

Psilocybin Manufacturer License Application Guide for Applications Submitted by Online

PUBLIC HEALTH DIVISION
CENTER FOR HEALTH PROTECTION
Oregon Psilocybin Services (OPS)
http://oregon.gov/psilocybin

Table of Contents

Introduction	3
Manufacturer License Application Packet Checklist	4
Getting Started with TLC	5
TLC Dashboards	6
TLC Messaging	7
Begin a Manufacturer License Application	8
Manufacturer Applicant Information Tab	9
Previous License or Permit	10
Individual and Legal Entity Applicant Information Tab	11
Individual Applicant Information Form	12
Adding Individual Applicants in the TLC Application	14
Upload Photo Identification and Individual Applicant Information For	m16
Legal Entity Applicant Information Form	17
Adding Legal Entity Applicants in the TLC Application	20
Designated Primary Point of Contact	22
Upload Legal Entity Applicant Information Form	22
Financial Interest Tab	23
Manufacturer Endorsements Tab	24
Residency Requirements (Expires 2025)	25
Land Use Compatibility Statement (LUCS)	27
Property Owner Statement Form	27
Premises Plan	27
Social Equity Plan	28
Authorized Individuals of the Named Licensee Form	28
Documents Tab	29
Fee Information and Submitting the Application	30
Non-Refundable Application Fee: \$500 USD	30

Non-Refundable Manufacturer Annual License Fee: \$10,000 US	יט or
\$5,000 USD if applicant qualifies for Reduced License Fee	30
Accepted Payment Methods	31
Fee Payment Clearance	31
Review and Submit Tab	31
Online Fee Payment	32
Online Application Fee Payment	32
Online Annual License Fee Payment	33
Mailed or In-Person Fee Payment and Remittance Form	33
Mailed or In-Person Application Fee Payment	33
Mailed or In-Person Annual License Fee Payment	34
Background Checks	35
Application Review	36
Incomplete and Insufficient Applications	36
Application Approval and Proof of License	36
Notification of Changes	38
Frequently Asked Questions (FAQs)	38

Introduction

The purpose of this guide is to provide additional support to applicants submitting a psilocybin manufacturer license application **ONLINE**. The most current version of this guide and the online application guide can be found on the web at <u>Oregon Psilocybin Services (OPS) – Manufacturer License webpage.</u> Applicants must read, understand, and agree to adhere to the Oregon Psilocybin Services statutes and administrative rules, outlined in <u>Oregon Revised Statute (ORS) Chapter 475A</u>, <u>Oregon Administrative Rules (OAR) Division 333, Chapter 333</u>, as well as any other applicable statutes or laws.

The <u>Oregon Psilocybin Services – Training Program, Licensing, and Compliance system (TLC)</u> is an online platform where applicants can apply for psilocybin licenses, worker permits, and training program curriculum approval. Please visit https://psilocybin.oregon.gov to complete the application online. If you are unable to complete the application packet online, you may print, complete, and mail the application packet and pay the application fee following the instructions provided in the remittance form at the end of this application. Printable application forms may be found here.

Everyone has a right to know about and use Oregon Health Authority (OHA) programs and services. OHA provides free help. If you need these written materials in other languages, braille, large print, or other formats, please contact:

OHA.Psilocybin@oha.oregon.gov (971) 673-0322

For all other questions and concerns regarding licenses and permits, please contact:

<u>Licensing.Psilocybin@oha.oregon.gov</u> (971) 673-0304

DISCLAIMER: Psilocybin remains a schedule I drug under the federal Controlled Substances Act. Applicants are responsible for making their own determinations regarding the legal risks associated with participating in this program. The information provided in the application materials, including applicant and instructor names, is subject to disclosure under Oregon's public records laws.

Manufacturer License Application Packet Checklist

Please use the following checklist to assist in planning and ensuring the application is complete.

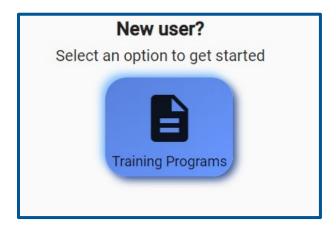
- ✓ Completed and signed manufacturer license application in TLC
- ✓ Copy of the front and back of a valid, unexpired government-issued photo identification for **each individual applicant**. Applicants must be age 21 or older. Accepted identification includes:
 - o Passport;
 - Driver license, whether issued by the State of Oregon or by another state of the United States;
 - Identification card issued under ORS 807.400;
 - United States military identification card;
 - An identification card issued by a federally recognized Indian tribe with photo, name, and date of birth; or
 - Any other identification card issued by a state or territory that bears a picture of the person, the name of the person, the person's date of birth and a physical description of the person.
- ✓ Copies of Individual and Legal Entity Applicant Information forms for each applicant
- ✓ Copy of the approved Land Use Compatibility Statement (LUCS)
- ✓ Copy of the Property Owner Statement (if applicable)
- ✓ Copy of the Premises Plan including boundaries and camera plan
- ✓ Copy of the Social Equity Plan
- ✓ Copy of the Authorized Individuals Form
- ✓ Copy of reduced licensing fee documentation (if applicable). Please provide the supporting documentation of the manufacturer's nonprofit status.
 - If the proposed licensed manufacturer is a non-profit entity, please provide supporting documentation of the manufacturer's non-profit status.
 - If the proposed licensed manufacturer is an individual applicant, please include a copy of one of the following required supporting documents
 - A copy of a current monthly Social Security Income benefit statement showing dates of coverage
 - A copy of the applicant's current eligibility statement or card if enrolled in Oregon Health Plan
 - A copy of current proof of food stamp benefits from the Oregon Supplemental Nutrition Assistance Program

- A copy of proof of having served in the Armed Forces, such as but not limited to, submitting a Veteran's Administration form DD-214
- √ \$500 Non-refundable license application fee

Getting Started with TLC

Please visit https://psilocybin.oregon.gov to access TLC and create and account.

