Privileges and Duties of Entheogenic Practitioners [Draft v.9]

DEFINITIONS (OAR 333-XXX-XXX1)

For the purposes of OAR 333-XXX-XXX1 through 333-XXX-XX10:

- (1) "Ceremonial space" means a building, room, yurt, or other structure or part of a structure or outdoor location where a ceremony occurs.
- (2) "Ceremony" means a psilocybin administration session in which entheogenic practitioner privileges are utilized.
- (3) "Entheogenic facilitator" means a person holding a psilocybin services license who has received entheogenic practitioner privileges.
- (4) "Entheogenic manufacturer" means a psilocybin manufacturer that has received entheogenic practitioner privileges.
- (5) "Entheogenic practitioner" means the holder of a facilitator, manufacturer, or service center operator license who is utilizing entheogenic practitioner privileges granted to them by the Oregon Health Authority.
- (6) "Entheogenic practitioner privileges" means the privileges described in 333-XXX-XXX5.
- (7) "Entheogenic service center" means a psilocybin service center that has received entheogenic practitioner privileges.
- (8) "Financial interest" has the same meaning as defined in _____.
- (9) "Indigenous plant medicine community" means one or more indigenous communities who engage in the religious, ceremonial, or sacramental use of psilocybin mushrooms or other plant medicines.
- (10) "Non-directive" has the same meaning as defined in OAR _____.
- (11) "Nonprofit organization" has the same meaning as defined in ORS 65.001(33).
- (12) "Peer support assistance" means assistance provided by one client to another client during a ceremony, including harm reduction assistance.
- (13) "Reciprocal exchange program" means a program that partners with an indigenous plant medicine community for the purpose of:
 - (a) Promoting the preservation or dissemination of indigenous knowledge or wisdom; or
 - (b) Minimizing or reversing the impacts of colonialism, extraction, or cultural appropriation on that community.

Statutory Authority	: B	allot Me	asure	109	(2020),	Section	8(2)(c)
Statutes Implement	ed:	Section	8(2)(2),			

<u>APPLICATION FOR ENTHEOGENIC PRACTITIONER PRIVILEGES</u> (OAR 333-XXX-XXX2)

- (1) The Oregon Health Authority shall grant entheogenic practitioner privileges to an individual or legal entity that:
 - (a) Is or is affiliated with a nonprofit organization that was formed primarily for religious or spiritual purposes;
 - (b) Signs an attestation demonstrating that entheogenic practitioner privileges would advance the good faith practice of a sincerely held belief or conviction;¹
 - (c) Agrees to exercise their entheogenic practitioner privileges in accordance with the applicable special duties described in OAR 333-XXX-XXX4; and
 - (d) Agrees to exercise their entheogenic practitioner privileges in a manner that is not dangerous to the health of clients or others who are in the proximity of the clients.²
- (2) The requirement of (1)(b) does not apply to facilitator who is applying for entheogenic practitioner privileges.
- (3) Notwithstanding (1) of this section, the authority shall be entitled to deny an application for entheogenic practitioner privileges if:
 - (a) The applicant has a history of conduct suggesting the applicant may not be willing or able to act in accordance with the duties described in OAR 333-XXX-XXX4; or
 - (b) The authority has previously suspended or revoked the applicant's entheogenic practitioner privileges.
- (4) Eligibility for entheogenic practitioner privileges is limited only to:
 - (a) Individuals who hold a psilocybin services facilitator's license;

¹ An editorial decision has been made to avoid using the word "religion" throughout these proposed regulations. The primary reason was to avoid potential scrutiny under Oregon's Constitution, which protects "religious believers and nonbelievers alike." *Meltebeke v. Bureau of Lab. & Indus.*, 322 Or 147. The term "entheogenic" was preferred because it includes non-religious spiritual communities who may wish to avail themselves of entheogenic practitioner privileges.

² Compare this language to Oregon's statute that protects religious use of peyote, ORS 475.752:

⁽⁴⁾ It is an affirmative defense in any prosecution under this section for manufacture, possession or delivery of the plant of the genus Lophophora commonly known as peyote that the peyote is being used or is intended for use:

⁽a) In connection with the good faith practice of a religious belief;

⁽b) As directly associated with a religious practice; and

⁽c) In a manner that is not dangerous to the health of the user or others who are in the proximity of the user.

