

Oregon Psilocybin Services

How to become a licensed laboratory 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.

Under ORS 475A, a licensed laboratory must test psilocybin products produced by a licensed manufacturer. Licensed laboratories must be accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP). Under OAR 333-333, psilocybin products are required to be tested to confirm the presence of psilocybe cubensis, as well as tested for potency and, if applicable, solvents. Licensed laboratories are prohibited from testing psilocybin products from unlicensed sources.

General Laboratory License Requirements:



- 1) Must be 21 years of age or older.
- 3) Must be accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP).
- 4) Must pass a criminal background check.
- 5) Must pass a site inspection as part of the license application process.

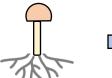
Steps to Become a Licensed Laboratory

- 1. Review and understand statutory (<u>ORS 475A</u>) and administrative rule (<u>OAR</u>, <u>Chapter 333-333</u>) requirements related to an OPS laboratory license.
- 2. Become accredited through the Oregon Environmental Laboratory Accreditation Program (ORELAP). The process begins by registering for a username in the ORELAP Data Input and Edit (ODIE) system. Once registered, the user can create an initial application for accreditation. The laboratory's application will be reviewed and invoiced. Once the invoice has been paid, ORELAP will arrange for an onsite assessment. The assessment will determine the laboratory's compliance to the accreditation rules and the 2016 (TNI) Standards.
- 3. **Complete a scaled floor plan and premises plan.** As part of the license application process, you will need to submit a scaled floor plan of the proposed licensed premises. Please see the OPS General Premises Plan Checklist and also the OPS Laboratory Premises Plan Checklist.
- 4. **Prepare materials for the application process.** You will need to submit a Social Equity Plan. Please refer to the OPS Social Equity Plan Resources for resources that can support applicants in meeting this requirement.
- 5. **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.
- 6. **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.

- 7. **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 Laboratory Applicants</u> to ensure that you are prepared for the site inspection.
- 8. Pay the annual license fee of \$10,000. If you are approved for a license, you will be required to pay an annual license fee of \$10,000. 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, Oregon Psilocybin Services (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: Licensing.Psilocybin@oha.oregon.gov

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



You can get this document in other languages, large print, braille or a format you prefer. Contact: Oregon Psilocybin Services at 971-341-1713 or email OHA.Psilocybin@oha.oregon.gov. We accept all relay calls or you can dial 711.