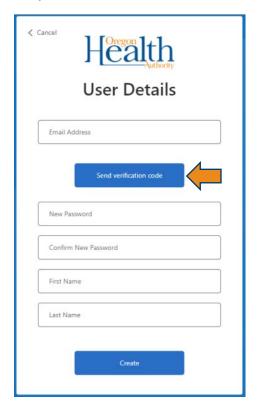
To begin an online application, account registration is required. To register a new account, select the new user button and click "Get Started!"



If you don't have an account registered, click "Sign up now"



Enter your email address, first name, last name, and create a password to create an account. To proceed, an email verification code must be entered. After clicking "Send verification code," enter the code sent to the email address provided.

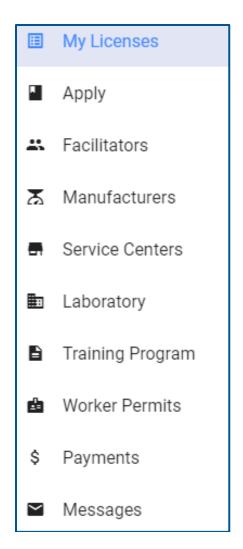




TLC Dashboards

Each license type and worker permits have unique dashboards in TLC. You can access each dashboard by clicking the type in the menu on the left side of the screen. The following dashboards are available in TLC:

- My Licenses
- Apply
- Facilitators
- Manufacturers
- Service Centers
- Laboratory
- Training Program
- Worker Permits
- Payments
- Messages



TLC Messaging Dashboard

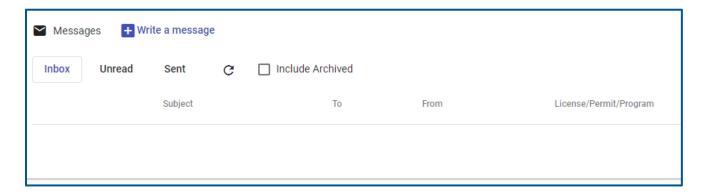
Messages is a platform to communicate with the Oregon Psilocybin Services Licensing and Compliance teams. From this dashboard you can send messages to and receive messages from the license and compliance teams. You can include attachments and write a message in the open text field.

To navigate to Messages, select "Messages" from the menu on the left side of the screen.



To write a new message select the 'Write a message' button. Then, select which team you are sending the message to. Please include the application, license, or permit ID number you are reaching out about with your message.

If your question is related to applying for a license, worker permit, or training programs, please direct your message to the licensing team. If your message is related to compliance or compliance rules questions, please direct your message to the compliance team. If you are unsure which team to send the message to, please select the team you think is most relevant and our teams will work together to answer the message.



Begin a Manufacturer License Application

When you are ready to begin a manufacturer license application, please click "Apply" from the left menu on the screen. All application types will be displayed. In the yellow Manufacturer box, click the "Apply" button.



You may also begin the manufacturer application by clicking "Manufacturers" from the left menu on the screen and then selecting "Start Application."

Start Application

Review all information on the "Getting Started" page of the application before proceeding through the application.

Manufacturer Applicant Information Tab

Please provide the following information in the "Applicant Information" tab:

- Named Licensee (required)
 - The named licensee is an individual or entity who is listed on the license certificate.
- Website (optional)
- Registered Business Information (required)
 - The application asks if the manufacturer is registered as a business with the Oregon Secretary of State. If yes, please provide the SOS business registry number.
 - If no, the application asks if the manufacturer is registered to do business in another state, US territory, or freely associated state. If yes, please provide the business registry number.
 - US territories: American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, Puerto Rico, US Virgin Islands
 - Freely associated states: the Federated States of Micronesia, the Republic of the Marshall Islands, Republic of Palau
 - Review and initial the statement indicating you understand and agree licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration (required)
- Physical Address (required)
- Mailing Address (required)
 - Provide a brief description of the premises including any information to assist OPS with planning for and travelling to a site inspection

Applicant Information			
Legal Name			
First	Last		
Test	Test	Middle	
Preferred Name First	Last	Middle	
Prior Names and Aliases This information is used for the purposes of t	he background check		
Name, other name, any other names		Date of Birth	ĵ

 As part of your application for an initial or renewal license, Federal and State laws require you to provide your Social Security Number (SSN), if you have one, to Oregon Psilocybin Services for child support enforcement purposes (42 USC § 666(a)(13) & ORS 25.785). If you are an applicant or licensee and you have an SSN but fail to provide your SSN, Oregon Psilocybin Services may refuse to process your application. Your SSN will be used only for child support enforcement purposes unless you confirm your agreement that OPS can use it for administrative purposes as well.
IMPORTANT NOTE: If you do not have a social security number, you may still be licensed or permitted by Oregon Psilocybin Services.
Based on our authority under OAR 333-333-4100, we are requesting your voluntary consent to use your SSN for the

• Based on our authority under OAR 333-333-4100, we are requesting your voluntary consent to use your SSN for the following administrative purposes only: to positively confirm your identity during the criminal records check. Oregon Psilocybin Services will not deny you any rights, benefits or privileges otherwise provided by law if you do not consent to use of your SSN for these administrative purposes (5 USC§ 552(a)). Please check the appropriate box next to the social security field indicating whether you consent or do not consent.

SSN	
123-45-5678	I don't have a social security number
Do you consent to use of SSI	N for purposes of confirming identity during a criminal records check?
✓ Yes	
□ No	

Previous License or Permit

*SOCIAL SECURITY NUMBER DISCLOSURE:

If the named licensee has ever applied for or received any other licenses from Oregon Psilocybin Services, please provide this information within the online application.

Named Licensee			
Named Licensee			
Manufacturer Website	Manufacturer Website		
Website			
Registered Business			
Is the applicant registered Yes No	as a business w	ith the Secretary of S	tate (SOS) in Oregon?
I understand licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration per OAR 333-333-4400 (11).			
Previous License or Permit Has this applicant applied for or received any other licenses from Oregon Psilocybin Services			
Physical Address Street Apt/Unit/Suite	City	Sta Of	
Zip County	*		
Please provide a brief description of the public describe the Premises	premises		
Mailing Address	ysical		
Street Apt/Unit/Suite	City	St	ate/US territory/freely associated state
Zip			

Individual and Legal Entity Applicant Information Tab

An application for a psilocybin manufacturer license must identify all individuals and legal entities who qualify as applicants as described in <u>OAR</u> 333-333-1010 and <u>OAR</u> 333-333-4030. Applicants are responsible for

ensuring all individuals and legal entities who meet the definition of an applicant are identified.

