

November 21, 2023

VIA EMAIL ([publichealth.rules@odhsoha.oregon.gov](mailto:publichealth.rules@odhsoha.oregon.gov))

Oregon Health Authority  
Public Health Division, Oregon Psilocybin Services

Re: Comments on November 2023 Proposed Rules

To Whom it May Concern:

This letter contains our firm's comments to the proposed administrative rules published by the Oregon Health Authority (the "OHA") on November 1, 2023 (the "Proposed Rules") to implement ORS Chapter 475A, the Oregon Psilocybin Services Act (the "Act").

We are submitting this letter on behalf of our law firm and not on behalf of any specific client of ours.

Our comments to the Proposed Rules are as follows. With respect to any proposed changes to each specific Proposed Rule: (i) the changes are highlighted in red; (ii) new text is underlined; and (iii) deleted text is indicated with a strikethrough.

- 333-333-1010(19) Definitions – "Client records" means written information held ~~or known~~ by a service center or facilitator that may be used to identify a client ~~or prospective client~~, including any written communication made by a client ~~or prospective client~~ and any written information related to providing psilocybin services or selling psilocybin services to a client.<sup>1</sup>
- 333-333-1010 Definitions (NEW DEFINED TERM) – ~~(XX)(a)~~ "Client" means an individual that is provided psilocybin services in this state. (b) An individual becomes a client of a licensee on the earliest to occur of the following: (A) when the licensee first provides psilocybin services to the individual; and (B) when the licensee and the individual enter into a contract for the provision of psilocybin services.<sup>2</sup>

<sup>1</sup> There are two issues with this Proposed Rule. First, the term "client records" should not be so broad that it includes information that has not been reduced to writing and that is merely known in a person's memory. The term "client records" is used many times throughout the Proposed Rules, but always in a context that obviously contemplates written records. Various Proposed Rules mention "accessing," "altering," "storing," and "destroying" client records. The definition should be revised so that it is logically consistent with how the term is used throughout the Proposed Rules. Second, we do not believe that the various "client record" rules should apply to "prospective clients." Communications with prospective clients could take so many different forms and occur in so many different contexts that it would be very difficult to determine exactly who is a prospective client. Further, we do not believe that the OHA has the legal authority to require OHA licensees to store or maintain communications with prospective clients. The term "prospective client" does not appear anywhere in ORS Chapter 475A, and the confidentiality requirements in ORS Chapter 475A apply only to "clients." See ORS 475A.450.

<sup>2</sup> The term "client" is defined in ORS Chapter 475A, but it is not defined anywhere in the Proposed Rules. ORS 474A.220(2) provides: "Client means an individual that is provided psilocybin services in this state." Because so many

