Comments on Proposed Permanent Rulemaking—
OAR Chapter 333, Division 333 ("Oregon Psilocybin Services Rules")

Prepared for: Rules Coordinator, Oregon Psilocybin Services, Oregon Health Authority Public Health Division

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Thank you for the opportunity to provide public comment on the proposed permanent rules to implement OAR Chapter 333, Division 333 ("Oregon Psilocybin Services Rules"), pursuant to ORS Chapter 475A.

Reason Foundation is a national 501(c)(3) public policy think tank that offers pro-bono research and technical assistance to public officials and other stakeholders to help design and implement policy solutions in a variety of areas, including public finance, public pension solvency, infrastructure, and drug policy. The emerging regulatory framework governing certain controlled substances across various states—including medical and adult use recreational cannabis and psychedelics—is an area of particular interest. We have advised officials on emerging drug policy transformations in states like Michigan, New Jersey, and Nevada. We are also a founding member of the Cannabis Freedom Alliance, which seeks to advance federal cannabis legalization in a manner that respects state autonomy to self-design their own policies and ensure low barriers to market entry to maximize opportunity for potential entrepreneurs, especially those communities that have been most severely impacted by the drug war.

We recognize and appreciate the rigor and diligence with which the Oregon Health Authority, Oregon Psilocybin Services (OPS) and the Oregon Psilocybin Advisory Board has conducted the important, albeit challenging, work of building out the operating regulatory framework to guide implementation of ORS chapter 475A. The process overall appears to have generated a prudent set of rules that will create a program that balances client safety with strong licensee oversight under a flexible set of program rules. As a first-in-the-nation exercise in developing such a robust framework, your work overall appears to have been successful and will provide a worthy template for other states to consider following.

Our review of the proposed permanent rules related to Oregon Psilocybin Services yielded the following observations for consideration as you approach final rulemaking:

- **Proposed Rule 333-333-2015:** We understand that for the purposes of launching a manageable regulatory framework for psilocybin services that the inclination of the

advisory board centers on offering a limited scope of products derived from one authorized psilocybin species (*Psilocybe cubensis*).

As we indicated in a previous submission commenting on proposed program rules in April 2022, we hope the agency will give routine, periodic consideration to authorizing additional strains of psilocybin species as the program matures in the future. We also recommend expanding the range of allowed products to include alternative, non-oral consumption modalities in the interest of encouraging product diversity and a wide range of potential product price points, which could help ensure affordable access to psilocybin services consistent with the intent of ORS chapter 475A.

- **Proposed Rule 333-333-4020**: This proposed section appears to require each applicant to develop a social equity plan tied to a set of "objective performance metrics." Having not been outlined in advance by the Oregon Health Authority, these metrics would presumably be self-defined by each applicant, making them inherently subjective in nature. Further, upon license renewal the licensee would be required to report back to the Authority with regard to their adherence to their self-defined performance metrics. Since there will be no consistency among metrics if they are self-defined by applicants/licensees—and thus no ability for the Authority to truly gauge objective performance toward social equity goals—then it is unclear how much value this process will add overall, what performance thresholds would trigger denial of a license renewal, and what standards the Authority would use to evaluate overall performance of licensees in a holistic and meaningful way.

- **Proposed Rule 333-333-4040**: The proposed rule would require any applicant or licensee to maintain a full list of financial interest holders along with contact information for the representatives of these financial interest holders. While we understand the state's desire to monitor the financial affairs of licensees, there may be a case for restricting "financial interest" holders to holders of an "ownership interest." Technically, a short-term lender providing working capital finance, for instance, would be a financial interest holder even though that entity exerts no control over the licensee and its only interest is in the repayment of principal plus interest. If a licensee is in need of short-term liquidity it may not be able to timely amend its list of financial interest holders.

- **Proposed Rule 333-333-4050**: The proposed residency rules would require applicants representing at least 50 percent ownership in a venture to have lived in Oregon the previous two years in order to qualify for a license under ORS chapter 475A until January 1, 2025. We understand the intention of "localizing" the nascent industry during its incubation period, but the exclusion of non-Oregon actors and firms from the process runs the risk of limiting the pool of quality actors entering the applicant pool. There are also important legal ramifications to consider, as a series of recent federal court decisions have struck down state residency requirements as violative of the Dormant Commerce Clause. The Dormant Commerce Clause is a doctrine developed through

precedent that essentially declares invalid most restrictions on the free movement of persons, goods or capital between the states. In 2019, the U.S. Supreme Court declared Tennessee could not require an applicant to have been a state resident for the preceding two years in order to be awarded a retail liquor license. Earlier this year, the federal First Circuit Court of Appeals struck down a similar requirement in Maine that applicants be state residents before they could be awarded a commercial cannabis license. This latter decision was significant because it makes clear that the Dormant Commerce Clause extends even to state-regulated markets that are not legally recognized by the federal government. We believe these decisions create disfavorable precedent for the proposed residency requirements.