Applicants are individuals or legal entities who:

- Hold or control an interest of more than 20 percent in the entity proposed to be licensed;
- Are entitled to receive 20 percent or more of revenue, profits or proceeds from the entity proposed to be licensed; or
- Are entitled to exercise control over the entity proposed to be licensed

If a legal entity is an applicant, the following individuals within the legal entity are also applicants:

- If an applicant is a limited partnership, each general partner in the limited partnership
- If an applicant is a limited liability company, each manager and managing member of the limited liability company
- If the applicant is a for-profit corporation, each principal officer of the corporation
- If the applicant is a non-profit entity, each principal officer of the entity
- Any individual within the legal entity who meets the definition of applicant in OAR 333-333-1010

All applicants must be identified in the online application. If an individual within a legal entity is identified as an applicant, please be sure include them as an individual applicant.

Individual Applicant Information Form

Each individual applicant must complete an Individual Applicant Information Form. Applicants are responsible for completing and ensuring all individual applicant information forms are uploaded into the online application. Individual applicant information forms can be found on the Oregon Psilocybin Services - Apply for a Manufacturer License webpage.

Each individual applicant must complete and sign their own applicant information form.

Within this form, an individual applicant will provide the following information:

- Indicate which type of license the individual applicant is associated with: manufacturer, laboratory, or service center (required)
- Provide the manufacturer named licensee listed on the application. (required)
- Provide the name(s) of the legal entity applicants the individual may be associated with *(required is applicable)*
- Legal Name (required)
- Preferred Name (optional)
- Prior Names and Aliases (required)
 - This information is used for the purposes of the background check
- Date of Birth (required)
- Social Security Number (required if you have one)
 - If you do not have a social security number, you may still be licensed or permitted by Oregon Psilocybin Services
 - As part of your application for an initial or renewal license, Federal and State laws require you to provide your Social Security Number (SSN), if you have one, to Oregon Psilocybin Services for child support enforcement purposes (42 USC § 666(a)(13) & ORS 25.785). If you are an applicant or licensee and have an SSN but fail to provide your SSN, Oregon Psilocybin Services may refuse to process your application. Your SSN will be used only for child support enforcement purposes unless you confirm your agreement that OPS can use it for administrative purposes as well
 - In the application, we ask for voluntary consent to use your social security number, if you have one, to confirm your identity during the criminal records check. We will not deny you any rights, benefits, or privileges otherwise provided by law if you do not consent to use of your SSN for these administrative purposes
 - Check the appropriate box next to the social security field indicating whether you consent or do not consent (required)
- Primary Phone Number (required)
- Alternate Phone Number (optional)
- Primary Email Address (required)
- Preferred Language (optional)
- Preferred Pronouns (optional)

- Physical Address (required)
- Mailing Address (required)
- Residential History Outside of Oregon in the Past 5 Years (required if applicable)
 - This information is used for the purposes of the background check

Previous License or Permit

If the individual applicant has ever applied for or received any other licenses or permit from Oregon Psilocybin Services, please provide this information within the form.

Worker Permit

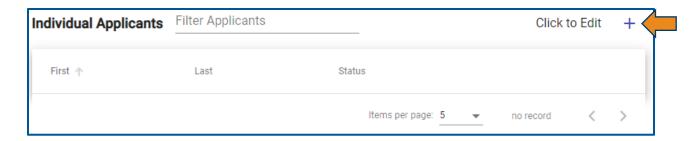
An individual who is a licensee or a licensee representative must have a valid worker permit if the individual participates in:

- The provision of psilocybin services at a licensed premises
- The possession, manufacturing, securing, or selling of psilocybin products at a licensed premises
- The recording of the possession, manufacturing, securing, or selling of psilocybin products at a licensed premises
- The verification of any document described in ORS 475A.445

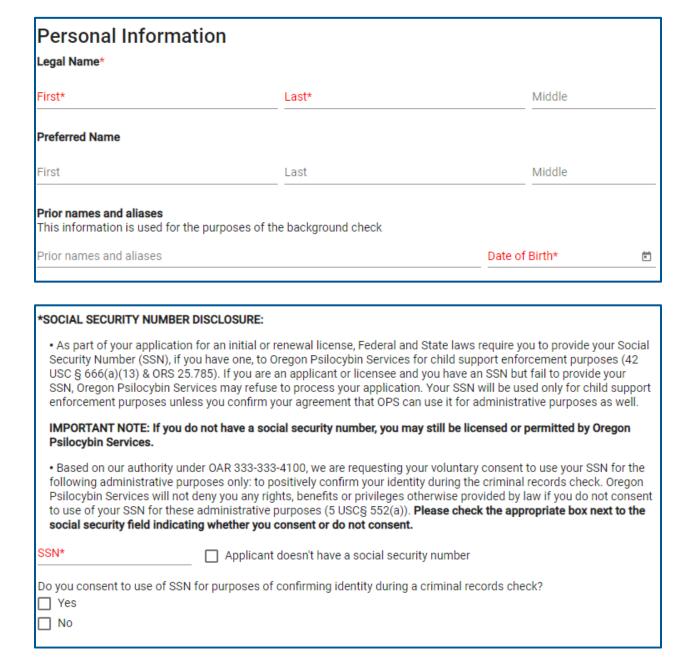
Please review the worker permit application and application guide by visiting the <u>Oregon Psilocybin Services (OPS) – Worker Permit webpage.</u> Individuals may apply for a worker permit online by visiting <u>Oregon Psilocybin Services – Training Program, Licensing, and Compliance system (TLC).</u> If an individual applicant does not want or is unable to apply online, the worker permit application may be submitted with the manufacturer license application or mailed separately.

Important note: An individual person identified as a license applicant is not required to undergo a criminal background check and fitness determination if that person has completed a criminal background check and fitness determination in connection with another license application within 30 days of their current license application.

Adding Individual Applicants in the TLC Application To add an individual applicant, click the "+" symbol.



