

DATE: December 27, 2022

TO: Hearing Attendees and Commenters –
Oregon Administrative Rules chapter 333, division 333
Oregon Psilocybin Services Rules

FROM: Brittany Hall, Hearing Officer

SUBJECT: Presiding Hearing Officer’s Report on Rulemaking Hearings and Public
Comment Period

Hearing Officer Report

Date of hearings: November 15, 2022, November 16, 2022, and November 17, 2022, via Zoom

Purpose of hearings and public comment period: To receive testimony and comments regarding the Oregon Health Authority (OHA), Public Health Division's proposed permanent adoption of Oregon Administrative Rules in chapter 333, division 333 related to Oregon Psilocybin Services.

The Oregon Health Authority, Oregon Psilocybin Services (OPS) section is proposing to adopt administrative rules in chapter 333, division 333. The proposed rules implement ORS chapter 475A, the Oregon Psilocybin Services Act (“the Act”). The Act creates a first of its kind regulatory framework for licensed production of psilocybin products and sale of psilocybin products and services to clients. The rules address all aspects of this framework and support the Act’s goals of promoting access and equity while protecting health and safety. The rules are necessary to implement the Act which requires that they must be adopted by January 1, 2023. The rules address a variety of subject matter including requirements for licensure including storage and security, standards for psilocybin products, packaging and labeling requirements, safety standards and guidelines for provision of psilocybin services, client rights and informed consent processes, facilitator duties, compliance, product tracking and transportation.

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Comments and testimony received: In OHA’s Notice of Proposed Rulemaking, OHA announced that individuals could submit written comments by sending them to OHA’s designated email address for receiving such comments, or by fax or mail. In addition, OHA took public testimony at the public hearings that were held on November 15, 2022, November 16, 2022, and November 17, 2022. OHA received oral testimony from 113 speakers at the public hearings (some individuals testified at both hearings) and received many written public comments. OHA staff have considered the written comments and public testimony received prior to the deadline on November 21, 2022, at 5:00 p.m. Pacific Time. OHA thanks all Oregonians who provided public comment and appreciates the varied input they have provided to the rulemaking process.

Themes of the testimony and written comments relevant to the current proposed rules, in no particular order, are summarized below. Copies of audio recordings of the hearings and hearing transcripts are available online at <https://www.oregon.gov/oha/PH/RULESREGULATIONS/Pages/index.aspx>.

OHA received detailed comments in memos from the Oregon Psilocybin Services Collaborative Community (OPSCC) and many comments from individuals stating their support for the information contained in both the original memo from OPSCC and a supplemental memo. OHA also heard from many individuals with comments similar to those described in the memos. These memos and individual comments addressed the following items:

- Lower dose administration sessions (“micro dosing”) – Proposed new category for session duration for extremely low dose sessions involving 2 mg or less and not requiring any session duration minimum after the first session with a client. This will enable service centers to offer safe and effective treatment for returning clients at a much lower cost and enable service centers to meet the needs of clients across the economic spectrum.

OHA also heard concern about allowing a zero-time stay for micro doses and that there be an expectation that all clients will be supervised during administration and assessed before being released, regardless of the dose of psilocybin that is consumed.

Agency response:

ORS 475A does not use the term “micro dose” and the statute is silent regarding minimum doses for psilocybin products. However, the statute does direct the agency to adopt rules related to public health and safety, which includes minimum durations for administration sessions. Many members of the public expressed support for a subperceptual or “micro dose” option to increase access by allowing clients an opportunity to consume small doses of psilocybin at a lower cost. The final rules on duration of administrative sessions have been revised to create a new tier for subperceptual doses. These doses are defined as products containing less than 2.5 mg of psilocybin analyte. After a client’s initial session, the minimum duration for a

subperceptual dose of 2.5 mg or less is 30 minutes. Other rules and requirements designed to support client safety are unchanged for clients consuming subperceptual doses. OPS has made this change in the hope that subperceptual doses will increase access and promote equity by providing clients a lower-cost product and easier access for receiving psilocybin services.

- Allowing Valuable Individuals into Administration Sessions – Request for expansion of the definition of "client support person" in OAR 333-333-1010(17) in order to allow facilitators to include individuals who they believe would enhance the experience and outcomes for clients and to whom the client(s) have consented.

