BC ASSOCIATION of CLINICAL COUNSELLORS

HEALTH CANADA GUIDELINES TO WORKING WITH PSYCHEDELICS

Implications for Registered Clinical Counsellors

October 2024

BC ASSOCIATION of CLINICAL COUNSELLORS

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Health Canada Guidelines to working with Psychedelics and Implications for Registered Clinical Counsellors.

Psychedelics have come into focus once again in the counselling and psychotherapy sphere over the past ten years. Health Canada, in recent years, changed the guidelines and legislation related to working with Psychedelics to protect individuals and provide guidance for those professionals working with psychedelics and other restricted substances.

At the date of this document, there exists a distinct lack of consistency in professional practice when working with psychedelics and other restricted substances. The BC Association of Clinical Counsellors (BCACC) recognizes the need for standards and accreditation for training in psychedelic and other substance-assisted therapy, which supports the BC Centre for Disease Controls Harm Reduction Policies and Guidelines, risk management, engagement with best practices, current research, ethical and effective clinical care for clients.

BCACC recognizes that in this growing area of interest, there is a need for standards of practice and clarity in professional practice with psychedelic-assisted therapy. This discussion encourages Registered Clinical Counsellors (RCC's) to understand alongside BC legislation, and BCACC's Standards of Clinical Practice and Code of Ethical Conduct, their scope of practice, individual competence, the value of appropriate training and supervision when collaborating with clients in this way, and the crucial importance of staying up to date with regulations. These recommendations are intended to supplement appropriate clinical knowledge, legal advice, or recommendations from Health Canada and those who are experts in this activity.

What is psychedelic-assisted therapy?

The term psychedelic-assisted therapy refers to "a particular mode of using psychedelic substances in which the effects of the drug, both biological and psychological, play a significant role in facilitating a psychotherapeutic intervention" (Guss et al., 2020). Most current studies and clinical trials involve three types of sessions—preparatory, medication administration, and integration—preceded by patient screening and assessment (Bogenschutz & Forcehimes, 2016). Uses of psychedelic medications unaccompanied by psychotherapy do not meet this definition of psychedelic-assisted therapy.

Psychedelic-assisted therapy (PAT) involves the use of psychedelic substances as an adjunct to psychotherapy for facilitating therapeutic breakthroughs and insight (e.g., MDMA-AT, ketamine-AT, psilocybin-A (Canadian Public Health Forum, 2023))

How do clients access Psychedelic-assisted therapy?

Health Canada recognizes there are times when access to unauthorized drugs, such as psychedelics may be appropriate. Psychedelics can be supportive for clients who have tried many other approaches to therapy and medical interventions and who have not experienced relief from symptoms through these efforts. Clients who continue to struggle with mental health conditions and diagnoses should continue conversations on other treatment options with appropriately trained medical professionals familiar with their case. These medical professionals could include psychiatrists, psychologists, and Primary Care Practitioners. These professionals are already regulated under a regulatory college. (Health Canada, 2022)

In some circumstances, with the support of a legislatively regulated healthcare practitioner, it may be possible for individuals to legally access certain psychedelics through one of three pathways:

1. Clinical trials
2. Special Access Program
3. Individual subsection 56(1) exemptions from the CDSA

Clinical trials and Health Canada's Special Access Program are existing regulatory options through which a legal source of certain psychedelics may be accessed. These pathways should be pursued instead of an individual exemption under the CDSA. Both clinical trials and the Special Access Program have safeguards and requirements in place to protect the health and safety of patients, help ensure the quality of the drug and provide for administration and oversight by a qualified professional.

Currently, recommended access to psychedelics for the use of psychedelic-assisted therapy is through clinical trials or the Special Access Program. In both these circumstances, the support of a multidisciplinary team, appropriate risk management procedures, ethical standards, and safeguards for the client should be in place. RCC's should ensure that they ONLY offer their services to sanctioned clinical trials or programs. Clinical Trials or programs offering access and the opportunity to work with psychedelics meet the requirements for clinical trials, which can be found here.

Definitions of Terms

The following definition are provided in the Health Canada websites.