Please use the completed individual applicant information form to enter required information in the fields on the individual applicant screen.



Contact Information		
Primary Phone*	Alternate Phone	
Phone*	Alt Phone	
Primary Email Address*	Confirm Email Address*	
Email*	Confirm Email*	
Preferred Language Language	_	
Previous License or Permit Check if this individual has applied for or received any other licenses from Oregon Psilocybin Services.		
Address		



Upload Photo Identification and Individual Applicant Information Form

The following documents are uploaded on the Individual Applicant Information page:

- Photo Identification
- Individual Applicant Information Form

Upload a copy of the individual applicant's photo identification and Individual Applicant Information Form by clicking "Browse" and selecting the file(s) you would like to upload.

Identity Verification Incomplete Please visit the OPS-Manufacturer License webpage to download required forms. You must upload a copy of the front and back of a valid, unexpired government-issued photo identification. Accepted identification includes: Passport; Driver license, whether issued by the State of Oregon or by another state of the United States: Identification card issued under ORS 807.400; · United States military identification card; An identification card issued by a federally recognized Indian tribe with photo, name and date of birth; or Any other identification card issued by a state or territory that bears a picture of the person, the name of the person, the person's date of birth and a physical description of the person A copy of proof of having served in the Armed Forces, such as but not limited to, submitting a Veteran's Administration form DD-214. For each document select the requirements it verifies ☐ Identification • Applicant Information Form Browse

Legal Entity Applicant Information Form

Each legal entity applicant must complete a Legal Entity Applicant Information form. Applicants are responsible for completing and ensuring all legal entity applicant information forms are uploaded into the online application. Legal Entity Applicant Information forms can be found on the Oregon Psilocybin Services – Apply for a Manufacturer License webpage.

Within this form, the legal entity will provide the following information:

- Indicate which type of license the legal entity applicant is associated with: manufacturer, laboratory, or service center *(required)*
- Provide the Manufacturer Named Licensee listed on the application. (required)
- Legal Entity Name
- Registered Business Information (required)
 - The application asks if the manufacturer is registered as a business with the Oregon Secretary of State. If yes, please provide the SOS business registry number.

- If no, the application asks if the manufacturer is registered to do business in another state, US territory, or freely associated state. If yes, please provide the business registry number.
 - US territories: American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, Puerto Rico, US Virgin Islands
 - Freely associated states: the Federated States of Micronesia, the Republic of the Marshall Islands, Republic of Palau
- Review and initial the statement indicating you understand and agree licensees that are required to be registered with the Oregon Secretary of State must register prior to receiving a license and maintain registration (required)
- Primary phone number (required)
- Alternate phone number *(optional)*
- Primary email address (required)
- Preferred language (optional)
- Headquarters/Main Office Address (required)
- Physical Address (required)
- Mailing Address (required)

Previous License or Permit

If the legal entity applicant has ever applied for or received any other licenses or permit from Oregon Psilocybin Services, please provide this information within the form.

Financial Interests and Restriction on Multiple Licenses

Applicants and licensees must create and maintain complete lists of all individuals and legal entities that hold a financial interest in a manufacturer, including contact information for each individual or entity and a description of their financial interest. Applicants and licensees must provide the information required to Oregon Psilocybin Services within 15 calendar days of the written request for such information.

If a legal entity holds a financial interest, the following individuals within the legal entity also hold a financial interest:

For limited partnerships, each general partner in the limited partnership

- For limited liability companies, each manager and managing member of the limited liability company
- For for-profit corporations, each principal officer of the corporation
- For non-profit entities, each principal officer of the entity

Restriction on financial interests on multiple licenses (ORS 475A.280) An individual may not have a financial interest in:

- More than one psilocybin product manufacturer; or
- More than five psilocybin service center operators

The legal entity applicant must initial each of the following statements indicating they understand and agree:

- I have read, understand, and agree to adhere to the financial interest requirements outlined in ORS 475A and OAR Chapter 333, Division 333
- I understand every individual and legal entity applicant in the proposed manufacturer to be licensed must comply with the requirements of ORS 475A.280, Restriction on financial interests in multiple licenses

Associated Individual Applicants

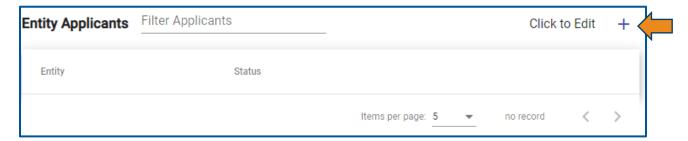
The following individuals within the legal entity are also applicants:

- If an applicant is a limited partnership, each general partner in the limited partnership
- If an applicant is a limited liability company, each manager and managing member of the limited liability company.
- If the applicant is a for-profit corporation, each principal officer of the corporation
- If the applicant is a non-profit entity, each principal officer of the entity
- Any individual within the legal entity who meets the definition of applicant in OAR 333-333-1010

The legal entity applicant must provide the names and dates of birth of all individuals who meet the definition of an applicant. Those individuals must complete an Individual Applicant Information Form.

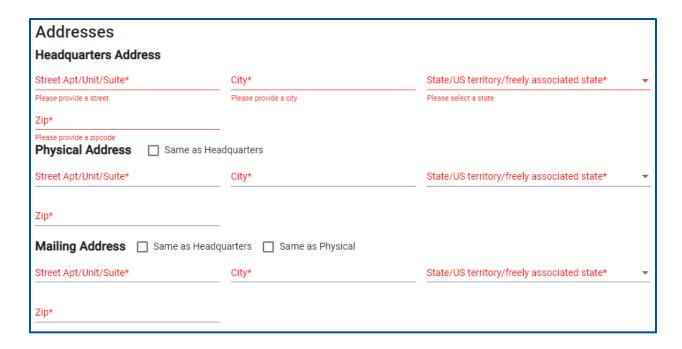
Adding Legal Entity Applicants in the TLC Application

To add a legal entity applicant, click the "+" symbol.