Agency response:

While some comments requested that clients be allowed to include any individual of their choosing in an administration session, other comments and discussion during the RAC suggested that doing so could present a public safety issue or cause unforeseen difficulties for facilitators. Also, unlicensed persons present during an administration session are not subject to a background check. After considering the risks of expanding this provision, the agency chose not to amend the draft rules at this time without more robust discussions about ways to ensure client and facilitator safety.

- License Fees – The proposed license fees do not consider the size of the operation seeking licensure, and the fees for facilitators are excessively high. A tiered fee structure is proposed with larger, more capital-intensive businesses paying more while allowing small businesses to pay less, and facilitators across the board would pay a significantly reduced license fee. Request that indigenous people be included in the list of individuals eligible for additional discounts and adding an additional reduced fee beyond the 50% discount for non-profit organizations exclusively dedicated to serving low-income and disadvantaged communities.

Agency response:

The agency works within the statutory requirements of ORS 475A as well as the requirements of the larger state agency system in Oregon to establish the program budget and license fees. Oregon Psilocybin Services is a fee-based section, which means that the license fees must cover the costs of the section's work. The section is required to demonstrate sustainability in the 2023-2025 budget biennium and going forward through licensing fees. Oregon Psilocybin Services worked within our state agency budgeting process to demonstrate sustainability for three biennia.

Creating a tiered license fee structure is not feasible due to the work required to identify appropriate tiers and evaluate license applications and supporting documentation to determine which tier is appropriate. This work would need to be supported by allocating additional budget resources, which would result in higher license fees overall. Finally, if many applicants were approved for lower license fees, the license fees overall would

most likely increase since fees must cover the costs of the section's work and no additional funds are available to support the section.

- Change Emergency Circumstance Obligations to Reduce Harm – Concern that the current rules require facilitators and license representatives to immediately call emergency services when any activity or condition endangers the safety of any person or whenever someone needs immediate medical attention. Request for additional language that permits license representatives to remediate the endangering condition or activity or address minor medical issues on their own or by calling non-emergency services.

Agency response:

The draft rules were revised in several sections to address this concern. OAR 333-333-4460 (Service Center Emergency Plans) was amended to require service centers to document policies and procedures for response to client emergencies. OAR 333-333-4700 (Duty to Contact Emergency Services) and OAR 333-333-5150 (Transportation Plans) were both amended to require facilitators and service centers to first take reasonable steps to mitigate safety issues before contacting emergency services.

- Make Intoxicant Rules More Reasonable – Current rules prohibit "on-site consumption of any intoxicants other than psilocybin by any individual, except for clients consuming psilocybin products during an administration session." This creates operational and facility inefficiencies for service centers by making it cost-ineffective to offer a variety of legal care modalities such as ketamine assisted psychotherapy, cannabis therapy, and MDMA therapy. The current rules also prevent clients, facilitators, and other workers from using caffeine or nicotine, as well as other substances prescribed or recommended by licensed practitioners that do not interfere with their ability to deliver or receive psilocybin services. The current rules also prevent retreat-style service centers from allowing clients to consume alcohol outside of their psilocybin service sessions. Request to exclude caffeine, nicotine and substances prescribed or recommended by licensed practitioners, and allowing consumption of intoxicants on licensed premises by individuals outside of psilocybin services.

Agency response:

The definition of intoxicant has been amended to clarify that it does not include caffeine or nicotine. The draft rules are otherwise unchanged in response to this comment. The risks of drug interaction with psilocybin are unknown and therefore a prohibition on consuming other substances simultaneously with psilocybin is appropriate. Also, this comment reflects a misunderstanding of license location requirements. The rules allow a business to have a restaurant with a liquor license on the same lot as a service center, but the rules require the two businesses to operate independently in separate areas. Finally, ORS 475A addresses psilocybin exclusively and does not contemplate

concurrent consumption of psilocybin and other intoxicants. In fact, ORS 475A.504 creates a criminal misdemeanor for providing psilocybin to a person who is intoxicated.

- Lower Cost by Eliminating Unnecessary Staff Requirement – Current rules require a license representative to be present in addition to the facilitator in all sessions. This will add significant financial burden and drive up the cost of psilocybin services for clients. Any safety benefit of requiring both a license representative and a facilitator to be present can be addressed through the use of back-up facilitators, on-call license representatives and engaged client support persons. Request to allow "client support person" to those permitted to monitor clients during facilitator restroom breaks.

