October 21, 2024

VIA EMAIL ONLY (*publichealth.rules@odhsoha.oregon.gov*)

Oregon Health Authority
Public Health Division, Oregon Psilocybin Services

Re: Written Public Comment to Proposed Rule Amendments Published October 1, 2024

To Whom it May Concern:

We have grave concerns about several proposed rule amendments, which, if adopted, would increase costs for all licensees, and further push psilocybin services out of reach for many Oregonians. The purposes of Oregon Psilocybin Services ("OPS") include "improv[ing] the physical, mental, and social well-being of all people in this state," "ensuring that psilocybin services will become and remain a safe, accessible and affordable therapeutic option of all persons 21 years of age and older in this state for whom psilocybin may be appropriate," and "[t]o protect the safety, welfare, health and peace of the people of this state by prioritizing this state's limited law enforcement resources in the most effective, consistent and rational way."[1]

We applaud the OHA for proposing some changes that promote the above purposes, such as allowing clients to choose anyone to serve as a client support person and eliminating the requirement for an on-call back-up facilitator. Many of the proposed amendments, however, contravene those purposes because, if adopted, they would make psilocybin services less affordable and less accessible to eligible individuals in this state without a corresponding increase in the safety, welfare, or health of Oregonians. Less affordable and accessible services encourage Oregonians to seek relief from underground sources, which undermines the regulated system and increases demands on limited law enforcement resources. We are informed that, out of approximately 13,000 legal administered psilocybin analyte doses, licensees have contacted emergency services a total of four times. This indicates that psilocybin services under the current regulatory regime are extremely safe and militate for limited, if any, additional regulation.

Many proposed amendments would increase the amount of information and paperwork that licensees must collect, maintain, store, and transfer, without a clear need to do so. This would impose additional costs in time and money on licensees, which would translate to higher costs to clients for services. We count over 25 individual revisions that either require new forms, documents, or logs or require changes to current required forms or paperwork. If adopted, those rules alone would require significant time and resources to implement. We encourage OHA to consider reducing or eliminating many revisions that require changes to or additional paperwork, unless absolutely necessary for client safety, and to consider delaying the effective date for new paperwork requirements to give licensees time to change their forms, procedures, etc. to comply with any such new requirements.

Other amendments impose costly and arbitrary obligations on licensees such as reporting one another for any suspected rule violation, no matter how minor, requiring facilitators to partner with service centers merely to store client records (whether or not the facilitator conducts a single administration session at that service center), and prohibiting a facilitator from simply observing a person experiencing the effects of psilocybin outside a service center. These and other proposed amendments suggest that OHA ignores the fact that virtually all

[1] ORS 475A.205.

licensees are small business owners who cannot provide services at a financial loss. They also contradict OHA's stated mission to ensure that all people and communities have "access to quality, affordable health care" and to transform the health care system in Oregon by "[l]owering or containing the cost of care so it's affordable to everyone."[2] Many proposed amendments also violate OHA's statutory duty to "reduce the economic impact of [rules] on small business."[3]

We do not wish to shame, alienate, or antagonize OHA; we sympathize with OHA's awesome responsibility to regulate a brand new federally illegal industry with the many uncertainties and potential risks it carries. We wish only to provide comments in the interest of preserving and promoting the industry for the benefit of all participants with the hope that the industry not only survives, but thrives, and can serve as a model for other states and the world in providing safe, high-quality, and affordable psilocybin services for all.

Please see the attached public comments to select proposed rule amendments, which we think represent the most detrimental threats to the industry. We encourage OHA to review all proposed rule changes for the impact they would have on licensees' ability to operate, as well as for benefits to public health and safety, because, without licensees, no industry would exist to regulate.

Thank you so much for the opportunity to provide these comments and for partnering with the industry to foment a robust, responsible, safe, and accessible program.

Sincerely,

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[2] https://www.oregon.gov/oha/pages/portal-about-oha.aspx#:~:text=Mission,so%20it's%20affordable%20to%20everyone
[3] ORS 183.540.

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333-333-010 Definitions

OHA Proposed Amendment:
(5~~3~~9) "Post-session reaction" means a medical or behavioral reaction reported by a client occurring within 72 hours of the client's release from an administration session that resulted in contacting emergency services or the client receiving care from a medical care provider.

Comment:

The definition of this term strikes us as unnecessarily broad and could skew the data OHA collects under 333-333-4910. For example, many clients may receive care from a medical care provider within 72 hours of an administration session for a regular check-up or physical or for conditions completely unrelated to psilocybin consumption, such as the flu or COVID.

Such non-psilocybin-related reports would inflate the number of "post-session reactions" attributed to psilocybin, when, in fact, they are completely unrelated.

