

# Psilocybin Manufacturer License Renewal Application Guide for Renewal Applications Submitted Online

PUBLIC HEALTH DIVISION
CENTER FOR HEALTH PROTECTION
Oregon Psilocybin Services (OPS)
<a href="http://oregon.gov/psilocybin">http://oregon.gov/psilocybin</a>

# **Table of Contents**

Introduction	2
Manufacturer License Renewal Application Packet Checklist	4
Getting Started with TLC	6
TLC Dashboards	6
TLC Messaging Dashboard	7
Begin a Manufacturer License Renewal Application	g
Residency Requirements (Expires 2025)	10
Manufacturer Applicant Information Tab	12
Individual and Legal Entity Applicant Information Tab	14
Individual Applicant Information Form	15
Legal Entity Applicant Information Form	20
Designated Primary Point of Contact	25
Financial Interest Tab	26
Manufacturer Endorsements Tab	27
Documents Tab	29
Social Equity Plan	30
Annual Social Equity Evaluation Report	30
Fee Information Tab	31
Review and Submit Tab	34
Online Fee Payment	34
Mailed or In-Person Fee Payment and Remittance Form	35
Background Checks	37
Application Review	37
Incomplete Applications	37
Application Approval and Proof of License	37
Notification of Changes	39
Frequently Asked Questions (FAQs)	40

### Introduction

The purpose of this guide is to provide support to applicants submitting a psilocybin manufacturer license renewal application **ONLINE**. The most current version of this guide can be found on the <u>Oregon Psilocybin</u> Services (OPS) – Manufacturer License webpage.

Applicants must read, understand, and agree to adhere to the OPS statutes and administrative rules, outlined in <u>Oregon Revised Statute (ORS)</u>
<u>Chapter 475A</u>, <u>Oregon Administrative Rules (OAR) Division 333</u>, <u>Chapter 333</u>, as well as any other applicable statutes or laws.

The OPS – Training Program, Licensing, and Compliance system (TLC) is an online platform where applicants can apply for psilocybin licenses, worker permits, training program curriculum approval and renewals. Please visit TLC at <a href="https://psilocybin.oregon.gov">https://psilocybin.oregon.gov</a> to complete the renewal application online. If you are unable to complete the renewal application packet online, you may print, complete, and mail the application packet. Printable renewal application forms may be found on the OPS <a href="Manufacturer License webpage">Manufacturer License webpage</a>.

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

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

For all other questions and concerns, 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.

All psilocybin license types have a one-year term. Your initial license is valid for one year from the date it was issued and must be renewed on an annual basis. The expiration date can be found on your proof of licensure and in the Training License Compliance (TLC) system under the "My Licenses and Permit" tab.

To ensure license continuity, you must submit a complete renewal application at least 60 days before your license expires. OAR 333-333-4250.

- Renewal applications that are complete, submitted according to requirements, and submitted at least 60 days before the license expires will be considered timely under OPS rules. Licensees who submit timely applications may continue to operate on an expired license if OPS is unable to process the renewal application prior to the license expiration date. Incomplete renewal applications will not be considered timely unless they are made complete at least 60 days before the license expires.
- Renewal applications that are submitted less than 60 days before the license expires will be considered untimely under OPS rules. Licensees who submit untimely applications are prohibited from continuing to operate on an expired license if OPS is unable to process the renewal application prior to the license expiration date. Licensees are prohibited from exercising license privileges on the date their license expires if OPS is unable to process their renewal application before the expiration date and the renewal application is untimely.

We encourage licensees to begin the renewal process as soon as the renewal window in TLC opens. The renewal window in TLC opens 120 days prior to your license expiration date. To begin your renewal application, please use the "Start Renewal" button in TLC. If you are experiencing challenges or delays in creating your renewal application in TLC, please immediately contact OPS Licensing. We request that you do not start a new renewal application if you are experiencing technical challenges. This may create duplicate records that need to be deleted by TLC system administrators and may cause additional delays.

OPS will review applications in the order received, and the review process may take several weeks. Thank you for your patience and please contact us with any questions by emailing the OPS Licensing Program at: <a href="mailto:licensing.psilocybin@oha.oregon.gov">licensing.psilocybin@oha.oregon.gov</a>.

