**Psilocybin Service Center Proposed Rules Draft (July 29th, 2021)**

Note: the word “consumer” was used in the July 28th draft. The Ballot Measure uses “client”. The draft rules were updated to use “client” in place of “consumer” and it was added to the definitions below on July 29th, 2021.

**Definitions:**

1. “Psilocybin service center” means an establishment:
	1. At which administration sessions are held; and
	2. At which other psilocybin services may be provided.
2. “Premises” includes the following areas of a location licensed under sections 3 to 129 of this 2020 Act:
	1. All public and private enclosed areas at the location that are used in the business operated at the location, including offices, kitchens, rest rooms and storerooms;
	2. All areas outside a building that the Oregon Health Authority has specifically licensed for the manufacturing of psilocybin products or the operation of a psilocybin service center; and
	3. For a location that the authority has specifically licensed for the operation of a psilocybin service center outside a building, that portion of the location used to operate the psilocybin service center and provide psilocybin services to clients.

1. “Premises” does not include a primary residence. Should we state other options, e.g. rented office space? A Yurt? A mobile home?
2. “Client” means an individual that is provided psilocybin services in this state.
3. A psilocybin service center is not a health care facility subject to ORS chapter 441. Add: may be located within an existing health care facility.

**Location:**

1. The OHA must ensure that the psilocybin service center is located in an area that is not:
	1. Within the limits of an incorporated city or town; and
	2. Zoned exclusively for residential use except as provided in section 27 of this 2020 Act,
	3. Located within 1,000 feet of:
		1. A public elementary or secondary school for which attendance is compulsory under ORS 339.020; or
		2. A private or parochial elementary or secondary school, teaching children as described in ORS 339.030 (1)(a); and
			1. (f) Must meet the requirements of any rule adopted by the authority under subsection (3) of this section.

* + - 1. Add section re: compatibility with local land use codes
			2. Notwithstanding subsection 2(e) of section 26 of this 2020 Act, a psilocybin service center may be located within 1,000 feet of a school if:
				1. The psilocybin service center is not located within 500 feet of:

A public elementary or secondary school for which attendance is compulsory under ORS 339.020; or

A private or parochial elementary or secondary school, teaching children as described in ORS 339.030 (1)(a); and (2)

* + - * 1. The Oregon Health Authority determines that there is a physical or geographic barrier capable of preventing children from traversing to the premises of the psilocybin service center.
				2. Establishment of school after issuance of license:

If a school described in subsection 2(e) of section 26 of this 2020 Act that has not previously been attended by children is established within 1,000 feet of a premises for which a license has been issued under section 26 of this 2020 Act, the psilocybin service center operator located at that premises may remain at that location unless the Oregon Health Authority revokes the license of the psilocybin service center operator under section 64 of this 2020 Act.

