



Psychedelic Drug Treatment Services Standards

Mental Health Services Protection Regulation

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About these standards

The Psychedelic Drug Treatment Services Standards (“Standards”) are made pursuant to the *Mental Health Services Protection Regulation* (“Regulation”) under the *Mental Health Services Protection Act* (“Act”). The Standards, along with the Act and the Regulation, set the minimum requirements that a licensed psychedelic drug treatment services provider must comply with in the provision of psychedelic drug treatment services.

The Act and the Regulation define certain terms used in regulating psychedelic drug treatment services. For example, the Act defines “employee” and the Regulation defines “drug” and “designated psychedelic drug”. Where defined terms have been set out in the Act or the Regulation, they may be used but not defined in these Standards. These Standards do define new terms and these are set out in section 1 of these Standards.

Definitions

1 In these Standards,

- (a) “Crown fiscal year” is a period of one year beginning on April 1 through to the following March 31;
- (b) “patient” means an individual who receives or has requested to receive psychedelic drug treatment services from a service provider;
- (c) “person” includes a self-employed individual, corporation other than a professional corporation, professional corporation or partnership;
- (d) “personnel” includes an employee and any other person engaged by a service provider to provide psychedelic drug treatment services;
- (e) “service agreement” means the service agreement in the form determined by the service provider and containing the content as required in section 7 of these Standards;
- (f) “service provider” in these Standards means a licensed psychedelic drug treatment services provider.

Eligibility criteria

2 A patient is eligible for psychedelic drug treatment services if

- (a) the prescribing authorized regulated member has determined that the psychedelic drug treatment services are in the patient’s best interests, and
- (b) the patient has capacity to consent to the psychedelic drug treatment services.

Patient assessment

3(1) The medical director of a service provider shall ensure that a patient undergoes a complete psychiatric and medical assessment prior to receiving psychedelic drug treatment services.

(2) The complete psychiatric and medical assessment required by subsection (1) shall include a comprehensive patient drug history, including past prescription and non-prescription drug or other substance use.

(3) A psychiatrist who is an employee of the service provider, or is otherwise engaged by the service provider to provide psychedelic drug treatment services, shall direct and be responsible for the psychiatric and medical assessment of a patient as required in subsections (1) and (2).

Patient consent requirements

4 As part of the process of obtaining consent from a patient, a service provider shall ensure that the consent process includes the following:

- (a) information about the treatment including
 - (i) whether the treatment includes therapeutic touch and, if so, an explanation of the use of such,
 - (ii) the experimental nature of the treatment,
 - (iii) the potential benefits of the treatment and all risks of the treatment, and
 - (iv) the evidence respecting the potential benefits and risks of the treatment;
- (b) information on reasonable alternatives to the psychedelic drug treatment services for the patient and the relative benefits and risks;

- (c) full, frank and timely disclosure of any real, potential or perceived conflict of interest of the service provider, or any authorized regulated member providing services on behalf of the service provider and responsible to obtain consent, respecting the decision to recommend psychedelic drug treatment services as opposed to other conventional treatments.

Standard of care respecting consent

5 The legal standard of care respecting obtaining consent from a patient under section 4 of these Standards is no lower than what the law otherwise requires, and includes the duty to provide information to the standard of care expected of a competent authorized regulated member, regardless of the actual knowledge, abilities or competence of any individual authorized regulated member who obtains consent from a patient for psychedelic drug treatment services.

Consent for collection of health information using a device and patient right of access to a recording

6(1) Where a service provider, or any personnel of a service provider, uses a device to collect health information, including a device to monitor or record treatment provided to a patient, consent for this collection of health information shall be obtained from the patient in accordance with legal requirements, including section 23 of the *Health Information Act*.

(2) A patient has a right of access to any record created using a device to monitor or record treatment provided to the patient that is in the custody or control of the service provider in accordance with the *Health Information Act*.

Service agreement content requirements

7(1) The service agreement that shall be used by the service provider shall contain the requirement to obtain a legally valid consent to the proposed treatment, including the requirement to comply with the consent requirements as set out in sections 4 and 6 of these Standards.

(2) The service provider may add additional content to the service agreement, so long as the additional content does not conflict with the content required under subsection (1), and may determine the form of the service agreement.