# **Manufacturer License Renewal Application Packet Checklist**

Please use the following checklist to assist in planning and ensuring the renewal application is complete.
☐ Completed and signed manufacturer license renewal application in TLC.
<ul> <li>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:         <ul> <li>Passport</li> <li>Driver license, whether issued by the State of Oregon or by</li> </ul> </li> </ul>
<ul> <li>another state of the United States</li> <li>Identification card issued under ORS 807.400</li> <li>United States military identification card</li> <li>An identification card issued by a federally recognized Indian tribe with photo, name, and date of birth, or</li> <li>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</li> </ul>
☐ Copies of Individual Applicant Information forms and Legal Entity  Applicant Information forms for each applicant.
Attestation that all information on Individual Entity and Legal Entity Information forms are true and accurate.
□ Copy of the Social Equity Plan and Annual Social Equity Evaluation Report.

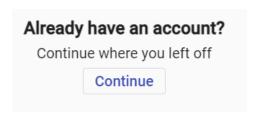
☐ Copy of reduced licensing fee documentation (if applicable).

- 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
- o If the proposed manufacturer is a legal entity, or there are more than one individual applicants on the renewal application, they may be eligible for a reduced license fee if every individual applicant within the entity meets to requirements for reduced fees in OAR 333-333-4060(4). Please include a copy of **one** on of the following supporting documents for every individual applicant within the entity.
  - 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.

## **Getting Started with TLC**

Please visit <a href="https://psilocybin.oregon.gov">https://psilocybin.oregon.gov</a> to access TLC and log into your account.

To begin an online renewal application, log into your existing TLC account by selecting "Already have an account? Continue where you left off."



Click "Continue"

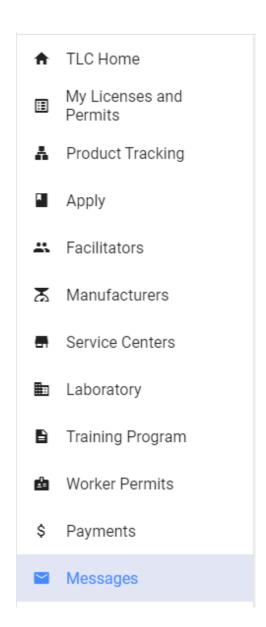


Sign in using your email address and password. Use "Forgot Password" if original password needs to be recovered.

### **TLC Dashboards**

All license types 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.

Dashboards:



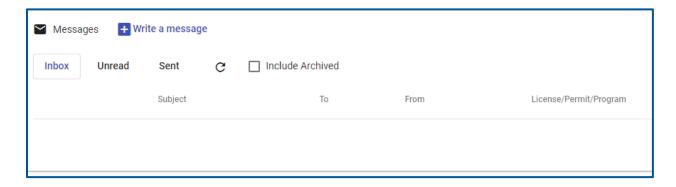
# **TLC Messaging Dashboard**

Messages is a platform to communicate with the Oregon Psilocybin Services Licensing and Compliance Programs. From this dashboard you can send messages to and receive messages from the OPS Licensing and Compliance Programs. 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.

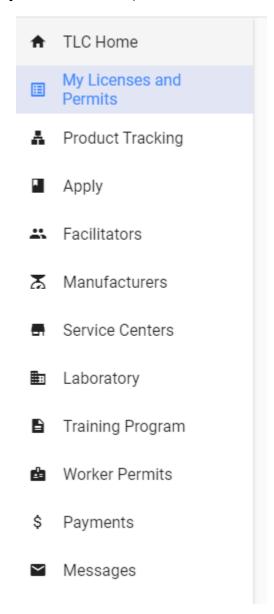


Then, select which program you are sending the message to. If you have a question related to applying for a license, worker permit, or training program curriculum approval, please direct your message to the OPS Licensing Program. If your message is related to site inspections, premises requirements, compliance with administrative rules, or investigations, please direct your message to the OPS Compliance Program. If you are unsure which program to send the message to, please select the program you think is most relevant and our teams will work together to answer the message.

Please include the application, license, or permit ID number you are reaching out about with your message.