Practitioner/ Health Care Practitioner: As per section C.01.001 of the Food and Drug Regulation, a person who is entitled under the laws of a province to treat patients with a prescription drug and is practicing their profession in that province.

Director – Psychiatrist or Medical Doctor overseeing a clinical trial or operationalizing the access through the SAP.

Medical Professional – A regulated professional in their jurisdiction where the practice/ clinical trial is taking place.

The definitions below are often referred to in regulatory colleges and other regulatory bodies who regulate activities.

Standards- the professional behaviors expected of the practitioner against which actual practitioner behavior is measured.

Limits- the boundaries of practitioner practice (what they can and cannot do)

Conditions- the circumstances under which a practitioner may do something (i.e., with additional formal education, under supervision, etc.)

What is BCACC's Role?

BCACC's intent is not to supersede or override the expertise of those conducting clinical trials or working through the Special Access Program (SAP) to deliver psychedelic-assisted therapy. These guidelines may be broadened to include ketamine- assisted psychotherapy. Ketamine, while not a traditional psychedelic, will be, for the purposes of this discussion, included under psychedelic-assisted psychotherapy. The intent of this document is to provide:

- RCCs with information and links that support increased awareness of the risks of working with adjunct tools such as psychedelics
- Identify for the RCC, the expectation of the development of strategies to manage risks
- links to current legislation and relevant government websites
- resources to help individuals who may wish to explore and /or pursue training, certification, and supervision in this area.

Scope of Practice for Registered Clinical Counsellors

Psychotherapy is the act of assessing, engaging in, and treating cognitive, behavioral, emotional, and relational distress and conditions, delivered through structured communication within a psychotherapeutic relationship of care.

In the course of practicing psychotherapy, a person may:

a. assesses a client's behavioral, cognitive, emotional, and relational functioning

b. determine a course of care to be delivered by psychotherapeutic approaches and means

c. engage and treat a client's distress, condition or disorder of behavior, cognition, emotion, relationship, or other psychological domain that impairs their adaptive functioning, wellness, and quality of life.

RCCs are highly qualified mental health professionals with at least a master's degree in counselling psychology or a closely related field. They are trained to provide psychotherapy and often other interventions to support clients with various mental health challenges. RCCs can be and often seek training and additional certification in adjunct methodologies and technical therapies that are not, in-and-of-themselves, psychotherapy. Some RCCs have pursued additional specialized training in psychedelic-assisted therapy to incorporate this approach into their practice. The role of an RCC in this context might include:

1. Conducting certain pre-treatment assessments and screening under the supervision of a regulated medical professional.
2. Providing preparatory sessions before psychedelic experiences
3. Offering support and guidance during psychedelic sessions under medical supervision
4. Facilitating integration sessions after psychedelic experiences
5. Ensuring ethical and safe practice aligned with BCACC Standards of Clinical Practice and Code of Ethical Conduct.

Restricted activities.

As various professionals also come under the Registered Clinical Counsellor designation, RCCs wishing to use these tools alongside their current practice need to understand:

- Health Canada Guidelines and relevant legislation,
- Relevant regulatory college requirements when engaging in these activities,
- Standards of Clinical Practice and Code of Ethical Conduct (the professional behaviors against which their professional behavior is measured)
- Limits of their education and training and conditions of their work environment,
- Their individual competence of the activity they wish to engage with.

The BCACC encourages all RCCs to be familiar with the BC Harm Reduction Strategies and Services Policy and Procedures (British Columbia Centre for Disease Control, 2023) when supporting individuals who are using or wish to use substances considered controlled substances, Illicit or licit substance use and their role in the reduction of harm. This document defines harm reduction principles, practices and approaches that will inform the RCC.

RCCs are not considered medical professionals; therefore, their engagement with activities should be understood through this lens. This understanding is crucial for RCCs to keep their professional boundaries and ensure the safety of their clients.

RCCs cannot procure, prescribe, dispense medications, or administer them to clients. Only regulated medical professionals and other regulated health professionals authorized through profession-specific regulation in their jurisdiction to prescribe, dispense and administer controlled drugs and substances can do this, and this can only occur within a clinical trial or with the Special access program or exemption 56(1) for individuals.