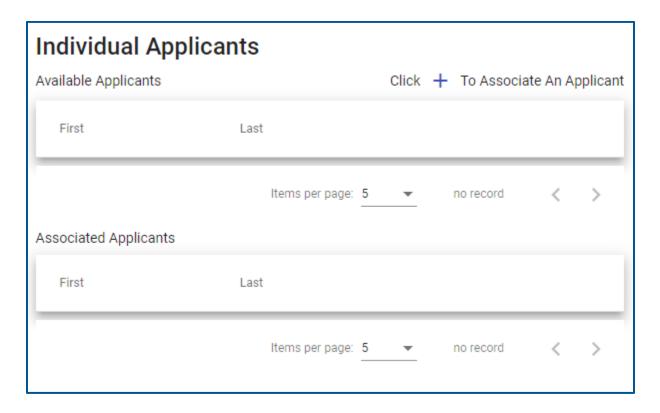
Please use the completed Legal Entity Applicant Information Form to enter required information in the fields on the individual applicant screen.

Contact Information		
Legal entity name		
Entity Name*		
Please provide the legal entity name		
Registered Business		
Is the applicant registered as a business with the Secretary Yes No	of State (SOS) in Oregon?	
I understand licensees that are required to be registered with the Oregon Secretary of State must register prior to		
receiving a license and maintain registration per OAR 3	33-333-4400 (11).	
Previous License or Permit Has this applicant applied for or received any other lice	nses from Oregon Psilocybin Services?	
Contact Phone	Preferred Language	



Associating Individual Applicants in TLC

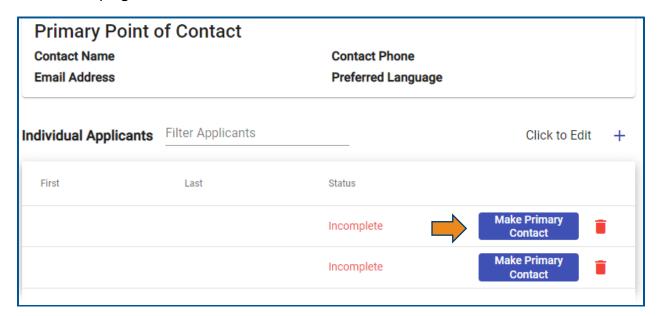
If an individual applicant is associated with a legal entity applicant, please associate them in the legal entity applicant information page by clicking the "+" symbol. Helpful note: To do this successfully, you must enter individual applicants before entering legal entity applicants.



Designated Primary Point of Contact

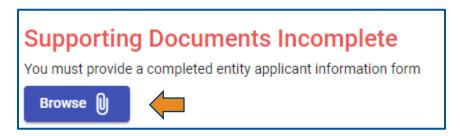
One applicant must be designated as the Primary Point of Contact for communication. The primary point of contact is responsible for ensuring all persons identified as licensees or applicants are aware of relevant communications, including but not limited to notices issued under ORS Chapter 183.

Please indicate which individual **or** legal entity applicant is designated as the Point of Contact by selecting **only one** on the Applicant Information tab. Once selected, the Primary Point of Contact information will populate on the same page.

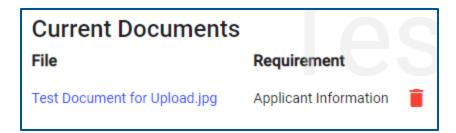


Upload Legal Entity Applicant Information Form

Upload a copy of the Legal Entity Applicant Information Form by clicking "Browse" and selecting the file(s) you would like to upload.



Once the file is uploaded, it will appear in the adjacent box titled "Current Documents". If you uploaded the incorrect file, you may delete the upload by clicking on the trash icon.



Financial Interest Tab

Applicants and licensees must create and maintain complete lists of all individuals and legal entities that hold a financial interest in a manufacturer, including contact information for each individual or entity and a description of their financial interest. Applicants and licensees must provide the information required to Oregon Psilocybin Services within 15 calendar days of the written request for such information.

If a legal entity holds a financial interest, the following individuals within the legal entity also hold a financial interest:

- For limited partnerships, each general partner in the limited partnership
- For limited liability companies, each manager and managing member of the limited liability company
- For for-profit corporations, each principal officer of the corporation
- For non-profit entities, each principal officer of the entity

Restriction on financial interests on multiple licenses (<u>ORS 475A.280</u>) An individual may not have a financial interest in:

- More than one psilocybin product manufacturer; or
- More than five psilocybin service center operators

The named licensee applicant must review and acknowledge the following statements indicating they understand and agree:

- I have read, understand, and agree to adhere to the financial interest requirements outlined in ORS 475A and OAR Chapter 333, Division 333
- I understand every individual and legal entity applicant in the proposed manufacturer to be licensed must comply with the requirements of ORS 475A.280, Restriction on financial interests in multiple licenses

Manufacturer Endorsements Tab

A manufacturer may only produce and sell psilocybin products if the manufacturer has received an endorsement from Oregon Psilocybin Services for that type of product. An applicant for a manufacturer license must request an endorsement upon submission of an initial application but may also request to add or remove an endorsement at any time following licensure.

An individual manufacturer may hold multiple endorsements. Applicants must select the endorsements requested in the application. At least one endorsement type must be requested and multiple or all endorsements may be requested.

Endorsement Types

- Fungi cultivation
- Psilocybin extraction
- Edible psilocybin production

Endorsement Types	
Select the endorsements requested. At least one endorsement type must be requested and multiple or all endorsements may be requested.	
☐ Fungi Cultivation	
Psilocybin Extraction	
☐ Edible Psilocybin Production	

It's important to note the rules outlined in <u>OAR 333-333-4300</u> regarding manufacturers with an edible psilocybin production endorsement:

- (4) A manufacturer with an edible psilocybin production endorsement may not:
 - (a) Engage in processing at a location in an area that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited-service restaurant, single event temporary restaurant, commissary, mobile unit, bed and breakfast, or warehouse licensed under ORS chapter 624;
 - (b) Share a food establishment where psilocybin will be produced, with another person or entity;
 - (c) Process food intended for commercial sale that does not contain psilocybin; or

(d) Use a psilocybin product to produce edible psilocybin products unless that psilocybin product was processed or cultivated in a food establishment licensed by the Oregon Department of Agriculture in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.