# **Begin a Manufacturer License Renewal Application**

When you are ready to begin a manufacturer license renewal application, please navigate to "my licenses and permits" on the left-side menu.



Click on the Manufacturer license to be renewed and navigate to the button to begin your renewal.

**Continue Renewal** 

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

## **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.

If applicants are being added to an existing OPS Manufacturer License, the application must go through a change request process, which includes the submission of an Individual Applicant Information Form and/or Entity Applicant Information Form. A change request fee for each applicant is required, and payment must be received and cleared before OPS will review the change request. New applicants must pass a background check and complete residency attestation before the change request can be approved. More information about change requests can be found on the OPS Manufacturer License page.

# **Manufacturer Applicant Information Tab**

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

- Operational Name (fixed-unable to be changed) means an individual, legal entity or business name listed on an application and license certificate of a service center, manufacturer, or laboratory license that the licensee(s) will use for purposes of advertising and doing business with the public.
- Website (can be edited for accuracy)
- Verify Registered Business Information (fixed- unable to be changed)
  - 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 (fixed- unable to be changed)
- Mailing Address (can be edited for accuracy)

#### Previous License or Permit

If the operational name has ever applied for or received any other licenses from OPS, please provide this information within the online renewal application.

Manufacturer Information Operational Name		
Operational Name *		
Manufacturer Website		
Website		
Registered Business		
Is the applicant registered as a business with the Secretary of State (SOS) in Oregon?  Yes No		
Is the applicant registered as a business in another state, US territory or a freely associated state?  Yes No		
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).		
Other OPS Licenses or Permits		
Check the box if the applicant applied for or received any  other licenses or permits from Oregon Psilocybin Services?		

## **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 <a href="#">OAR 333-333-1010 and OAR 333-333-4030</a>. Applicants are responsible for ensuring all individuals and legal entities who meet the definition of an applicant are identified.

### OAR 333-333-1010(7):

"Applicant" means an individual who applies for a facilitator license and an individual or legal entity who:(a) Holds or controls an interest of more than 20 percent in the entity proposed to be licensed;

- (b) Is entitled to receive 20 percent or more of revenue, profits or proceeds from the entity proposed to be licensed; or
- (c) Is entitled to exercise control over the entity proposed to be licensed.

### OAR 333-333-4030(4)

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

- (a) If an applicant is a limited partnership, each general partner in the limited partnership.
- (b) If an applicant is a limited liability company, each manager and managing member of the limited liability company.
- (c) If the applicant is a for-profit corporation, each principal officer of the corporation.
- (d) If the applicant is a non-profit entity, each principal officer of the entity.
- (e) 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 renewal application. If an individual within a legal entity is identified as an applicant, please be sure to include them as an individual applicant.

# **Individual Applicant Information Form**

Each individual applicant must complete an <u>Individual Applicant Information</u> Form. Applicants are responsible for completing and ensuring all individual applicant information forms are uploaded into the online application.

# 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 operational name 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 a worker 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

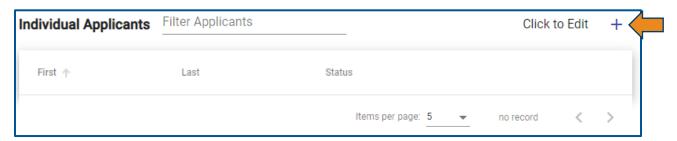
All licensed facilitators that provide psilocybin services to clients and all employees that work on a licensed manufacturer, service center, or laboratory premises must have a worker permit if the individual participates in provision of psilocybin services, possession, manufacture, selling or storage of psilocybin products or recording any information related to these activities.

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.