Initiation of service provision

8 A patient may begin to receive psychedelic drug treatment services when

- (a) the patient's eligibility to receive psychedelic drug treatment services has been determined or confirmed by the service provider in accordance with the eligibility criteria in section 2 of these Standards,
- (b) a complete psychiatric and medical assessment has been completed as required in section 3 of these Standards,
- (c) consent to initiate treatment as required under sections 4 and 6 of these Standards has been obtained, and
- (d) a service agreement that meets the requirements of section 7 of these Standards has been signed by the patient and a person authorized by the service provider to sign on behalf of the service provider.

Duty respecting administration of designated psychedelic drugs to end of life patients

9 A medical director shall ensure there are processes in place for the appropriate administration of designated psychedelic drugs to patients at or near the end of life in settings outside of the facility or other location at which psychedelic drug treatment services are provided.

Duties respecting monitoring, treatment and care of patients

10(1) The monitoring required under section 37(5) of the Regulation shall be continuous monitoring of a patient.

(2) A medical director shall determine appropriate monitoring, treatment and care requirements and ensure that the monitoring, treatment and care of a patient as required under subsection (1) and section 37(5) of the Regulation is conducted in an appropriate manner.

Duty respecting supervision of individuals

11 A medical director shall ensure that there are processes in place to determine and ensure the appropriate supervision of an individual monitoring, treating or caring for a patient as required under section 37(6) of the Regulation.

Additional duties of the medical director

12 The medical director is responsible for and shall:

- (a) ensure that quality psychedelic drug treatment services are provided;
- (b) ensure that assessments, including examinations and diagnostic procedures, and treatment provided are clinically indicated and appropriate;
- (c) ensure that sufficient numbers and types of appropriately qualified and trained personnel are engaged to provide the psychedelic drug treatment services;
- (d) provide effective direction and supervision of all persons engaged to provide psychedelic drug treatment services, ensuring compliance with applicable legislation, standards of practice, and the policies and procedures of the service provider;
- (e) ensure that all personnel who are responsible to obtain patient consent are aware of and qualified to provide patients with information as required by law respecting conventional treatments;
- (f) ensure that patient records, whether physical or electronic, are accurate, available and retained securely and in accordance with applicable legislation;
- (g) ensure that an effective program of quality assurance and quality management is in place respecting the psychedelic drug treatment services;
- (h) ensure that effective and appropriate safety and emergency preparedness procedures are in place to provide for the safety of all patients, personnel and visitors to the facility or other location where psychedelic drug treatment services are provided;
- (i) ensure that designated psychedelic drugs are appropriately procured, received, stored, secured, handled and disposed of;
- (j) review and approve all policies and procedures of the service provider and ensure that all such policies and procedures are appropriate and support the provision of quality psychedelic drug treatment services in each facility or other location where psychedelic drug treatment services are provided;
- (k) create or adopt any additional clinically related policies, procedures or clinical practice guidelines to support the provision of quality psychedelic drug treatment services in each facility or other location where psychedelic drug treatment services are provided.

Policies and procedures required

13 A service provider shall ensure that written policies and procedures are established, implemented and periodically reviewed respecting the following:

- (a) patient assessment;
- (b) consent;
- (c) use of designated psychedelic drugs;
- (d) administration of designated psychedelic drugs to patients at or near the end of life;
- (e) monitoring, treatment and care of patients;
- (f) patient safety;
- (g) safety and emergency preparedness respecting patients, personnel and visitors to the facility or other location where psychedelic drug treatment services are provided, including incident and critical incident prevention and response;
- (h) duty to report abuse of patient;
- (i) medication storage, security and handling;
- (j) quality assurance and quality management;
- (k) criminal record checks, vulnerable sector searches and ongoing employee duty to disclose criminal charges or convictions;
- (l) any other matter necessary to facilitate the provision of quality psychedelic drug treatment services in accordance with the Act, Regulation and these Standards.

Patient assessment policy and procedure

14 A service provider shall have a patient assessment policy and a patient assessment procedure setting out how to assess patients referred or otherwise presenting for psychedelic drug treatment services.

