO against a physician who uses chelation therapy to treat children with autism. The ICRC reached the conclusion that there was no evidence that the physician was practising outside of the scope of the CPSO’s CAM policy and that there was a clear consent process in place for the physician’s patients, and decided to take no further action with respect to the complaint. The Health Professions Appeal and Review Board dismissed application for review, concluding that the ICRC investigation was adequate and the decision to take no further action was reasonable, and the Divisional Court of the Ontario Court of Appeal dismissed application for judicial review of the Board decision. In its decision, the Court noted that s 5.1 of the *Medicine Act, 1991*, permits the use of non-traditional therapies by physicians.

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<sup>11</sup> Natalie de Paulsen, [The Regulatory Gap: Off-Label Drug Use in Canada](#), (2005) 63 UT Fac L Rev 183 - 211, at paragraphs 15, 25 and 26.

<sup>12</sup> Email communication with the CPSO, May 10, 2021.

### 3.2 Premises

Administration of ketamine via injection in a private clinic (out-of-hospital premises) is subject to inspection by the CPSO pursuant to the OHIP (Part XI of the *General*, O Reg 114/94). Section 45(1) of O Reg 114/94 says that all premises where a procedure is or may be performed on a patient by a practitioner in connection with their practice are subject to inspection by the CPSO. "Procedure" is defined as to include "any act that ... is performed under the administration of, general anaesthesia ..." (s 44(1)(a)(i)). As ketamine is a general anaesthetic drug, the treatment of psychiatric illnesses ("any act") with ketamine ("general anaesthesia") falls in the category of "procedure" and the premises wherein this procedure is performed is subject to inspection by the CPSO pursuant to s 45(1).

Note that the abovementioned provisions apply only to intravenous, subcutaneous or intra-muscular administration of ketamine as the CPSO has determined that intra-nasal or oral administration of ketamine is outside the scope of the OHIP.

Before a physician commences using the premises for the purposes of performing procedures, it is necessary to give prior notice in writing to the CPSO of the intention to do so and have the premises passing an inspection or passing an inspection with conditions (s 49(1)).

### 3.3 Injection Procedure

The administration of a substance by injection in the course of providing health care services to an individual is a controlled act pursuant to s 27(2)(5) of the *RHPA*. The only persons authorized to perform that controlled act are listed in s 27(1). That subsection reads:

- 27(1) No person shall perform a controlled act set out in subsection (2) in the course of providing health care services to an individual unless,
- (a) the person is a member authorized by a health profession Act to perform the controlled act; or
  - (b) the performance of the controlled act has been delegated to the person by a member described in clause (a).

The delegation of a controlled act by or to a member must be in accordance with any applicable regulations under the health profession Act governing the member's profession (*RHPA*, s 28). "Member" as defined in s 1(1) of the *RHPA* means a member of a College.

Subject to the terms, conditions and limitations imposed on his or her certificate of registration, Physicians and nurses are authorized to administer a substance by injection or inhalation (*Medicine Act*, 1991, s 4(5) and *Nursing Act*, 1991, s 4(2), respectively). Registered Nurses who hold an extended certificate of registration may also administer a substance by injection or inhalation, in accordance with the

regulations. They may also administer a substance by injection or inhalation at the behest of a physician (*Nursing Act, 1991*, ss. 5.1(1)(6) and 5.1(2)). Pharmacists may not administer ketamine by injection to a patient because ketamine is not among the substances pharmacists are allowed to administer by injection (*General, O Reg 202/94*<sup>13</sup>, s 34(1)(1) read with Schedule 1 to the regulation).

### 3.4 Conclusion

Pursuant s 5.1 of the *Medicine Act, 1991*, physicians are permitted to use non-traditional therapies. The guidelines for those therapies is set out in the CPSO's CAM policy. Physicians may prescribe, dispense, sell or compound a drug; however, only if they have the knowledge, skill and judgment to do so safely and effectively (*Medicine Act, 1991*, s 4(8) and O Reg 865/93, ss 2(1)(c) and 2(5)). There is no prohibition, whether federal or provincial, to the off-label use of a drug.

The premises where ketamine is injected in patients must pass an inspection by the CPSO OHPIP (Part XI of O Reg 114/94). The procedure of injecting ketamine is a controlled act and may be exercised only by physicians and some nurses (*RHPA*, ss 27(1) and 27(2)(5)); *Medicine Act, 1991*, s 4(5); *Nursing Act, 1991*, ss 4(2), 5.1(1)(6) and 5.1(2)).

For those reasons, there is no legal prohibition to non-conventional treatment of psychiatric illnesses with the off-label use of injectable ketamine in a patient under a physician's professional care and in an out-of-hospital premises approved by the CPSO. The ketamine must be prescribed by a physician that has knowledge, skill and judgement to do so effectively, and the procedure may be performed only by a physician or a nurse part of certain categories of nurses.

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<sup>13</sup> O Reg 202/94, *General*, enacted under the *Pharmacy Act, 1991*, SO 1991, c 36.