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



Psilocybin Manufacturer License Application

Thank you for your interest in applying for a Manufacturer License through Oregon Psilocybin Services (OPS). More detailed information to support the application process can be found in the <u>Manufacturer License Application</u> Guides.

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

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

or (971) 341-1713

For all other questions and concerns regarding Manufacturer Licenses, please contact:

Licensing.Psilocybin@oha.oregon.gov

or (971) 341-1509

Manufacturer License Application Packet Checklist

An application packet must contain the following to be considered complete and to be considered for approval. Please complete this checklist to ensure you have all the necessary items. ☐ Completed and signed Manufacturer license application

☐ 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:

- 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.

☐ Copy of the Approved Land Use Compatibility Statement (LUCS)
☐ Copy of the property owner statement (if applicable)
☐ Copies of individual and entity applicant information forms for each applicant
☐ Copy of the premises plan including boundaries and camera plan
☐ Copy of the social equity plan
☐ Copy of the Authorized Individuals form
\square Copy of reduced licensing fee documentation (if applicable). Please provide the
required supporting documentation:

- 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
 - o 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 with payment remittance form (payment must clear before application will be reviewed)

Important Notes:

- Please review each section of the application to ensure it is complete
- Toward the end of the application, the fee payment remittance form will describe how to submit the application fee which may be paid by mail or inperson
- Applicants must read, understand, and agree to adhere to the Oregon Psilocybin Services Revised Statutes (ORS) Chapter 475A, Oregon Administrative Rules (OAR) Chapter 333, Division 333, as well as any other applicable statutes or laws
- OPS will not review an application packet until the application fee is paid and cleared. You have 90 days from the date of application submission to pay the application fee or it will be closed

Incomplete and Insufficient Application Statuses: Please review the application guide for more detailed information on all application statuses.

- Incomplete: 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.
- Insufficient: 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.

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 you provide in your application materials, including applicant name, is subject to disclosure under Oregon's public records laws.

PUBLIC HEALTH DIVISION CENTER FOR HEALTH PROTECTION Oregon Psilocybin Services

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Psilocybin Manufacturer License Application

Application	on Date:		
	cturer Applicant Information		
	optional):		
Is the app Oregon? If yes, ple	olicant registered as a business with the Secretar ☐ Yes ☐ No ease provide the Oregon SOS Registration Numl proceed to the address section of the application	ry of State(ber:	•
freely ass If ye stat regi	ne applicant registered as a business in another ociated state ² ? Yes No s, please provide the location (state, US territory e ²) where the manufacturer is registered as a bustration number. ation Registered Registration Num	y ¹ , or freely siness and	associated the
I un	itial the following statement indicating you ur derstand licensees that are required to be register of State must register prior to receiving a licens on.	ered with th	e Oregon
Physical	Address		
Street		Unit/Suite	
City		State	Oregon
County		Zip code	

¹US territories: American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI), Guam, Puerto Rico, US Virgin Islands

²Freely associated states: the Federated States of Micronesia, the Republic of the Marshall Islands, Republic of Palau

Mailing Address		
☐ Same as Physical Address		
Street	Unit/Suit	е
City	State	
County	Zip code	
Please provide a brief description of the p	oremises:	
Previous License Has this applicant applied for or received Psilocybin Services? □ Yes □ No	any other licenses from (Oregon
	11	
f yes, please provide the license name a	nd license ld(s) for each:	
f yes, please provide the license name a	nd license ld(s) for each:	

Applicant Information

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

Important Information

- All applicants must be identified in this application
- If an individual within a legal entity is identified as an applicant, please be sure to add them as an individual applicant
- Individual and Legal Entity Applicant Information Forms
 - Each individual and legal entity applicant must complete an applicant information form where they will provide their applicant information, agree to be added as an applicant to the application, agree to the designated point of contact for the application, and complete attestations. Applicants are responsible for completing and ensuring all applicant information forms are included with the mailed application. Individual and legal entity applicant information forms can be found on the Oregon Psilocybin Services Apply for a Manufacturer License webpage.
- An 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 checkbox under the Point of Contact Columns

Individual Applicants		Point of Contact
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	

Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
Legal Name:	Date of Birth:	
	ded, please use the supplemental applicant form at t	ne end
of this application.		
		Point of
Legal Entity Applican	<u>ts</u>	Contact
Legal Entity Name:		
	ded, please use the supplemental applicant form at t	he end
of this application.	, p	
	tatement indicating you understand and agree.	
	egon Psilocybin Services will charge a change fee of	
	change to a previously approved license that results	
• •	ant. This change fee applies regardless of whether th	
•	e change at renewal or during the term of their license	
	egon Psilocybin Services may deny an application if	
•	an applicant for the entity proposed to be licensed do	
	applicant in OAR 333-333-1010; or a person who m	
• • •	t in OAR 333-333-1010 has not been disclosed on th	е
application.		