For that reason, we recommend the following rule revision:

(5~~3~~9) "Post-session reaction" means a medical or behavioral reaction reported by a client occurring within 72 hours of the client's release from an administration session that resulted in contacting emergency services or the client receiving care from a medical care provider provided that emergency services or the medical care provider indicated the subject reaction was likely related to psilocybin consumption.

333-333-3070 Psilocybin Facilitator Practicum Requirements

OHA Proposed Amendments:

(2) ~~If a practicum site is available, p~~After January 1, 2027, all practicum must take place at a practicum site. Practicum training shall include placement at a practicum site where students can observe psilocybin services under the supervision of a practicum site supervisor.

(6) ~~I~~Until January 1, 2027, if a practicum site is not reasonably available or accessible to students, a training program may identify alternative practicum in its application for approval that reasonably approximates training at a practicum site. For alternative practicum, the lead educator or training program director is responsible for developing students' alternative practicum skills and evaluating students' alternative practicum performance, focusing on services with clients. Alternative practicum may not be used to satisfy the requirements of this rule on or after January 1, 2027.

Comment:

We propose that OHA does not adopt these proposed revisions. The revisions presuppose that at least one licensed service center opts to serve as a designated practicum site, which may not always be the case. Although we understand that many training programs currently partner with service centers functioning as practicum sites, this may not always be the case, and does not justify OHA enshrining this requirement in rule. If at some future time no service center serves as a practicum site then no training program curriculum can obtain OHA approval and OHA could not license any new facilitators.

Further, the revisions would leave training programs at the mercy of service centers. If a training program cannot work out a deal with a service center to use its premises as a practicum site, through no fault of the training program, then OHA would not approve the training program and force the program to shut down. The proposed revisions, therefore, threaten the future viability of training programs by forcing training programs to contract with service centers, potentially on unfavorable terms. Mandating

that training programs make deals with service centers for practicum site use may negatively impact the industry and potentially drive up costs for training programs and students.

OHA Proposed Amendment:

(3) Any licensed ~~S~~service ~~C~~center can function as practicum site for training programs with curriculum approved by the Oregon Health Authority (Authority) subject to the requirements of OAR 333-333-4470. If a training program uses a ~~S~~service ~~C~~center as a practicum site to satisfy the requirements of this rule, the training program shall notify the ~~Oregon Health Authority (Authority)~~Authority in a form and manner prescribed by the Authority.

Comment:

This revision would prevent a service center from functioning as a practicum site for training programs located in other states with approved and regulated psilocybin programs. For example, Colorado is currently crafting its own psilocybin regulations, including providing for approved facilitator training programs. But, because Colorado has no currently approved locations for in-person psilocybin-consumption practicum sites, training students have limited options to take advantage of valuable practicum experience. We propose revising this rule to allow students enrolled in out-of-state approved training programs to observe administration sessions at a service center functioning as a practicum site as follows:

(3) Any licensed service center can function as practicum site for training programs with curriculum approved by the Oregon Health Authority (Authority) subject to the requirements of OAR 333-333-4470 or training programs with curriculum approved by the applicable authority of another state. If a training program uses a service center as a practicum site to satisfy the requirements of this rule, the training program shall notify the Oregon Health Authority (Authority)Authority in a form and manner prescribed by the Authority.

333-333-4200 Notification of changes

OHA Proposed Amendment:

(6) The Authority may require a licensee to submit a new application including all required forms and documents and the fee specified in OAR 333-333-4060 for a change in ownership structure if the change in ownership structure results in changing the licensee's status from a non-profit entity to another type of entity, or the licensee no longer qualifies for a reduced fee for any other reason.

Comment:

We strongly oppose this revision. It completely contradicts OHA's stated goal of increased equity and access in the psilocybin services space. The revision effectively penalizes licensees who qualified for reduced license fees for improving their economic conditions. For example, a licensee who qualifies for a reduced fee as an OHP or SNAP recipient may pay a reduced annual fee for their initial or renewal license, and then, if their circumstances improve within a week or a month after receiving their license – even marginally enough to no longer qualify for OHP or SNAP, OHA may require the licensee to submit a new application, including the full cost of another annual licensing fee, which means the licensee pays 1.5x the fee that a non-reduced fee licensee pays for a single annual license.

This amendment is clearly regressive and allows OHA to punish reduced fee applicants for improving their financial circumstances, even slightly. We, therefore, request striking this proposed amendment.

333-333-4280 ~~License~~ Surrender

OHA Proposed Amendments:

(1) A licensee may request t~~he Authority accept the surrender of a license. The license remains in effect until the Authority accepts the surrender. If the Authority accepts the~~o surrender a license in a form and manner prescribed by the Oregon Health Authority (Authority). Each individual person identified as a licensee must submit a separate request, including a product plan and client record plan if applicable. The license remains in effect until the Authority accepts the surrender. The Authority may request additional information and require additional site inspections prior to accepting the surrender.