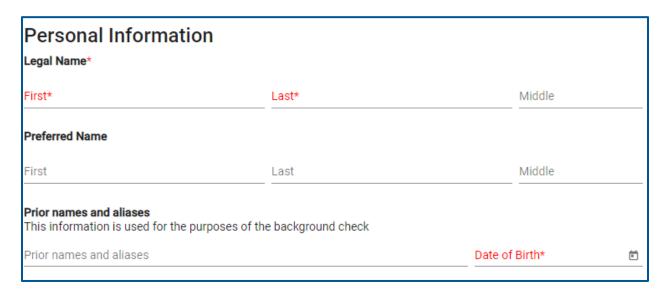
# Adding Individual Applicants in the TLC Application

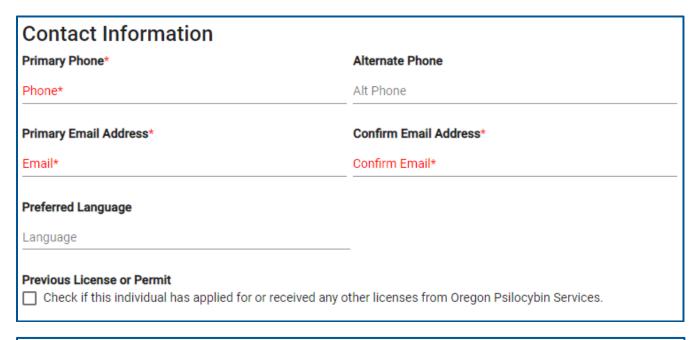
To add an individual applicant, click the "+" symbol.

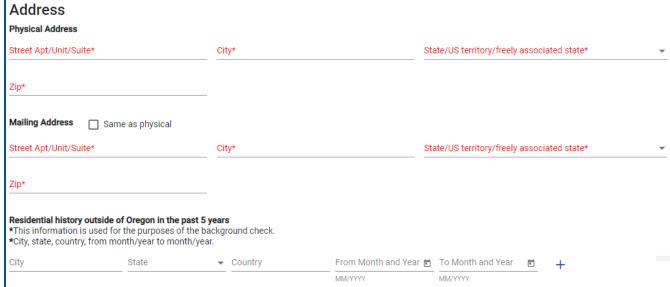
\*Note: any applicants added to the application will need to be added through a change request process with OPS which will require a change fee and a background check for each new applicant.



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







# Individual Applicant Attestation

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

- Attest to no new criminal convictions.
- Attest to personal information still being true and accurate.

Upload a copy of the individual applicant's photo identification (if the applicant does not already have current photo identification saved in TLC)

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;
<ul> <li>Identification card issued under ORS 807.400;</li> </ul>
<ul> <li>United States military identification card;</li> </ul>
<ul> <li>An identification card issued by a federally recognized Indian tribe with photo, name and date of birth; or</li> </ul>
<ul> <li>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</li> </ul>
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 U

## **Legal Entity Applicant Information Form**

Each legal entity applicant must complete a <u>Legal Entity Applicant</u> <u>Information form</u>. Applicants are responsible for completing and ensuring all legal entity applicant information forms are uploaded into the online application.

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 Operational Name listed on the application. (required)
- Legal Entity Name
- Registered Business Information (required)
  - 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 (able to be changed for accuracy)
- Alternate phone number (able to be changed for accuracy)
- Primary email address (able to be changed for accuracy)
- Preferred language (fixed- requires notification to OPS)
- Headquarters/Main Office Address (fixed-requires a change order)
- Physical Address (fixed- requires notification to OPS)
- Mailing Address (able to be changed for accuracy)

### Previous License or Permit

If the legal entity applicant has ever applied for or received any other licenses or a worker 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 person or entity holds an

interest of twenty percent or more, they are an applicant in addition to holding a financial interest.

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 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:

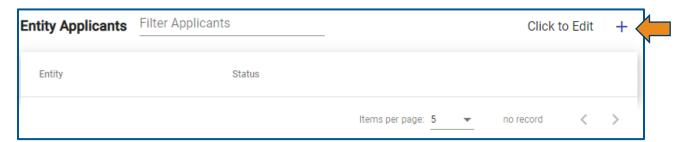
- If an applicant is a limited partnership, each general partner in the limited partnership
- If an applicant is a limited liability company, each manager and managing member of the limited liability company.
- If the applicant is a for-profit corporation, each principal officer of the corporation
- 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, including individuals who hold or control an interest of more than 20 percent of the entity proposed to

be licensed, individuals who are entitled to receive 20 percent or more of the revenue from the entity proposed to be licensed and any individual who is entitled to exercise control over the entity proposed to be licensed.

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.