- (b) Nonprofit organizations who hold one or more psilocybin service center operator's license; and
- (c) Nonprofit organizations who hold a psilocybin manufacturer's license.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) Statutes Implemented: Section 8(2)(c), ____

CLIENTS SEEKING PSILOCYBIN SERVICES OR PRODUCTS INVOLVING ENTHEOGENIC PRACTITIONER PRIVILEGES (OAR 333-XXX-XXX3)

In order for a client to receive psilocybin services or products that utilize entheogenic practitioner privileges, the client must:

- (1) Complete a Confidential Information Form and screening procedures and protocols in accordance with established best practices, provided that such intake and screening does not ask a client to disclose particular details of their trauma history;
- Provide informed consent to accept the particular risks associated with the particular entheogenic practitioner privileges being asserted, including if applicable the utilization of peer support assistance, consuming psilocybin products that were produced by an entheogenic manufacturer, and the supervision by a facilitator who is participating or is stationed outside of the ceremonial space;
- (3) Either:
 - (a) Be formally affiliated with an entheogenic service center; or
 - (b) Sign an attestation demonstrating a good faith intention to practice or explore their religion or spirituality;³
- (4) Agree to conduct themselves in a manner that is not dangerous to the health of the client or others who are in the proximity of the client;⁴
- (5) Receive information about the available procedures for filing a complaint with both the entheogenic service center and the Oregon Health Authority; and
- (6) Participate in or donate to a reciprocal exchange program.

Statutory Authority:	Ballot Measure	109 (2020),	Section	8(2)(c)
Statutes Implemented	d: Section 8(2)(c	e),		

SPECIAL DUTIES OF ENTHEOGENIC PRACTITIONERS (OAR 333-XXX-XXX4)

(1) The duties of an entheogenic practitioner include:

³ Compare with ORS 475.752(4)(a).

⁴ This language is borrowed from ORS 475.752(4)(c).

- (a) For an entheogenic facilitator:
 - (A) To remain alert and attentive to client needs when participating in a ceremony;
 - (B) [deleted]
 - (C) To not consume psilocybin products during a ceremony in which the facilitator participates;
 - (D)To remain alert and attentive to client needs when supervising a ceremony from outside the ceremonial space, and to maintain aural, visual, or other methods of being alerted when assistance is needed;
 - (E) To intervene in a ceremony to the extent necessary to enhance, preserve, or restore client safety;
 - (F) To have candid conversations during a preparation session about the possible risks associated with consuming high doses of psilocybin, if the client intends to consume a high dose;
 - (G)To provide clients with written information on how to submit complaints to both the entheogenic service center and to OHA;
 - (H)To conduct themselves and to supervise entheogenic administration sessions in a manner that is not dangerous to the health of the client or others who are in the proximity of the client;⁵
 - (I) To fulfill all other duties ordinarily required of a psilocybin services facilitator except as provided in OAR 333-XXX-XXX5.
- (b) For an entheogenic manufacturer:
 - (A) To provide safe psilocybin products;
 - (B) To store psilocybin products in a reasonable manner;
 - (C) To prevent the diversion of psilocybin products to anywhere other than entheogenic service centers or accredited testing laboratories;
 - (D)To provide the purchaser of its psilocybin products with a written explanation of the information required on standard product labels in accordance with OAR ______, to the extent such information is known by the entheogenic manufacturer;
 - (E) To keep the premises of the entheogenic manufacturer sanitary and free from nuisances as defined by state and local law;
 - (F) To conduct manufacturing and all other activities in a manner that is not dangerous to the health of clients or people who are on or in the proximity of the entheogenic manufacturer premises;⁶
 - (G)The duty to preserve records of manufacturing activities and sales, and provide those to OHA in accordance with OAR ______;

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⁵ Again, this is borrowed from ORS 475.752(4)(c).

⁶ This is borrowed from ORS 475.752(4)(c).