**Physical Environment Requirements**

1. The Center must continue to meet all applicable building and physical environment standards, including but not limited to structural, mechanical, electrical, plumbing, fire and life safety codes that were in effect at the time of licensure, or the standards that applied at the time of a major alteration or new construction as required by this rule.
2. Design: the Center may be an adaptation of a house**.** It must include rooms of adequate size to meet the needs to accomplish the administration of psilocybin and to allow for privacy.
3. A facility must meet applicable codes for ordinary construction and meet ADA accessibility requirements and for water supply and sewage disposal. The building and equipment must be kept clean and in good repair. (Add info re: Yurt/tent mobile unit requirements.) The Center must include:
	1. Kitchen facilities, including a refrigerator for the storage of staff and client’s meals and snacks.
	2. A drinking water source.
		1. A filtered self-dispensing drinking water source shall be provided."
4. **Storage of Psilocybin**: proper and safe storage of psilocybin and maintenance of proper records means housing drugs and devices under conditions and circumstances that:
	1. Assure retention of their purity and potency;
	2. Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;
	3. Assure security and minimize the risk of their loss through accident or theft;
	4. Accurately account for and record their receipt, retention, dispensing, distribution or destruction;
	5. Protect the health, safety and welfare of the facilitator, service center operator or other staff and the general public from harmful exposure to hazardous substances.
5. There shall be an **administrative center** or station. This space shall include provisions for storage of administrative supplies, a worksurface with equipment for documentation, and secure storage of staff personal belongings.
6. **Storage**: Each Center must allow for space for secure private individual storage for the personal effects of each client.
7. **Individual Client rooms** must be designed and equipped for adequate care, comfort, and privacy of the client and shall meet the following conditions:
	1. Measure at least 80 square feet.
	2. Have adequate ventilation. (Define)
	3. Have direct access to an exit or an exit corridor.
	4. Be designed or equipped to assure safety and privacy for each client. Design for privacy shall not restrict patient access to the toilet, room entrance, window, or other shared common areas.
	5. Be furnished with the functional furniture appropriate to the client’s needs, including at least one chair or sofa.
8. **Group Session Rooms** must be designed and equipped for the adequate care and comfort of each client and shall meet the following conditions:
	1. Must not exceed the Fire Code regulations for the number of occupants in the room.
		1. The occupant load shall be assigned by the fire code official in accordance with the anticipated use. The fire code official may require the posting of occupant loads in areas of assembly (OFC 1004)
		2. Approved exit signs are required when two exits are required or when the occupant load exceeds 50 persons.
	2. Have direct access to an exit or exit corridor.
	3. Be furnished with the functional furniture appropriate to the client’s needs, including seating options for each client, as requested by the client.
9. **Plumbing and Sanitary Environment**.
	1. Each client shall have access to a toilet room. One toilet room shall serve no more than four client rooms.
	2. The toilet room shall contain a toilet and a handwash station.
	3. For persons attending a group session:
		1. Provide not less than one unisex toilet room that contains at least one water closet and one lavatory for not more than 30 clients; or
		2. Provide not less than two accessible toilet rooms, one for each sex, that contain at least one water closet and one lavatory for not more than 100 occupants; or
		3. Provide not less than two accessible unisex toilet rooms that contain at least one water closet and one lavatory each for with not more than 100 clients.
	4. Hot water used for hand washing shall have a water temperature between 105 and 120 degrees Fahrenheit.
	5. If not required by other sections, hand sanitation dispensers shall be permitted to be used in lieu of hand-washing stations.
10. **Sanitary Precautions**
	1. Provisions shall be made for the proper cleaning of linen and other washable goods and proper disposal of all refuse.
	2. All garbage and refuse shall be stored and disposed of in a manner that will not create a nuisance or a public health hazard. Infectious waste shall be stored and disposed of in accordance with OAR chapter 333, division 56.
	3. Measures shall be taken to prevent the entry of rodents, flies, mosquitoes, and other insects. Adequate measures shall include but are not limited to preventing their entry through doors, windows, or other outside opening.
	4. The walls and floors shall be of a durable and cleanable composition necessary to maintain a sanitary environment appropriate to the use of the area. The building shall be kept clean and in good repair.
	5. A service center shall develop and enforce policies and procedures related to cleaning, disinfection or disposal of:
		1. Client items;
		2. Equipment used for individual clients
		3. Furnishings; and
		4. The immediate environment.
11. **Facility Safety and Emergency Preparedness**
	1. The physical environment in which psilocybin services are furnished must afford and maintain a functional, clean, sanitary, safe, and comfortable setting for patients, staff, and the public.
		1. **Smoking/Vaping Prohibition:** In accordance with the Clean Indoor Air Act, the service center owner or facilitator may not permit a person to smoke or vape in the facility or within 10 feet of a doorway, open window or ventilation intake of the center