Applicants must review and acknowledge each of the following statements indicating they understand and agree:

- I understand a manufacturer with an edible psilocybin production endorsement may only process in a food establishment licensed by the Oregon Department of Agriculture (ODA) and must comply with the applicable provisions of OAR Chapter 603, Division 21, Division 24, Division 25, and Division 28.
- I understand a manufacturer with an edible psilocybin production endorsement may not use a psilocybin product to produce edible psilocybin products unless that psilocybin product was processed or cultivated in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR Chapter 603, Division 21, Division 24, Division 25, and Division 28.
- I understand Oregon Psilocybin Services may deny a manufacturer's request for an endorsement or revoke an existing endorsement if the manufacturer cannot or does not meet the requirements outlined in OAR Chapter 333, Division 333.

Residency Requirements (Expires 2025)

Residency requirements are outlined in <u>OAR 333-333-4050</u>. Until January 1, 2025, to qualify for a manufacturer license:

- If the direct owner of the proposed named licensee is organized as a legal entity, an applicant must provide proof that more than 50 percent of the shares, membership interests, partnership interests, or other ownership interests of the legal entity are held, directly or indirectly, by one or more individuals who have been residents of this state for two or more years
- If the direct owner of the proposed named licensee is a partnership that is not a legal entity, an applicant must provide proof that more than 50 percent of the partnership interests of the partnership are

- held, directly or indirectly, by one or more individuals who have been residents of this state for two or more years
- If the direct owner of the proposed named licensee is an individual, an applicant must provide proof that the individual has been a resident of this state for two or more years

Applicants for a manufacturer license must review and acknowledge the following statement indicating they understand and agree: I understand that the individual, partnership, and legal entity applicants in this application must meet the Oregon resident requirements outlined in ORS 475A and OAR 333-333-4050

This statement will be found in three places:

- Review and Submit Tab in the Manufacturer Application Form
- Applicant Statements in the Individual Applicant Information Form which must be completed and signed by each individual applicant
- Applicant Statements in the Legal Entity Applicant Information Form which must be completed and signed by each legal entity

Applicants and licensees must retain documentation that demonstrates they meet the residency requirement. Applicants and licensees must provide documentation to OPS within 15 calendar days of written request. Proof of residency may be demonstrated by providing:

- A valid Oregon driver license or Oregon identification card issued at least two years prior to the date of application
- Oregon full-year resident tax returns for the last two years
- Proof of Oregon voter registration issued at least two years prior to the date of application.
- Utility bills, lease agreements, rental receipts, mortgage statements or similar documents that contain the name and address of the applicant dated at least two years prior to the date of application and from the most recent month
- Letter from a homeless shelter, nonprofit entity, employer, or government agency attesting that applicant has been an Oregon resident for at least two years
- Any other documentation that the Authority determines to reliably demonstrate proof of Oregon residency for the last two years

Land Use Compatibility Statement (LUCS)

ORS 475A requires applicants for manufacturer licenses to request a Land Use Compatibility Statement (LUCS) from the city or county where the proposed business is located. The LUCS must be completed as a condition of licensure, and it must show that the location's zoning is consistent with the proposed use. For convenience, we provide a standard LUCS form located on the OPS-Local Government webpage. The approved LUCS must be uploaded into the online application form.

Although <u>ORS 475A</u> and the <u>OAR Chapter 333</u>, <u>Division 333</u> rules outline land use and zoning requirements for psilocybin manufacturers, specific questions regarding land use and zoning must be directed to the local government planning and zoning offices.

Property Owner Statement Form

If the applicant for a manufacturer license is not the owner of the real property proposed to be licensed, a written statement signed by the property owner that shows that the owner consents to manufacturing of psilocybin products on the property must be uploaded with the application.

Applicants must use the designated Property Owner Statement Form which may be found on the <u>Oregon Psilocybin Services (OPS) – Manufacturer License webpage.</u>

Premises Plan

Manufacturer license applicants must upload a premises plan as part of the application. A premises plan must include:

- A map or sketch of the proposed license premises, including the boundaries of the licensed premises relative to its location
- Identification of any unlicensed areas within the building where the licensed premises is located including suite numbers (if applicable)
- Identification of any residence or other unlicensed structures located on the same tax lot as the premises proposed to be licensed
- A scaled floor plan identifying all points of ingress and egress
- Identification of camera locations
 - o A licensed premises must have camera coverage for:

- All points of ingress and egress to and from indoor areas of the licensed premises
- All areas where psilocybin products are stored or produced
- All areas where psilocybin waste is required to be stored, destroyed, or rendered unusable as required by OAR 333-333-8000
- Identification of limited access areas
- Identification of areas where psilocybin products will be stored within the licensed premises.

Social Equity Plan

Applicants must upload a social equity plan with their application. An applicant may determine the format and structure of the social equity plan while meeting the requirements in <u>OAR 333-333-4020</u> which describes the following:

Social equity plans must include a description of the following:

- Application of diversity, equity, justice and inclusion principles to the licensee's internal practices and policies.
- Objective performance measures that the licensee will use to evaluate their social equity plan.

Important Reminders:

- An applicant for license renewal must provide documentation of the evaluation of implementation of their social equity plan based on the objective performance measures required in social equity plans.
- Licensees must provide written notice, in a form and manner prescribed by the Authority, of any material changes to their social equity plan within 60 days of making the change.

Authorized Individuals of the Named Licensee Form

Manufacturer, service center, and laboratory license applicants must upload the Authorized Individuals Form which identifies the individual applicants authorized to make decisions on behalf of the Named Licensee. At least one individual must be identified.

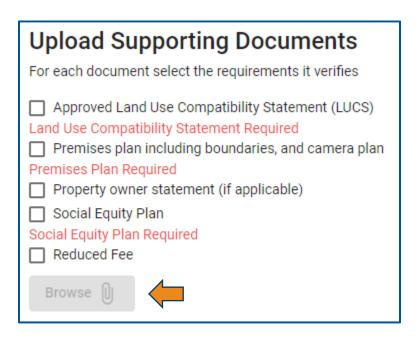
Applicants must use the Authorized Individuals of the Named Licensee Form which may be found on the <u>Oregon Psilocybin Services (OPS) – Manufacturer License webpage.</u>

Documents Tab

Please upload the following documents in the Documents Tab of the application.

