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New Rules

SB 303 Definitions

(x) “303 data” Means any information, including personally identifiable information and de-identified information, that Oregon Laws 2023, chapter 150 requires service centers to collect, store, aggregate and report.

(x) “Client records” means information held or known by a service center or facilitator that may be used to identify a client, including any communication made by a client and any information related to providing psilocybin services or selling psilocybin products to a client, Client records include 303 data.

(x) “Severe adverse reaction” for purposes of collecting and reporting 303 data means an adverse behavioral or medical reaction that requires hospitalization.

(x) “Less severe adverse reaction” for purposes of collecting and reporting 303 data means an adverse behavioral or medical reaction that does not require hospitalization.

(x) “Aggregate” for the purpose of reporting 303 Data means to de-identify, combine and categorize quantitative data in a manner that prevents a client or an individual from whom the data was collected, from being identified, taking into consideration how the data could be used in combination with other data sources.

(x) “Disciplinary Actions” for the purpose of Oregon Laws 2023, chapter 150 means any notice of violation issued to a licensee in accordance with ORS 183 and any subsequent action resolving a notice of violation.

Statutory/Other Authority: Oregon Laws 2023, chapter 150

Statutes/Other Implemented: Oregon Laws 2023, chapter 150

333-333-4900 Collection and Maintenance of 303 Data

(1) Beginning on January 1, 2025, service centers must collect 303 data in a form and manner prescribed by the Authority, and consistent with OAR 950, Division 30, by using the form published by the Authority on its website for every client who participates in an administration session at the licensed premises.

(2) Service centers must store, maintain and destroy 303 data, in a manner that prevents unauthorized access and protects client confidentiality, consistent with these rules. 303 data is a client record and service centers must comply with all requirements in these rules related to client records.

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(3) 303 data may only be accessed by licensee representatives of a service center for the purposes of aggregating and reporting the data as required by OAR 333-333-4910.

(4) Prior to beginning an administration session, every client must provide written confirmation, in a form and manner prescribed by the Authority, that the client has had an opportunity to request that 303 data related to their receipt of psilocybin services is withheld from data submitted to the Authority.

(5) Failure to comply with this rule is a violation.

Statutory/Other Authority: Oregon Laws 2023, chapter 150

Statutes/Other Implemented: Oregon Laws 2023, chapter 150

333-333-4910 Required Reporting of 303 Data

(1) Beginning April 15, 2025, a service center must submit 303 data in a form and manner prescribed by the Authority on a quarterly basis no later than 15 days after the last day of the quarter.

(2) 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:

(a) The race, ethnicity, preferred spoken and written languages, disability status, sexual orientation, gender identity, income, age and county of residence, if applicable, of each client who participated in an administration session at the licensed premises.

(b) The reasons, or reasons, for which each client requested psilocybin services.

(c) The number of clients served.

(d) The number of individual administration sessions provided.

(e) The number of group administration sessions provided.

(f) The number of individuals to whom the psilocybin service center denied psilocybin services and the reasons for which psilocybin services were denied.

(g) The number of:

(A) Severe adverse reactions experienced by clients, of which the psilocybin service center operator is aware.

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(B) Less severe adverse reactions experienced by clients, of which the psilocybin service center operator is aware.

(C) Severe adverse medical reactions experienced by clients, of which the psilocybin service center operator is aware.

(D) Less severe medical reactions experienced by clients, of which the psilocybin service center operator is aware.

(h) The average number of times per client that psilocybin services were received.

(i) The average number of clients participating in each group administration session.

(j) The average dose of psilocybin per client per administration session.

(3) Service centers must report data in a manner that prevents unauthorized access and protects client confidentiality.

(4) Failure to comply with this rule is a violation.

Statutory/Other Authority: Oregon Laws 2023, chapter 150

Statutes/Other Implemented: Oregon Laws 2023, chapter 150

333-333-4920 Sale of Client Records

Service Centers may not sell or otherwise monetize client records, including 303 data.

Statutory/Other Authority: ORS 475A.235, Oregon Laws 2023, chapter 150

Statutes/Other Implemented: ORS 475A.235, Oregon Laws 2023, chapter 150

Conforming Amendments

333-333-1010

Definitions

(2) “Adverse behavioral reaction” means a client’s behavioral reaction to consuming psilocybin products that required contacting emergency services or a medical care provider that occurred during an administration session or up to 72 hours following an administration session. ~~client behavior that a facilitator reasonably believes may endanger the safety of the client, facilitator, or others.~~

(3) “Adverse medical reaction” means a client’s medical reaction to consuming psilocybin products that required contacting emergency services or a medical care provider that occurred during an administration session or up to 72 hours following an administration session

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~~physiological reaction occurring during an administration session that a facilitator reasonably believes may lead to medical harm. For example, a cardiac event or other health emergency~~

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333-333-5000

Preparation Session Requirements

(1) A facilitator must complete a preparation session with every client who will participate in an administration session at least twenty-four hours but no more than 90 days prior to the commencement of the client's first administration session with the facilitator. If different facilitators will conduct a client's preparation, administration sessions or integration session, the client must provide written consent as described in subsection (7)(g) of this rule. A client must have an opportunity to approve and meet any facilitator who will provide psilocybin services prior to receiving services from that facilitator.