Agency response:

The requirement for additional staff was included to support client and facilitator safety, and this rule requirement remains in place. Additionally, ORS 475A requires psilocybin services to be provided by licensed psilocybin facilitators and defines psilocybin services to include "services provided to a client before, during or after the client consumption of a psilocybin product." Allowing individuals who are not facilitators to monitor clients is inconsistent with this requirement.

- Allow Valuable Supportive Touch with Consent – The approach to supportive touch in the current rules is more restrictive than necessary. Request to change rules to allow facilitators to provide any supportive non-sexual touch and using body parts beyond the hands, such as feet or arms. Consenting adults should be able to, in the Preparation session, determine the type of touch that best supports them without violating other rules prohibiting sexual touch.

Agency response:

The rules have been amended to include feet in the definition of supportive touch. No other changes have been made to address this comment. Clients are unable to consent to touch while experiencing the effects of consuming psilocybin products, and there have been documented instances of abuse in the unregulated space. In light of these risks, clear and consistent rules on touch are appropriate.

- Improve Client Data Protections – The current rules limit clients' right to confidentiality and privacy to "while receiving psilocybin services", and do not give clients' control of their de-identified data. Client privacy and confidentiality should go beyond their sessions, and their right to control their data should extend to de-identified data to better protect clients from potential reputational damage, adverse employment impact, and federal law enforcement risk. Request that clients are not required to share de-identified data with anyone outside service centers for research or other purposes unless they specifically opt-in, and clients are not required to opt-in as a condition of receiving psilocybin services.

Agency response:

The agency appreciates privacy concerns raised during the public comment period and is committed to client confidentiality. Several rule changes have been made to address the issue. The agency has amended the definition of “de-identified” data to clarify that it means aggregate data. The agency also made technical changes to OAR 333-333-4810 to broaden protections for client confidentiality and clarify requirements for disclosure when facilitators and service centers intend to share de-identified data. Specifically, the revised disclosure form provides clients the ability to opt-out of sharing de-identified data.

- Reduce Cost and Burden of Restroom Requirements – The current rules require an accessible single occupancy restroom within the licensed area of every psilocybin service center and requires all clients to use that restroom first. The rules also require the facilitator as the only escort for restroom visits outside the licensed premises, which becomes infeasible in group administration sessions when a single facilitator is required to both escort the client and maintain contact with the rest of the group. Most commercial buildings where small centers can be located have restrooms that are shared by more than one tenant, and the current rules will exclude a significant number of already too few locations or impose a significant construction cost that will drive up service center costs and thereby reduce access to services. Request to remove the requirement for restrooms in the licensed premises and allow service centers to use restrooms outside the licensed premises. Request to allow licensed representatives and client support persons to escort clients to restrooms off the licensed premises in order to make group sessions feasible without requiring facilitators above the required ratios.

Agency response:

The Oregon Psilocybin Advisory Board recommended that clients have access to single occupancy restroom while receiving psilocybin services. Clients experiencing the effects of consuming psilocybin products may be at risk if they are required to use shared restrooms with members of the public. The agency has no regulatory oversight over members of the public, and members of the public could pose a risk or threat to client safety, including retraumatizing clients, while clients are in vulnerable, alternate states. The rules have not been changed to address this comment; however, it should be noted that the rules do allow use of a secondary restroom if the restroom located within the licensed premises is occupied.

- Allow Animals on Licensed Premises – The current rules prohibit service centers from allowing animals (except service animals) on licensed premise, which significantly constrains the practice of psilocybin services without material benefit or safety enhancement and is impossible in the case of wildlife in outdoor administration areas. Request to only prohibit those "that pose a risk to the health and safety of individuals present on the licensed premises."

Agency response:

Animals that are bonded with their owners may behave unpredictably when observing a client experience the effects of consuming psilocybin products. Therefore, it is not feasible to determine which animals pose a risk. As such, the current rule language is appropriate.

- Let Facilitators Increase Group Sizes when Appropriate – The current rules require minimum facilitator-to-client ratios that leave no room for flexibility when those minimums are out of proportion to the safety needs of the particular client group. Request to amend rule to allow facilitators to deviate from the facilitator-to-client ratios after the facilitator considers the particular safety factors for a particular client group.

OHA received written comments requesting a rewrite of and flexibility for facilitator ratios and session durations based on doses of psilocybin.

