



September 19, 2022

Oregon Psilocybin Advisory Board
Atheir Abbas, Chair
Angela Carter, Vice-Chair
Jessie Uehling, Vice Chair

Dear Board Members:

Thank you for providing recommendations to the Oregon Psilocybin Services (OPS) section in accordance with ORS 475A by June 30, 2022. In total, the board's recommendations represent a body of work spanning sixteen meetings of the full advisory board and many hours of subcommittee work.

We have considered the board's recommendations in drafting the attached administrative rules. The draft rules will be further refined after the Rules Advisory Committee (RAC) meetings in September and the Rules Public Comment Period in November. OPS will then finalize and adopt rules by December 30, 2022. While most of the board's recommendations were incorporated into the draft rules, some were not. Some recommendations were modified to account for administrative feasibility or for health and safety reasons. The proposed rules center public health and safety, equity and access, and operational flexibilities.

Equity and Access

The Oregon Psilocybin Advisory Board (OPAB) and OPS have been exploring ways to create equity and accessibility within ORS475A. Reducing costs for licensees is an important factor that will impact client access to psilocybin services. To this point, the draft rules allow for reduced license fees for applicants who meet certain conditions. OPS recognizes that there may be concerns with the amounts proposed for license fees; however, ORS475A created a fee-based structure. This means that OPS is entirely fee funded, and the cost of our operations must be fully supported by license fees. The proposed fees are based on estimates of the number of applicants we expect to issue licenses to and the costs of implementing

statutory requirements. If more licenses are issued than anticipated, the fees may be lowered in the future.

Following the board's recommendation, the draft rules require each licensee to create and maintain a social equity plan that describes how they will apply diversity, equity, justice, and inclusion principles in their work. OPS is committed to equity and justice centered approaches that align with the agency's goal of eliminating health inequities, as well as the State Health Improvement Plan (SHIP).

The draft rules also allow for outdoor administration and group facilitation under certain conditions. The requirements for these sessions are designed to support client safety while also allowing flexibilities for various kinds of practices. Group sessions may also allow opportunities to reduce costs for clients.

The draft rules contain provisions that allow for a client support person to be present during an administration session. A client support person may increase access to psilocybin services for clients with additional support needs, such as mobility assistance, toileting assistance, or assistance with communication or medical devices. Additionally, the draft rules also require informed consent forms and other documents to be translated into a client's preferred language and require interpretation to be provided for preparation, administration, and integration sessions. By centering inclusivity and accessibility, clients that have been underserved or excluded from access because of additional needs will have better access to psilocybin services.

Safety

Providing complete and accurate information is a key component to ensuring client safety. OPAB recommendations included client bill of rights and informed consent documents which inform clients of potential risks of receiving psilocybin services, as well as client rights and responsibilities for directing their own experience. OPS incorporated these documents into the draft rules with slight adjustments to include requirements found in other rule sections.

In addition to the documents recommended by the board, the client consent process further supports client safety by requiring reporting of misconduct and consent for specific activities. The draft rules require clients to consent to the use of appropriate supportive touch during an administration session and prohibit all other types of touch. While video recording a client without

their consent is not permitted, clients have the option to consent to video recording. This option provides an additional tool for client-centered experience. The draft rules also require facilitators and service center employees to report any conduct that harms or endangers clients. In addition, the draft rules require client consent for release of identifying information but allow release of de-identified information consistent with the standards outlined in the Oregon Psilocybin Services Act, specifically ORS 475A.450

The psilocybin advisory board recommended requiring a transportation plan to prevent clients from operating a motor vehicle at the conclusion of an administrative session. The draft rules include this recommendation and expand the transportation plan requirements to specify that facilitators are required to take action if a client fails to follow their agreed upon plan.

The Oregon Psilocybin Services Act requires facilitators to use a client information form to assess client suitability to receive psilocybin services. OPAB made detailed recommendations on the client information form and risk assessment framework. The draft rules modify the recommended framework to allow for greater flexibility for clients to direct their own experience. Except for clients taking Lithium, the proposed rules employ an inclusive, informational approach to clients accessing psilocybin services. Through informed consent and client intake, medications and conditions that may be contraindicated are addressed without excluding clients from services. This approach supports client access and non-directive facilitation.

The draft rules also revised the client information form to ensure that facilitators offer services within their scope of practice. Facilitators will be unable to effectively evaluate a client's health history without performing activities which require independent professional licensure outside of ORS475A. The proposed rules address client safety issues by requiring an individualized safety and support plan when the client and facilitator agree that it is necessary to address specific risk factors presented by the client's individual circumstances.

Flexibility

The draft rules supplement OPAB recommendations by requiring a minimum duration for administration sessions. Because the minimum duration is dependent on the amount of psilocybin consumed, this requirement promotes client health and public safety while still allowing for a range of client experiences. Similarly, the proposed group facilitation ratios

are dependent on consumptions levels to allow clients and facilitators more options for group administration sessions.

Both OPAB and the Rules Advisory Committee convened earlier this year stressed the importance of allowing psilocybin manufacturers and service centers to share a location with unlicensed businesses. The draft rules create flexibility for shared locations by proposing several requirements for access and security at licensed premises that all applicants will need to meet without explicitly preventing a licensed premises from being located on the same tax lot or mailing address as an unlicensed business. The draft rules allow OPS to evaluate each application on a case-by-case basis to determine whether it meets our premises requirements. In some instances, this will allow licenses the option to share an address or equipment with unlicensed business to reduce operating costs.

OPAB made recommendations on packaging that are not reflected in the draft rules. Specifically, OPAB recommended childproof packaging, a universal symbol, and a packaging pre-approval process. In weighing the safety benefits of the proposed recommendations against the cost to licensees, OPS determined that these recommendations are unnecessary. Unless a psilocybin product is illegally removed from a service center, minors will never have access to these products. As such, the packaging recommendations do very little to promote public health and safety. By omitting these recommendations, the draft rules allow licensees greater flexibility to choose cost-efficient and environmentally friendly packaging.

OPAB made many helpful recommendations that are not addressed in this letter. These recommendations are incorporated throughout the draft rules and include subjects such as staffing levels, product storage, security requirements, and product tracking. The board's work has been comprehensive and formed the foundation of the draft rules. We look forward to continuing this work with you. If board members would like to provide feedback to draft rules in their individual capacity, please participate in the public comment period, from November 1 to November 21, 2022.

With much gratitude,

André Ourso, Administrator, Center for Health Protection
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