Preparation Session Standards

Purpose

Preparation sessions establish clinical readiness, safety planning, and informed participation prior to the administration of medical psilocybin.

Preparation sessions serve to:

- Build rapport between the facilitator and the patient to create psychological safety, trust, and openness for therapeutic work.
- Identify therapeutic intentions and goals for administration.
- Assess psychological, emotional, behavioral, and medical readiness for participation.
- Identify strengths, vulnerabilities, and support systems affecting treatment outcomes.
- Determine appropriate **Clinical Support Tier placement**.
- Establish clear expectations regarding program structure, boundaries, and participation.

Preparation also ensures participants understand the psychological, environmental, and experiential aspects of psilocybin administration.

Minimum Preparation Requirements

A participant must complete a minimum of two formal preparation sessions of at least an hour each, with a minimum of three hours total with a trained facilitator prior to administration.

Preparation sessions must:

- Occur **at least 24 hours prior to administration**.
- Occur **no more than 60 days prior to administration**.
- Be conducted by the **facilitator who will be present during administration whenever possible**.
- Be documented in the participant's clinical record prior to administration.

Preparation sessions may be conducted **in person or via telehealth when clinically appropriate**.

Informed Consent

Informed consent must be obtained through a **direct discussion between facilitator and participant**, and may not be satisfied solely by signature on a written form.

Consent discussions must address:

- Risks, benefits, and uncertainties
- Potential psychological effects
- Possible physical effects
- Altered states of consciousness
- Potential impairment of decision-making during administration
- FDA has not evaluated and approved of psilocybin as a treatment

Written disclosures must include:

- Facilitator identity and permit number
- Qualifications and level of training
- Any ceremonial aspects of the session to ensure patient/facilitator alignment
- Participant right to terminate services at any time
- The Facilitator retains the right to terminate the session

Treatment Orientation

Participants must receive an orientation to the treatment process including:

- What medical psilocybin services involve
- The role and scope of the facilitator
- The overall treatment process before, during, and after administration
- Develop an integration plan for post-administration

Participants must discuss:

- Their goals, intentions, and expectations

- Reasons for seeking treatment
- Realistic expectations for outcomes

Set and Setting Preparation

Preparation must include discussion of environmental and psychological factors that may influence the experience.

Topics must include:

- Physical, emotional, and mental readiness
- Lighting, temperature, and physical comfort
- ADA and other accommodation needs
- Music or sensory elements used during sessions
- Privacy and environmental safety of the administration location
- Access to restrooms and comfort areas

Participants must understand how the **environment may influence the experience and safety of administration**.

Safety and Support Planning

Participants and facilitators must collaboratively develop a safety plan that includes:

- Emergency procedures
- Movement within authorized facility spaces
- Fire and environmental safety procedures
- Emergency medical services access

Participants must also develop:

- A **transportation plan** ensuring the participant will not operate a motor vehicle for **24 hours following administration (after dosing).**
- Identification of support persons if needed.
- Planning for post-session support needs.

Boundaries and Participant Protections

Preparation must establish clear expectations regarding boundaries during administration*.

Participants must inform the practitioner/facilitator of:

- Whether physical touch may occur
- What types of touch, if any, are acceptable
- How consent for touch will be communicated (during the administration session)
- How boundaries will be protected during altered states of consciousness

Participants must also inform the practitioner/facilitator if any of the following may occur:

- Presence of a co-facilitator
- Presence of additional support persons
- Audio or video recording of the session

*note, in an emergency, touch may be required, ie, taking vitals, falls, etc...

Reviewed to this point.

Group Preparation

If administration occurs in a group setting:

- At least **one individual preparation session** must occur prior to group participation.

Preparation must include discussion of:

- Total number of participants in the session
- Facilitator-to-participant ratio
- Expectations for participant interaction
- Confidentiality expectations
- Physical contact between participants

Documentation

Facilitators must document completion of preparation sessions in the participant record prior to administration.

Documentation must include:

- Date and format of the preparation session
- Confirmation of informed consent discussion
- Clinical screening results
- Clinical Support Tier placement
- Safety planning completion
- Confirmation that the participant meets eligibility requirements

Timing and Readiness

Preparation should occur close enough to administration to remain clinically relevant while allowing sufficient time for participant reflection and readiness.

Preparation must not be conducted so close to administration that it becomes merely procedural or rushed.