Agency response:

The client to facilitator ratios were designed to support client and facilitator safety. As the program evolves, the agency will have an opportunity to re-evaluate these ratios. At the current time, it is not appropriate to allow facilitators to determine ratios based on undefined safety factors for a particular client group.

- Change Emergency Transportation Obligations to Reduce Harm – The current rules require the facilitator to make reasonable efforts to prevent the client from operating a motor vehicle and require the facilitator to call emergency services if a client's failure to follow their transportation plan creates a danger to the safety of the client or others. The obligation to "prevent" could result in more, not less, danger to individuals. Request to change the obligation from "preventing" to "discouraging" departure by motor vehicle to ensure facilitators can rely on words rather than physical action to prevent motor vehicle operations. Request to change the obligation to call emergency services from "mandatory" to "permissive" in order to provide facilitators protection should they decide to call emergency services without creating a mandatory burden and potential liability should the client cause injury to themselves or others that the facilitator might not have reasonably anticipated.

Agency response:

OAR 333-333-5150 has been amended to require facilitators and service centers to first take reasonable steps to mitigate safety issues before contacting emergency services.

- Require Translators to Translate, Not Service Centers – The current rules impose an obligation on service centers to make reasonable efforts to translate product packaging into other languages as required for certain clients. For clients requiring translation, a translator will already be engaged by the facilitator for the client's psilocybin services including translating consent forms and other documents, so that translator should provide translation of the product documentation as well. This reduces the added cost

and risk of translation to service centers while leveraging the existing translation mechanism already contemplated by the rules.

Alternatively, OHA heard that the requirement for translation of product packaging should be the responsibility of the manufacturer, and that product information could be available in different languages via QR codes.

Agency response:

The agency has prioritized the importance of equity and access throughout the development period. Spanish and ASL interpretation services have been available for public hearings, listening sessions, and other events. The agency will make some forms required by rule available in English and Spanish. Because equity and access are foundational to this work, licensees should also be responsible for ensuring that clients are able to access documents and services in their preferred language. This requirement both increases access, centers equity, and promotes client safety.

- Reduce Excessive Visitor Escort Requirement – The current rules require any permitted visitors to be escorted at all times by a license representative. Request that the rule only require escorts when the visitor has access to psilocybin products, such as when they are in the area where psilocybin is stored or performing maintenance on the safe.

Agency response:

OAR 333-333-4400 has been amended to require supervision rather than escort of visitors and limits this requirement to areas where psilocybin products or clients may be present.

- Allow Cloud-based Video Surveillance Systems – The current rules place unreasonable specification on video surveillance systems by seemingly requiring on-premises physical recording equipment in a dedicated secured room and a minimum of one monitor on premises capable of viewing video. These requirements are impractical, expensive, and not in accordance with modern video surveillance technology which typically uses encrypted cloud storage allowing authorized users to view footage on a computer or mobile device. Request to clarify the rule to allow remote and online recording and storage of video footage as long as such storage is secure and encrypted. Also, to better protect client confidentiality, the requirements for locations of cameras should also be reduced to limited access areas where psilocybin is stored and not in client areas.

Regarding use of video surveillance, OHA also heard that video cameras should not be used at service centers at all.

Agency response:

The draft rules were not intended to prohibit cloud storage and they have been amended to clarify that cloud video storage is permitted. Video requirements for

common areas, like the facility entrance, mitigate the risk of armed robbery and other criminal activities that pose a risk to licensees and clients.

- Have Training Centers Contribute to OPS Program Costs – The current program and proposed rules do not require that Facilitator Training Programs pay annual fees despite their substantial role, comparable to that of service centers or manufacturers. Request to impose fees on training programs in order to reduce the burden on facilitators, manufacturers, service centers, and laboratories to cover the costs of the program through their fees.

Agency response:

Fees for training program curriculum approval were adopted in May of 2022; therefore, this comment is outside the scope of the current rule making. The agency's statutory authority for training programs is limited to approving curriculum rather than general authority to regulate training programs operations. The current fee is appropriate.

- Respect for Indigenous Peoples – Recommendation that OPS do more to acknowledge and incorporate the unique circumstances of indigenous peoples into the rules, and to provide greater recognition and respect of tribes and their lived experiences. Specifically, request that all license fees for indigenous peoples who are experienced facilitators within their communities be waived; waive the practicum requirement; waive core training hours; or waive the training requirement completely.