- **Proposed Rule 333-333-4060:** We have two key observations regarding the proposed annual license fee structure for manufacturing, service center, facilitator and laboratory applicants. First, in contrast with the other three licenses, the facilitator license is the virtual equivalent of an occupational license, and the proposed fees are set at levels that could serve as a barrier to entry for some seeking to enter that profession. Second, given that administrative costs of operating the new psilocybin program are as of yet unknown, it may be warranted to consider the current fee structure as provisional for a temporary period and to seek a cost assessment after the first 2-3 years of program implementation in order to evaluate the adequacy of the proposed fee structure and calibrate, if necessary.

- **Proposed Rule 333-333-4100**: The proposed rules would prudently prevent the Authority from considering certain previous convictions for the manufacture or possession of marijuana or other controlled substances during the applicant background check process. This furthers the mission of improving outcomes for former offenders and unwinding some of the social and economic harms created by a legacy of prohibitionist drug policies. We would respectfully suggest that consideration be given to expanding this provision to cover a wider array of previous convictions. Additionally, it may be worth calibrating the timing of the marijuana manufacturing exclusion to align with the original implementation of the state's recreational marijuana law on the grounds that it would not be prudent to accept license applicants that have been convicted for illegal marijuana manufacturing after the implementation of a legalized, state-licensed marijuana manufacturing regime in Oregon.

- **Proposed Rule 333-333-4110**: The proposed rules require cities and counties to submit a "land use compatibility statement" related to each application in order for the Authority to review and make decisions on individual applications. Because there is no required deadline or response period associated with this mandate, it is possible that applications could suffer delays and inaction based on poor responsiveness or other subjective preferences of local government administrators. We recommend that cities and counties be given no more than 21 days to review applications for land use compatibility, lest the application be automatically presumed to be compliant.

- **Proposed Rule 333-333-4400**: The proposed rules seem unnecessarily restrictive by preventing clients from legally consuming any other legal intoxicants during a session, even prescribed medications and tobacco or cannabis products. We would suggest a more limited restriction allowing clients more flexibility for responsible use of legal intoxicants.

- **Proposed Rule 333-333-5090**: This proposed rule requires the client to sign an attestation in an acknowledgement document that they have received or completed the client bill of rights document, the informed consent document, the client information form, and the transportation plan. Given that proposed rule 333-333-5080 mandates the development of "safety and support plans" for each client's administration session, it may be worth considering the inclusion of those plans in this attestation too.

Additionally, we want to commend the prudent approach applied to several elements of the proposed permanent rules:

- ***Group and Outdoor Administration***: The rules as proposed would ensure regulatory flexibility for service center providers to offer regulated group and outdoor administration of psilocybin services, which we believe will lower the costs of services, meet a wider range of client preferences, and expand access to a wider range of the population, particularly lower-income and historically marginalized populations. While we realize that these rules may require calibration over time, the proposed limitations on group size (no more than 25 per group administration session, subject to a 100-person cap per service center at any given time) and the proposed sliding scale related to facilitator/client ratios appear to provide sufficient scope of action and flexibility.
- ***Product Quantity Limits, Consumption Limits, and Packaging/Serving Sizes***: The proposed caps on product quantity, consumption amounts, and packaging and serving sizes all appear to be reasonable limitations from the perspective of both ensuring that licensees have access to sufficient quantities of psilocybin products on hand and that clients have access to sufficient dosages during individual administration sessions. That said, there may be situations where the current two serving (50mg) maximum allowed limitation may be insufficient for particular clients depending on individual conditions, where a higher cap could be justified if paired with adequate client warnings regarding typical dosage strengths.
- ***Safety and Support Plans***: We believe the intentional inclusion of contingency planning in the process before administration occurs is an important way to for all parties to mitigate risk and capably navigate challenging situations if they arise.
- ***Clarification of Taxable Products and Services***: Though implied in ORS 475A, the rules clarify that a service center may only collect the 15% retail sales tax on psilocybin products and no other goods, and they also reiterate that service centers may not impose a tax on psilocybin services.

We hope this information is useful, and we welcome any related questions or dialogue. Please let us know if you have any questions or need additional information.

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