(2) A service center, manufacturer or laboratory license that requests to surrender its license must submit a products plan, in a form and manner prescribed by the Authority, in order to complete its surrender request. An identical products plan must be signed by every individual person identified as a licensee and must describe the licensees' plan to dispose of psilocybin products in inventory by destroying the products or transferring psilocybin products to another license in compliance with these rules. All psilocybin products designated as waste or transferred to another license must be recorded in the product tracking system.

(3) A service center that requests to surrender its license must submit a client records plan, in a form and manner prescribed by the Authority, for approval in order to complete is surrender request. An identical client records plan must be signed by every individual licensee affiliated with the licensed premises and must describe the service center's plan to:

(a) Destroy client records; or¶

(b) Obtain client's written consent as described in OAR 333-333-4810 and transfer client records to another service center.¶

(4) The Authority will review product plans and client record plans and may require revisions to plans prior to accepting a surrender request. If the Authority accepts a surrender request, the Authority will notify the licensee in writing of the date of acceptance. The licensee must cease all license privileges on this date through the remainder of the licensing period. The licensee must receive a new license before engaging in any licensed activities.

Comment:

These proposed changes conflict with basic principles of corporate and agency law and make license surrender so onerous that we suspect that, if adopted, no service center or manufacturer would request surrender. Further, the changes would likely inhibit the sale of licensed businesses because, presumably the seller must surrender its license prior to OHA approving the change of ownership. Subsections (1) and (2) require that each individual person identified as a licensee submit a separate surrender request and sign identical products plans.

These requirements fail to account for the wide variety of individuals who may qualify as licensees. For example, many individuals are 20 percent or greater direct or indirect owners of a licensed entity (thereby qualifying as licensees), but they do not have legal authority to decide whether or not to surrender the license on behalf of the licensed business entity. What's more, some individuals may qualify as licensees with no equity ownership or management authority over the licensed entity at all, such as a contractor entitled to 20 percent or more of the entity's revenue. Yet this revision would require that person to submit a separate request and sign a product plan before the licensed entity may surrender its license or sell its licensed business.

Consequently, a single individual who technically qualifies as a licensee could unilaterally block the surrender, or sale, if that individual is unreachable or uncooperative, regardless of that individual's legal authority over the license itself.

Subsection (3) proves even more onerous. That section requires "every individual licensee affiliated with the licensed premises" to submit a client records plan to OHA for approval to complete a service center's surrender. "Affiliated with the licensed premises" could include every facilitator who has conducted a preparation, integration, or administration session at the service center throughout the service center's existence, which could amount to several years. So, to surrender the license, or sell their business, a service center apparently must contact every facilitator who has ever used the service center and obtain a client records plan from them, which is simply infeasible.

We believe the rule as written defeats its own purpose. It would be far more efficient for a licensee, especially a service center licensee, to let their license lapse rather than go through the laborious and time-consuming process outlined in the above amendments. Plus, the amendment greatly inhibits a licensee's ability to sell their business.

For all these reasons, we suggest OHA withdraw this proposed amendment.

333-333-4810 Client Confidentiality

OHA Proposed Amendment:

(2) A service center or ~~facilitator~~ must have a completed client consent form to disclose identifiable client information that contains the following: . . .

Comment:

We cannot discern the reasoning behind this proposed amendment. Why would OHA exempt a facilitator from the requirement to obtain a completed and signed client consent form to disclose identifiable information about the client? This directly conflicts with subsection (1) of the same rule which states: "A service center or facilitator may not disclose any information that may be used to identify a client, or disclose any communication made by a client related to psilocybin services . . . except with a client's consent or otherwise as allowed by ORS 475A.450."

How can a facilitator obtain consent to disclose a client's personally identifiable information without a consent form? A facilitator may need to share information identifying a client for many reasons. The facilitator may need to share identifying information with one or more service centers where the facilitator may provide services to the client. A facilitator may need to refer the client to another facilitator at the client's request. A facilitator who conducts a preparation session may need to share client information with a different facilitator who conducts the administration session with the client.

Perhaps this proposed revision reflects OHA's apparent desire for client records to be held and stored only by service center licensees, but that lacks feasibility for many reasons, including the reasons stated above. Many situations may arise in which a facilitator must share information which may identify a client to another party, including other licensees, clients, client support persons, etc., before a client or potential client selects a service center. And that presupposes that a client determines to undergo an administration session, which the client may not. We provide further applicable comments in the section below on recordkeeping and retention.

For the above reasons, we urge OHA to withdraw the above proposed revision. A facilitator must be free to share identifying client information with client consent, without first having a service center collect a client consent form.