Agency response:

The term Indigenous is very broad and includes groups of people living all over the world and from various tribal, racial, and ethnic affiliations. The agency upholds the values of centering equity while also being intentional about policy making to prevent further inequities from causing harm to Black, Indigenous, People of Color, and Tribal members. In addition, the agency has engaged Oregon's nine federally recognized tribes as part of our government-to-government relationship, worked with community based organizations that represent immigrants, refugees, and communities of color, and provided opportunities for culturally responsive community circles to gain insight and feedback from various communities.

This comment requests changes to training requirements that are not included in current rule making. The agency looks forward to finding ways to address equity in license fees while also ensuring that we do not create additional inequities within communities that have already experienced harm or have not been served or well-served by government institutions.

- Support for Community Practitioner (Entheogenic) Framework – Recommendation that the community practitioner framework proposed by Jon Dennis be fully adopted and incorporated into the program and if not fully adopted, the principles and practices of the framework be brought into the existing rules.

Agency response:

The Oregon Psilocybin Advisory Board considered this framework and did not include it in recommendations to OHA. The proposed framework is very broad. Although it has not been incorporated into the rules in its entirety, certain portions are reflected in the rules. For example, outdoor administration areas, group administration sessions, reduced license fees for non-profit organizations, and streamlined requirements for preparation sessions are included.

- Removal of Upper Dosage Limit – Throughout the rulemaking hearings, members of the public shared that their personal, spiritual, and/or therapeutic dosage requirements were above the 50mg limit in the current proposed rules. Request to remove or increase the upper cap.

Conversely, OHA heard that the maximum administration dose at 50mg seems too high and not in line with medical research.

Agency response:

Clinical trials typically administer between 25 and 35 mg of psilocybin. Anecdotal reports from the unregulated market may be unreliable because products consumed in that setting are unlikely to be tested for psilocybin content. In selecting 50 mg, the agency has allowed a maximum limit that exceeds amounts typically administered in clinical trials. By doing so, we have already taken steps to address the concerns raised by this comment.

- Client Bill of Rights – The current bill of rights should include restroom breaks alongside emergencies as the exception to receiving "psilocybin services from a licensed facilitator for the duration of those services, except in case of emergency."

Agency response:

ORS 475A requires psilocybin services to be provided by a licensed facilitator.

OHA also heard oral testimony or received written comments on the following items:

- Regarding video recording of administration sessions, OHA heard that these recordings should be mandatory and there should not be the option for the client or the facilitator to withdraw consent to be recorded mid-session. For the safety of clients and facilitators, and to protect the psilocybin services program generally from federal intervention, there should be video recording of administration sessions. However, in order to protect client confidentiality, request to return the client right to request deletion and require video recordings to be automatically deleted after 30 or 60 days unless a report of abuse or other violation of administrative rules is reported to OHA.

Agency response:

The rules on video recording of administration sessions are intended to balance client safety and privacy. They provide clients and facilitators an option to record their administration session. Once recordings are made, the rules require them to be retained to ensure that safety issues can be addressed at a later time if necessary. Required retention also helps to avoid disputes when multiple individuals are recorded together but only some parties request deletion.

- Regarding client safety, OHA received comments from a group of advocates that requested changes to strengthen safety requirements in the draft rules. The requested changes include changes to OAR 333-333-3200 (Facilitator Exam), OAR 333-333-5020 (Group Preparation Sessions), OAR 333-333-5040 (Informed Consent), and OAR 333-333-5050 (Client Information Form) and OAR 333-333-5080 (Safety and Support Plans). Specifically, the comments requested inclusion of additional risk factors in the informed consent documents and additional questions in the client information form.

Agency response:

The agency has made some changes to the draft rules in response to these comments. The agency has declined to make changes when doing so is inconsistent with equitable access, not yet supported by available data, or would require licensed facilitators to act outside of their scope of practice.

The agency declined to change rules for the facilitator exam, which is designed to ensure equitable access for facilitator applicants. The rules have been amended to include discussion of additional safety concerns during group preparation sessions. The rules have also been amended to require additional emergency planning for service centers.

