

MEMORANDUM

To: Mayor and Council
From: Eric Mitton, City Attorney
Study Session Date: July 28, 2022
Subject: **Psilocybin: state rulemaking and local responses**

COUNCIL DIRECTION

Staff is providing information related to Oregon Health Authority rulemaking regarding psilocybin and the practical challenges related to the City implementing time-place-manner regulations if no temporary opt-out occurs, and providing Councilmembers a forum to have the policy discussion amongst themselves as to the City's more long-term policy stance regarding psilocybin facilities.

PRESENTATION OUTLINE

- Presenters:
 - Ryan Martin, Chief Financial Officer, Deputy City Manager
 - Alicia Wilson, Senior Assistant City Attorney
 - Carla Paladino, Principal Planner
 - Winnie Shepard, City Recorder

PREVIOUS STUDY SESSIONS AND G-3 MEETINGS ON THE TOPIC

- Staff conferred with Councilmembers at this topic at the G-3 meetings that took place on June 28 and June 30, 2022.
- Staff then presented the matter to Council at the July 21, 2022 Council meeting. At that meeting, Council postponed the vote until August 4, 2022 and requested a study session before that date.

BACKGROUND

Psilocybin is a psychoactive and hallucinogenic chemical found in certain varieties of fungi (frequently referred to as “magic mushrooms”). In November 2020, Oregon voters approved Ballot Measure 109,¹ otherwise known as the Oregon Psilocybin Service Act, which allows for manufacture, delivery, and administration of psilocybin at licensed facilities. However, that measure expressly allows local jurisdictions to opt out of allowing production

¹ Although the majority of voters in the State as a whole voted for Measure 109, the majority of voters in the City of Medford voted against Measure 109.

or service centers, so long as that issue is referred to local voters at a general election. The question directly before Council is whether or not to refer this issue to the voters in the City of Medford.

I. Psilocybin service centers.

Psilocybin service centers are facilities where individuals take psilocybin under the direction of a “facilitator.” A facilitator is an individual with a license from the Oregon Health Authority but is not necessarily a doctor, nurse practitioner, psychologist, psychiatrist, or other medical professional. The OHA requirements for a facilitator license are a high school diploma and 120 hours (three weeks) of training.

Consumption of psilocybin will be on-site at the service center; individuals are not allowed to take psilocybin home for home use. Recipients of psilocybin will likely be required to stay at the service center for some amount of time for observation, and then will be discharged with some sort of safety plan intended to prevent DUII or other dangerous behavior outside of the facility. However, what those safety regulations look like in practice, either within the facility or surrounding client discharge, have not been answered by Oregon Health Authority at this time.

II. Substantive arguments against a local opt-out.

Staff takes no position on the substantive policy question of opting out or not in the long term. Staff is setting forth arguments both for and against opting out to assist readers in understanding the policy question presented to Council. Arguments against opting out include the potential benefit for certain mental health and addiction treatment:

High-dose psilocybin produced large decreases in mood and anxiety along with increases in quality of life, life meaning and optimism and decreases in death anxiety. At six-month follow-up, these changes were sustained with about 80% of participants continuing to show clinically significant decrease in depressed mood and anxiety.

Johns Hopkins University School of Medicine study, as summarized by Healing Advocacy Fund (a proponent of psilocybin use).

Effect of psilocybin therapy on personality structure in patients with treatment-resistant depression...Neuroticism scores significantly decreased while Openness scores also significantly increased following psilocybin therapy. These changes in personality are more pronounced than similar changes occasioned by traditional pharmaceutical depression treatment.

Imperial College London study, as summarized by Healing Advocacy Fund.

A prior study found that psilocybin treatment, in combination with cognitive behavioral therapy (CBT) for smoking cessation, resulted in substantially higher six-month smoking abstinence rates than are typically observed with other medications or CBT alone. This follow-up study determines whether these abstinence rates were maintained after 12 and 16+ months. ... Researchers found at 12-month follow-up, 10 participants (67%) were confirmed as smoking abstinent. At long-term follow-up (>16 months), nine participants (60%) were confirmed as smoking abstinent.

Johns Hopkins University School of Medicine study, as summarized by Healing Advocacy Fund.

III. Substantive arguments in favor of a local opt-out.

Staff takes no position on the substantive policy question of opting out or not in the long term. Staff is setting forth arguments both for and against opting out to assist readers in understanding the policy question presented to Council. Arguments in favor of opting out include the concern that the FDA has determined that psilocybin warrants further controlled studies but has not yet determined that it is safe or effective:

As medical experts in psychiatric care, we are concerned about determining medical treatment by ballot initiative. Such treatment should be evidence-based and determined solely by professional standards of care. Science does not yet indicate that psilocybin is a safe medical treatment for mental health conditions. While the FDA has granted psilocybin breakthrough therapy status, this does not establish the safety and efficacy of this treatment, it merely establishes the process by which to further study the treatment.

Chief Executive Officer of the American Psychiatric Association's statement regarding Measure 109.

We are concerned that the FDA approval process, which was developed specifically to protect the public from speculative drug treatments that are potentially dangerous, is being bypassed. The Phase 3 trials for psilocybin have not yet even started. We agree with our colleagues at the OPPA and APA: using ballot initiative to bypass professional standards and public safety measures is dangerous.

Executive Council of the Oregon Council of Child and Adolescent Psychiatrists' statement regarding Measure 109.