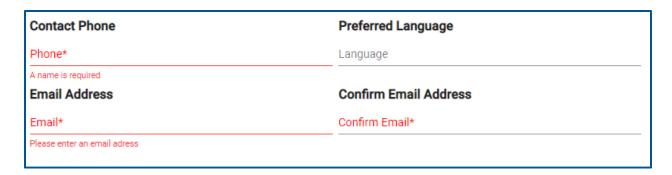
## Adding Legal Entity Applicants in the TLC Application

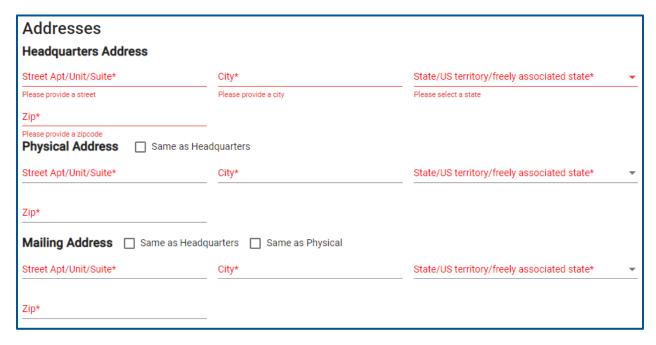
To add a legal entity applicant, click the "+" symbol.



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





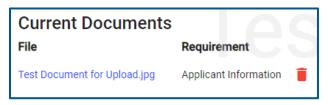


### Upload Legal Entity Applicant Information Form

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

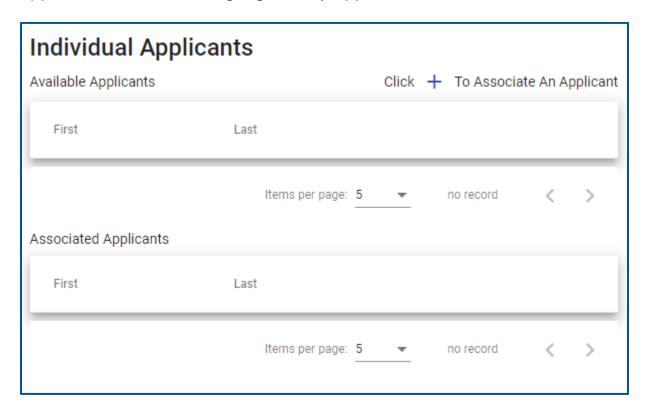


Once the file is uploaded, it will appear in the adjacent box titled "Current Documents". If you uploaded the incorrect file, you may delete it by clicking on the trash icon.



### 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**

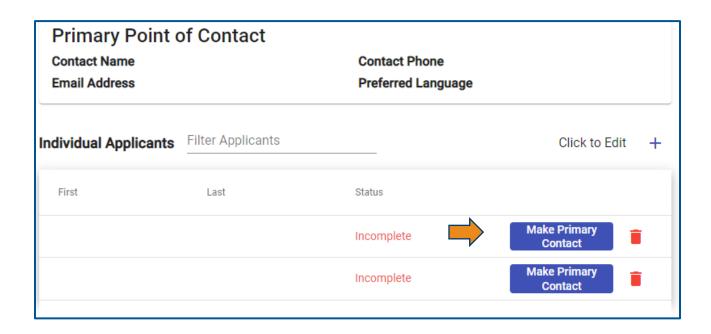
One applicant must be designated as the Primary Point of Contact for communication. The primary point of contact is responsible for ensuring all persons identified as licensees or applicants are aware of relevant communications, including but not limited to notices issued under ORS Chapter 183. See OAR 333-333-4010.

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.

Communication about your application will be sent via TLC-Messages. You will be able to access new messages using the email address shown in the primary point of contact.

If the email address is the email address you used to create the TLC account for this application, you will receive TLC-Messages on the TLC account that was created for this application.

If the email address above does not have a TLC account, you will need to make a new TLC account for it to receive TLC-Messages.



### **Financial Interest Tab**

Applicants must attest to understanding the information below:

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.

If a person or entity holds an interest of twenty percent or more, they are an applicant in addition to holding a financial interest.

Applicants 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.