The comments requested specific information be added to the informed consent document regarding known risks of consuming psilocybin for a list of physical and mental health conditions. However, the comments do not identify known risks. The informed consent document required by rule was created based on Oregon Psilocybin Advisory Board recommendations and available data on known risks of consuming psilocybin. As more data becomes available, the informed consent document may be amended to capture additional risk factors.

The comments request significant additions to the client information form. The rules have been amended where it is appropriate to do so. The rules were not amended when requested changes were inconsistent with facilitator scope of practice. OAR 333-333-5050 (Informed Consent) has been modified to include required questions for self-harm, psychosis, and pregnancy. Clients with a history of psychosis or present thoughts of harm to self or others will be ineligible to receive psilocybin services. The rules have not been amended to address requested changes regarding contraindicated medications. Although the comments request that clients taking contraindicated

medications should not receive psilocybin services, they do not list any contraindicated medications. Lithium is the only medication identified as contraindicated in the rules, and it was included as the result of a published study. As more information regarding contraindicated medications becomes available, the rules may be amended accordingly. The rules were not amended to include required questions for additional health conditions, family history, and living situations. Psilocybin facilitators are not clinicians and may not practice under other license types while providing psilocybin services. The additional questions were not included because they are not appropriate in the context of non-directive facilitation of psilocybin services.

- Regarding the OAR 333-333-5130 (Facilitator Scope of Practice), OHA heard concerns that the rule prevents providers from billing insurance. As written, the rule will inequitably limit access and increase cost to Oregon residents. Request that the phrase "psilocybin services" be changed to "administration sessions" allowing the preparation and integration to be conjointly offered with mental health services. By allowing Qualified Mental Health Associates, Professionals, Peer Professionals and Wellness Specialists to deliver and bill for screening, education and training services within the scope of their license and in conjunction with facilitation services, the overall cost to individual consumers will be reduced by appropriately sharing healthcare costs with their health plan.

Also, regarding OAR 333-333-5130, OHA heard concern that a prohibition on practicing any other profession (such as psychotherapist) simultaneously with practicing as a facilitator will lead to confusion about what facilitators are and are not allowed to do and could prevent facilitators from assisting clients in need during a crisis. Clarification is suggested that when another profession overlaps with the facilitator's role, the facilitator may engage in that profession in ways that are aligned with the facilitator's role.

In addition, regarding facilitator scope of practice, OAR 333-333-5120 suggests facilitators may have different limits of competence while OAR 333-333-5130 states that all facilitators must have the same scope of practice. Request for clarification as to under what circumstances would two facilitators have different limits of competence, given that all facilitators must learn from the same curriculum and may not apply any outside licensure expertise to their psilocybin facilitation.

Agency response:

ORS 475A does not create a medical model. Regardless of the Oregon statutory model, facilitators will likely not be able to bill insurance without a change to psilocybin's federal status. Facilitators who hold additional professional licenses are responsible for knowing the activities that constitute practicing under that license. The agency has made technical clarifications to OAR 333-333-5120 to address the issue of facilitator competency.

- OHA heard a request to update labeling requirements for psilocybin products in OAR 333-333-2400 to require the inclusion of solvents, pesticides and allergens.

Agency response:

The rules require a Product Information Document to be provided to every client who will consume psilocybin products. This document is intended to include information that doesn't easily fit onto product labels and most of the items requested are included. OAR 333-333-2410 requires allergens to be listed on the Product Information Document as well as test results for required solvent testing. Pesticides are not included because all pesticides are prohibited under the rules,

- Regarding language in OAR 333-333-4500 (Licensee Prohibitions) and OAR 333-333-6000 (Prohibited Conduct) concerning "booster" doses of psilocybin when service center license representatives provide additional psilocybin products to clients who are under the influence of psilocybin consumed during an administration session, OHA heard that the rule as drafted by OHA adds an exception to prohibited conduct not found within and directly in conflict with ORS 475A.504, which is a misdemeanor crime.

Agency response:

OAR 333-333-4500, OAR 333-333-5240 and OAR 333-333-6000 have been amended to remove conflicts with ORS 475A.504.

- Regarding OAR 333-333-4100 (Background Checks), OHA heard that the rule as drafted using "may" and "as required by rule" is internally inconsistent and fails to specify standards for criteria for when OHA will require a background check as part of the application process. It is noted that the prior "must" language in this rule was changed to "may" and appears the language is intended to allow OHA, in their discretion, to ask for a background check as part of the application process but the "as required by this rule" language constrains the authority of OHA to require a background check only as otherwise required by rule. The rule otherwise only provides for a background check for post license criminal conduct, which is not part of the application process. Recommendation that if background checks are going to be discretionary, OHA should provide standards and criteria to determine which applicants will be required to undergo a background/fitness determination.