333-333-5040 Informed Consent

OHA Proposed Amendment:

32. I understand that if a service center license is surrendered or revoked that service center may transfer my records to another service center license with my prior written consent or destroy the record and I will receive notice of the status of my client records when a service center closes.

Comment:

We strongly recommend removing the portion of this revision that states "I will receive notice of the status of my client records when a service center closes." First, "closes" is not defined, so it is impossible for a service center to know when it must notify a client of the status of their client record. Is it upon surrender? Temporary or seasonal cessation of operations?

Second, requiring a service center to notify every client whose records the service center stores would be onerous to the point of unworkable. A service center may serve thousands of clients over the life of the business. Notifying each of those clients could take hundreds of hours and cost a service center, which is already closing, thousands of dollars to pay employees to comb through records and send the notices. Further, client information on file with the service center may be outdated and it may not be possible to contact some clients, which would violate the proposed rule.

We therefore request that OHA remove this clause from the proposed revision as follows:

32. I understand that if a service center license is surrendered or revoked that service center may transfer my records to another service center license with my prior written consent or destroy the record. ~~and I will receive notice of the status of my client records when a service center closes.~~

333-333-5120 Facilitator Conduct

OHA Proposed Amendment:

(13) A facilitator may not supervise, observe, or otherwise support individuals experiencing the effect of consuming psilocybin products at any location other than a service center.

(14) These rules do not prevent a facilitator from providing harm reduction assistance to members of the public if urgent or emergent events occur.

(15) These rules do not prevent a facilitator from supervising, observing, or otherwise supporting individuals experiencing the effect of consuming psilocybin products at locations outside of Oregon if they hold the necessary license or authorization or it is otherwise lawful to do so.

Comment:

The proposed new subsection (13) of this rule unnecessarily subjects licensed facilitators to possible violations for activities and conduct that occur outside the OPS system and reaches beyond OHA's authority under ORS 475A.

OHA lacks the authority to regulate otherwise legal activity outside the OPS regulation-enabling statute. No Oregon law prohibits the mere "observation" or "support" of individuals experiencing the effect of psilocybin products outside of a service center. Again, OHA does not have authority to regulate lawful activity that a licensee performs in their personal private lives outside the OHA-regulated OPS system.

Many facilitators may also serve as medical or mental health professionals whose licensed profession requires that they support and assist individuals experiencing the effect of psilocybin. The at-once vague and specific exception in subsection (14) for "providing harm reduction assistance to members of the public if urgent or emergent events occur" does not adequately protect a licensee's civil right to act in a lawful manner to assist and protect their fellow human beings.

Subsection (13) would likely have the opposite effect than intended, by encouraging skilled facilitators to exit the legal regulated system and enter the black market to provide their services, which would further diminish the regulated system, increase demand, and, therefore, costs for skilled facilitators, which, in turn would drive up costs for services and encourage clients to seek less expensive black-market products and services.

Subsection (13) is anathema to the goals of ORS 475A and the OHA. We, therefore, implore OHA to withdraw subsections (13) and (14) from the final proposed rule amendments.

OHA Proposed Amendment:

(16) A facilitator is prohibited from conducting preparation or integration sessions at a location outside of the United States of America or U.S Territories or the freely associated states Republic of Marshall Islands, Palau, and the Federated States of Micronesia.

Comment:

No rule prevents preparation and integration sessions from being conducted remotely through the Internet. We do not see any reason that OHA should prohibit a facilitator from conducting a remote session from anywhere in the world. Conversely, OPS should be available to clients from all over the world, and the wording of this proposed amendment does not specify whether a facilitator may conduct a remote preparation or integration session from the US with a client located outside the US.

For that matter, the purpose of this rule is unclear. What is the difference between conducting an in-person or remote preparation or integration session outside of Oregon (which the amendment allows) and doing the same outside the US (which the amendment prohibits)?

This amendment appears unnecessary and creates more confusion than clarity. We, therefore, request that OHA remove it in its entirety.

333-333-5140 Duty to Report Misconduct

OHA Proposed Amendment:

(1) Any licensee, licensee representative or permittee who witnesses or becomes aware of ~~conduct involving a clien~~licensee or permitted worker conduct that violates ORS chapter 475A or these rules must report that conduct to the Oregon Health Authority (Authority) within 24 hours.

(2) Any licensee, licensee representative or permittee who witnesses or becomes aware of conduct that harms or potentially endangers a client must report that conduct to the Authority within 24 hours in a form and manner prescribed by the Authority.

(3) Failure to report as required by sections (1) and (2) of this rule is a violation, separate from any violations that may have occurred as a result of the underlying conduct.

Comment:

The proposed revision to subsection (1) is extremely concerning. It creates a violation for licensees, employees, contractors, and anyone with a worker permit for failure to report <u>any potential rule violation</u> they may witness, or even hear about second- or third hand, no matter how major or minor, and for conduct that has no impact on a client or public safety.