If endorsements are being added to an existing OPS Manufacturer License, the application must go through a change request process, which may include submission of additional paperwork, such as a Land Use Compatibility Statement or Certificate of Occupancy. A change request fee for each applicant is required, and payment must be received and cleared before OPS will review the change request. Adding new endorsements may also require a site inspection and additional oversight from Oregon Department of Agriculture (for Psilocybin Extraction or Edible Psilocybin Production endorsements). More information about change requests can be found on the OPS Manufacturer License page.

You must select at least one endorsement type
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
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.

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.

### **Documents Tab**

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

- Reduced Fee supporting documentation (if applicable)
- Updated Social Equity Plan (not required)
- Annual Social Equity Evaluation Report
- Updated Premises Pictures (not required, but will be required before site inspection)

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.

# **Upload Supporting Documents**

For	each document select the requirements it verifies
	Approved Land Use Compatibility Statement (LUCS)
	Premises plan including boundaries, and camera plan
	Property owner statement (if applicable)
	Reduced Fee
	Updated Social Equity Plan
	Social Equity Plan Evaluation
	Updated premise pictures
E	Browse U

## **Social Equity Plan**

Applicants must upload a social equity plan with their renewal 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>

For guidance on creating or updating a social equity plan, please see the OPS Social Equity Plan Guidance and Resources document.

If a facilitator is an employee of a licensed service center, the social equity plan requirements can be fulfilled by uploading a statement that references the service center's social equity plan. If a facilitator is an employee of more than one service center, the statement must identify each service center that employs the facilitator. If a facilitator contracts with a service center, they must submit their own social equity plan.

## **Annual Social Equity Evaluation Report**

Renewal applicants must also upload an Annual Social Equity Evaluation Report with their renewal application.

For guidance on this requirement, please see the <u>Guidance for OPS</u> <u>Licensees on Preparing Annual Social Equity Evaluation Reports</u>.

### **Fee Information Tab**

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

If OPS determines that the manufacturer renewal license application meets all licensing requirements, you will receive an email request to pay the non-refundable annual license fee. The annual license fee must be paid within 30 days of the request and 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
- If the proposed manufacturer is 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 to requirements for reduced fees in OAR 333-333-4060(4). Please include a copy of one on of the following supporting documents for every individual applicant within the entity.
  - 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

A renewal application will not be approved until the application fee payment has been received and cleared. If an applicant fails to pay the application fee within 30 calendar days of receiving notice that payment is due, the application is considered incomplete.

A license will not be renewed until the license fee is paid and cleared.

To ensure license continuity, you must submit a complete renewal application at least 60 days before your license expires. See OAR 333-333-4250.

 Renewal applications that are complete, submitted according to requirements, and submitted at least 60 days before the license expires will be considered timely under OPS rules. Licensees who submit timely applications may continue to operate on an expired license if OPS is unable to process the renewal application prior to the license expiration date. Incomplete renewal applications will not be considered timely unless they are made complete at least 60 days before the license expires.

 Renewal applications that are submitted less than 60 days before the license expires will be considered untimely under OPS rules. Licensees who submit untimely applications are prohibited from continuing to operate on an expired license if OPS is unable to process the renewal application prior to the license expiration date. Licensees are prohibited from exercising license privileges on the date their license expires if OPS is unable to process their renewal application before the expiration date and the renewal application is untimely.

### **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."

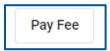
Once OPS determines that your renewal application meets all licensing requirements, you will receive an email request to pay the non-refundable annual license fee. You will also see the application status "Renewal Approved, pending fee payment and clearance" in the Manufacturer dashboard. Applicants may pay their annual license fees through TLC, by mail or in-person.

## **Online 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".

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

### **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. Please note that if you pay by personal check, there is a 21 day hold before OPS can consider the payment complete.

Once OPS determines that your renewal application meets all licensing requirements, you will receive an email request to pay the non-refundable annual license fee and submit the fee remittance form. You will also see the license status "Renewal approved, pending fee payment and clearance" in the Manufacturer dashboard. Please include the remittance form with the annual license fee payment.

### Do not pay the annual license fee until OPS notifies you.

The fee payment remittance form is provided in TLC. 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".

