



May 20, 2022

To Members of the Public,

Oregon Psilocybin Services (OPS) would like to thank all members of the public who took time to offer comments on our proposed administrative rules on Training Curriculum, Products and Testing. OPS received approximately 200 written and verbal comments during the public comment period that took place April 1-22, 2022 and relied on these comments to further refine the final rules. As a reminder, the rulemaking process was informed by recommendations from the Oregon Psilocybin Advisory Board (OPAB), input from Rulemaking Advisory Committees (RACs) and comments received during the public comment period. Please remember that these expedited rules are a just a portion of the rules that will be adopted to regulate the production of psilocybin products and the provision of psilocybin services in Oregon. The remainder of the rules will be considered later this fall and adopted by December 31, 2022.

The final copy of the executed rules can be found at:

<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=7102>

In some cases, public comments were incorporated in the adopted rules and in others they were not. OPS weighed competing priorities and viewpoints that were received throughout the rulemaking process when making revisions, while considering equity, public health and safety. In addition, OPS considered the statutory authority of the Oregon Psilocybin Services Act and the scope of current rulemaking. OPS received numerous comments that may be relevant to future rulemakings but were not related to the content of the proposed rules in this subset of rules. It is important to note that this letter does not address every change to the draft rules. Instead, it responds to the most frequent themes observed from the public comment period.

Many members of the public expressed support for an “Entheogenic Framework” for licensing. This framework refers to a document that that has been presented to Oregon Psilocybin Advisory Board subcommittees and proposes an alternative set of

requirements for licensees who qualify as entheogenic practitioners. Because the framework proposes exceptions to rules that have not yet been drafted, and because the Oregon Psilocybin Advisory Board has yet to consider the proposal, OPS did not address these comments in the current rulemaking. OPS is committed to understanding the impact of statute and rules on entheogenic practices through collaboration and partnerships with communities.

OPS received several comments regarding scope of practice and the difference between therapy and facilitation. OPS is unable to regulate the scope of practice of licensed clinicians and other professionals. Under the Oregon Psilocybin Services Act, facilitation is non-directive, and clients are not required to be diagnosed as a condition of receiving services. OPS has adjusted rule language in several places to ensure the practice is specific to psilocybin services based on feedback received.

Some members of the public expressed concern that proposed testing rules are overly burdensome and the cost of testing will be passed onto clients. To clarify, potency and speciation are the only tests required at regular intervals in the final rules. Tests for pesticides, heavy metals and microbial contaminants will be requested on a less frequent basis like the “market basket” model for testing agricultural crops. Also, batch size is solely a testing requirement. Manufacturers who wish to harvest more than one kilogram may do so, but they must group product in separate batches for testing if it will be sold as whole fungi. OPS removed the two percent minimum sample increment identified in the draft. The Oregon Environmental Laboratory Accreditation Program (ORELAP) will be working on additional rules on sampling.

OPS received comments requesting that the rules allow additional species of mushrooms and use of additional substrates. The Oregon Psilocybin Advisory Board recommended limiting cultivation to *Psilocybe Cubensis* and prohibiting substrates that may pose a risk to health and safety. To avoid the risk associated with deadly, poisonous look-alikes and the potential for wood lover’s paralysis and animal-borne pathogens, OPS has upheld this recommendation in final rules. That said, although raw manure is prohibited, finished compost is allowed. OPS looks forward to consideration of additional species in the future through continued dialog with the public and recommendations from the Oregon Psilocybin Advisory Board.

Some comments stated that the required hours for facilitator training were insufficient, while others stated that the required hours were overly burdensome. The final rules do make some adjustments to training requirements based on consideration of comments received. Required hours for the pharmacology module

have been reduced and hours for the group facilitation module have been increased. The in-person training requirement for core training modules has been eliminated, and the rules have been clarified to state that practicum must be conducted in-person. OPS included a requirement that training program personnel must approve student readiness for the facilitator licensing exam. Accelerated training hours have been amended to specify that preparation, administration and integration modules are not eligible for accelerated credit hours. The decision to exclude these additional modules was made to support positive client outcomes through adequate training on the foundational components of psilocybin services in Oregon. Finally, OPS will not allow partial training programs as a matter of client safety. Due to increased concerns about facilitator abuse, it is critical that training programs certify student readiness to apply for a facilitator license. That said, partial training programs that specialize in certain subjects could partner or contract with a comprehensive training program to teach a portion of their curriculum.

Access to services is critical to the success of implementation. Several comments requested that rules allow for expanded product delivery methods to increase accessibility. OPS is unable to accommodate this request due to the language used in the Oregon Psilocybin Services Act. The Act consistently uses the terms “consume” and “consumption” when referring to psilocybin products and administration sessions. The common meaning of consume means “to eat, drink or ingest”. After evaluating the issue, OPS determined that the text of the measure limits psilocybin products to those products that can be consumed orally, and the rules reflect this understanding. In addition, statutory language does not allow for consumption of psilocybin products or provision of psilocybin services on any premise other than a licensed service center. For that reason, psilocybin services are confined to the licensed service center during an administration session.

Affordability is also critical for access to services. While creating access to services is a priority, OPS does not have statutory authority to regulate the costs of psilocybin products or psilocybin services. Because OPS is a fee-based program, the cost of administering the section’s work must be covered by licensing and application fees.

OPS appreciates the support for small businesses highlighted in many of the comments. It is important to note that OHA cannot discriminate against businesses, regardless of size. Licenses will be issued to those that meet the criteria specified in statute and rule. OPS will strive to support the regulatory community as much as possible and is working with partners to bring resources and information to small business owners later this year.

Finally, many comments requested changes in rule that conflict with the text of the statute. In these cases, OPS is unable to adopt rules that are inconsistent with statutory requirements. For example, land use compatibility statements requirements and local opt-out regulations cannot be superseded by administrative rule. OPS encourages potential applicants to work with their local governments to assess the viability of opening a service center or manufacturer license at a specific location.

Thank you again for the time and energy you have dedicated to successful implementation of the Oregon Psilocybin Services Act. We appreciate you!

Sincerely,

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