	2. Fire and Safety — State and local fire and life-safety codes apply with specific attention to demonstration of adequate ingress and egress of occupants, placement of smoke alarms, emergency lighting, fire extinguishers or sprinkler systems, fire escape routes, and fire reporting plans. The Center must have an emergency plan in effect on premises available to all staff. There must be evidence of an annual fire inspection.
	3. All interior and exterior materials and surfaces and all equipment necessary for the health, safety and comfort of clients shall be kept clean and in good repair. Examples include, but are not limited to: floors, walls, roofs, ceiling, windows, furnishings and equipment;
	4. Floor surfaces shall be relatively level and free of tripping hazards.
	5. All premises shall be maintained in good condition with sound structural integrity; and
	6. The facility shall be in compliance with local codes, laws and ordinances.
	7. A Service Center shall have telephone or another reliable communication method to summon help in case of fire or other emergency.
	8. The emergency plan shall address the availability of sufficient supplies for staff and clients to shelter in place or evacuate to an agreed upon alternative location for a minimum of two days, in coordination with local emergency management, under the following conditions:
		1. Extended power outage;
		2. No running water;
		3. Replacement of food or supplies is unavailable;
		4. Staff members do not report to work as scheduled; and
		5. The client is unable to return to their previous setting.
		6. There must be evidence of an annual emergency drill which may be table-top exercise. (Check OSHA/adult foster home language for suggested language.)
		7. All employees shall be trained in the emergency plan.
12. **Outdoor Spaces**:
	1. Outdoor spaces may be provided for clients and staff. The design and use of outdoor activity spaces shall be described in the plan for the premises.
	2. If a tent is used, exit signs are required in tents requiring two or more exits (i.e. when the occupant load exceeds 50 persons.)
	3. Have a physical plant and overall facility environment that is developed and maintained in such a manner that the safety and well-being of clients are provided for.
	4. (? Add more language about requirements for the use of Outdoor spaces for individual or group sessions. E.g. walkways, paths, fencing, signage, access to toilet facilities, etc.)
13. **Signage:**
	1. A licensee must post:
		1. Proof of licensure in a prominent place on the premises.
		2. A client’s Bill of Rights
		3. At every licensed premises signs that read: “No Minors Permitted Anywhere on This Premises”; and
		4. At all areas of ingress or egress to a limited access area a sign that reads: “Do Not Enter – Limited Access Area – Access Limited to Licensed Personnel and Escorted Visitors.”
	2. All signs required by this rule must be:
		1. Legible, not less than 12 inches wide and 12 inches long, composed of letters not less than one-half inch in height;
		2. In English and Spanish; and
		3. Posted in a conspicuous location where the signs can be easily read by individuals on the licensed premises.
14. **Security Requirements**
	1. A licensee is responsible for the security of all psilocybin items on the licensed premises or in transit, including providing adequate safeguards against theft or diversion of psilocybin items and records that are required to be kept.
	2. The licensee must ensure that commercial grade, non-residential door locks are installed on every external door, and gate if applicable, of a licensed premises where psilocybin items are present.
	3. During all hours when the licensee is not operating a licensee must ensure that:
	4. All points of ingress and egress from a licensed premises are securely locked and any keys or key codes to the enclosed area remain in the possession of the licensee, licensee representative, or authorized personnel;
	5. All psilocybin products on the licensed premises of service center are kept in a locked, enclosed area within the licensed premises that is secured with at a minimum, a properly installed steel door with a steel frame, and a commercial grade, non-residential door lock; and
	6. All psilocybin items on a service center’s premises are kept in a locked, secured location or enclosure within any area such that psilocybin items are not visible from any area outside the licensed premises.
	7. A licensee must:
		1. Have an electronic back-up system for all electronic records; and
		2. Keep all video recordings and archived required records not stored electronically in a locked storage area. Current records may be kept in a locked cupboard or desk outside the locked storage area during hours when the licensed business is open.
15. **Alarm System**
	1. A licensed premises must have a fully operational security alarm system, activated at all times when the licensed premises is closed for business.
	2. The security alarm system for the licensed premises must:
		1. Be able to detect unauthorized entry onto the licensed premises and unauthorized activity within any limited access area where mature psilocybin plants, usable psilocybin, cannabinoid concentrates, extracts or products are present;
		2. Be programmed to notify a the licensee, licensee representative or authorized personnel in the event of an unauthorized entry; and
		3. Have a mechanism to ensure that the licensee, licensee’s employees and authorized representatives can immediately notify law enforcement or a security company of any unauthorized entry. This subsection may be satisfied in one of the following ways:
			1. Having at least two operational "panic buttons" located inside the licensed premises that are linked with the alarm system that immediately notifies a security company or law enforcement; or
			2. Having operational “panic buttons” physically carried by all licensee representatives present on the licensed premises that are linked with the alarm system that immediately notifies a security company or law enforcement; or