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 renewal 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

## **Background Checks**

Individuals applying for a manufacturer license renewal are required to inform OPS of any new convictions on their record. This may necessitate a new background check. Please do not disclose specific details of any new background check items to Oregon Psilocybin Services. Please send the Licensing Program a message in TLC informing them of the new conviction on your record, and OPS will communicate when the background check process has started. Any specifics of any new convictions on the record can be disclosed to the Oregon Background Check Unit.

# **Application Review**

It may take OPS several weeks to review applications and applications will be reviewed in the order received. Thank you for your patience.

## **Incomplete Applications**

An application is considered **incomplete** if the application is missing required information (e.g., missing/incomplete documents). If the application is incomplete, we will notify you by email to give you an opportunity to make your application complete. If you fail to do so, the application may be closed.

## **Application Approval and Proof of License**

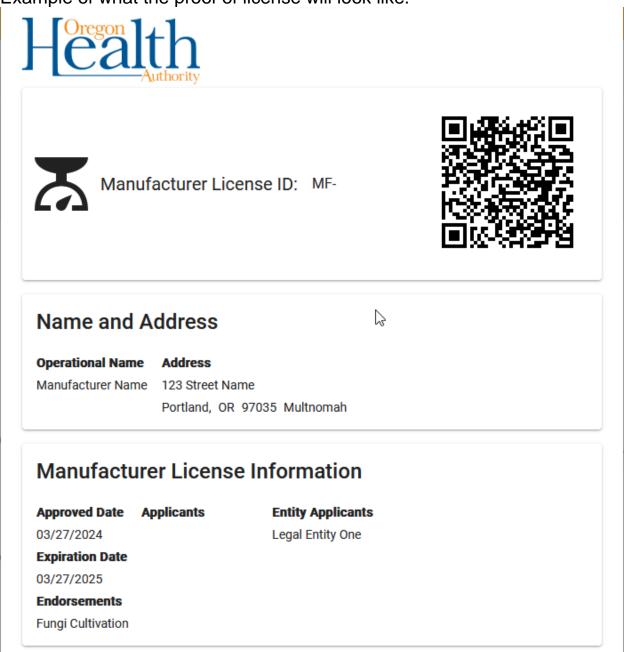
Once the renewal application has been evaluated, we will notify you by email that the annual license is approved. The Point of Contact will be emailed an updated proof of license which will include the manufacturer named licensee, license ID number, address, license effective date, license expiration 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** manufacturer may not operate without a license.

## **Notification of Changes**

Please review all rules for Notification of Changes as described in <u>OAR</u> <u>333-333-4200</u>. An applicant or licensee must notify OPS in writing within 10 business days of the changes described in rule regardless of whether the change occurs at renewal or another time. 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.
- A change in the licensee's operational name
- 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 new conviction related to criminal history.
      - Please DO NOT provide any conviction details in the notification to OPS.
    - A criminal background check may be required if 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.

Licensees are required to use the forms below for Change of Location requests, Modification of Premises requests, and Manufacturer Endorsement Change requests. These forms must be submitted to the OPS Licensing team through TLC. Please attach the necessary form and any other required documents to a TLC message and send to the OPS Licensing team.

Change of Location Request

Modification of Licensed Premises Request

Request to Change Manufacturer Endorsement(s)

For any other change requests not listed above, please message the licensing team in TLC messenger with your request.

# **Frequently Asked Questions (FAQs)**

### When do I need to file my renewal application?

In order to ensure continuity in your business, you should submit your renewal application at least 60 days before your license expires. These renewal applications will be considered timely and manufacturers who submit timely applications can continue to operate on an expired license if OPS is unable to process their renewal application prior to the license expiration date. For renewal applications that are not timely, licensees will need to cease operations on the date their license expires if OPS is unable to process their renewal application before the expiration date.

### Is the annual license fee refundable?

No. The annual license fee is nonrefundable.

## How long will it take OPS to review renewal applications?

OPS will review applications in the order received. 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 renewal 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 renewal application requires more information. What do I do now?

If the renewal application is lacking required information, OPS will notify you and specify a time period to complete your application. If you fail to do so, the application will be considered incomplete and will be closed.

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

If the application is closed, you may reapply. 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 renewal 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.

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