While we understand and support prioritizing compliance for the sake of client safety and public health, forcing colleagues, employees, managers, co-workers, contractors, other licensees, etc. to report on each other, even for something as minor as a missing form or a bathroom break lasting longer than 5 minutes, would foster an environment of mistrust and suspicion in the industry and at licensed premises. We posit that such an environment endangers client safety, rather than protects it, because constant concern that a colleague may file a complaint for any minor infraction may interfere with a licensee's ability to sufficiently focus on the client. The revision would also have the opposite effect of its intended purpose because it discourages open communication between licensees, licensee representatives, and permittees about any issue or occurrence that may constitute a violation for fear that anyone who "becomes aware" of the conversation is required to report it.

The sheer breadth and number of rules already makes it virtually impossible to comply with every single rule in every conceivable situation. Psilocybin services are unpredictable. Providing psilocybin services already requires intense focus, quick thinking, and expending vast mental and spiritual resources. Adding the stress and anxiety that a co-worker, competitor, or employee must report any mistake or face disciplinary action themselves, would not improve psilocybin services or make them any safer. It would do the opposite.

For those reasons, we ask OHA to reconsider its proposed revision to subsection (1). Without that revision, all individuals, licensees, clients, and members of the public, would still be free to submit a complaint. The existing rule in subsections (1) and (2) provide more than enough protection for clients by requiring reporting of violations that involve a client or conduct that harms or potentially endangers a client. We strongly encourage OHA to withdraw the proposed revision to subsection (1) and leave the rule as currently written.

OHA Proposed Amendments:

<u>(4) For purposes of this section "retaliate" means taking a negative action related to employment, contracting or the provision of services but does not include making ordinary business decisions that are unrelated to reports, cooperation or participation in an Authority investigation or hearing process. A licensee or permittee may not retaliate against an individual or entity on the basis that the individual or entity has:
(a) Reported in good faith to the Authority that the licensee or permittee is alleged to have violated ORS chapter 475A or these rules; or
(b) Cooperated or participated in an Authority investigation or hearing process.
(5) This rule does not prevent service centers and facilitators from refusing to provide services to clients as described in ORS 475A.370.</u>

Comment:

This proposed rule strikes us as overbroad, vague, and unnecessary. Oregon already has a strong "whistleblower" statute which prohibits private employers from discriminating or retaliating against an employee who in good faith reports unlawful activity. See ORS 659A. The Oregon Psilocybin Services Act also contains its own whistleblower protection provisions for employees. ORS 475A.489.

Here, the proposed revision does not just restrict adverse employment action or implement ORS 475A.489, but prohibits "taking a negative action," which is undefined, "related to employment, contracting or the provision of services." The "contracting" provision is particularly concerning because that could prohibit a licensee from simply refusing to enter into or renew a contract with a third-party who routinely submits complaints about a licensee. OHA should not force a licensee or permittee to enter into or fulfill a private contract with a third-party contractor if the licensee or permittee does not wish to or the existing contract allows the licensee to terminate the contract for any reason, including filing complaints with OHA. We doubt whether OHA has authority under ORS 475A, or any other statute, to interfere with private contracts.

Further, subsection (5) negates the prohibition against taking "negative action related to . . . the provision of services" because it reiterates state law allowing a "licensee or licensee representative to refuse or to cease providing psilocybin services to a client for any or no reason." ORS 475A.370.

Because Oregon already has strong "whistleblower" protections, OHA lacks authority over private contracts, and a licensee may refuse to provide or may cease providing psilocybin services to any client for any or no reason, we believe subsections (4) and (5) are unnecessary, redundant, overbroad, exceed OHA's authority, and should be withdrawn.

333-333-5200 Administration Session Requirements

OHA Proposed Amendment:

(10) ~~If licensee representatives of a service center are scheduled to be present during an administration session,~~Service centers must provide notice to every client participating in the administration session ~~must receive notice~~ of the names of the licensee representatives ~~and have an opportunity to meet the licensee re~~who may be present at~~ives who may be present prior to~~ the service center while their administrati~~ve~~on session ~~beginning~~ takes place.

Comment:

This strikes us as another unnecessary and onerous revision. How does a client's knowledge of the name of every licensee representative who may be on a service center premises during that client's administration session promote the client's safety and welfare? It seems far more reasonable that a client should know the name and have the opportunity to meet any licensee representative who will be present for any portion of an administration session, as the rules currently require.

When scheduling an administration session, a service center may be aware of every licensee representative who may be anywhere on the premises during that future administration session. And, regardless, licensee representatives must maintain the confidentiality of any client who comes to the premises and only facilitators, client support persons, other clients (for group administration sessions), and licensee representatives, may be present during an administration session. Current rules further require that a client must provide consent for all individuals who will be present at an administration session. Requiring notification of the names of individuals who the client is unlikely to encounter during an administration session seems superfluous and unnecessary.