			3. Having a landline telephone present in all limited access areas that is capable of immediately calling a security company or law enforcement.
	3. A licensee that has at least one authorized representative physically present on the licensed premises at all times when it is closed for business is not required to comply with section (1) and sections (2)(a) and (b) of this rule.
	4. Upon request, licensees shall make all information related to security alarm systems, monitoring and alarm activity available to the Oregon Health Authority.
	5. Upon request, licensees shall make all information related to security alarm systems, monitoring and alarm activity available to the Oregon Health Authority.
16. **Video Surveillance Equipment**
	1. A licensed premises must have a fully operational exterior video surveillance recording system.
	2. Video surveillance equipment must, at a minimum:
		1. Consist of:
			1. Digital or network video recorders;
			2. Cameras capable of meeting the requirements of OAR 845-025-1450 and this rule;
			3. Video monitors;
			4. Digital archiving devices;
			5. A minimum of one monitor on premises capable of viewing video; and
			6. Interface devices, if required to adequately operate system or machinery such as a mouse and keyboard.
	3. Have the capability of producing and printing a still photograph from any camera image;
	4. Be equipped with a failure notification system that provides, within one hour, notification to an authorized representative of any prolonged surveillance interruption or failure; and
	5. Have sufficient battery backup to support a minimum of one hour of recording time in the event of a power outage.
	6. Except for mounted cameras and monitors, all video surveillance equipment and recordings must be stored in a locked secure area that is accessible only to authorized personnel, The Oregon Health Authority employees and contractors, and other state or local government officials that have jurisdiction over some aspect of the licensed premises or licensee.
17. **Required Camera Coverage and Camera Placement**
	1. A licensed premises must have camera coverage, as applicable, for:
		1. All points of ingress and egress to and from the licensed premises;
		2. All limited access areas as that term is defined in OAR [**\_\_\_-\_\_\_-\_\_\_**](https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=213409);
		3. All client sales areas;
		4. All points of ingress and egress to or from limited access areas;
		5. The surveillance room or surveillance area as defined in [**\_\_\_-\_\_\_-\_\_\_**](https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=213409);
		6. Any other area that the Oregon Health Authority believes presents a public safety risk based on the overall operation and characteristics of the licensed premises; and
		7. All areas where psilocybin waste is required to be stored, destroyed or rendered unusable as required by OAR [**\_\_\_-\_\_\_-\_\_\_**](https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=213409).
	2. A licensee must ensure that cameras are placed so that they capture clear and certain images of any individual and activity occurring:
		1. Within 15 feet both inside and outside of all points of ingress and egress to and from the licensed premises; and
		2. In all locations within limited access areas, and client sales areas on the licensed premises.
	3. Failure to comply with subsection (1)(a) through (e) of this rule is a Category I violation and may result in license revocation.
	4. Failure to comply with subsection \_\_\_\_\_ of this rule is a Category III violation.
18. **Video Recording Requirements for Licensed Facilities**
	1. A licensee must have cameras that continuously record, 24 hours a day:
		1. In all areas where mature psilocybin plants, immature psilocybin plants, usable psilocybin, cannabinoid concentrates, extracts, products or waste may be present on the licensed premises; and
		2. All points of ingress and egress to and from areas where mature psilocybin plants, immature psilocybin plants, usable psilocybin, cannabinoid concentrates, extracts, products or waste may be present.
	2. A licensee must:
		1. In all areas where camera coverage is required, use cameras that record at a minimum resolution of 1280 x 720 px and record at 10 fps (frames per second);
		2. Use cameras that are capable of recording in all lighting conditions;
		3. Have and keep surveillance recordings for a minimum of 90 calendar days;
		4. Have and keep off-site backup recordings described in (2)(k) of this rule for a minimum of 30 days;
		5. Maintain surveillance recordings in a format approved by the Oregon Health Authority that can be easily accessed for viewing and easily reproduced;
		6. Upon request of the Oregon Health Authority, keep surveillance recordings for periods exceeding the retention period specified in section (2)(c) of this rule;
		7. Have the date and time embedded on all surveillance recordings without significantly obscuring the picture;
		8. Archive video recordings in a format that ensures authentication of the recording as a legitimately-captured video and guarantees that no alterations of the recorded image has taken place;
		9. Make video surveillance records and recordings available immediately upon request to the The Oregon Health Authority in a format specified by the Oregon Health Authority for the purpose of ensuring compliance with ORS Chapter 475B and these rules;
		10. Within 48 hours notify the Oregon Health Authority of any equipment failure or system outage lasting 30 minutes or more; and
		11. Back up the video surveillance recordings off-site and in real time for the surveillance room or surveillance area.
	3. Notwithstanding the requirements in section (1) of this rule a licensee or laboratory licensee may stop recording in areas where psilocybin items are not present due to seasonal closures or prolonged periods of inactivity.
	4. At least 24 hours before stopping recording, a licensee or laboratory licensee must submit written notice to the Oregon Health Authority by email using a designated form as published by the Oregon Health Authority on its website and the notice must include:
		1. A copy of the licensee’s plot plan or diagram as described in OAR 845-025-1030 showing which cameras will be deactivated, the total number of cameras that will be deactivated, and a description or list of areas or applicable labels of the deactivated cameras.
		2. The date and time recording will stop.
		3. An explanation for why recording will be stopped.
		4. The date and time recording will resume.
	5. A licensee or laboratory licensee:
		1. May not stop the recording or continuous real time back up of the recording for a surveillance area unless all other cameras on the licensed premises are shut down under this rule.
		2. Must resume all required recording no later than the date and time specified in the notice submitted under subsection (a) of this section.
		3. May not engage in any licensed privileges in any areas where recording was stopped under this section.
	6. Failure to comply with subsections (2)(e), (g) or (h) of this rule is a Category I violation and may result in license revocation.
	7. Failure to comply with subsections (1)(a), (b) or (2)(f), or (i) of this rule is a Category II violation.
	8. Failure to comply with subsection (2)(a), (b), (d), (j), or (k) is a Category III violation.
	9. Failure to comply with subsection (2)(c) of this rule is:
		1. For the first violation in a two-year period:
			1. A Category I violation if the licensee maintained surveillance recordings for 7 days or less;
			2. A Category II violation if the licensee maintained surveillance recordings for more than 7 days but less than 30 days; or¶
			3. A Category III violation if the licensee maintained surveillance recordings for more than 30 days but less than 90 days.
			4. A Category I violation for any subsequent violation in a two-year period.
	10. A licensee may not engage in any privileges of the license in an area that does not have camera coverage as described in OAR [**\_\_\_-\_\_\_-\_\_\_**](https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=213409) and [**\_\_\_-\_\_\_-\_\_\_**](https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=213409) or in an area where camera coverage has been stopped pursuant to section (3) of this rule, including but not limited to possessing, storing, cultivating, transporting, transferring, or receiving psilocybin items.
19. **Location and Maintenance of Surveillance Equipment**
	1. A licensee must:
		1. Have the surveillance room or surveillance area in a limited access area; and
		2. Have the surveillance recording equipment housed in a designated, locked, and secured room or other enclosure with access limited to:
			1. The licensee, licensee representatives, and authorized personnel;
			2. Employees of the Oregon Health Authority;
			3. State or local law enforcement agencies for a purpose authorized under ORS Chapter 475B, these rules, or for any other state or local law enforcement purpose; and
			4. Service personnel or contractors.
	2. Off-site storage must be secure and the recordings must be kept in a format approved by the Oregon Health Authority that can be easily accessed for viewing and easily reproduced.
	3. A licensee must keep a current list of all authorized employees and service personnel who have access to the surveillance system and room on the licensed premises.
	4. Licensees must keep a surveillance equipment maintenance activity log on the licensed premises to record all service activity including the identity of any individual performing the service, the service date and time and the reason for service to the surveillance system.
	5. Off-site monitoring of the licensed premises by a licensee or an independent third-party is authorized as long as standards exercised at the remote location meet or exceed all standards for on-site monitoring.
20. **Changing, Altering, or Modifying Licensed Premises**
	1. The Authority issues licenses with the expectation that the licensee will operate the business as proposed at the time of licensing. A licensee may not make any physical changes to the licensed premises that materially or substantially alter the licensed premises or the usage of the licensed premises from the plans originally approved by the Authority without the Authority’s prior written approval.
	2. A licensee who intends to make any material or substantial changes to the licensed premises must submit a form prescribed by the Authority, and submit any information identified in the form to be submitted, to the Authority, prior to making any such changes.
	3. The Authority must review the form and other information submitted under subsection (2) of this rule, and will approve the changes if the changes would not result in an initial or renewal application denial under OAR \_\_\_\_\_\_\_\_\_\_.
	4. If the Authority denies the change the licensee must not make the proposed changes. If the licensee makes the proposed changes, the licensee must surrender the license or the Authority will propose to suspend or revoke the license.
	5. If the Authority approves the change, the Authority may require a site inspection of the changed area and a modification of the licensee’s security plan prior to the licensee exercising any license privileges.
	6. For purposes of this rule a material or substantial change requiring approval includes, but is not limited to:
		1. Any increase or decrease in the total physical size or capacity of the licensed premises;
		2. The sealing off, creation of or relocation of a common entryway, doorway, passage or other such means of public ingress or egress, when such common entryway, doorway or passage alters or changes limited access areas, such as the areas in which administration of psilocybin occurs within the licensed premises;
		3. Any physical change that would require the installation of additional video surveillance cameras or a change in the security system; or
		4. Any addition or change of location of a primary residence located on the same tax lot as a licensed premises.