- 333-333-4060(4) License Fees – The Proposed Rule properly corrects a substantive error that existed in the 2022 version of the rules. Under the 2022 version of the rules, if an individual who satisfied the income eligibility requirements in OAR 333-333-4060(5) was applying for a manufacturer or service center license, the individual would nevertheless be denied the reduced license fee simply because the individual decided to form a legal entity to own the manufacturing or service center business (like any sensible business would), rather than own the business as a sole proprietor and risk unlimited personal liability to plaintiffs and creditors. This “Catch-22” scenario obviously made no logical sense and was merely the result of a 2022 drafting error. Consequently, we believe it would be fair to remedy the error by giving those otherwise-eligible individuals who decided to own their business through a legal entity in 2023 a \$5,000 credit if they renew their license in 2024. In other words, if a licensee was eligible for a reduced \$5,000 license fee in 2023 because they satisfied the income eligibility requirements in OAR 333-333-4060(5), but the licensee nevertheless paid the \$10,000 license fee merely because they formed a legal entity, then the licensee should be entitled to a \$5,000 credit if they renew their license in 2024.
- 333-333-4130(2) Application Denial – Until January 1, 2025, the Authority shall deny an application for a service center or manufacturer license if: (a) An individual applicant who does not qualify as an Oregon resident owns or controls greater than 50 percent of the entity proposed to be licensed; or (b) At least 50 percent of shares, membership interests, partnership interests, or other ownership interests in the entity proposed to be licensed are held by individuals who do not qualify as Oregon residents. For clarity, an applicant for a service center or manufacturer license may submit an application before January 1, 2025 or before any earlier date on which the applicant would satisfy the Oregon residency requirement. In such case, the Authority will process the application in the ordinary course.<sup>3</sup>
- 333-333-4130(3) Application Denial – Until January 1, 2025, the Authority shall deny an application for a facilitator license if the applicant is not an Oregon resident. For clarity, an applicant for a facilitator license may submit an application before January 1, 2025 or before any earlier date on which the applicant would satisfy the Oregon residency requirement. In such case, the Authority will process the application in the ordinary course.<sup>4</sup>
- 333-333-4300(6)(b) Licensed Premises Location Requirements – This Proposed Rule has so many issues that we are not attempting to provide any suggested language. Additionally, we believe that this Proposed Rule will likely be extremely and needlessly burdensome to service center operators. Consequently, we are strongly suggesting that this Proposed Rule be substantially revised or (better yet) deleted in its entirety. As an initial point, the OHA rule makers should understand that many service center operators have adopted a business model where the service center operators will be authorizing the temporary use of their licensed premises for activities unrelated to psilocybin services on a potentially frequent basis. Activities unrelated to psilocybin service could include various therapy, counseling, and other sessions that are unrelated to ORS Chapter 475A, yoga, meditation, and any number of other wellness activities. If this Proposed Rule is intended to require a service center operator to provide 5 days’ advance written notice to the OHA *for every single temporary use* of the licensed premises for an activity unrelated to psilocybin services, then we believe that service centers will be sending frequent and repetitive notices to the OHA. With that said, the following issues are of concern:

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Proposed Rules apply to “clients,” we believe it would be useful for the OHA to promulgate a rule that clarifies exactly when an individual becomes a “client.” We also believe that the OHA has the legal authority to do this. We suggest the following new definition, which is consistent with ORS 475A.220(2).

<sup>3</sup> This proposed revision clarifies that the OHA would not deny an application solely on the basis of the residency requirement if, under the OHA’s normal processing timeline, the application would otherwise be approved after January 1, 2025 or after the applicant would otherwise satisfy the Oregon residency requirement, as applicable.

<sup>4</sup> Seen note 3.

- The scope of the Proposed Rule and its effect is difficult to determine without seeing the “form” prescribed by the OHA.
  - What is the scope of the disclosure? How specific will the disclosures need to be?
  - What has to be disclosed? The type of event? The company or business that will be paying the service center to temporarily use the space? Every single individual who will be present?
  - What is the point of the advance notice? What will the OHA do with the advance notice? Unless the advance notice mentions an activity that is obviously in conflict with ORS Chapter 475A or the OHA’s Rules, it does not seem like the OHA *could* do anything with the notice. Is this just bureaucratic information gathering?
  - What are “multiple events”? Would a blanket advance disclosure covering numerous potential events be sufficient?
  - For example, could a service center operator notify the OHA as follows: “*For the next 90 days, we will be authorizing the temporary use of our licensed premises for numerous activities and events that are unrelated to psilocybin services and that are not prohibited by ORS Chapter 475A or the OHA’s Rules. Such activities and events may include, but not be limited to, therapy sessions, counseling sessions, yoga classes, meditation classes, and various other wellness classes.*”
  - If the foregoing hypothetical broad disclosure will work, then perhaps this Proposed Rule may not end up being overly burdensome. Of course, if the foregoing hypothetical broad disclosure will work, then again, one could ask what is the point of the Proposed Rule?
  - In short, the entire scope, meaning, and application of the Proposed Rule appears to be entirely dependent on the OHA form itself, which is not a part of the Proposed Rule. Consequently, it is difficult for any member of the public to provide meaningful comments to the Proposed Rule.
- 333-333-4300(6)(c) Licensed Premises Location Requirements – Psilocybin products may not be sold or transferred, and no psilocybin services may be provided, within any client administration area during an authorized temporary use of such client administration area.<sup>5</sup>
  - 333-333-4450(3) Client Administration Areas – Indoor client administration areas must be used located and constructed in a manner that effectively maintains confidentiality for clients during the participating in an administration session, subject to OAR 333-333-4810.<sup>6</sup>
  - Last sentence of 333-333-4520(1) Client Bill of Rights – Facilitators and service center operators may decline services to a client for any reason.<sup>7</sup>
  - 333-333-4640(2) Video Recordings of Administration Sessions – Service centers must make recordings made under this rule available to the clients and facilitators who were recorded to view upon request at the service center’s licensed premises, or if a client or facilitator requests, via electronic delivery. Service centers must