- (H)To participate in or donate to a reciprocal exchange program; and
- (I) To provide to OHA an annual report describing the entheogenic manufacturer's participation in or donations to a reciprocal exchange program.
- (c) For an entheogenic service center operator:
 - (A) To take reasonable steps to ensure that the activities occurring at the entheogenic service center, including ceremonies, are conducted in a manner that is not dangerous to the health of clients or people who are on or in the proximity of the entheogenic service center;⁷
 - (B) To develop and implement policies and procedures for addressing complaints, and to disclose these policies and procedures upon request;
 - (C) To exercise reasonable judgment in the provision of entheogenic facilitation and peer support assistance.
 - (D)To be reasonably involved with the activities of the entheogenic service center;
 - (F) Provide written notice to all facilitators who provide psilocybin services in affiliation with the entheogenic service center that the service center has been granted entheogenic practitioner privileges;
 - (G)To provide periodic reports, no less than once each year, describing the entheogenic service center's participation in or donations to a reciprocal exchange program;
 - (H)To collect information and submit periodic reports, no less than once each year, describing clients' participation in or donations to a reciprocal exchange program, to the extent that the entheogenic service center is involved with such participation or donations;
 - (I) To complete and submit to OHA an incident report upon the occurrence of any of the criteria described in OAR _____. Such report shall include:
 - a. The date and time and a description of the incident;
 - b. The names of any clients who were leading ceremony;
 - c. The names of any clients who were providing peer support assistance in the ceremony;
 - d. The names of the facilitators who were supervising the ceremony; and
 - (J) To fulfill all other duties ordinarily required of a psilocybin services center except as provided in OAR 333-XXX-XXX5.

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⁷ See ORS 475.752(4)(c).

- (2) In addition to the duties described in subsection (1) of this section, entheogenic manufacturers and entheogenic service centers who operate with co-located licensing in a non-segregated manner are subject to the following duties:
 - (a) To keep all public portions of the premises clean, safe, and sanitary;
 - (b) To provide only psilocybin products that are safe and sanitary;
 - (c) To prevent diversion of psilocybin products into the black market;
 - (d) To maintain records of all psilocybin products that are manufactured and sold.
- (3) The system described in subsections (1)(c)(B) of this section may include restorative justice models of conflict resolution, provided that the entheogenic service center makes clear to any complainant or other participant in that system that their participation is voluntary.
- (4) The special duties in this section apply:
 - (a) With respect to entheogenic facilitators, any time the facilitator is providing psilocybin services in affiliation with a psilocybin service center that has entheogenic practitioner privileges; and
 - (b) With respect to an entheogenic service center operator or entheogenic manufacturers, at all times.
- (5) If a psilocybin service center operator is granted entheogenic practitioner privileges at a particular service center and has a financial interest in or affiliation with a psilocybin service center that does not have entheogenic practitioner privileges:
 - (a) The duties described in this section do not apply to service centers that do not have entheogenic practitioner privileges; and
 - (b) The service center operator must take reasonable steps to ensure clients and potential clients are not confused about whether a service center has entheogenic practitioner privileges.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) Statutes Implemented: Section 8(2)(c), ____

PRIVILEGES OF ENTHEOGENIC PRACTITIONERS (OAR 333-XXX-XXX5)

Entheogenic practitioners may enjoy the following privileges:

- (1) For facilitators:
 - (a) To supervise outdoor group ceremonies;
 - (b) To supervise ceremonies in which clients freely engage in spiritual or religious rituals or exercises, provided they are safe;

- (c) To supervise ceremonies that are led by one or more clients who have consumed psilocybin products;
- (d) To supervise ceremonies that meet their facilitator requirements through the application of OAR 333-XXX-XXX6;
- (e) To supervise or assist in the sale and consumption of psilocybin products produced by an entheogenic manufacturer;
- (f) To supervise or assist in the sale of psilocybin products on a flat-fee basis;
- (g) To not be restricted to any particular limit in the amount of psilocybin that a client may use in an individual ceremony;
- (h) To facilitate any number of administration sessions for a client after completing one preparation session;
- (i) To facilitate any number of psilocybin administration sessions for a client who has submitted one completed Client Information Form within the last 12 months;
- (j) To not be limited in the number of preparation or integration sessions to a client who takes psilocybin pursuant to OAR 333-XXX-XXX3(3);
- (k) To actively participate in ceremonies in which the entheogenic facilitator is providing psilocybin services, provided that the entheogenic facilitator does not consume psilocybin products during the ceremony; and
- (1) To supervise ceremonies from outside the ceremonial space, except to the extent required by OAR 333-XXX-XXX4(1)(a)(E).