RCCs can, with the appropriate training, be involved with the preparation of an individual or a group for the use of psychedelics, during the use of the psychedelic when the client is in an altered state (on a journey) and importantly, during the integration phase. (Mocanu et al., 2022, Rochester, et.al., 2021)

What Does BCACC Expect of RCCs?

Registered Clinical Counsellors are encouraged to measure their engagement with activities, such as Psychedelic-assisted therapy, which is considered to be an adjunct tool, against the BCACC Standards of Clinical Practice in particular:

- Standard 1: Client- Centered Care Consent
- Standard 2: Competence and Quality Assurance
- Standard 6: Clinical and Counselling Assessment and Reporting
- Standard 8: Relationships, Boundaries and Conflict of Interest
- Standard 9: Sexual Misconduct
- Standard 12: Documentation and Record Keeping
- Standard 13: Ethical Conduct
- Code of Ethical Conduct

and the Health Canada guidelines for collaborating with individuals in this way. Psychedelic-assisted therapy is viewed as a supplementary tool to talk therapy as outlined in the scope of practice; therefore, it requires rigorous training, oversight, and supervision, typically within a multi-disciplinary team, to ensure public protection, exceptional clinical care, and risk management. This responsibility is a key part of the RCC's commitment to their profession and the well-being of their clients.

How to access training and supervision

When looking for an increased understanding of working with Psychedelics, it is required that RCCs participate in a robust training course as noted in the Standard of Clinical Practice 2: Competence and Quality Assurance. (Mocanu et al., 2022, Rochester, et.al., 2021)

What should the training include?

Courses linked with educational institutions or multi-professional teams that incorporate at the minimum all of the following:

- Theory,

- Science and overview of various psychedelics,
- History and development of psychedelic assisted therapy,
- Ethical requirements for researchers conducting clinical trials,
- Ethical behavior for various professionals,
- Informed Consent
- Recommendations for best practices, and standards across health professions
- A broad overview of current research and how to stay up to date,
- Federal AND in particular, provincial regulations,
- Standards of Practice,
- Risk management strategies and practices,
- Practicum with ongoing supervision during and post training.
- Indigenous and cultural connection to plant medicines (including those which are psychedelic in nature).

While various training organizations and universities across Canada and internationally provide robust training opportunities, the RCC is required to understand the legislation and regulations of Canada and the province they choose to practice within as noted in Standard of Clinical Practice Standard 2: Competence and Quality Assurance, and Standard 13

BCACC encourages training and supervision in any area of specialized services or client focus, as discussed in the Standards of Clinical Practice and Code of Ethical Conduct. This ensures the RCC's ongoing clinical development and adoption of up-to-date knowledge of current legislation and Acts in relation to high-risk activity.

Specialized training should provide RCCs with broad knowledge of the potential physical, psychological, and spiritual effects of psychedelics and of the core principles of psychedelic-assisted therapy. Psychedelic-assisted therapy practitioners endeavor to understand the potential physical effects of psychedelics as they might for other medications or procedures *within their scope of practice*. However, psychological, as well as spiritual or existential, effects can be unique to psychedelic-assisted therapy. Psychedelic-assisted therapy practitioners aim to understand these effects so that they can appropriately support clients as they encounter such experiences (American Psychedelic Practitioners Association, 2023)

Comprehensive training and oversight through clinical supervision and oversight by medical health professionals within a multidisciplinary team is recommended.

The Special Access Program: What is it?

The information presented below has been adopted from the Health Canada Website to inform Registered Clinical Counsellors about the nature of the program and provide them with access to more information. RCCs are not qualified to apply through the Special Access Program and should only engage with programs who meet the Health Canada requirements to conduct clinical trials and the SAP. To assess and manage the risks associated with using psychedelics please read the information provided in the links carefully, seek supervision and training from those who offer appropriate services.

Any RCC choosing to engage in the practice of Psychedelic-assisted therapy need to be sure that they comply with the BCACC's Standards of Clinical Practice and Code of Ethical Conduct and their regulatory college if they are also part of a regulated college.

Guidelines for use of Psychedelics through the Special Access Program

Purpose

Health Canada recognizes the growing interest in the use of psychedelic-assisted psychotherapy and the possible psychological and physical risks to patients associated with this type of therapy. This notice outlines the information that healthcare practitioners need to know when applying for access to psychedelic drugs through Health Canada's Special Access Program (SAP) for psychedelic-assisted psychotherapy.