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<sup>5</sup> Certain service centers may have numerous client administration areas, some of which could be a substantial distance away from each other, or even on different wings or floors of the service center. It seems needlessly restrictive to prohibit multiple events from happening simultaneously, especially at large service centers. For example, if a service center has 10 separate rooms that serve as 10 different client administration areas, the service center operator should be able to hold an administration session in client administration area #1 while simultaneously holding a yoga class in client administration area #10.

<sup>6</sup> Certain service centers may have one or more client administration areas that are not completely physically enclosed by walls and doors. However, such administration areas could still be *used* in a way that maintains client confidentiality. For example, if a service center has a large “open” client administration area for group sessions, it would be possible for the service center to ensure that nobody other than the permitted participants are in the entire licensed premises, thereby ensuring client confidentiality.

<sup>7</sup> Adding service center operators to this sentence is consistent with ORS 475A.370(1) and removes any negative implication that may arise by omitting service center operators.

create and maintain records that documents when and to whom recordings are made available. Service centers are prohibited from charging a fee to view recordings.<sup>8</sup>

- 333-333-4810(2)(d) Client Confidentiality – The date and signature of the ~~patient~~ client.
- 333-333-4810(7) Client Confidentiality – ~~A service center or facilitator may not condition the provision of psilocybin services on whether a client consents to the use or disclosure of their information.~~<sup>9</sup>
- 333-333-4820(1) Record Retention – Licensees shall store, maintain and destroy records, including client records, in a manner that prevents unauthorized access, protects client confidentiality and prevents alteration of client records. (a) ~~If a client participates in an administration session at a service center, all~~ All client records and copies of client records, including records relating to the administration session that are created by ~~facilitators a facilitator and that are provided to the service center operator by the facilitator,~~ must be stored at the service center ~~where the client participates or intends to participate in an administration session.~~ (b) Electronic records may be stored on cloud-based platforms that use security measures to effectively prevent unauthorized access and protect client confidentiality. Electronic records must be accessible at the licensed premises. (c) Client records that are stored and made accessible in accordance with subsection (b) of this section are considered to be stored at the service center for purposes of subsection (a) of this section.<sup>10</sup>
- 333-333-4900(1) Collection and Maintenance of 303 Data – On or after January 1, 2025, service centers must collect 303 data in a manner prescribed by the Oregon Health Authority (Authority), consistent with OAR chapter 950, division 30, by using the form published by the Authority on its website for every client who

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<sup>8</sup> Certain clients (especially out-of-state clients) may find it a hardship to revisit a service center’s premises and may prefer the electronic delivery of a recording.

<sup>9</sup> We do not believe that the OHA has the legal authority to promulgate or enforce this rule, and that the rule should be deleted in its entirety. The rule is in direct conflict with ORS 475A.370(1), which expressly states that any licensee may refuse to provide psilocybin services to any potential client for any or no reason. (Note that the “subject to other applicable law” clause that appears at the beginning of ORS 475A.370(1) is obviously intended to make allowance for other statutes and constitutional rights (such as anti-discrimination statutes and rights), and not to permit the OHA to promulgate rules that completely contradict ORS 475.370(1).) The rule is also in direct conflict with the last sentence of OAR 333-333-4520(1). Further, as a practical matter, it will be nearly impossible for *any* licensee to conduct business without requiring clients to sign some type of consent form required by OAR 333-333-4810(2) as a condition to engagement. See note 10 below.