(2) For manufacturers:

- (a) To store, handle, and discard psilocybin products in a manner in accordance with one's beliefs or convictions, provide that such storage, handling, and discarding are safe;
- (b) To be located at or near a ceremonial space of a service center;9
- (c) To not be restricted in the species of psilocybin-containing mushrooms that may be cultivated;
- (d) To not be restricted in the growing techniques or growing substrates that may be used;
- (e) To offer fresh mushrooms for retail sale;
- (f) To provide psilocybin products to clients free of charge, provided that such giving does not violate M109 Section 114(6)(a);
- (g) To sell or give products on a flat-fee basis; and
- (h) To not have its psilocybin products tested except upon written request by the Authority or upon its own initiative.

(3) For service centers:

⁹ This means allowing "non-segregated" co-located licensing of manufacturing and service centers.

- (a) To host outdoor group ceremonies;
- (b) To host ceremonies in which clients freely engage in spiritual or religious rituals or exercises, provided they are safe;
- (c) To host ceremonies that are led by one or more clients who have consumed psilocybin products;
- (d) To host ceremonies in which entheogenic facilitators supervise the ceremony from outside the ceremonial space, except to the extent required by OAR 333-XXX-XXX4(1)(a)(E);
- (e) To host ceremonies in which entheogenic facilitators participate, provided that the facilitator does not consume psilocybin products during the ceremony;
- (f) To sell or assist in the sale of any amount of psilocybin to a client for use in a particular psilocybin administration session;
- (g) To host ceremonies that meet their facilitator requirements through the application of OAR 333-XXX-XXX6;
- (h) To host any number of psilocybin administration sessions for a client who has completed one preparation session;
- (i) To host psilocybin administration sessions for clients who have submitted only one completed Client Information Form within the prior 12 months;
- (j) To sell or assist in the sale of psilocybin products produced by an entheogenic manufacturer; and
- (k) To sell or assist in the sale of psilocybin products on a flat-fee basis.
- (6) Facilitators who supervise a ceremony from outside the ceremonial space shall be prohibited from using visual, audio, or similar recording or live-streaming technology in supervising a ceremony.
- (7) Entheogenic practitioner privileges are conditional upon the entheogenic practitioner's reasonable and diligent performance of the duties described in this section. Failure to exercise entheogenic practitioner privileges reasonably or diligently shall be grounds for discipline as described in OAR 333-XXX-XXX9.

Statutory Authority:	Ballot Measure	109 (2020),	Section	8(2)(c)
Statutes Implemente	d: Section 8(2)(c	e),		

PEER SUPPORT ASSISTANCE (OAR 333-XXX-XXX6)

- (1) Before a client may provide peer support assistance:
 - (a) The entheogenic service center must:
 - (A) Provide synchronous instruction to the client on how to provide peer-support assistance in accordance with the Facilitator's

- Code of Conduct, the duties described OAR 333-XXX-XXX4, and other generally-accepted best practices;
- (B) Certify upon knowledge that the client is qualified and capable of providing such assistance; and
- (C) Submit to OHA a copy of a document certifying that the client has completed the instructional requirements of this section and, in the entheogenic service center's judgment, is qualified and capable of providing peer-support assistance; and
- (b) The client must sign a declaration agreeing to abide by the Facilitator's Code of Conduct, the duties described OAR 333-XXX-XXX4, and the duties described in subsection (3) of this section.
- (2) Before a client begins receiving the instruction described in subsection (1)(a)(A) of this section, the client must participate in no fewer than [8?] ceremonies at the entheogenic service center from which the client is to receive instruction on peer-support assistance. [Nix this subsection and trust the entheogenic practitioners to self-regulate?]
- (3) A client who provides peer support assistance during a ceremony is obligated to fulfill the following duties:
 - (a) To provide peer-support assistance in accordance with generally-accepted best practices;
 - (b) In situations when the facilitators' supervision occurs from outside of the ceremonial space, to alert the facilitators when additional assistance would be helpful in enhancing, preserving, or restoring client safety or wellbeing;
 - (c) When disagreement arises with a facilitator as to the best manner of promoting client safety or wellbeing, to defer to the facilitator concerning the course of action to be taken; and
 - (d) To remain capable of performing peer-support assistance at all times during the ceremony.
- (4) A client's authority to provide peer-support assistance is limited to entheogenic service centers whose operators have certified upon knowledge that the client is qualified and capable of providing that assistance.
- (5) Entheogenic service centers and entheogenic facilitators that utilize peer-support assistance pursuant to this section shall have discretion to deviate from the generally applicable facilitator-client ratios found at OAR 333-XXX-XXXX. In exercising their discretion pursuant to this subsection, an entheogenic service center or entheogenic facilitators shall consider all relevant factors, including:
 - (a) The operator's and facilitator's familiarity with the clients participating in a ceremony;

