Oregon Psilocybin Services

How to become a licensed psilocybin manufacturer in Oregon

In November 2020, Oregonians passed The Oregon Psilocybin Services Act (M109), which is now codified into Oregon law in <u>ORS 475A</u>. This statute establishes a licensing and regulatory framework for psilocybin services in Oregon. Before taking steps to become licensed, please go to the: "<u>Training Video on ORS 475A</u>: What is the <u>Oregon Psilocybin Services Act?</u>" and "What are <u>Psilocybin Services?</u>" to learn more.

Licensed manufacturers may only cultivate or process products containing the species *Psilocybe Cubensis*. Synthetic psilocybin and wild harvesting of fungi are not permitted. Psilocybin products may include whole dried mushrooms, ground homogenized fungi, extracts, and edible products. Applicants for a manufacturer license will need to apply for specific endorsement types, which include fungi cultivation, psilocybin extraction, and edible psilocybin production. There is no additional cost for endorsements; however, an applicant will need to understand all requirements related to the endorsements they are planning to apply for.

General Manufacturer License Requirements:



- 1) Must be 21 years of age or older.
- 2) Must acquire a Land Use Compatibly Statement (LUCS) form, signed by local city or county, which demonstrates that the proposed use of the property is consistent with local land use and zoning codes.
- 3) If not the owner of the property, must acquire written permission from the property owner for proposed use.
- 4) Prepare a Premises Plan, which must be submitted as part of the application process.
- 5) If planning to apply for an Edible or Extract endorsement, an Oregon Department of Agriculture Food Safety License will be required.
- 6) Must pass a criminal background check.
- 7) Must pass a site inspection as part of the license application process.

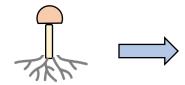
Steps to Become a Licensed Manufacturer

- 1. Review and understand statutory (<u>ORS 475A</u>) and administrative rule (<u>OAR</u>, <u>Chapter 333-333</u>) requirements related to a manufacturer license.
- 2. Decide which endorsements to apply for.
- 3. Before submitting an application, you will need to work with your local city or county jurisdiction to complete an OPS Land Use Compatibility Statement (LUCS) form which identifies an applicant name listed on the license application and demonstrates that the proposed property is in compliance with local land use and zoning requirements. Your local jurisdiction will need to review and approve the LUCS. Once you make the request, your local jurisdiction is required to respond within 21 days.
- 4. **Complete the Property Permission Form**. If you are not the owner of the proposed premises, you must submit an <u>OPS Property Permission Form</u> that has been signed by the property owner and demonstrates that the owner understands and consents to the proposed use of the property for manufacturing psilocybin products.
- 5. Complete a scaled floorplan and premises plan. As part of the license application process, you will need to submit a scaled floorplan of the proposed licensed premises. Please see the <u>General OPS Premises Plan Checklist</u> and the <u>OPS Manufacturing Premises Plan Checklist</u> for more information.
- 6. **Prepare materials for the application process.** You will need to provide proof of being 21 years of age or older. If the applicant is a legal entity, please see the <u>Legal Entity Applicant Information Form Instructions</u>. You will also need to submit a social equity plan. Please refer to the <u>OPS Social Equity Plan Resources</u> for resources that can support applicants in meeting this requirement.
- 7. **Begin your license application process with OPS.** To begin an online application, account registration is required. Go to the OPS Training Program, Licensing, and Compliance (TLC) platform at: https://psilocybin.oregon.gov to access TLC and create an account. For TLC tips or to troubleshoot TLC issues, please view the OPS
 TLC Login and TLC Messages Guidance Document. If you are unable to complete the application online using the TLC platform and would like OPS to mail a paper application to you, please contact the OPS Licensing Program at 971-673-0304 or email licensing.psilocybin@oha.oregon.gov.

- 8. **Complete the criminal background check process.** Once you have submitted a license application to OPS, you will be sent more information about how to complete the required background check. To prepare, please see this handout on the OPS Background Check Process.
- 9. Pay a \$500 application fee. OPS will review your application as quickly as possible after the payment has cleared. You will want to monitor your email inbox for messages about next steps. OPS staff will need to visit your proposed location and perform a site inspection to ensure your premises is compliant with statute and rule requirements. Please refer to the <u>Inspection Orientation for Manufacturer</u>
 Applicants to ensure that you are prepared for the site inspection.
- 10. Pay the annual license fee of \$10,000. If you are approved for licensure, you will be required to pay an annual license fee of \$10,000. Individual applicants who are veterans, receiving Supplemental Security Income, receiving food stamp benefits, or are enrolled in the Oregon Health Plan may qualify for a reduced annual licensure fee of \$5,000. If applicants are part of a legal entity or there are more than one individual applicants, they may be eligible for a reduced license fee if every individual applicant within the entity meets requirements for reduced fees in OAR 333-333-4060. More information can be found in administrative rules.

How do psilocybin products get to a service center?

- 1) Psilocybin products are cultivated, produced, and/or processed by a licensed manufacturer and tracked in a product tracking system.
- 2) Psilocybin products are tested by a <u>licensed</u> <u>laboratory</u> that is accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP). Test results are entered into the product tracking system.
- 3) Psilocybin products are sold or transferred from a licensed manufacturer to a licensed service center and tracked in the product tracking system.









Safety and Compliance

OPS will investigate complaints, incidents, or concerns related to safety issues or statute and rule violations that occur on licensed premises and during the provision of psilocybin services. Once we receive a complaint, OPS will determine if there are potential violations of ORS 475A or OAR 333-333 and whether the Oregon Health Authority is the agency with jurisdiction to take further action. Oregon Psilocybin Services will only investigate violations of ORS 475A or ORS 333-333. Complaints related to criminal activity are a matter for law enforcement. Complaints are subject to public disclosure under Oregon's Public Records Law. If a complainant is concerned about their privacy or safety, OPS will make effort to keep their identity confidential to the extent permitted by law.

During an investigation, OPS will conduct interviews with the complainant, witnesses, and licensees involved. If needed, we will also interview clients. OPS will request all relevant records and any security camera footage, if available. If statute or rule violations are discovered and there is enough evidence to prove the violation, the licensee will be issued a notice of a proposed administrative action that proposes some disciplinary licensing action and/or civil penalty. Administrative sanctions depend on the severity of violation and may include restriction of a license, civil penalties, or suspension or revocation of a license. A licensee will have between 20-30 days to request a hearing, depending on what the proposed sanction is. If requested, the hearing would be conducted by an Administrative Law Judge (ALJ). After the hearing, the ALJ would issue their proposed order and then OHA would issue a final order. For more information on categories of OPS's administrative violations, please reference OAR 333-333-6200.

Members of the public can <u>File a Complaint</u> on the OPS website.

The Oregon Psilocybin Services team is committed to providing education and technical assistance to our regulated community. If you have any questions about the licensing process, please contact: <u>Licensing.Psilocybin@oha.oregon.gov</u>

For other inquiries about Oregon Psilocybin Services, please contact: OHA.Psilocybin@oha.oregon.gov



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