If one of the purposes of the amendment, however, is to relieve the service center of having to provide every client with the opportunity to meet every licensee representative who may be present at an administration session and require only sharing of the names of licensee representatives, then we support that reasoning and we propose the following rule amendment:

(10) If licensee representatives of a service center are scheduled to be present during an administration session, every client participating in the administration session must receive notice of the names of the licensee representatives ~~and have an opportunity to meet the licensee representatives~~ who may be present prior to the administrative session beginning.

333-333-5250 Duration of Administration Session

OHA Proposed Amendment:

(1) The minimum duration of an administration session shall be dependent on the total amount of psilocybin analyte a client consumes during that session, including any secondary does consumed. If a client consumes a single dose, the minimum duration begins when a client consumes the psilocybin product. If a client consumes secondary doses of psilocybin products, the minimum duration begins when the final secondary dose is consumed and is based on the total amount of psilocybin analyte consumed during the session.

Comment:

This proposed revision would unnecessarily increase costs of psilocybin services without a demonstrable increase in benefits or safety to clients or the public. By mandating that the minimum duration of an administration session begins upon the consumption of a final secondary dose and that the duration be measured by total psilocybin analyte consumed, regardless of the potency or timing of the final secondary dose, OHA would require facilitators to work longer hours and service centers to accommodate longer administration sessions than necessary.

For example, under the above revision, if a client consumes an initial dose of 12 mg of psilocybin analyte and then consumes a final secondary dose of another 12 mg two hours into the administration session (under the new proposed three-hour minimum duration for this potency), the administration session's minimum duration becomes a total of seven hours, which is three hours longer than the minimum duration a single 24 mg dose; or one hour longer than the minimum duration of a session in which the client consumes one 50 mg (maximum) dose, even though the client has consumed less than half that amount.

The above example reflects how the revision could nearly double the cost of an administration session for the same amount of psilocybin analyte consumed. OHA has not shown that the circumstances warrant this major increase in the cost of services. All clients are different. And many times, a client requires a secondary dose merely to "launch" the psilocybin's effects after the initial dose fails to do so. In those, and many other cases, the secondary dose does not compound the length and intensity of the experience such that the entire minimum duration must reset upon consuming the secondary dose. This revision would leave many clients sitting with their facilitator for hours after the effects have worn off. Because a facilitator may only ascertain the intensity and length of the psilocybin's effects in real time during an administration session, OHA should not arbitrarily require licensees to restart the minimum duration clock upon consumption of a final secondary dose.

Without this revision, the rules still require that the total minimum duration corresponds with the total amount of psilocybin analyte consumed. The rules also still require that a facilitator and client determine when an administration session ends after the minimum duration expires and that a client comply with

their transportation plan. We have not seen any reports suggesting that the current minimum duration requirements risk client or public safety. The OHA should trust highly trained facilitators to coordinate with clients when the administration session should end after the minimum duration for the total amount of psilocybin analyte consumed expires.

For those reasons, we recommend that OHA remove the proposed language in subsection (1) stating: "If a client consumes secondary doses of psilocybin products, the minimum duration begins when the final secondary dose is consumed."

333-333-6160 Investigations

OHA Proposed Amendments:

(1) For purposes of this rule and OAR 333-333-6040, "evidence" includes but is not limited to, physical objects, documents, records, video recordings and interviews with an Oregon Health Authority (Authority) authorized representative.

(2) An applicant, licensee or permittee must cooperate with the Authority, during any investigation of compliance with ORS 475A.210 to 475A.722 and these rules and must promptly provide the Authority with evidence when requested to do so, in a manner specified by the Authority.

(3) The requirement to provide evidence promptly means:

(a) Producing evidence within 10 business days of the Authority's request unless the Authority grants an extension.

(b) Participating in an interview within a reasonable timeframe identified by the Authority.

Comment:

We believe that OHA should abide by due process principles in conducting its violation investigations and providing licensees, who may or may not have committed a violation, the time and ability to competently defend themselves against allegations, while still being able to run their businesses.

We therefore request that OHA provide some flexibility for licensees to respond to investigations. For example, 10 business days may not suffice for a licensee to provide all evidence the OHA requests, considering that "evidence" includes physical objects and records. It may require more than 10 business days for a licensee to even learn of the OHA's investigation and evidence requests, if, for example, the licensee is on vacation when OHA initiates the investigation.