- (b) The types of ceremonial activities the group intends to engage in;
- (c) The group and its members' prior experience with psilocybin or other entheogenic plants or psychedelics;
- (d) The amount of cohesion or discord present in the group, if known to the operator or facilitator;
- (e) The relevant experience of the clients who are providing peer-support assistance;
- (f) The relevant experience, skill, and number of entheogenic facilitators who are providing supervision; and
- (g) Any other risk factors that the operator or facilitator knows or should know about.
- (6) Entheogenic service centers that utilize peer-support assistance shall ensure that the ratio of clients who provide peer support assistance to clients who do not provide such assistance is no less than 1:5 in any ceremony. [Probably nix this subsection and trust the entheogenic practitioners to self-regulate.]
- (7) Clients who provide peer-support assistance may not receive compensation for the services. However, clients who provide peer support assistance may receive gifts of nominal monetary value. [nix?]

Statutory Authority:	Ballot Measure 109	(2020), Section	8(2)(c)
Statutes Implemente	d: Section 8(2)(c),		

<u>LIMITATIONS ON ENTHEOGENIC PRACTITIONER PRIVILEGES</u> (OAR 333-XXX-XXX7)

- (1) Entheogenic practitioner privileges may be used or asserted only:
 - (a) At a psilocybin service center or manufacturing premises that has been granted entheogenic practitioner privileges; and
 - (b) In connection with the activity of a spiritual or religious organization with which the entheogenic practitioner is affiliated.
- (2) Psilocybin products produced utilizing entheogenic practitioner privileges may not be sold, transferred, or consumed to or at a service center that does not have entheogenic practitioner privileges.

Statutory Authority:	Ballot Measure 109	(2020),	Section	8(2)(c)
Statutes Implemente	d: Section 8(2)(c),			

RECIPROCAL EXCHANGE PROGRAM DATA (OAR 333-XXX-XXX8)

The Oregon Health Authority shall publish and maintain the reports obtained from entheogenic practitioners concerning their participation in or donations to reciprocal exchange programs.

Statutory A	Authority:	Ballot M	easure	109	(2020),	Section	8(2)(c)
Statutes In	nplemente	d: Sectio	n 8(2)(c),			

DISCIPLINARY PROCEEDINGS (OAR 333-XXX-XXX9)

- (1) The Oregon Health Authority may discipline an individual or organization if it finds by a preponderance of the evidence that the entheogenic practitionef ailed to exercise entheogenic practitioner privileges in a reasonable manner or failed to fulfill the duties under OAR 333-XXX-XXX4 in a reasonable and diligent manner;
- (2) The disciplinary authority of the Oregon Health Authority includes the authority to suspend or revoke entheogenic practitioner privileges in part or in full.
- (3) If the authority revokes or suspends only the entheogenic practitioner privileges of a license holder, but not the whole license, the license holder may continue to work or operate or produce without the use of entheogenic practitioner privileges.
- (4) Nothing in this section shall limit the authority of OHA to discipline a license holder.
- (5) The authority may discipline a facilitator, manufacturer, or service center that utilizes entheogenic practitioner privileges without authorization.

Statutory Authority:	Ballot Measure 109	(2020), Section 8	3(2)(c)
Statutes Implemente	d: Section 8(2)(c),		

MISCELLANEOUS (OAR 333-XXX-XXX10)

- (1) If a city or county adopts local land use or zoning ordinances concerning psilocybin licensees, such city or county must conform with the Religious Land Use and Institutionalized Persons Act (42 U.S.C. 2000cc et seq.) in the terms and application of such ordinances.
- (2) When assessing the fees required by Ballot Measure 109 (2020), Section 23 (4)(b) and 26(3)(b), the Oregon Health Authority shall enact a progressive fee structure in which nonprofit organizations are assessed a lesser fee amount than other organizations.

Statutory Authority:	Ballot Measure 109	(2020), S	Section	8(2)(c)
Statutes Implemente	d: Section 8(2)(c),			