Financial Interests

Applicants and licensees must create and maintain complete lists of all individuals and legal entities that hold a financial interest in the Manufacturer, including contact information for each individual or entity and a description of their financial interest. Applicants and licensees must provide the information required by this section 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

Please initial the following statements indicating you 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

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. Select the endorsements requested. 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	
Please initial the following statements indicating you understand and	
agree: I understand a manufacturer with an edible psilocybin production endorsement may only process in a food establishment licensed by the Oregor Department of Agriculture (ODA) and must comply with the applicable provisior 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 provision of OAR Chapter 603, Division 21, Division 24, Division 25 and Division 28.	S
I understand Oregon Psilocybin Services may deny a manufacturer's requenter 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.	

Fee Information

Non-Refundable Application Fee: \$500

The manufacturer license application will not be reviewed until the application fee payment has been received and cleared. Details on how to submit the application fee payment are located on page 12 of this application.

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

If the license application is approved, pending license fee payment and clearance, you will receive a request to pay the licensing fee. At that time, we will provide a licensing fee remittance form to submit with your licensing fee payment.

To request a reduced fee, please include copies of the required supporting documentation, as described in the Manufacturer License Application Packet

Checklist and in the Manufacturer Application Guide. If you qualify for a reduced license fee, the fee will be reduced accordingly.

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.

Applicant Statements

Please initial each statement indicating you understand and agree.
I certify the information provided in this application is true and complete to the best of my knowledge. I understand falsifying an application, supplying misleading information, or withholding information is grounds for denial of my application or revocation of my license.
I understand I am responsible for making my own determination regarding the legal risks associated with a Schedule 1 substance under the Federal Controlled Substances Act.
I understand manufacturer licenses are only valid for the licensed premises and are only issued to the individuals or entities listed on the application or subsequently approved by the Authority.
I understand the information provided in application materials, including applicant name, is subject to disclosure under Oregon's public records laws.
I understand all individual applicants must complete and pass a background check as a condition of licensure.
I understand that the individual and legal entity applicants in this application must meet the Oregon resident requirements outlined in ORS 475A and OAR 333-333-4050
I understand individual applicants are required to obtain a psilocybin worker permit if they participate in activities outlined in OAR 333-333-4070 (1) (a), (b), (c), (d).
I understand and will adhere to the requirements for Notification of Changes as outlined in OAR 333-333-4200.
I understand Oregon Psilocybin Services will charge a change fee of \$250 per inspection for any change to a previously approved license that requires an

inspection of the licensed premises. This change fee applies regardless of whether the licensee requests the change at renewal or during the term of their license.
I have read, understand, and agree to adhere to the Oregon Psilocybin Services Revised Statutes (ORS) Chapter 475A, Oregon Administrative Rules (OAR) Chapter 333, Division 333, as well as any other applicable statutes or laws.
I understand that failure to adhere to these statutes and rules may result in my application being denied or disciplinary action taken against any future licenses issued by Oregon Psilocybin Services.
I certify the proposed licensed premise meets the location requirements outlined in OAR 333-333-4300.
I understand the Manufacturer license has a term of one year from the effective date of licensure. If I wish to renew the license after that term, a renewal application must be submitted.
I understand a license will not be issued until the license fee payment is paid and cleared. A licensee may not operate until the effective date of licensure.
I understand the Manufacturer application and annual license fees are non-refundable.
Printed Name of Individual Authorized to Act on Behalf of the Named Licensee:
Signature of Individual Authorized to Act on Behalf of the Named Licensee: Date:

Please be sure to submit all required documents as outlined in the Manufacturer License Application Packet Checklist.

Instructions for submitting the application packet and fee payment can be found in the Manufacturer License Fee Payment Remittance Form on page 12 of this packet or by visiting Oregon Psilocybin - Manufacturer License.

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Manufacturer Named Licensee

http://oregon.gov/psilocybin



Psilocybin Manufacturer License Application Fee Payment Remittance Form

	Manulacturer Maine	tu Licerisee		
	Point of Contact Name			
	Point of Contact Phone Number		r	
	Point of Contact En	nail		
	Application Date	-		
	Type of Paym	nent		Payment Purpose
□ Ca:	Type of Paym shier's Check	nent		Payment Purpose ☐ New Application Fee \$500
_	• • • • • • • • • • • • • • • • • • • •	nent		•
□ Мо	shier's Check			•

Instructions for Submitting the Application and Fee Payment by Mail or In-Person

Money orders and checks are payable to: **Oregon Psilocybin Services**Personal and business checks will be held for 21 days to ensure payment clearance.
Applications will be reviewed once payment has been cleared.

Mailing the application packet, money order or check, and remittance form:

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: Licensing.Psilocybin@oha.oregon.gov or (971) 341-1509

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Manufacturer License Application Supplemental for Additional Individual Applicants and Entity Applicants

This form is OPTIONAL and is only used if you need more space to provide information for additional Individual Applicants and Entity Applicants.

Individual Applicants

Date of Birth:
Date of Birth:

Legal Entity Applicants

Legal Entity Name:	
Legal Entity Name:	
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