OHA also heard concerns about background checks being required at all due to psilocybin previously being a contraband and illegal substance. Request that prior convictions not be considered.

Agency response:

ORS 475A gives the agency authority to perform background checks and they are an important tool for supporting client safety. OAR 333-333-4100 has been amended in order to provide more clarity regarding frequency of background checks.

- OHA heard that the license fees are understated and should be increased, especially for Service Center and Manufacturing licenses. OHA also heard that the co-location of these two license types should be prohibited, requiring licensed premises for these license types to be located no closer than a quarter mile from one another.

Agency response:

The agency works within the statutory requirements of ORS 475A as well as the requirements of the larger state agency system in Oregon to establish the program budget and license fees. Oregon Psilocybin Services is a fee-based section, which means that the license fees must cover the costs of the section's work. The section is required to demonstrate sustainability in the 2023-2025 budget biennium and going forward through licensing fees. Oregon Psilocybin Services worked within our state agency budgeting process to demonstrate sustainability for three biennia.

- Regarding OAR 333-333-6110 (Advertising Media, Coupons, and Promotions), OHA heard that the advertising/marketing rules need to be tightened up in general, and that prohibition/marketing on the backside of other commercial receipts (grocery store/convenience store receipts for example) should be banned explicitly.

Agency response:

The advertising rules were adopted under the agency's authority to prohibit advertising that appeals to minors, promotes excessive use, or promotes illegal activity. The commentor does not share how their requested changes relate to these authorities.

- OHA heard that limiting service center hours is unnecessarily restrictive and does not benefit public health. Request that limitations as to what hours a service center may operate be removed from OAR 333-333-4480.

Agency response:

Hours of operation were established in rule to support public safety and impacts to community livability associated with late night operations.

- OHA heard concern about practicum site supervisors, who have a role of evaluating trainees, being allowed to give trainees psilocybin in this role (OAR 333-333-5120, Facilitator Conduct). Trainees who receive psilocybin from supervisors or those with an evaluator role are at risk of being exploited or harmed and this practice should not be allowed. Trainees can seek a facilitator who is not in an evaluator or supervisory capacity for a private experience if they wish to take psilocybin.

Agency response:

The rules have been amended to clarify that no person is required to receive services from their supervisor and that any client, including a practicum student, has the right to access an alternate facilitator.

- Regarding psilocybin product storage requirements, OHA heard a request for an additional allowance to be made for the use of commercial refrigerators with locking doors, as most products will need to be refrigerated. This change would alleviate the need for the storage room to be retrofitted with a steel door and prevent significant construction costs.

Agency response:

The rules have been amended to allow storage in a locked refrigerator or freezer located within a limited access area.

- OHA heard concern regarding the mandate to provide an indoor area to participants in outdoor group sessions. The current draft rules require that service centers provide clients in outdoor sessions with an indoor administration area if they request it. The concern is that this rule is impractical in a group session with a facilitator-to-client ratio of less than 1:1. Request that the rule be changed to exempt group sessions from the requirement to honor requests by clients to go indoors.

Agency response:

The rules have been amended to remove this requirement for group administration sessions.

- OHA heard that there is an absence in rulemaking on "Proximity of psilocybin service center to school" (ORS 475A.310) and received recommendation that OHA develop rules pertaining to this subject as the statutory framework suggests this is a topic where OHA rules should exist. The current rules are silent on how the OHA determination regarding physical or geographic barrier for proximity to schools of the service center is made and how that interacts with the cities or counties issuing the Land Use Compatibility Statement (LUCS) as part of the application process.

Agency response:

The rules do not describe how this determination will be made in order to preserve flexibility for unforeseen geography. In other contexts, identical statutory language has been interpreted to include barriers such as interstate highways and bodies of water.

- OHA heard that in order to offset the financial burden for facilitator licensing, OHA should charge a fee of \$250 for the facilitator exam via online interface. Consideration should also be made for a continuing education requirement for facilitators.