References:

* Chapter 676 — Health Professions Generally 2019 EDITION: <https://www.oregonlegislature.gov/bills_laws/ors/ors676.html>
* Health Licensing Office OREGON REVISED STATUTES (UNOFFICIAL COPY) CHAPTER 676.560 – 625 & 676.992 2019 EDITION <https://www.oregon.gov/oha/PH/HLO/Laws/HLO_Statutes.pdf>
* Division 71 SICF OARs: <https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1280>
* Division 76 ASC and ESC OARs: (Includes Birthing Centers) <https://secure.sos.state.or.us/oard/displayDivisionRules.action;JSESSIONID_OARD=cCSXrSINs4_qJnvesVud56IeQjQJ1IH5lqLaA8COltAg3eF9vQAW!-348175955?selectedDivision=1285>
* Division 700 Licensing Standards for Outpatient Renal Dialysis Centers <https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1397>
* OREGON FIRE CODE Interpretations and Technical Advisories <https://www.oregon.gov/osp/Docs/TA15-01.pdf>
* Minimum Number of Toilet Room Plumbing Fixtures in Small Drinking and Dining Establishments <https://www.portland.gov/sites/default/files/2020/web-ibc29-1-122314-minimum-number-of-plumbing-fixtures-in-small-bars-taverns-and-restaurants_hd.pdf>
* 2019 Oregon Structural Specialty Code (OSSC) <https://up.codes/viewer/oregon/ibc-2018>

<https://up.codes/viewer/oregon/ibc-2018/chapter/29/plumbing-systems#29>

Respectfully submitted on July 28th, 2021

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