Even after a licensee becomes aware of an evidence request, it may take a licensee substantial time to deliver a physical object to OHA in Salem depending on where the evidence is located and the licensee's work and personal schedule. Plus, considering the sheer number of records OPS rules require of a service center, for example, it may take several days to locate, separate, collect, and prepare the records for transmission. OHA Investigators often require several complete client records which may comprise forms, emails, texts, notes, and other documents held in highly secure databases with access to only certain licensee representatives.

Further, licensees should have sufficient time to prepare for an OHA interview, including to retain counsel, obtain public records related to the investigation, and review its own records to refresh their memory and ascertain the facts surrounding the incident that triggered the investigation. It's often the licensee's entire livelihood at stake in these investigations.

Lastly, there should be some self-imposed limitations on the nature and scope of an investigation. The OHA should not permit itself to go on "fishing expeditions" in search of possible violations that are completely unrelated to the facts which triggered the investigation in the first place. Doing so wastes OHA's limited resources, which should be spent investigating complaints, not a licensee's entire operation. Unnecessarily broad, invasive, and time-consuming investigations also inhibit a licensee's ability to focus on their operations, maintain the trust of their colleagues and clients, and require licensees to spend time and money defending themselves rather than putting those resources into running their businesses and serving clients.

Considering the above, we request the following alternate amendment:

(3) The requirement to provide evidence promptly means:

(a) Producing evidence within 15 business days of awareness of the Authority's request unless the Authority grants an extension, which shall not be unreasonably withheld.

(b) Participating in an interview within a reasonable timeframe identified by the Authority, provided that the applicant, licensee or permittee has had ample time to retain legal counsel, obtain and review public records pertaining to the investigation, and the Authority has provided a list of the alleged rule violations that triggered the investigation.

Recordkeeping and Retention

OHA Proposed Amendments:

333-333-4820 Record Retention

(1)(a) All client records and copies of client records, including records created by facilitators must be stored at the service center where the client participates or intends to participate in an administration session. No client records, nor copies of client records may be stored at a location other than the service center where the client participates or intends to participate in an administration session except for client records that are transferred due to license surrender pursuant to the requirements of OAR 333-333-4280.

333-333-5100 Facilitator ~~and Service Center~~ Record Keeping and Confidentiality

(1) A facilitator shall create the following records for every client to whom they provide psilocybin services. ~~These records must be shared with the serv~~ in a form and manner prescribed by the Oregon Health Authority. All physical and electronic~~e center and sto~~opies of these records must be transferred ~~a~~to the service center where the client ~~received services~~participated or intends to participate in an administration session and stored and maintained as required by OAR 333-333-4820: . . .

(6) Records that are transferred to a service center as required by section (1) of this rule must be transferred withing 48 hours of their creation. If the service center where the client participated or intends to participate in an administration session is unknown at the time a facilitator creates the records, the facilitator must transfer these records to any service center and inform the client of the service center where the records are stored.

Comment:

We understand the above revisions reflect OHA's desire to have all OPS records stored by service centers, presumably to make it easier on OHA to locate a given record. However, the above revisions do not account for how psilocybin services and businesses work. The above amendments effectively prevent

facilitators from keeping any client records and require facilitators to store all records at a service center within 48 hours of the record's creation, even if the subject client never participates in an administration session and never steps foot in a service center.

These revisions do not account for how facilitators or preparation and integration sessions work. Many, if not most, facilitators work for themselves, not as employees for a specific service center. Service centers often merely rent space to the client or facilitator for administration sessions and facilitators hold preparation and integration sessions remotely or otherwise outside of a service center. That means that a client may not choose a service center for their administration session until after several interactions or preparation sessions with a facilitator. Some clients and potential clients may never have an administration session or set foot in a service center. In all these circumstances, the facilitator has necessarily created and kept "client records," which include emails, texts, communications, and notes that may be used to identify a client or prospective client. Plus, if the facilitator holds one or more preparation sessions, the facilitator may have collected several client forms required by rule; all before the client even determines to participate in an administration session.

Yet the above revisions would require a facilitator to transfer each client record to a service center within 48 hours of creation. That would obligate a facilitator to enter into a relationship with a service center even if the facilitator never holds an administration session there. and would implicitly obligate a service center to accept what could ultimately amount to hundreds or thousands of pages of records from random facilitators for clients who never use the service center or pay the service center to hold and maintain those records.

The revisions also raise concerns about client confidentiality. Again, the revisions require a facilitator to deposit client records at a service center even if the client has not determined to have an administration session at that service center. If, for example, a client shares any personal information with a facilitator before opting to use a particular service center, the facilitator must send that client record to "any service center," regardless of whether the client consents to sharing that record with the service center. If the client eventually opts for an administration session at a different service center, then the service center with the records must obtain an Authorization to Disclose Personal Identifiable Information form from the client to transfer the client records to the service center where the client will attend the administration session. So, the service center who initially receives the client records from the facilitator must expend resources to receive, store, maintain, and transfer the records without ever having a relationship with, or collecting payment from, the client.