- Approved Land Use Compatibility Statement
- Premises Plan including boundaries and camera plan
- Property Owner Statement (if applicable)
- Social Equity Plan
- Authorized Individuals Form
- Reduced Fee supporting document

Upload files by selecting the check box(es) indicating the type(s) of document. Click "Browse" and select the file(s) you would like to upload. You may upload documents individually or all at once.



Once the files are uploaded, it will appear in the adjacent box titled "Current Documents". If you uploaded the incorrect file, you may delete the upload by clicking on the trash icon.



Fee Information Tab

Non-Refundable Application Fee: \$500 USD

The manufacturer license has an application fee of \$500 USD and will not be reviewed until the application fee payment has been received and cleared. The application fee may be paid online, by mail, or in person.

Non-Refundable Manufacturer Annual License Fee: \$10,000 USD or \$5,000 USD if applicant qualifies for Reduced License Fee

If the manufacturer license application is approved, pending license fee payment and clearance, you will receive an email request to pay the non-refundable annual license fee. You will also see the "approved, pending annual license fee payment and clearance" status reflected in TLC. The annual license fee may be paid online, by mail, or in person.

To qualify for a reduced fee, an applicants must qualify under one of the following circumstances:

- ✓ If the proposed licensed manufacturer is a non-profit entity, please upload supporting documentation of the manufacturer's non-profit status.
- ✓ If the proposed licensed manufacturer is an individual applicant, please upload a copy of one of the following required supporting documents
 - A copy of a current monthly Social Security Income benefit statement showing dates of coverage
 - A copy of the applicant's current eligibility statement or card if enrolled in Oregon Health Plan
 - A copy of current proof of food stamp benefits from the Oregon Supplemental Nutrition Assistance Program

 A copy of proof of having served in the Armed Forces, such as but not limited to, submitting a Veteran's Administration form DD-214

To request a reduced fee, please upload a copy of the required supporting documentation. If the named licensee applicant qualifies for a reduced license fee, the fee will be reduced accordingly and will be reflected in the annual licensing fee payment request.

Accepted Payment Methods

OPS accepts the following payment methods for online applications:

- Online
- Money Order
- Cashier's Check
- Personal/Business Check
 - Personal and business checks will be held for 21 days to ensure payment clearance
- Cash (Please Do Not Mail Cash)

Fee Payment Clearance

An application will not be reviewed until the application fee payment has been received and cleared. If an applicant fails to pay the application fee within 90 calendar days of submitting the application, the application is considered incomplete and will be closed.

A license will not be issued until the license fee is paid and cleared. A licensee may not operate until the effective date of licensure. If an applicant fails to pay the annual license fee within 180 calendar days of being notified of the licensed being approved, pending license fee payment and clearance, the application is considered incomplete and will be closed.

Review and Submit Tab

Please review the application details you entered. You must confirm and attest to all the statements at the end of the application. Once the application is completed and reviewed, please enter your signature.

Once you click "Submit," the application is submitted and the application status will display "Submitted."

Online Fee Payment

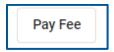
Applicants may pay their application and annual license fees through TLC. If you prefer to pay fees by mail or in-person, please review the "Mailed or In-Person Fee Payment and Remittance Form" section of this guide.

Online Application Fee Payment

To pay fees online, click the "Pay Fees" button after you submit your application. You will be taken to the Payments section of TLC. This may also be accessed by selecting "Payments" from the navigation bar on the left side of the screen. Payments captures all payments for all license or permit applications.



Select the fee you would like to pay online by clicking "Pay Fee"



Scroll to the bottom of the payment instructions and select "Pay Online Now"



You will receive a warning that you are being directed to a third-party payment processor. Click "Proceed to Payment" to be transferred to the third-party payment processor and complete payment.

Proceed to Payment:

If you have any questions, please contact the licensing team through the Messages function in TLC or by email/phone at:

Licensing.Psilocybin@oha.oregon.gov or (971) 673-0304

Online Annual License Fee Payment

Once a license application has been approved, pending fee payment and clearance, you will be notified by email. You will also see the application status "approved, pending fee payment and clearance" in the Manufacturer dashboard.

Use the same instructions described above to generate, print, and pay the annual license fee online.

Mailed or In-Person Fee Payment and Remittance Form

If you do not want to pay fees online, you may pay fees by mail or inperson. A remittance form is required if an applicant pays fees by mail or in person.

Mailed or In-Person Application Fee Payment

An application fee payment remittance form is provided in TLC once the application is submitted. The remittance form can be viewed and printed by clicking the "Pay Fees" button.



By clicking the "Pay Fees" button, you will be taken the Payments section of TLC. This may also be accessed by selecting "Payments" from the navigation bar on the left side of the screen. "Payments" captures all payments for any license or permit application.

To view and print the remittance form, scroll to the bottom of the instructions and select "View Remittance Slip".



The remittance form will display instructions for payment.

Money orders and checks are payable to: Oregon Psilocybin Services Applicants can mail the application packet, money order or check, and remittance form to the following address:

Oregon Health Authority - Public Health Division Fiscal Services RE: OPS PO Box 14260 Portland, OR 97293-0260

In-person payment with a money order or check:

To make an in-person fee payment with a money order or check, proceed to Cashier's Office on the second floor of the Portland State Office Building at:

800 NE Oregon St, Suite 200 Portland, OR 97232 Hours: 9am to 4pm, Mon to Fri

Additional instructions: The Cashier's Office window is located on the second floor next to the Vital Health Statistics window. If security asks if you have an appointment, you may let them know you are dropping off a payment for Oregon Psilocybin Services at the Cashier's Office window which does not require an appointment. Please include the remittance form with the payment and provide the application, if not already submitted by mail.

To make cash payment arrangements or for payment questions, please contact the licensing team through the Messages function of TLC or by email/phone: <u>Licensing.Psilocybin@oha.oregon.gov</u> or (971) 673-0304

Mailed or In-Person Annual License Fee Payment

Once an application has been approved, pending fee payment and clearance, we will email you an annual licensing fee remittance form to submit with your license fee payment. You will also see the license status "approved, pending fee payment and clearance" in the Manufacturer

dashboard. Please include the remittance form with the annual license fee payment.