(2) Preparation sessions required under this rule must be conducted privately with each individual client to allow clients to share personal information.

(3) For every client who will participate in an administration session, a facilitator must receive a completed client information form as described in OAR 333-333-5050.

(4) For every client who will participate in an administration session, a facilitator must receive written confirmation, in a form and manner prescribed by the Authority, that the client has had an opportunity to request that 303 data related to their receipt of psilocybin services is withheld from data submitted to the Authority.

~~(5)~~ For every client who will participate in an administration session, a facilitator must complete a transportation plan as described in OAR 333-333-5150 in coordination with the client. The transportation plan may not approve a client to operate a motor vehicle, bicycle, or other form of self-operated transportation following the administration session.

~~(6)~~ For every client who will participate in an administration session, a facilitator must coordinate with the client to complete a safety and support plan as described in OAR 333-333-5080.

~~(7)~~ A facilitator must review each of the following documents with a client during a preparation session:

(a) Informed consent document as described in OAR 333-333-5040.

(b) Client Bill of Rights as described in OAR 333-333-4520.

(c) Product information document as described in OAR 333-333-2410 for any products that may be consumed during an administration session.

(d) Documentation of the fees charged for provision of psilocybin services prepared in coordination with the service center. This documentation must indicate whether fees for services will be paid to the service center or directly to the facilitator. This documentation must describe

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applicable refund policies for psilocybin services and any additional fees, including but not limited to cancellation fees, that could be charged to the client.

(e) Documentation of the price charged for sale of psilocybin products prepared in coordination with the service center. This documentation must list product prices separately from taxes as required by OAR 333-333-5180.

(f) Applicable sections of the service center emergency plan required by OAR 333-333-4460.

(g) The service center's policy on possession of firearms and weapons required by OAR 333-333-4480(4).

(~~8~~7) In addition to the documents required by sections (3), (4), (5), ~~and (6)~~ and (7) of this rule, a facilitator must obtain prior written consent from a client during a preparation session for the following activities and circumstances:

(a) Participation in a group administration session, including the opportunity to meet other clients and facilitators participating in the group session as described in OAR 333-333-5020.

(b) Use of supportive touch during an administration session, if any, as described in OAR 333-333-5120(6).

(c) Participation in a training practicum, including information regarding training program students and instructors who will be present during the client's administration session. The client must have an opportunity to meet any students or instructors who will be present during their administration session prior to the commencement of an administration session.

(d) Video or audio recording of an administration session pursuant to requirements of OAR 333-333-4640.

(e) Presence of an interpreter or client support person allowed by OAR 333-333-5070, in the administration area during an administration session.

(f) Sharing of identifiable client data as described in OAR 333-333-4810(2).

(g) The use of different facilitators to conduct a client's preparation, administration sessions or integration session.

(h) Consuming secondary doses of psilocybin products after the administration session has begun, including the maximum amount of psilocybin analyte that a client has agreed to consume, not to exceed 50 mg of psilocybin analyte.

(i) Participating in an administration session where licensee representatives of a service center will be present pursuant to OAR 333-333-5200(9).

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(j) Disclosure form for de-identified client data required by OAR 845-025-4810(5).

(~~98~~) If a facilitator or service center intends to share de-identified data related to the client's receipt of psilocybin product or services, a facilitator or service center must provide a disclosure form required by OAR 333-333-4810(~~65~~) during the client's preparation session.

(~~109~~) During a preparation session, facilitators must provide clients an opportunity to discuss internal and external factors that could impact a psilocybin experience including but not limited to the client's intention and expectations. If the client will participate in an outdoor administration session, the facilitator must provide an opportunity to discuss the client's specific concerns that may be relevant to participating in an outdoor administration session, including but not limited to allergies and sensitivity to sun exposure.

(~~110~~) Preparation sessions may be completed in person or virtually using video conferencing technology.

(~~124~~) The requirements of this rule may be satisfied by conducting multiple preparation sessions.

(~~132~~) A facilitator must complete an initial preparation session with every client before conducting an administration session with that client for the first time. After a client completes an initial preparation session at a service center, the client is not required to complete additional preparation sessions prior to participating in an administration session at the same service center for a period of 12 months.

(~~143~~) If a facilitator does not complete additional preparation sessions as allowed by section (12) of this rule, the facilitator must confirm that the information contained in the client's previously completed client information form remains accurate prior to conducting additional administration sessions.

(~~154~~) A facilitator must discuss the process for verification of license status and process for making complaints to the Authority during a preparation session.

(~~165~~) The documents described in sections (~~76~~), (~~87~~) and (~~98~~) of this rule must be provided to a client prior to a preparation session upon the client's request.

Statutory/Other Authority: ORS 475A.235 & ORS 475A.340

Statutes/Other Implemented: ORS 475A.340

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