<sup>10</sup> The OHA rule makers should understand that many service center operators have adopted a business model where the service center operators are merely entering into space use arrangements with various facilitators. In other words: (i) many service center operators are not hiring or engaging any facilitators as employees or independent contractors at all; and (ii) the service center operators and the various facilitators who use the service center’s licensed premises are operating completely separate and distinct businesses. The suggested changes to subsection (a) recognize and take into account this fact. They also recognize that a facilitator and a client may have any number of off-site preparation sessions or other meetings with a client where the client *intends* to participate in an administration session at a particular service center, but never does for one reason or another. In such cases, there is no rule requiring the facilitator to (or reason why the facilitator would) deliver the facilitator’s records to a service center operator when nothing ever took place at the service center. Likewise, a facilitator and a client may have any number of off-site integration sessions or other meetings with a client that have nothing to do with the service center and that could theoretically go on for months or years after the administration session. Again, there is no rule requiring the facilitator to (or reason why the facilitator would) deliver the facilitator’s records to a service center operator for potentially numerous integration sessions that have nothing to do with the service center. The suggested change to subsection (c) is intended solely as a clarification to ensure that subsections (a) and (b) are consistent with each other.

participates in an administration session at the licensed premises. Notwithstanding the foregoing, clients are not required to respond to every question on the form published by the Authority.<sup>11</sup>

- 333-333-4900(5) Collection and Maintenance of 303 Data – A service center must collect 303 data from every client to the extent provided by the client, even if a client requests their information be withheld from data submitted to the Authority.<sup>12</sup>
- Introductory Paragraph of 333-333-4910(2) Required Reporting of 303 Data – For purposes of reporting under section (1) of this rule, a service center must aggregate and submit the following aggregated data that pertains to the previous quarter in a form and manner prescribed by the Authority, for clients who participated in an administration session at the licensed premises, except for clients who have requested that 303 data be withheld from being submitted to the Authority and except for clients who have not provided 303 data:<sup>13</sup>
- 333-333-4920 Sale of Client Records – (1) Except as otherwise provided in subsection (2) of this section, licensees Licensees may not sell or otherwise monetize a client’s client records unless: (a) the client expressly and specifically authorizes the licensee to do so; and (b) the licensee provides some monetary or other consideration to the client in exchange for the client’s authorization. (2) Licensees may not sell or otherwise monetize 303 data.<sup>14</sup>
- 333-333-5000(7)(c) Preparation Session Requirements – Product information document as described in OAR 333-333-2410 for any products that may be consumed during an administration session, except as provided in OAR 333-333-2410(2).

If you have any questions or comments, please let us know. Thank you.

Sincerely,



Dave Kopilak  
Attorney



Kaci Hohmann  
Attorney



Alex Berger  
Attorney



Sean Clancy  
Attorney

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<sup>11</sup> We assume that neither Oregon Senate Bill 303 nor the Proposed Rules would *require* a service center to deny a client’s participation in an administration session simply because the client refused to respond to a single question on the form published by the Authority. If that is the intention, then Oregon Senate Bill 303 is not consistent with ORS Chapter 475A’s stated purposes of access and affordability.

<sup>12</sup> This is consistent with our suggested comment to 333-333-4900(1).

<sup>13</sup> This is consistent with our suggested comment to 333-333-4900(1).

<sup>14</sup> Licensees and clients should be able to enter into arrangements where the licensee sells a client’s data, if the client agrees to the arrangement and the client is offered some consideration for doing so. This may be a way for licensees to offer clients lower costs for psilocybin services, thereby improving access and affordability.