Use of designated psychedelic drugs policy and procedure

15 A service provider shall have a use of designated psychedelic drugs policy and procedure that addresses the appropriate use of designated psychedelic drugs, and any contraindications of such use, for the treatment of psychiatric disorders.

Patient safety policy and procedure

16 A service provider shall have a patient safety policy and procedure that addresses patient safety during the provision of psychedelic drug treatment services, including matters respecting safe discharge of patients following each treatment procedure.

Patient safety procedure respecting risk counselling

17 A patient safety procedure respecting discharge of patients shall include how patients must be counselled and informed respecting risks of the after-effects of the administration of designated psychedelic drugs.

Duty to report abuse of patient policy and procedure

18 A service provider shall have a duty to report abuse of a patient policy and procedure that includes:

- (a) a duty of a personnel member of the service provider who has reasonable grounds to believe that a personnel member of the service provider has abused a patient during the provision of psychedelic drug treatment services to report information respecting this belief to the service provider;
- (b) a process by which a personnel member of the service provider who has a reasonable belief as set out in subsection (a) must report this to the service provider;
- (c) a process for the receipt and handling of a complaint by a patient, or a person acting on behalf of a patient, respecting alleged abuse of the patient by personnel of the service provider during the provision of psychedelic drug treatment services;
- (d) a process to determine when such information received by the service provider under subsections (b) or (c) may or must be reported to external persons, including a college under the *Health Professions Act* or a police service;
- (e) a duty to inform patients of this policy and procedure, including information respecting how a patient may make a complaint to the service provider;
- (f) a duty to provide patients with information respecting options for reporting of abuse to persons other than the service provider.

Medication storage, security and handling policy and procedure

19 A service provider shall have a medication storage, security and handling policy and procedure that prescribes access by authorized personnel and sets out how designated psychedelic drugs must be procured, received, stored, secured, prescribed, prepared, handled, used and disposed of.

Quality assurance and management policy and procedure

20 A service provider shall have a quality assurance policy and procedure that establishes the quality assurance and quality management activities that must be conducted and the quality indicators that shall be used to measure patient outcomes.

Criminal record check and vulnerable sector search policy and procedure

21 A service provider shall have a criminal record check and vulnerable sector search policy and procedure that establishes the service provider's policy respecting criminal record checks and vulnerable sector searches and the procedure for requesting and following up further to such requests and any results received.

Duty to ensure employees or other persons comply with legislative requirements, policies and procedures

22(1) A service provider shall enter into a written agreement with a person who the service provider wishes to engage to provide psychedelic drug treatment services, including any part of psychedelic drug treatment services, prior to the person's provision of psychedelic drug treatment services on behalf of the service provider.

(2) The duty of a service provider under subsection (1) applies whether the person engaged by the service provider is an individual or other person, and regardless of whether the person is engaged as an employee, consultant, contractor, volunteer or otherwise.

(3) An agreement entered into under subsection (1) shall require the person engaged by the service provider, regardless of whether the person is also a service provider, to comply with

- (a) all requirements directly or indirectly applicable to employees of the service provider under the Act, Regulation and these Standards,
- (b) any requirements established or direction given by the medical director of the service provider pursuant to the medical director's duties and authorities under the Regulation or these Standards, and
- (c) all policies and procedures of the service provider

as applicable.

(4) A service provider continues to be responsible for compliance with the Act, Regulation and these Standards and must not purport to transfer any responsibilities of the service provider to other persons through agreement or otherwise, including agreements entered into under this section of the Standards.

Training and qualification requirements for personnel

23 A service provider shall ensure that personnel are qualified, or complete training to become qualified, in any matters required by the medical director.

Criminal record check requirements

24(1) A service provider shall require that a criminal record check satisfactory to the service provider that is dated not more than 90 days prior to a written offer of employment or other written proposed offer of engagement from the service provider is provided by the individual who has applied for and been selected to fill an employee position with the service provider or to otherwise be engaged to provide psychedelic drug treatment services on behalf of a service provider.

(2) If an individual, who has applied for and been selected to fill an employee position with the service provider or who has otherwise been engaged by the service provider, has been in a position with the service provider unrelated to psychedelic drug treatment services prior to the written offer of employment or engagement respecting psychedelic drug treatment services, the service provider may require an updated criminal record check satisfactory to the service provider.