Use the same instructions described above to generate, print, and pay the annual license fee by mail or in-person. Do not pay the annual license fee until OPS notifies you the application is approved, pending fee payment.

Background Checks

Individual applicants for a manufacturer license are required to pass a criminal background check to be issued a license. Within the Individual Applicant Information form, individual applicants will be asked to provide information required to initiate the background check process. The following information in the form will be used to initiate the background check:

- Legal name
- Prior names and aliases
- Date of birth
- Social security number
 - We ask for voluntary consent to use your social security number, if you have one, to confirm your identity during the criminal records check. We will not deny you any rights, benefits, or privileges otherwise provided by law if you do not consent to use of your SSN for these administrative purposes
- Physical address
- Mailing address (if different)
- Phone number
- Email
- Residential history outside of Oregon in the past five years

Do not submit fingerprints until Oregon Psilocybin Services requests that you do so.

Once we initiate a criminal background check, the individual applicant will receive an electronic letter by email that explains how to schedule an appointment with a <u>FieldPrint</u> vendor. FieldPrint vendors are private contractors and are not associated with a government agency. Visit <u>this link</u> to find the nearest FieldPrint vendor.

For more detailed information on background checks, please review the OPS - Overview of the Background Check Process document.

Application Review

OPS will review applications once the application fee payment is paid <u>and</u> cleared. It may take OPS several weeks to review applications and it will be reviewed in the order received. Thank you for your patience.

Incomplete and Insufficient Applications

An application is considered **incomplete** if the application is missing required information (e.g., the application fee has not been paid or the applicant did not submit fingerprints). If the application is incomplete, we will notify you by email to give you an opportunity to make your application complete. You have 90 days from the initial date you are notified to complete your application. If you fail to do so, the application will be closed.

An application is considered **insufficient** if the complete application or site inspection does not meet requirements outlined in statute or rule. If the application is insufficient, we will notify you by email to give you an opportunity to meet requirements. You will have 90 days from the initial date you are notified to meet requirements, or your application will be denied.

Application Approval and Proof of License

Once the application has been approved (after the license fee is paid and cleared), we will notify you by email that the annual license is approved. The Point of Contact will be emailed a proof of license which will include the manufacturer named licensee, license ID number, address, license effective date, license expiration date, and a QR code which can be scanned to verify license status. Please note, the public facing license verification look-up and QR code will only confirm a license ID number, effective date, and expiration date.

From the Manufacturer dashboard in TLC, you can view and print your proof of license by clicking the "Print License" button.

Print License

The proof of license will display on the screen. Click the "Print" button. A PDF file will download to your computer that can be saved or printed. You may also revisit TLC anytime to print the proof of license.

Example of what the proof of license will look like:



As outlined in <u>OAR 333-333-4120</u>, Manufacturer licensees must display a proof of licensure in a prominent place on the licensed premises. **A** licensee may not operate until the effective date of licensure.

Notification of Changes

Please review all rules for Notification of Changes as described in <u>OAR</u> 333-333-4200. An applicant or licensee must notify OPS in writing within 10 business days of the changes described in rule. Please notify the OPS Licensing Team of these changes by emailing <u>licensing.psilocybin@oha.oregon.gov</u>.

Changes which need to be reported by manufacturer license applicants and licensed Manufacturers include:

- Adding or removing an individual or legal entity who qualifies as an applicant under OAR 333-333-1010 or OAR 333-333-4030
- A change in contact information for any person listed as an applicant or licensee.
- Any closure of the licensed premises lasting more than 30 days.
- Any conviction for any misdemeanor or felony committed by an individual listed as an applicant or licensee.
 - When notifying the OPS licensing team of changes to conviction history, please only include the following information:
 - Legal Name
 - Manufacturer License ID Number
 - A statement notifying OPS of a change to criminal history conviction
 - Please DO NOT provide any conviction details in the notification to OPS
 - A criminal background check is required if we learn that an individual has been convicted of a crime after their license has been issued.
- Any arrest for conduct that occurred on the licensed premises.
- Any theft of psilocybin products or cash from the licensed premises.

Frequently Asked Questions (FAQs)

Is the \$500 application fee refundable?

No. The application fee is nonrefundable.

Is the annual license fee refundable?

No. The annual license fee is nonrefundable.

How long will it take OPS to review applications?

OPS will review applications once the application fee payment is paid and cleared. Due to limitations in predicting application volume, it may take OPS several weeks to review applications. Thank you for your patience.

How do I know the status of my application?

Due to limitations in predicting application volume, it may take OPS several weeks to review applications. You may also monitor the status of your application on the Manufacturer dashboard.

If you have questions about the status of your application, please send a message through TLC or email/call:

<u>Licensing.Psilocybin@oha.oregon.gov</u> (971) 673-0304

OPS sent me a notice that the application is incomplete or insufficient. What do I do now?

If the application is incomplete, you have 90 days from the initial date you are notified to complete your application. If you fail to do so, the application will be closed. If the application is insufficient, you will have 90 days from the initial date you are notified to meet requirements, or your application will be denied. You may also request withdraw of the application at any time by notifying OPS. Please note, the application fee is nonrefundable.

What happens if my application is closed? What happens if it is denied?

If the application is closed, you may reapply and pay the nonrefundable application fee. If OPS denies an application, OPS will provide notice of the denial in writing and you have a right to a hearing under ORS chapter 183.

Can I withdraw my application?

You may request withdraw of your application by sending us a TLC message or emailing/calling the OPS Licensing Team. Please note, the application fee is nonrefundable.

<u>Licensing.Psilocybin@oha.oregon.gov</u> (971) 673-0304

How long is the license valid?

The manufacturer license term is one year from the effective date. OPS is currently developing the application renewal process for manufacturer licenses.

How do I know what the TLC ID number assigned to my license is? The TLC ID number can be found on the Manufacturer dashboard.

Who do I contact about general questions regarding license and permit questions?

Please send us a message through TLC or email/call: <u>Licensing.Psilocybin@oha.oregon.gov</u> (971) 673-0304