Background

The information in this notice is relevant to all SAP requests involving drugs for psychedelic-assisted psychotherapy. Currently, the psychedelic drugs most frequently being used in psychedelic-assisted psychotherapy are psilocybin (one of the active ingredients found in "magic mushrooms") and MDMA ("ecstasy"). Psychedelic drugs produce an altered state of consciousness that can last for hours and may affect the emotional state of patients. ***For this reason, the setting in which the drug is administered can play a key role in reducing the psychological risk associated with the use of the drug. Thus, the environment should be psychologically safe during the acute drug effects.***

Psychedelic drugs are subject to the Food and Drugs Act (FDA) and its regulations, and most are also controlled under the Controlled Drugs and Substances Act (CDSA). Legally, to conduct activities with psychedelic-controlled substances in Canada, healthcare practitioners need appropriate authorizations from Health Canada under both the FDA and the CDSA. Regulatory amendments to the Food and Drug Regulations (FDR) made it possible for healthcare practitioners to request access to restricted drugs through the SAP as of January 2022. ***Psilocybin and MDMA are both classified as restricted drugs****.*

The decision to authorize a drug through the SAP, whether it is a psychedelic drug or any other class of drug, is based on sufficient evidence to support the requested use, including the drug information available to the SAP at the time of the request, as well as evidence of how it would benefit the patient based on their clinical history. SAP reviews requests on a case-by-case basis, and if authorized, the drug sale is considered exempt from FDR. An authorization from the SAP is not a broad statement or opinion that the drug is safe, efficacious, or of high quality; instead, it is a justifiable sale in the context of a medical emergency. Furthermore, the SAP is not intended to:

- *promote or encourage the early use of drugs.*
- *conduct research.*
- *bypass the clinical trial or drug review process.*

SAP authorizations and CDSA exemptions

If a restricted drug is authorized for sale through the SAP, parties (for example, practitioners, nurses, pharmacists, etc.) need an exemption under subsection 56(1) of the CDSA to legally conduct activities (for example, possession, transportation, etc.) with the restricted drug.

Health Canada has issued a class exemption to cover some types of potential SAP authorizations for psilocybin and MDMA, thereby avoiding the need for individual exemptions. The class exemption does not guarantee that a request will be authorized through SAP, as all requests are assessed case-by-case. If an SAP authorization for a restricted drug is granted and it is covered by the class exemption, anyone conducting activities related to the authorization must adhere to the terms and conditions set out in the

class exemption (for example, record keeping and security). Please note that the class exemption prohibits patients from possessing or transporting restricted drugs. The drugs must be used in the presence of the practitioner or the health care professional to whom the practitioner has delegated this activity. Parties will require an individual exemption if the class exemption does not cover SAP authorization for a restricted drug.

For more information on the process for submitting a request to the SAP and the practitioner's reporting requirements, please consult the guidance document Special Access Program for drugs: Guidance document for industry and practitioners.

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Links

- *Special Access Program for drugs: Guidance document for industry and practitioners*
- class exemption
- individual exemption
- Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications
- Notice to Stakeholders: Considerations regarding the proposed use of psilocybin mushrooms in clinical trials, or as a drug accessed through the Special Access Program (SAP)
- Notice to Stakeholders – Clarification of Requirements under the Food and Drug Regulations and the Controlled Drugs and Substances Act When Conducting Clinical Research with Psilocybin
- MDMA
- Psilocybin and psilocin (Magic Mushrooms)
- Professional Practice Guidelines for Psychedelic-Assisted Therapy Aug 2023 (brainfutures.org)
- sap-drugs-guid-ld-eng.pdf (canada.ca)
- PowerPoint Presentation (ubcm.ca)
- recent-updates-in-the-canadian-psychedelics-landscape.pdf
- Psychedelics - FAQs | CAMH
- 2023-psychedelics-forum-report.pdf (cpha.ca)
- Psychedelic-Assisted Psychotherapy Practices and Human Caring Science: Toward a Care-Informed Model of Treatment (watsoncaringscience.org)