Psilocybin affects serotonin levels in the brain and induces hallucinations. It could interact adversely with prescribed medications, worsen a patient's

mental health condition, or encourage a person to stop their current treatment without medical advice. In essence, it will allow prescribing of a controlled substance with effects on the body and the brain to a practitioner with no medical training.

Oregon Psychiatric Physicians Association statement on Measure 109.

Opponents also raise the concern that it can be dangerous to the users and others should a psychedelic crisis occurs (frequently referred to as a “bad trip”) if there are not adequate safety measures in place. A Johns Hopkins study found that of those who experienced a psychedelic crisis while taking psilocybin, 10% of individuals considered themselves a danger to themselves or others.² Risks of psilocybin use without adequate supervision or safety measures can include homicide, as occurred in Crescent City, California in 2010, or accidental death, as occurred in Snohomish County, Washington in March 2022. State regulation of the safety plans of psilocybin service centers is an unanswered question at this time.

IV. The state of OHA rulemaking and its effect

As of July 2022, the Oregon Health Authority (OHA) has not completed rulemaking, and in fact has not even released a public draft of most of the rules that would apply to psilocybin manufacture or psilocybin service centers.³ Only rules on such limited matters exist at this time, including the growth medium for psilocybin mushrooms and the training requirements for psilocybin facilitators.

There will be Rules Advisory Committees (RACs) appointed in the latter half of September 2022.⁴ Those RACs will work on draft rules that will be published for review and comment at some point in November 2022. The Oregon Health Authority will adopt final rules on or before December 31, 2022. Almost immediately after releasing those final rules, on January 2, 2023, the OHA is required to begin processing applications for psilocybin licenses. Oregon Health Authority declined to answer questions as to what future rules will look like during a June 17, 2022 meeting with various municipalities, including your City Attorney:

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https://www.hopkinsmedicine.org/news/media/releases/researchers_urge_caution_around_psilocybin_in_use

³ <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Laws-Rules.aspx>

⁴ <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-Rules-Advisory-Committees.aspx>

Are you able to provide some insight now as to what future rules will look like? Is there any chance the rules due out by the end of the year might be completed earlier?

As directed by M109, the Oregon Psilocybin Advisory Board (OPAB) will provide their final recommendations on rules by June 30, 2022. OPS [Oregon Psilocybin Services, a section of OHA] will then share the first set of draft rules in early September in time for the Rules Advisory Committee (RAC) meetings. Rules will be further revised based on RAC input, and an updated set of proposed rules will be posted by November 1st 2022. The public comment period will run from November 1 – November 18, 2022. We are unable to expedite this timeframe.

At that same meeting Oregon Health Authority also refused to answer local jurisdictions questions about the preemptive effect of its upcoming rules on local time-place-manner regulation, instead deferring to City Attorneys:

Can you give an overview of preemption with this new law?

Oregon Psilocybin Services is not able to offer guidance on this issue. This question is better suited to local counsel.

Your City Attorney's office believes that any local time-place-manner regulation would have to be consistent with the final rule adopted by December 31, 2022 to avoid preemption issues. Based upon prior experience with state rulemaking such as Climate-Friendly and Equitable Communities rulemaking, this office believes that prior drafts, especially prior to the November 1 draft, may differ substantially from the final rule; those prior drafts would not be a reliable starting point for local time-place-manner regulation.

In addition, while public testimony at the July 21 City Council meeting focused on psilocybin in a quasi-medical setting, during the June 17, 2022 meeting, the Oregon Health Authority also refused to answer local government questions about whether the rules would allow for retreat-style "service centers" as opposed to more clinical-style "service centers," and whether local governments would be preempted from banning through time-place-manner regulations such quasi-recreational operations:

Section 91(3) appears to give an affirmative right to a service center to lawful growers of the fungi. Service centers don't have much for sideboards in the ballot measure. If a grower asserts a right for, say, a service center consisting of a 3-day retreat with food service and overnight stays, is that presumed to supersede state and/or local land use prohibitions on retreat centers?

This is a complex question. As we get further into the rulemaking process, we'd be happy to reconvene with local government partners to discuss more details once they are known.

Furthermore, it should be noted that any application for a production facility or service center that is submitted before local regulations are finalized and adopted by City Council is allowed to rely on the state of regulations when the application is complete, for all time going forward. Based on prior experience with land use regulations, local time-place-manner land use regulations would take at absolute minimum seven months to draft as the code changes must go through Planning Commission study session(s), Planning Commission recommendation, City Council study session(s) and a City Council vote. Applications for psilocybin production facilities and service centers that were turned in prior to City regulations being adopted and approved could not be regulated through subsequently-adopted land use regulations; they would be deemed "prior nonconforming uses" and grandfathered in, exempt from that subsequently-adopted local regulation.

The time line of the State's rulemaking process, and its impact on local jurisdictions prevent staff from drafting and completing effective time-place-manner regulations before applications are accepted starting January 2, 2023. Staff takes no position on the substantive policy question of whether or not the City of Medford should allow psilocybin production and use within its borders in the long-term. However, if Council would like staff to consider drafting time-place-manner regulations on such operations before the operations can escape local regulation through the "prior nonconforming use" doctrine, a two-year opt-out would be necessary. Staff recommends referring a two-year opt-out on that specific basis.

DIRECTION SOUGHT

Although all options will be presented at the August 4, 2022 Council meeting for a final vote, Staff seeks Council direction both on whether a temporary opt-out should be referred for the reasons set forth above, as well as whether a permanent opt-out should be referred.

Thank you,
Eric B. Mitton
City Attorney