The 48-hour record transfer requirement would also prove overly burdensome for facilitators. A "client record" encompasses virtually all facilitator notes and client communications, including, but not limited to scheduling emails, meeting notes, and text messages. A facilitator may have many communications, meetings, etc. with many clients and potential clients in a given day. The facilitator then must remember to send every new communication or other record to a service center within 48 hours. That could take the bulk of a facilitator's time, again, without even knowing which, if any, service center the client may use for an administration session.

Lastly, we doubt if ORS 475A authorizes OHA to require facilitators to transfer their records to a service center, which effectively requires facilitators to enter into contractual relationships with service centers where the service centers provide custodial services to facilitators for the records they create.

Compliance with the above revisions would impose nearly impossible burdens on facilitators and service centers without any cognizable benefit to licensees or clients. We therefore strongly recommend the withdrawal of the proposed revisions and leaving the provisions as currently written.

Culturally and Linguistically Responsive Services.

OHA Proposed Amendments:

333-333-1010 Definitions

(26) "Culturally and linguistically responsive services" for the purpose of ORS 475A..210 to 475A.722 and these rules means psilocybin services offered by service centers and facilitators that are responsive to diverse cultural beliefs and practices, preferred languages, literacy, and other communication needs of clients.

333-333-4520 Client Bill of Rights

To receive information regarding culturally and linguistically responsive services offered to support client safety.

333-333-5000 Preparation Session Requirements

(7) For every client who will participate in an administration session, a facilitator must inquire whether the client requests any culturally and linguistically responsive services. Upon a client's request a facilitator must provide a description of culturally and linguistically responsive services offered by the facilitator and the service center where the client intends to participate in an administration session. If culturally and linguistically responsive services are requested, the facilitator must include a description of culturally and linguistically responsive services that will be provided in the client's safety and support plan described OAR 333-333-5080.

333-333-5040 Informed Consent

33. I understand that service centers and facilitators are required to provide information regarding culturally and linguistically responsive services upon request.

333-333-5075 Culturally and Linguistically Responsive Services

(1) Service centers and facilitators must create and maintain:
(a) Documentation of culturally and linguistically responsive services, if any, offered to clients that support client safety and access to services.
(b) Plans for identifying translation and interpretation resources and referring clients to other facilitators or service centers if the licensee is not able to provide culturally and linguistically responsive services requested by a client.
(2) Service centers and facilitators must share information regarding culturally and linguistically responsive services they offer, if any, with clients and prospective clients upon request in order to allow clients and prospective clients to make informed decisions about choosing a service center and facilitator that meets their individual needs.

333-333-5080 Safety and Support Plans

(1) A facilitator must work with every client who will participate in an administration session to draft a safety and support plan ~~tha~~in a form and manner prescribed by the Oregon Heath Authority. Safety and support plans must identifi~~esy~~ risks and challenges specific to the client's circumstances and resources available to mitigate those risks and challenges, including any culturally and linguistically responsive services requested by the client and the client's existing support network and appropriate external resources.

Comment:

While we think it's laudable that OHA wishes to encourage psilocybin services to accommodate the diverse cultural and linguistic preferences of clients, codifying this encouragement as a specific

obligation to offer a non-specific, vague, and highly subjective set of services only increases confusion and adds another layer of regulatory obligations that would be difficult if not impossible to meet for any and every client.

"Cultural beliefs and practices" and "literacy, and other communication needs of clients" are highly subjective, personally, and politically charged terms, which mean different things to different people. Mandating the provision of these amorphous services sets licensees up for failure; any client who is unsatisfied with their psilocybin services could complain to the OHA that a licensee did not provide them with sufficient culturally and linguistically responsive services, which could subject the licensee to a violation.

Without any specific guardrails for what constitutes sufficient culturally and linguistically responsive services, a licensee cannot reliably comply with any of the above rules. Licensees have limited resources and already struggle to make ends meet. Adding this layer of vague and uncertain requirements only increases costs for licensees and clients.

Clients may choose whichever facilitator and service center they like. A client may freely seek out licensees who meet their cultural and linguistic needs without OHA mandating that every licensee to determine what "culturally and linguistically responsive services" mean, create documentation explaining those services are, provide information about these undefined services to each client, and provide such amorphous and subject services.

While we support psilocybin services for all cultures and languages, <u>requiring</u> the provision of these vague and undefined services would be too burdensome for licensees already buried under a mountain of regulations, paperwork, and client records. We respectfully ask OHA to consider these proposals from the standpoint of a business owner struggling to make ends meet and then weigh the necessity of such a rule against the confusion and costs in time, money, and resources this additional regulation would incur. We believe such honest consideration should lead OHA to remove these proposed revisions from the final rule package.