Agency response:

The agency works within the statutory requirements of ORS 475A as well as the requirements of the larger state agency system in Oregon to establish the program budget and license fees. Oregon Psilocybin Services is a fee-based section, which means that the license fees must cover the costs of the section's work. The section is required to demonstrate sustainability in the 2023-2025 budget biennium and going

forward through licensing fees. Oregon Psilocybin Services worked within our state agency budgeting process to demonstrate sustainability for three biennia.

Required training for facilitators was addressed in the May 2022 rules.

- Regarding OAR 333-333-5000 (Preparation Session Requirements), OHA heard concern that after completing the initial preparation session with a client, a facilitator is not required to complete subsequent preparation sessions prior to administration sessions with that same client for a period of 12 months. Request that preparation sessions be required prior to **each** administration session. OHA also heard concern about preparation and integration sessions being limited to a non-directive approach.

Agency response:

The rule requirements for preparation sessions are designed to allow for increased access while maintaining measures that support client safety. OAR 333-333-5000 allows less frequent preparation sessions in order to reduce costs. However, the same rule also requires that clients who participate in additional preparation sessions update their facilitator regarding changes to their previously completed client information form.

- OHA heard that, as it stands, the developing highly regulated psilocybin program is on track to make services inaccessible for BIPOC and prohibitively expensive for low-income Oregonians. In order to provide equitable implementation of the program, uplifting Oregon based BIPOC patients and practitioners, OHA needs to integrate the measures advocates have requested throughout the rulemaking hearings including but not limited to creation of a community licensure fee structure; a sliding scale licensure structure; equity licenses; equitable data collection; scholarships for participants; translation services; and the hiring of culturally competent staff.

Agency response:

ORS 475A creates a highly regulated psilocybin program. As the implementing agency, OHA cannot change the terms of the statute, nor the funding mechanisms created by the statute. Specifically, the statute does not create another funding structure that would provide scholarships to students, support start-up costs for psilocybin business owners, or subsidize the costs of psilocybin services for clients. The agency has no authority to regulate costs of products or services. Additionally, the creation of “equity licenses” would require a statutory change. As described in prior sections of this report, the agency has made efforts to offer translation and interpretation services and support equity and accessibility considerations within the statutory framework of ORS 475A and within the fee-based structure.

Working within statutory framework, the agency has prioritized equity and access whenever possible. The rules require every applicant to submit a social equity plan in order to be licensed. The rules also require interpretation and translation in several sections and provide reduced license fees for non-profits and individuals who have

veteran status or receive certain forms of public assistance. Any requirements to produce identification documents in rule are written inclusively to avoid discrimination based on immigration status. Additionally, training rules adopted in May 2022 require that facilitators receive culturally responsive training.

The staff at Oregon Psilocybin Services represent a variety of diverse communities and professional and lived experience, including being part of or working with historically marginalized communities, including refugees, asylees, immigrants, communities of color, disability communities, LGBTQIA2S+ communities, low-income populations, houseless populations, veterans, and survivors of atrocities of war, PTSD, domestic violence, sexual abuse, and human trafficking. OHA staff are required to complete anti-racism training as part of the agency's strategic plan goal to eliminate health inequities and address racism and institutional bias in our work. The section has also launched the OPS Psilocybin Equity Project, which is an internal opportunity for the OPS team and division leadership to participate in quarterly discussions to address equity issues related to the intersectionality of psychedelics, anti-racism, power-sharing, unraveling bias, and the disproportionate impact of the War on Drugs on communities of color.

- OHA heard the request to allow co-location of cannabis and psilocybin operations at the same site.

Conversely, OHA heard that the final rules should prohibit co-location of psilocybin service centers with other activities involving recreational use of substances, specifically alcohol and marijuana.

Agency response:

The rules allow cannabis and psilocybin operations to be located on the same property. However, the rules do not allow a licensed psilocybin business to occupy the same space as a cannabis operation. This approach allows flexibility while ensuring the businesses are operated separately.

- OHA heard concern about the definition of "adulterant" under OAR 333-333-1010 (Definitions), as this is open to interpretation. Request to include whole herbs as "foods" and targeted and distilled extracts which could increase potency (such as 5-HTP extracts, GABA) be looked at separately.

Agency response:

The adulterant rule is designed to ensure that test results for psilocybin content (potency) can serve as an accurate predictor of client experience. Additives that increase potency are prohibited regardless of whether they are derived from natural products or other sources.