Vulnerable sector search requirements

25(1) A service provider shall require that a vulnerable sector search satisfactory to the service provider that is dated not more than 90 days prior to a written offer of employment or engagement from the service provider is provided by the individual who has applied for and been selected to fill an employee position with or be otherwise engaged by the service provider if the individual is offered an employment or other role that would place the individual in a position of trust and authority over patients.

(2) Personnel in a position of trust or authority over patients include any of the following:

- (a) personnel providing medical services;
- (b) personnel administering drugs;
- (c) personnel providing psychedelic assisted psychotherapy;
- (d) personnel providing monitoring or care of patients.

Requirement for on-going disclosure of criminal charges or convictions

26 A service provider shall require all personnel to disclose to the service provider on an ongoing basis any criminal charges or convictions as soon as reasonably possible.

Duty to create and maintain records

27 A service provider shall create and maintain records containing the following:

- (a) in respect of each patient,
 - (i) documentation respecting the assessment and determination of patient eligibility;
 - (ii) documentation of the patient's complete psychiatric and medical assessment;
 - (iii) documentation of the patient's treatment plan and treatment provided;
 - (iv) documentation of the details of the consent process, including rationale for providing the psychedelic drug treatment services rather than conventional treatment, as explained to the patient;

- (v) documentation of any relevant authorization obtained to provide the psychedelic drug treatment services to the patient or to patients more generally, including any authorizations under the *Controlled Drugs and Substances Act* (Canada) or the *Food and Drugs Act* (Canada);
 - (vi) a copy of the service agreement signed by the patient and a person authorized to sign on behalf of the service provider;
- (b) in respect of each employee,
- (i) documentation of information from the employee of any new criminal charges or convictions disclosed by the employee as required under section 25 of these Standards;
- (c) documentation of all reports of abuse of a patient during the provision of psychedelic drug treatment services made by personnel of the service provider to the service provider.

Reporting requirements respecting service utilization

28(1) A service provider's report respecting service utilization shall be submitted to a director every three months, shall apply to each quarter of the Crown fiscal year and shall be submitted to a director on dates to be determined by a director.

(2) The quarterly report respecting service utilization shall only apply to patients who received psychedelic drug treatment services during the time period reported on and shall include the following information, reported in a manner that sets out the information based on services provided at each facility or other location at which the psychedelic drug treatment services are provided:

- (a) total number of patients;
- (b) information respecting the number of visits per patient, including the minimum, maximum, mean and median number of visits per patient;
- (c) number of patients using each type of designated psychedelic drug as listed in section 33(a) of the Regulation;
- (d) names of psychiatric disorders for which patients have been provided with psychedelic drug treatment services and the number of patients who have received psychedelic drug treatment services for each of the named psychiatric disorders;
- (e) number of patient visits for
 - (i) administration of a designated psychedelic drug;
 - (ii) psychedelic assisted psychotherapy;
 - (iii) other purposes, including a description of the other purposes;
- (f) number of patients who, in the opinion of the authorized regulated member prescribing the designated psychedelic drug, were at or near the end of life and to whom a designated psychedelic drug was administered at a place other than a facility or other location at which the service provider is specifically authorized to offer or provide psychedelic drug treatment services as set out in its licence;
- (g) number of patients who were provided with psychedelic assisted psychotherapy as part of the psychedelic drug treatment services.

Reporting requirements respecting complaints received from patients

29(1) A service provider's annual report respecting complaints received from patients, or persons acting on behalf of patients, shall apply to the last Crown fiscal year and shall be submitted to a director within 60 days of the end of the last Crown fiscal year.

(2) A service provider's annual report respecting complaints received from patients, or persons acting on behalf of patients, shall include the following information:

- (a) the number of complaints received;
- (b) the number of complaints as related to the following categories:
 - (i) service delivery;
 - (ii) patient abuse or neglect;
 - (iii) staffing issues;
 - (iv) medical issues, including those related to designated psychedelic drugs;
 - (v) patient safety issues;
 - (vi) state of the facility;
 - (vii) failure to respond to a complaint or, in the complaint's opinion, to address a complaint adequately;
- (c) the number of complaints resolved;
- (d) the number of complaints outstanding.